BANK OF CANADA INTERNAL APPEAL

(Of denial of accommodation under the Bank of Canada's COVID-19 Vaccination Policy)

BETWEEN:

JOSEPH HICKEY

Appellant (Employee)

and

BANK OF CANADA

Defendant (Employer)

APPEAL SUBMISSIONS

Submitted by email pursuant to instructions received from [redacted], Bank of Canada, via emails dated Nov. 19, 2021 (at Tab 3), Nov. 23, 2021 (at Tab 5), and Feb. 10, 2022 (at Tab 6); and from [redacted], Raymond Chabot Grant Thornton, by letter dated Nov. 24, 2021 (at Tab 7) and by email dated Dec. 14, 2021 (at Tab 4)

SUBMITTED MARCH 16, 2022

Submitted by:

Dr. Joseph Hickey, PhD
Data Scientist, Canadian Economic Analysis Dept., Bank of Canada
[redacted]

Submitted to:

[redacted]
Senior Employee Relations Specialist, Human Resources Dept., Bank of Canada
[redacted]

[redacted]
Senior Case Manager & Project Lead in Service Operations, Raymond Chabot Grant Thornton
[redacted]

Summary

"The underlying values and principles of a free and democratic society are … the ultimate standard against which a limit on a right or freedom must be shown, despite its effect, to be reasonable and demonstrably justified." – Chief Justice of Canada Brian Dickson, in *R. v. Oakes*

The government is coercing me to receive a medical treatment by injection that has a proven risk of death, allegedly to protect my co-workers and to protect the population at large in Canada. There is no reliable scientific evidence that the injection provides any benefit to the subject or to anyone else. Moreover, even if the injection did provide benefit, it is unnecessary, because:

1. Asymptomatic transmission is never a driver of outbreaks.

   In the words of Dr. Anthony Fauci:[1]

   > "The one thing historically people need to realize, that even if there is some asymptomatic transmission, in all the history of respiratory borne viruses of any type, asymptomatic transmission has never been the driver of outbreaks. The driver of outbreaks is always a symptomatic person. Even if there's a rare asymptomatic person that might transmit, an epidemic is not driven by asymptomatic carriers."

   This means that asymptomatic people essentially do not transmit viral respiratory diseases.

2. Natural immunity provides robust and sufficient protection against viral respiratory infection, as has always been the case throughout the biological and evolutionary history of air-breathing animals on Earth.

3. Regular testing of unvaccinated employees is deemed sufficient in many workplaces, including the entire Quebec health system.

4. I do my work entirely from home by electronic communication, as was the case from March 13, 2020, to November 22, 2021, when I was placed on unpaid leave without benefits for declining to receive a COVID-19 vaccine.

Indeed, it would be difficult to imagine hypothetical circumstances in which I could not perform my work from home, and this situation has never arisen. My work as a data scientist is theoretical, and does not involve repairing or maintaining equipment or facilities, or providing personal physical contact with clients, co-workers, or supervisors.

Forcing an individual to accept an unwanted injection having proven risks of serious injury and death in order to access work is irreconcilable with a free and democratic society, and represents a repugnant authoritarian precedent. Even in Canadian school systems, where children have potential to transmit a

[1] Dr. Anthony Fauci, Director of the U.S. National Institute of Allergy and Infectious Diseases (NIAID), as quoted in R.F. Kennedy Jr., "The Real Anthony Fauci: Bill Gates, Big Pharma, and the Global War on Democracy and Public Health", Skyhorse Publishing (New York, 2021).

number of contagious diseases to one another, vaccination is not compulsory, in that parents can opt their child out of vaccination and the child can still attend school.

Because of the coercion to be injected, I have been excluded from my work, lost my salary and benefits, and been socially ostracized.

In these submissions (Section 2e), I describe the science that demonstrates that vaccination mandates for COVID-19 are arbitrary, irrational, unnecessary, injurious, and lethal.

I ask for a new evaluation of my request to be accommodated under the Bank of Canada's COVID-19 Vaccination Policy, and I submit additional medical reasons for declining vaccination, and additional information about the religious and human rights aspects of my accommodation request.

The additional medical reasons for declining vaccination (see Section 2e) include that:

- There was no emergency that caused large amounts of deaths in Canada in 2020-2021 that would justify vaccinating the entire population;
- There is no reliable evidence that the COVID-19 vaccine products provide any health benefit;
- Vaccine products injected via intramuscular routes are in-effect physiologically incapable of preventing infection and transmission of respiratory illnesses;
- There is autopsy, surveillance, and statistical evidence of grave dangers of COVID-19 vaccine products;
- There are more than 1000 peer-reviewed articles providing evidence of harm from COVID-19 vaccine products;
- There is a significantly increased risk of dangerous heart inflammation following injection with a COVID-19 vaccine product, especially for younger males, and this danger is heightened for those who engage in strenuous physical activity;
- Natural immunity provides robust and sufficient protection against respiratory illnesses; and
- It is a fundamental principle of medicine that individual assessment of risk is a personal and confidential choice and the decision to receive or not receive a medical intervention must be made with free and informed consent.

I ask to be permitted to continue working from home, as I did from March 2020 to November 2021, until the Bank of Canada's mandatory vaccination policy is repealed.

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Note: The tabs attached to these submissions and listed in the table above include all the scientific articles cited in these submissions that have not been published in peer-reviewed journals. More than one thousand peer-reviewed journal articles are also cited in these submissions, and they can be read by following the hyperlinks included in the corresponding references.

Section 1: Chronology

1a: Summary chronology

- The Bank of Canada (the "Bank"), a Crown corporation, was directed by the Government of Canada to create a policy requiring its employees to receive injections of a COVID-19 vaccine.[2] The Bank communicated its COVID-19 Vaccination Policy (the "Policy") to staff on Oct. 6, 2021.[3]
- On Nov. 12, 2021, I submitted to the Bank a letter detailing my request for accommodation under the Policy for medical, religious, and human rights (age & sex) reasons.[4]
- My request was denied by the Bank and I was placed on unpaid leave without benefits as of Nov. 22, 2021, and advised that my employment may ultimately be terminated.[5]

1b: Detailed chronology

- On Oct. 6, 2021, the Government of Canada announced a mandatory vaccination regime for employees of federally-regulated employers including the Bank of Canada.
- On the same day, the Bank communicated its COVID-19 Vaccination Policy to staff and instructed staff members to sign an attestation form indicating whether they were vaccinated, intending to become vaccinated, unvaccinated and declining to comply with the Policy, or unvaccinated and requesting an accommodation under the Policy.
- On Oct. 13, 2021, I signed the Bank's attestation form indicating that I would request an accommodation for medical, religious, or human rights reasons.
- In a letter dated Oct. 28, 2021, I detailed my requests for accommodation for medical, religious, and human rights (age & sex) reasons. The letter was addressed to [redacted], Senior Human Relations Specialist in the Bank's Human Resources Department.
- In response to my Oct. 28 letter, [redacted] instructed me to file my accommodation request through two separate streams, one concerning the religious and human rights (age & sex) aspects of my request for accommodation, and the other concerning the medical aspects of my request. [redacted] instructed me to send the former submission to her directly, and the latter submission to the firm Raymond Chabot Grant Thornton (RCGT).
- I therefore submitted my request to [redacted] on Nov. 3, 2021, and to RCGT on Nov. 12, 2021. The Nov. 12 letter contains the content of the Nov. 3 letter, plus the additions of Germany and France as countries that had halted (as of Nov. 10) mRNA vaccination for younger people.

[2] See Section 4a (i) of these submissions for details.
[3] Bank of Canada COVID-19 Vaccination Policy, at Tab 1.
[4] Accommodation Request Letter of J. Hickey of Nov. 12, 2021, at Tab 2.
[5] Email from [redacted] to J. Hickey of Nov. 19, 2021, at Tab 3.

- I sent the Nov. 12, 2021, version of my request letter to both RCGT and [redacted], and this letter, on its own, contains the entirety of my request for accommodation. I therefore refer solely to the contents of my Nov. 12 letter in the remainder of this appeal.
- In my email communications to [redacted] of Oct. 28, Nov. 3, and Nov. 12, 2021, I expressed that the three parts of my accommodation request (medical, religious, and human rights (age & sex)) were linked and inseparable, and I asked that my accommodation request not be divided into separate parts.
- My request for exemption from the vaccine policy was denied by the Bank and I was put on unpaid leave without benefits as of Nov. 22, 2021, and advised that my employment may ultimately be terminated.
- Following the Bank's decision to place me on unpaid leave, I inquired with [redacted] and RCGT about how to appeal the Bank's decision internally.
- I was informed by [redacted], Senior Case Manager & Project Lead in Service Operations at RCGT, that I would be permitted to appeal the medical aspects of the Bank's decision by making a submission to RCGT, and that my submission would be reviewed by a different medical doctor (MD) than the MD who reviewed my initial submission of Nov. 12, 2021.[6]
- I was informed by [redacted] that I could appeal the religious and human rights aspects of the Bank's decision by making a submission to [redacted].[7]

Section 2: Evaluation of the medical aspects of my accommodation request

The Bank produced two separate evaluations of my accommodation request: one evaluation pertaining to the religious and human rights (age & sex) aspects of my request, and another pertaining to the medical aspects of my request. The latter (medical) evaluation was conducted by the firm Raymond Chabot Grant Thornton (RCGT) using an anonymous medical doctor (the "MD").

This section concerns the evaluation of my accommodation request by RCGT's MD.

2a: Procedure used by RCGT to evaluate my request

The mandate given to RCGT by the Bank of Canada was as follows:

> "To validate whether or not there is a medical reason for the person requesting accommodation **not** to be vaccinated."[8]

[6] Email string between J. Hickey and [redacted] of Dec. 2-14, 2021, at Tab 4.
[7] Email from [redacted] to J. Hickey of Nov. 23, 2021, at Tab 5; Email from [redacted] to J. Hickey of Feb. 10, 2022, at Tab 6.
[8] Email from J. Hickey to [redacted] of Dec. 7, 2021, at 6:51 PM, at Tab 4.

Furthermore, according to RCGT:[9]

- RCGT instructed its doctors to "form a medical opinion as to whether or not there's a reason not to be vaccinated" for each particular accommodation request.
- RCGT did not give any additional or more specific instructions to its doctors regarding how to decide if there was a medical reason not to be vaccinated, such as a specific list of contraindicated medical conditions.
- It was not necessary for a Bank employee to have a specific condition in order to receive an accommodation on medical grounds.

Accordingly, the sole task of the MD who reviewed my request was to assess "whether or not there is a medical reason for [me] not to be vaccinated".

2b: The MD misrepresented my request submission

RCGT's MD reviewed my request on Nov. 13, 2021, and filled and signed a form entitled "Vaccine Exemption Medical Review Report – Bank of Canada".[10]

The MD wrote the following (in its entirety) in the section "Explanation of Assessment Outcome" of the said form:

> "This claimant requests an exemption to vaccination not on medical grounds, but mainly on grounds of principle, religion, and human rights. The only reference to medical issues in the claimant's letter are:
>
> - an opinion that there is no medical reason for vaccination if they are allowed to work at home with frequent testing for COVID, and
> - concerns about vaccine side effects.
>
> The claimant did not provide any supportive medical information to suggest that they have a medical contraindication to COVID vaccines.
>
> Decision – The criteria for a medical exemption for vaccination have not been made out in this case. Given the information before me, the claimant would need a letter from a specialist with supporting documentation indicating why they cannot receive an mRNA-based vaccine.
>
> It is not within my mandate as a medical reviewer to consider their non-medical reasons for requesting an exemption."

The MD's statement quoted above misrepresents my request for accommodation in three ways:

1. The MD's statement that "[t]his claimant requests an exemption to vaccination not on medical grounds" is false. In fact, I requested (and continue to request) that the Bank of Canada allow

[9] *Ibid.*
[10] MD's Vaccine Exemption Medical Review Report of Nov. 13, 2021, at Tab 7.

me to continue working from home without receiving COVID-19 injections, for the medical reasons given in my submissions.

2. The MD's first bullet point states that I submitted that "there is no medical reason for vaccination if [I am] allowed to work at home with frequent testing for COVID". This statement is false and misleading:

    i. I have never suggested that I would accept frequent testing for COVID while working from home.[11]

    ii. I did not submit nor imply that there is a valid medical reason for vaccination for individuals who work on-site. Rather, my submission is that there is no reliable evidence that the COVID-19 vaccine products provide any benefit (see Section 2e (ii)) and also that the injections are physiologically and medically incapable of providing any benefit with respect to infection and transmission of respiratory illnesses (see Section 2e (iii)).

3. The MD's second bullet point states that I have "concerns about vaccine side effects". I have never used the intrinsically biased term "side effects", because it suggests a hierarchical ordering, by importance or significance, of the effects of a biopharmaceutical product, with a presumed beneficial effect situated at the top of the hierarchy. Instead of this biased terminology, I only use unbiased terms such as "adverse effects" or "adverse events", which are also used by public health agencies such as Public Health Ontario.[12] The MD's use of the term "side effects" misrepresents my submission because it implies that I accept a net average benefit in a medical harms-benefit analysis of the injections. In fact, I submit that the harms-benefit balance falls squarely on the side of harm, using available medical knowledge (see Section 2e of these submissions).

The above-noted misrepresentations by the MD of my submission constitute strong evidence that the MD did not act in a diligent and dutiful manner and appeared to lack objectivity and/or was prejudiced in such a way as to preclude a proper and objective execution of his or her sole task of assessing "whether or not there is a medical reason for [me] not to be vaccinated."

My concerns are amplified by the fact that the MD in-effect agreed to participate in the evaluation under circumstances in which their identity would be hidden from the subject, thereby providing a constructed barrier against professional accountability.

2c: The MD did not consider two medical concerns in my submission

In addition to misrepresenting the medical aspects of my submission, the MD provides not one iota of any indication of having read or considered two of my medical submissions.

[11] However, for clarity, I would accept to be subjected to "rapid antigen testing" if required to work on-site at one of the Bank's offices, similar to the protocol currently in place for on-site staff in the Quebec healthcare system.
[12] See Footnote 10 of my Accommodation Request Letter, at Tab 2.

The first submission ignored by the MD is stated at pg. 3 of my Accommodation Request Letter,[13] as follows:

> "I am a scientist with B.Sc., M.Sc., and Ph.D. degrees in Physics, and I have carefully considered the scientific literature regarding the risks posed to me by COVID-19 and by the COVID-19 vaccines. Having done so, I have come to the deep personal conviction that the right choice for my health is for me not to take a COVID-19 vaccine. From my analysis of the available evidence, I have also come to the deep conviction that the government should not be recommending these vaccines for young and healthy individuals"

The above-quoted passage constitutes a "medical reason for [me] not to be vaccinated" and should have been considered by the MD. It states the position that "the scientific literature regarding the risks posed to me by COVID-19 and by the COVID-19 vaccines" is such as to provide a sufficient medical reason against vaccination for COVID-19.

The second submission ignored by the MD is stated at pgs. 3-4 of my Accommodation Request Letter,[14] as follows:

> "The Bank's policy (…) forces me to expose myself to a higher risk of a dangerous adverse health event (heart inflammation) than females and those older than me, in order to obtain the same employment opportunity of continuing my work at the Bank.
>
> Public Health Ontario's publication 'Weekly surveillance summary: adverse events following immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to October 17, 2021'[17] shows that heart inflammation (myocarditis or pericarditis) events after two doses of an mRNA (Pfizer or Moderna) vaccine occur:
>
> - 3.7 times more frequently in males than in females
> - 1.8 times more frequently in males aged 30-39 (my age group) than in females aged 12-17
> - 1.4 times more frequently in males aged 30-39 than in females aged 18-24
> - 3.8 times more frequently in males aged 30-39 than in females aged 25-29
> - 1.6 times more frequently in males aged 30-39 than in females aged 30-39
> - 9.8 times more frequently in males aged 30-39 than in females aged 40-49
> - 3.3 times more frequently in males aged 30-39 than in females aged 50-59
> - 7.2 times more frequently in males aged 30-39 than in females aged 60-69
> - 10.4 times more frequently in males aged 30-39 than in females aged 70-79
> - 6.6 times more frequently in males aged 30-39 than in females aged 80+
> - 2.1 times more frequently in males aged 30-39 than in males aged 40-49
> - 3.4 times more frequently in males aged 30-39 than in males aged 50-59
> - 3.3 times more frequently in males aged 30-39 than in males aged 60-69
> - 3.1 times more frequently in males aged 30-39 than in males aged 70-79
> - 4.5 times more frequently in males aged 30-39 than in males aged 80+
>
> Males aged 30-39 (my age group) are therefore clearly at a higher risk of developing heart inflammation following two doses of an mRNA vaccine than females or men older than 40. This

[13] Accommodation Request Letter of J. Hickey, at Tab 2.
[14] *Ibid.*

> (…) forces me to expose myself to greater health risk (of a dangerous adverse event following vaccine dosage) than members of other identifiable groups (…)."

The above-quoted passage expresses my concerns about the risks of heart inflammation (myocarditis or pericarditis) to me, and therefore constitutes a "medical reason for [me] not to be vaccinated" and should have been considered by the MD.

The two submissions ignored by the MD noted above were located under headings labeled "Religious" and "Human Rights (Age & Sex)", respectively, in my Accommodation Request Letter, and they are "medical reasons not to be vaccinated".

Furthermore, I expressly communicated that all sections of my Accommodation Request Letter were "linked and inseparable" and asked them to be evaluated as such in my emails to [redacted] of the Bank's Human Resources Department, dated Oct. 28, Nov. 3, and Nov. 12, 2021.

2d: The MD did not evaluate the validity of my medical concerns

In addition to my medical submissions ignored by the MD and noted in Section 2c, I expressed the following in my Accommodation Request Letter,[15] at pgs. 2-3:

> "I am concerned about the known and unknown medical risks of COVID-19 vaccines. Administration of the AstraZeneca vaccine was halted in Canada after several people died due to lethal blood clots caused by the vaccine.[4,5,6] Although the potential dangers were well-known internationally as early as March 11, 2021, and use of the AstraZeneca vaccine had already been halted in at least nine European countries,[7] Canadian provinces continued to administer hundreds of thousands of doses before finally discontinuing use of the AstraZeneca vaccine in mid-May because of the associated health risks.[8,9] The currently-available COVID-19 vaccines have also been associated with many serious adverse health events.[10] Due to the risks of heart inflammation (myocarditis and pericarditis), Germany, France, Norway, Denmark, Sweden, Iceland, and Finland have paused or are no longer recommending the Moderna vaccine for younger people,[11,12,13,14] and Ontario is no longer recommending Moderna for males aged 18-24.[15] These decisions by governments to stop administering or recommending COVID-19 vaccines demonstrate that my concerns about the medical risks associated with COVID-19 vaccines are legitimate."

The above-quoted passage, like the passages quoted in Section 2c, constitute "medical reason[s] for [me] not to be vaccinated", yet the MD made no evaluation whatsoever about the validity of any of my medical reasons not to be vaccinated. The MD ignored and did not evaluate any of my medical reasons not to be vaccinated:

- The scientific literature regarding the risks posed to me by COVID-19 and by the COVID-19 vaccines is such as to provide a sufficient medical reason against vaccination for COVID-19.
- Heart inflammation is a real medical risk to me, and is a medical reason not to be vaccinated.

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[15] *Ibid.*

I ask that the new MD reviewing these appeal submissions make reviewable evaluations of all of my "medical reason[s] for [me] not to be vaccinated", including the additional medical reasons that I provide herein (below).

2e: Additional medical reasons not to be vaccinated

I hereby extend my submission of "medical reasons not to be vaccinated" with the following additional reasons. I ask that these additional reasons be evaluated by the new MD reviewing these appeal submissions.

I ask the evaluating MD to note that I offer to provide additional materials if my submissions are not sufficient for them to make the evaluations on any point.

2e (i): There was no emergency that caused large amounts of deaths in Canada in 2020-2021 that would justify vaccinating the entire population

Fig. 1, below shows the number of deaths per week, of all causes, in Canada (blue lines in Fig. 1a and Fig. 1b) and in the USA, divided by 10 (orange line in Fig. 1b). The *x*-axes ranges from September 30, 2013, to January 31, 2022, and the yearly tick-marks correspond to January 1st for each year.

As can be seen, in the years before 2020, in both countries, there is a regular annual cycle in the number of deaths with a winter peak and summer trough. The additional deaths during the winter months compared to the summer trough levels ("excess deaths") are predominantly due to deaths of elderly people and are postulated (in a dominant scientific view) to be driven by viral respiratory illnesses including influenza, and associated co-morbidities (esp. pneumonia and heart conditions).

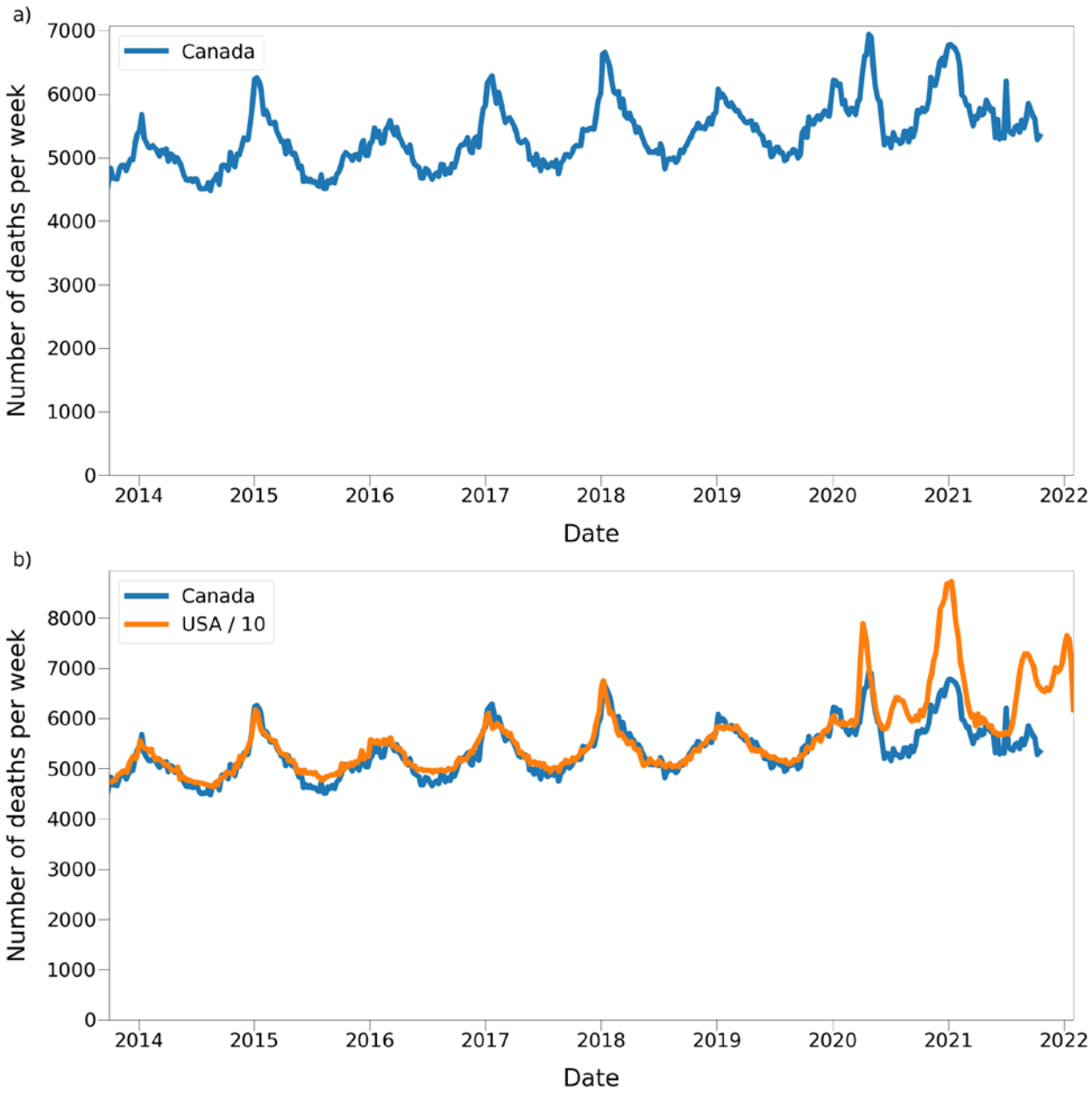

Figure 1: (a) Number of deaths per week (a) in Canada, (b) in Canada and in the USA (divided by 10). *x*-axis ticks are located at January 1st of the year. Canadian data from Statistics Canada,[16] USA data from the CDC.[17]

As can be seen from Fig. 1a, there is overall no exceptional change in the number of deaths per winter or per year in Canada in the period beginning with and following the winter of 2020 as compared to the period leading up to the winter of 2020. That is, the last two "winter peaks" of deaths in Fig. 1a (centred on the winter of 2020 and the winter of 2021) each correspond to approximately the same number of excess deaths as do each of the winter peaks from 2014-2019, and the deaths per week in the summer

[16] Statistics Canada, "Provisional weekly death counts, by age group and sex", https://www150.statcan.gc.ca/t1/tbl1/en/cv.action?pid=1310076801.
[17] CDC, "Pneumonia and influenza mortality surveillance from the National Center for Health Statistics Monitoring System", https://gis.cdc.gov/grasp/fluview/mortality.html.

troughs in the summers of 2020 and 2021 essentially follow the increasing linear trend of summer trough levels that spans all the data shown in the figure.

The largest abnormal distinct feature of the post-January 2020 part of the deaths per week data in Fig. 1a is the presence of a second, late-winter peak starting in March of 2020. This peak occurs immediately after the WHO declared the COVID-19 pandemic on March 11, 2020, and has features that are incompatible with the spread of a novel virus in a population without prior immunity, namely:[18]

- its sharpness, with a base to inflection-point time of only 3 weeks;
- its lateness in the infectious-season cycle, starting after week 11 of 2020, which is unprecedented for any large sharp-peak feature;
- the synchronicity of its onset, across continents, and immediately following the WHO declaration of the pandemic (in the many countries where a similar sharp peak occurs in March 2020);
- the fact that it is only present in a minority of Canadian provinces, whereas the seasonal cycle of all-cause deaths is normally remarkably homogenous across provinces (including when scaled by provincial population);
- the fact that it is much larger in Quebec than Ontario on a per capita basis, although these provinces share a border;
- the high degree of heterogeneity of absence or presence of a sharp March 2020 peak across states in the USA, and across sub-national jurisdictions within European countries.

Accordingly, negative impacts of government responses are a more plausible explanation for the March 2020 sharp peak in the number of deaths per week in Canada, as discussed by Rancourt et al. in the article attached at Tab 8 of these submissions.[19]

In contrast to the data for Canada, the number of deaths per week in the USA (Fig. 1b) shows a pattern that is qualitatively and quantitatively different in the period after March 2020 compared to the period leading up to March 2020. The main features of the post-March 2020 all-cause mortality by week in the USA are as follows:[20]

- Beginning immediately following the WHO declaration of a pandemic on March 11, 2020, there is a large peak in deaths that lasts approximately three months.
- The number of deaths per week does not descend to the summer baseline in the summer of 2020, and instead there is a broad mid-summer peak (approximately mid-June to mid-September) that is unprecedented in epidemiological records.
- There is an exceptionally large peak spanning approximately late-September 2021 to mid-March 2021.
- There is an anomalous (unprecedented) late summer-2021 upsurge in deaths followed by a relatively small decrease and then a late autumn-2021 upsurge in deaths.

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[18] D.G. Rancourt et al., "Analysis of all-cause mortality by week in Canada 2010-2021, by province, age and sex: There was no COVID-19 pandemic, and there is strong evidence of response-caused deaths in the most elderly and in young males", ResearchGate, 6 August 2021, http://dx.doi.org/10.13140/RG.2.2.14929.45921, at Tab 8.
[19] *Ibid.*, at pgs. 41-48.
[20] See D.G. Rancourt et al., "Nature of the COVID-era public health disaster in the USA, from all-cause mortality and socio-geo-economic and climatic data", ResearchGate, 25 October 2021, http://dx.doi.org/10.13140/RG.2.2.11570.32962, at Tab 9.

- The number of deaths per week again does not descend to the summer baseline, in the summer of 2021. There were no "epidemiological summers" in the USA in 2020 and 2021.

Therefore, the temporal evolution of the number of all-cause deaths per week was highly correlated between the two countries up to March 2020, but then diverged immediately following the WHO declaration of a pandemic on March 11, 2020, with the USA deaths per week rising to exceptionally high values and having little resemblance to the historic seasonal trend of the last decade or so.

The dramatic increase in above-trend all-cause deaths in the USA starting March 11, 2020, and extending throughout the COVID period is unique in magnitude among Western nations,[21,22] and corresponds to 1 million excess deaths up to January 31, 2022. This can be explained by the fact that the USA has:[23]

- a large proportion of the population having fragile health, correlated to state-wise poverty, obesity, prescriptions of antibiotics, diabetes, and so forth,
- climatic conditions in the southern states (high average temperatures in the summer) that impose a large thermal stress, especially affecting fragile individuals,[24]
- strict lockdown policies causing social isolation, psychological stress, and reduced ability to relieve thermal stress.

Rancourt et al. concluded that the COVID-period excess mortality in the USA was not caused by any special viral respiratory disease acting in a typical advanced Western nation:

> "We infer that persistent chronic psychological stress induced by the long-lasting government-imposed societal and economic transformations during the COVID-era converted the existing societal (poverty), public-health (obesity) and hot-climate risk factors into deadly agents, largely acting together, with devastating population-level consequences against large pools of vulnerable and disadvantaged residents of the USA, far above preexisting pre-COVID-era mortality in those pools. We also find a large COVID-era USA pneumonia epidemic [reported in CDC mortality data] that is not mentioned in the media or significantly in the scientific literature, which was not adequately addressed [prescriptions of antibiotics were reduced by half nation-wide]."[25]

That conclusion — that the large excess mortality in the USA was not primarily or largely caused by COVID — is supported by several medical reports and studies, as follows:

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[21] *Ibid.*

[22] R.F. Kennedy Jr., "The Real Anthony Fauci: Bill Gates, Big Pharma, and the Global War on Democracy and Public Health", Skyhorse Publishing (New York, 2021), at pgs. xviii-xix.

[23] D.G. Rancourt et al., "Nature of the COVID-era public health disaster in the USA, from all-cause mortality and socio-geo-economic and climatic data", ResearchGate, 25 October 2021, http://dx.doi.org/10.13140/RG.2.2.11570.32962, at Tab 9.

[24] J.F. Clarke, "Some effects of the urban structure on heat mortality", *Env. Res.* 5 (1972) 93-104, https://www.sciencedirect.com/science/article/abs/pii/0013935172900230.

[25] D.G. Rancourt et al., "Nature of the COVID-era public health disaster in the USA, from all-cause mortality and socio-geo-economic and climatic data", ResearchGate, 25 October 2021, http://dx.doi.org/10.13140/RG.2.2.11570.32962, at Tab 9.

1. A *BMJ* study by Woolf et al. found a much larger decrease in life expectancy in the USA between 2018 and 2020 compared to other high income nations:

> "Between 2010 and 2018, the gap in life expectancy between the US and the peer country average increased from 1.88 years (78.66 v 80.54 years, respectively) to 3.05 years (78.74 v 81.78 years). Between 2018 and 2020, life expectancy in the US decreased by 1.87 years (to 76.87 years), 8.5 times the average decrease in peer countries (0.22 years), widening the gap to 4.69 years. Life expectancy in the US decreased disproportionately among racial and ethnic minority groups between 2018 and 2020, declining by 3.88, 3.25, and 1.36 years in Hispanic, non-Hispanic Black, and non-Hispanic White populations, respectively. In Hispanic and non-Hispanic Black populations, reductions in life expectancy were 18 and 15 times the average in peer countries, respectively. Progress since 2010 in reducing the gap in life expectancy in the US between Black and White people was erased in 2018-20; life expectancy in Black men reached its lowest level since 1998 (67.73 years), and the longstanding Hispanic life expectancy advantage almost disappeared."[26]

2. 93,000 people died in the USA of overdoses in 2020 (a 30% increase compared to 2019).[27]

3. "During 2020, the proportion of mental health-related emergency department (ED) visits among adolescents aged 12-17 years increased 31% compared with that during 2019."[28]

4. "The increases in drug overdose deaths appear to have accelerated during the COVID-19 pandemic. (…) Synthetic opioids are the primary driver of the increases in overdose deaths. The 12-month count of synthetic opioid deaths increased 38.4% from the 12-months ending in June 2019 compared with the 12-months ending in May 2020 (Figure 1)."[29]

5. Mental health problems, including suicidal ideation, increased significantly after March 2020:

> "Elevated levels of adverse mental health conditions, substance use, and suicidal ideation were reported by adults in the United States in June 2020. The prevalence of symptoms of anxiety disorder was approximately three times those reported in the second quarter of 2019 (25.5% versus 8.1%), and prevalence of depressive disorder was approximately four times that reported in the second quarter of 2019 (24.3% versus 6.5%) (2). However, given the methodological differences and potential unknown biases in survey designs, this analysis might not be directly comparable with data reported on

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[26] S.H. Woolf et al., "Effect of the covid-19 pandemic in 2020 on life expectancy across populations in the USA and other high income countries: simulations of provisional mortality data", *BMJ* 373 (2021) n1343, https://doi.org/10.1136/bmj.n1343.

[27] B. Chappell, "Drug Overdoses Killed A Record Number Of Americans In 2020, Jumping By Nearly 30%", 14 July 2021, *NPR*, https://www.npr.org/2021/07/14/1016029270/drug-overdoses-killed-a-record-number-of-americans-in-2020-jumping-by-nearly-30.

[28] E. Yard et al., "Emergency Department Visits for Suspected Suicide Attempts Among Persons Aged 12–25 Years Before and During the COVID-19 Pandemic — United States, January 2019–May 2021", *Morb Mort Week Rep* 70 (2021) 888-894, https://www.cdc.gov/mmwr/volumes/70/wr/mm7024e1.htm.

[29] CDC Health Alert Network, "Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic", 17 December 2020, https://emergency.cdc.gov/han/2020/han00438.asp.

> anxiety and depression disorders in 2019 (2). Approximately one quarter of respondents reported symptoms of a TSRD related to the pandemic, and approximately one in 10 reported that they started or increased substance use because of COVID-19. Suicidal ideation was also elevated; approximately twice as many respondents reported serious consideration of suicide in the previous 30 days than did adults in the United States in 2018, referring to the previous 12 months (10.7% versus 4.3%) (6)."[30]

Indeed, if one were to accept the media and CDC-promoted interpretation that virtually all excess mortality in the COVID period in the USA is due simply and directly to COVID, then one has to explain how the presumed virulent pandemic pathogen, which caused 1 million excess deaths in the USA, did not cross the 3,000 km border into Canada, where there are virtually no excess deaths in the COVID period (see Fig. 1).

Two medical conclusions impose themselves:

1. Deaths "from COVID" cannot be analysed in terms of a textbook viral respiratory disease pandemic, in that socio-economic characteristics and jurisdictional regulatory responses are determinative.
2. There was no extraordinary health emergency in Canada that caused anomalous winter or yearly excess mortality in the COVID period, although features suggesting negative impact of jurisdictional regulatory responses are apparent (as discussed above).

Since there was no extraordinary health emergency in Canada that caused anomalous winter or yearly excess all-cause mortality in the COVID period (Fig.1), and since there was not a crash of the health-care system, a universal, nation-wide, multi-dose vaccine program was not and cannot be justified. The societal-scale disruption, costs and risks of the vaccine campaign outweigh any measurable death-avoiding advantage, which cannot be detected in robust all-cause mortality figures (much less causally attributed to COVID), while putting individuals at proven risk of disability and death.

All of the above constitutes a "medical reason for [me] not to be vaccinated".

2e (ii): There is no reliable evidence that the COVID-19 vaccine products provide any health benefit

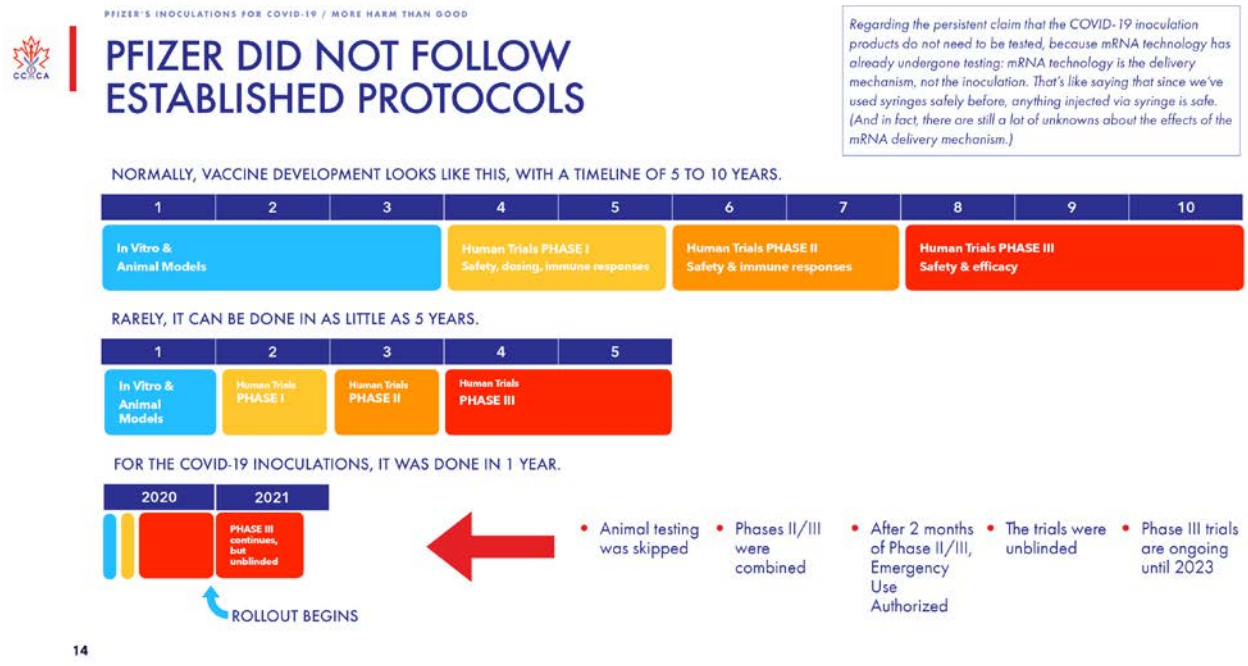
This section is divided into three parts:

- Context of vaccine product development renders clinical trials unreliable
- The clinical trials suffered from many fatal flaws
- Epidemiological studies post-rollout cannot on their own provide valid evidence of effectiveness

[30] M.E. Czeisler, "Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020", *Morb Mort Week Rep*, 69 (2020) 1049-1057, https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm.

Context of vaccine product development renders clinical trials unreliable

The figure below, copied from a Dec. 16, 2021, presentation by the Canadian Covid Care Alliance (CCCA),[31] shows the normal protocol for developing and marketing a vaccine product, compared with the steps followed by Pfizer in developing its COVID-19 vaccine:



As can be seen from CCCA's figure, the trials were rushed, with skipped steps and numerous exceptions to the established protocols.

Additionally, the producers of the vaccine products made astronomical profits from their sales in 2021. For example:[32]

> "In their Q3 financial statement, Pfizer forecast $36 billion in vaccine revenue for 2021. (…) Moderna's Q3 profit before tax for 9 months ending September 30 is $7.8 billion on $11.2 billion revenue giving a pre-tax profit margin of 70 percent. The company projects full year 2021 sales to be "between $15 billion and $18 billion". Using the lower end of the estimate —70 percent of $15 billion is $10.5 billion in profit for 2021. The vaccine is Moderna's only commercial product."

The COVID-19 vaccine products were developed in a rush, abandoning the established protocols for evaluating safety and efficacy, in a frenzied competition for enormous profits by private, self-interested

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[31] Canadian Covid Care Alliance (CCCA), "The Pfizer Inoculations for Covid-19: More Harm than Good" (2021): https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf, at Tab 10.

[32] Reliefweb, "Pfizer, BioNTech and Moderna making $1,000 profit every second while world's poorest countries remain largely unvaccinated", 16 November 2021: https://reliefweb.int/report/world/pfizer-biontech-and-moderna-making-1000-profit-every-second-while-world-s-poorest; https://archive.ph/oepHe, at Tab 11.

corporations. This is not a context in which any "evidence" produced by and funded by the said private corporations about the efficacy of their products can possibly be deemed "reliable", certainly not reliable enough to be a basis for coercive vaccination policies and mandates. Independent clinical trials conducted by organizations without conflicts of interest are needed, at the very least. There are none.

The clinical trials suffered from many fatal procedural flaws

Additionally, the trials suffered from many specific procedural flaws that render their results unreliable, notably:

- The trials were not double-blinded, since the person administering the vaccine was or could be aware of the contents (whether vaccine product or placebo) of the injection.[33,34]
- The trials tested for "mild covid", which was assessed using faulty methods (PCR[35] and generic symptoms).
- The trials used misleading demographics, focusing on the wrong age for the target population,[36] and testing on healthy but given to sick individuals.[37]
- The trials used inadequate control groups.[38]
- The trials had wrong clinical endpoints, and should have focused on all-cause mortality and illness.[39]
- The trials did not test for spread reduction, and there is "no evidence at all that [the COVID-19 vaccine products] reduce the spread of disease and transmission was never one of the study's endpoints".[40]
- The trials did not test all participants for COVID-19: "Instead, they instructed their investigators to test only those with a COVID-19 symptom and left it up to their discretion to decide what those were."[41]
- Missing data: "The fact that the Lost to Follow Up and Suspected but Unconfirmed numbers are higher - and here they are even significantly higher - than the End Point numbers means that this data is unreliable. The study should not have been accepted in this state. In normal scientific practice they should have returned to investigate further."[42]

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[33] P.D. Thacker, "Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial", *British Medical Journal*, 375 (2021) n2635, https://www.bmj.com/content/375/bmj.n2635.
[34] F.P. Polack et al., "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine", *New Eng. J. Med*. 383 (2020) 2603-2615 (see the "Protocol" file in the Supplementary Material section at the link here: https://www.nejm.org/doi/full/10.1056/nejmoa2034577).
[35] P. Borger et al., "External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results", ResearchGate, 27 November 2020, http://dx.doi.org/10.5281/zenodo.4298004, at Tab 12.
[36] Canadian Covid Care Alliance (CCCA), "The Pfizer Inoculations for Covid-19: More Harm than Good" (2021): https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf, slide 15, at Tab 10.
[37] *Ibid.* slide 16.
[38] *Ibid.* slide 17.
[39] *Ibid.* slide 19.
[40] *Ibid.* slide 20.
[41] *Ibid.* slide 21.
[42] *Ibid.* slide 22.

- Failure to report serious adverse events, including the case of 12 year old Pfizer trial participant Maddie de Garay.[43]

Epidemiological studies post-rollout cannot on their own provide reliable evidence of effectiveness

The "gold standard" for evaluating the safety and efficacy of a medical intervention is the randomized clinical trial. As explained above, the clinical trials of the COVID-19 vaccine products are unreliable.

Nonetheless, the vaccine products were approved for use by governments around the world and administered to their populations. Retrospective epidemiological studies (not randomized clinical trials) were then published based on data collected during the administration of the vaccines.

Such epidemiological studies cannot, on their own, be considered to provide reliable evidence for the effectiveness of a vaccine product. There must be clear evidence of benefit from procedurally flawless and conflict-of-interest-free randomized clinical trials before it can be said that reliable evidence exists in favour of the medical product.

An example of a retrospective epidemiological study that investigated the effectiveness of the Pfizer COVID-19 vaccine product is that of Dagan et al.[44] Referring to this study in an open letter addressed to the German Federal Chancellor and Members of European Parliament, a group of hundreds of German medical doctors wrote:[45]

> "With regard to the prevention of one death, the absolute risk is reduced by only 0.0039% by vaccination. This means that about 26,000 people need to be vaccinated to prevent *one* COVID death. The probability for the individual to be protected by the vaccination is therefore extremely low and must therefore be weighed against the risks of vaccination. In the meantime, there are numerous other observational studies with very similar results." [Emphasis in original.]

If such a small absolute risk reduction were to be found in a properly-conducted randomized clinical trial, it would need to be compared against the risk of death to the trial participants from the vaccine product itself or associated complications, in an active-surveillance framework, where the age-structure of the cohort is properly considered, and where a "COVID death" is assigned using a rigorous and accurate method. But this has not been done.

The submissions in this section show that there is no reliable evidence that the COVID-19 vaccine products provide any benefit. This is a "medical reason for [me] not to be vaccinated".

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[43] *Ibid*. slide 25.

[44] N. Dagan et al., "BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting", *New Eng. J. Med.* 384 (2021) 1412-1423: https://www.nejm.org/doi/full/10.1056/nejmoa2101765.

[45] Open letter "Doctors Stand Up" to European politicians signed by over 230 German doctors, 13 December 2021: https://ocla.ca/wp-content/uploads/2022/01/offener_brief_13_12_2021_englisch.pdf (English translation), at Tab 13; https://aerzte-stehen-auf.de/offener-brief/ (original German).

2e (iii): Vaccine products injected via intramuscular routes are in-effect physiologically incapable of preventing infection and transmission of respiratory illnesses

This point is explained by the eminent professor and medical researcher S. Bhakdi[46] and colleagues in the following passages:

> "A fundamental mistake underlying the development of the COVID-19 vaccines was to neglect the functional distinction between the two major categories of antibodies which the body produces in order to protect itself from pathogenic microbes.
>
> The first category (secretory IgA) is produced by immune cells (lymphocytes) which are located directly underneath the mucous membranes that line the respiratory and intestinal tract. The antibodies produced by these lymphocytes are secreted through and to the surface of the mucous membranes.
>
> These antibodies are thus on site to meet air-borne viruses, and they may be able to prevent viral binding and infection of the cells.
>
> The second category of antibodies (IgG and circulating IgA) occur in the bloodstream. These antibodies protect the internal organs of the body from infectious agents that try to spread via the bloodstream.
>
> Vaccines that are injected into the muscle – i.e., the interior of the body – will only induce IgG and circulating IgA, not secretory IgA. Such antibodies cannot and will not effectively protect the mucous membranes from infection by SARS-CoV-2. Thus, the currently observed "breakthrough infections" among vaccinated individuals merely confirm the fundamental design flaws of the vaccines.
>
> Measurements of antibodies in the blood can never yield any information on the true status of immunity against infection of the respiratory tract.
>
> The inability of vaccine-induced antibodies to prevent coronavirus infections has been reported in recent scientific publications."[47]

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[46] The Google Scholar profile of Sucharit Bhakdi contains the following information about his research credentials: h-index of 86, 25,334 total citations, i10-index (number of publications with at least 10 citations) of 276, and his five most-cited articles are: S. Bhadki and J. Tranum-Jensen, "Alpha-toxin of Staphylococcus aureus", *Microbiol Molec. Biol. Rev.* 55 (1991) 733-751 (1060 Google Scholar citations); P. Avirutnan et al., "Vascular leakage in severe dengue virus infections: a potential role for the nonstructural viral protein NS1 and complement", *J. Infect. Dis.* 193 (2006) 1078-1088 (578 Google Scholar citations); S. Bhakdi et al., "Complement and atherogenesis: binding of CRP to degraded, nonoxidized LDL enhances complement activation", *Arterioscler. thrombos. vasc. biol.* 19 (1999) 2348-2354 (538 Google Scholar citations); P. Avirutnan et al., "Dengue virus infection of human endothelial cells leads to chemokine production, complement activation, and apoptosis", *J. Immunol.* 161 (1998) 6338-6346 (481 Google Scholar citations); S. Bhakdi et al., "Mechanism of membrane damage by streptolysin-O", *Infect. and Immun.* 47 (1985) 52-60 (464 Google Scholar citations). Google Scholar profile of Prof. Bhakdi: https://scholar.google.com/citations?user=0vTPuO0AAAAJ&hl=en&oi=ao, at Tab 14.

[47] S. Bhakdi and A. Burkhardt, "On COVID vaccines: Why they cannot work, and irrefutable evidence of their causative role in deaths after vaccination", Doctors for Covid Ethics, 10 December 2021: https://doctors4covidethics.org/wp-content/uploads/2021/12/end-covax.pdf, at Tab 15.

> "In any case, prior to inflammation, practically no IgG will be present on the respiratory mucous membranes, which leaves them vulnerable to infection. This is why the current COVID-19 vaccines cannot prevent infection or transmission of the virus [5, 6]. Below is a direct quote from the review paper by McGhee et al. [6]:
>
> > *It is surprising that despite our current level of understanding of the common mucosal immune system, almost all current vaccines are given to humans by the parenteral route. Systemic immunization is essentially ineffective for induction of mucosal immune responses. Since the majority of infectious microorganisms are encountered through mucosal surface areas, it is logical to consider the induction of protective antibodies and T cell responses in mucosal tissues.*
>
> Note that this statement was made already three decades ago—yet nothing has changed, and the same flawed, outdated approach of intramuscular injection has been adopted yet again with the "modern" and "high-tech" COVID-19 vaccines.
>
> (…)
>
> The lack of protection against infection of the airways by serum IgG is not limited to SARS-CoV-2 and COVID. As early as 1984, Liew et al. demonstrated that the IgG found in the bloodstream is quite irrelevant for the protection against influenza virus; it is the sIgA on the mucous membranes that prevents the virus from establishing infection.
>
> In conclusion, sIgA on the mucous membranes, especially in the URT, is necessary for effective and protective immunity against respiratory viruses, and it is induced only when the antigen is introduced via the natural route—into the URT itself. This rule applies to both natural pathogens and vaccines."[48]

It is worth noting that reference "[6]" in the passage quoted directly above is an article published in the peer-reviewed journal *Vaccine* in 1992 that has 1151 citations in Google Scholar.[49]

Prof. Bhakdi has also explained these points in a video, at the link here: https://doctors4covidethics.org/the-covid-vaccines-were-designed-to-fail-nov-25th-2021/.

Prof. Steven Pelech has also made the same points, in a video dated Dec. 13, 2021.[50] Prof. Pelech was a founding member of the Biomedical Research Centre at UBC (an immunology institute),[51] and he has a

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[48] Anonymous MD, S. Bhakdi, and M. Palmer, "Why intramuscular COVID-19 vaccination must fail", Doctors for Covid Ethics, 7 December 2021: https://doctors4covidethics.org/wp-content/uploads/2021/12/summary-Abs2b.pdf, at Tab 16.

[49] J.R. McGhee et al., "The mucosal immune system: from fundamental concepts to vaccine development", *Vaccine* 10 (1992) 75–88, https://doi.org/10.1016/0264-410X(92)90021-B.

[50] Liberty Coalition Canada, "Dr. Steven Pelech, PhD: The Missing Science You Need on Antibody Immunity", 13 December 2021 (at 29:06), https://rumble.com/vq2joz-dr.-steven-pelech-phd-the-missing-science-you-need-on-antibody-immunity..html.

[51] *Ibid.*, at 01:15.

Google Scholar h-index of 77, an i10-index of 186, and his articles have accumulated 18,189 total citations.[52]

The points explained in this section can be said to be part of textbook immunology.[53] Many scientific studies published since mid-2021 support this textbook view of immunology, because they show that the COVID-19 vaccines have had little to no effect on infection and transmission, for example:

- "During July 2021, 469 cases of COVID-19 associated with multiple summer events and large public gatherings in a town in Barnstable County, Massachusetts, were identified among Massachusetts residents; vaccination coverage among eligible Massachusetts residents was 69%. Approximately three quarters (346; 74%) of cases occurred in fully vaccinated persons"[54]
- "Vaccination was associated with a smaller reduction in transmission of the delta variant than of the alpha variant, and the effects of vaccination decreased over time. PCR Ct values at diagnosis of the index patient only partially explained decreased transmission."[55]
- "[Secondary attack rate] among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% [95% CI 15–35] for vaccinated vs 23% [15–31] for unvaccinated). (…) fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts."[56]
- "In the 25 COVID-19 confirmed cases of ADSC, 6 patients caused transmission to household members. Forty-six household members were tested to assess secondary transmission from the ADSC outbreak (Fig. 2). Overall, the attack rate of household members for the outbreak was 23.9% (11/46). Among the 6 fully vaccinated index cases, the secondary attack rate (SAR) of unvaccinated and partially vaccinated household members were 27.8% (5/18) and 25.0% (5/20), respectively. The SAR of fully vaccinated household members were 12.5% (1/8)."[57]

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[52] Google Scholar profile of Prof. Steven Pelech, https://scholar.google.com/citations?user=hE_1ChsAAAAJ&hl=en&oi=ao.

[53] ScienceDirect, "Secretory Immunoglobulin", https://www.sciencedirect.com/topics/neuroscience/secretory-immunoglobulin; B.S. Bleier et al., "COVID-19 Vaccines May Not Prevent Nasal SARS-CoV-2 Infection and Asymptomatic Transmission", *Otolaryngol. Head Neck Surg.* 164 (2021) 305-307, https://journals.sagepub.com/doi/10.1177/0194599820982633.

[54] C.M. Brown et al., "Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021", *MMWR Morb Mortal Wkly Rep* 70 (2021) 1059-1062, https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm.

[55] D.W. Eyre et al., "Effect of Covid-19 Vaccination on Transmission of Alpha and Delta Variants", *New England Journal of Medicine*, (2022), https://www.nejm.org/doi/full/10.1056/nejmoa2116597.

[56] A. Singanayagam et al., "Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study", *The Lancet Infectious Diseases*, 22 (2022) 183-195, https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext.

[57] S. Yi et al., "SARS-CoV-2 Delta Variant Breakthrough Infection and Onward Secondary Transmission in Household", *J. Korean Med. Sci.* 37 (2021) e12, https://synapse.koreamed.org/articles/1148790.

- "Here, we report a case of breakthrough infection with the SARS-CoV-2 delta variant, and a secondary case in a family member (in which the index case was fully vaccinated and the secondary case had not been vaccinated) …"[58]
- "We identified 30 secondary cases of SARS-CoV-2 infection in residents from 7 states; date of SARS-CoV-2–positive specimen collection ranged from July 11 through July 29, 2021, resulting in 1,128 cluster-associated cases (Table 1). Persons with secondary cases were epidemiologically linked to 26 persons who had primary cases (Figure 2). Eighteen (60%) of 30 secondary cases occurred in fully vaccinated persons, as did 21 (81%) of 26 primary cases; there were 16 primary/secondary case pairs in which both persons were fully vaccinated. Most persons who had secondary cases (21, 70%) were household contacts of persons who had primary cases."[59]
- "Among 1497 fully vaccinated health care workers for whom RT-PCR data were available, 39 SARS-CoV-2 breakthrough infections were documented."[60]
- "Here we report the case of a breakthrough infection in a fully vaccinated HCW and the subsequent transmission of the virus to their spouse."[61]
- "Here, we describe a household cluster of Gamma variant COVID-19 cases occurring in vaccinated family members living in co-residence that resulted in mixed clinical outcomes. A detailed inspection of the epidemiological and clinical features of these cases, together with serology testing and genomic sequencing, suggest complex factors including partial immunity and unrecognized underlying autoimmunity, as potential contributors to breakthrough infections. Our data add to rapidly emerging literature on SARS-CoV-2 transmission dynamics within households of vaccinated persons."[62]

Given the above scientific studies showing little to no effect of the COVID-19 vaccines on infection or transmission, it is unsurprising that the Chief Medical Officer of Health for Ontario, Dr. Kieran Moore, stated at a Feb. 3, 2022, press conference that "[t]he vaccine isn't providing significant benefit at two doses against the risk of transmission, as compared to someone unvaccinated".[63]

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[58] Y. Moriyama et al., "A case report of breakthrough infection with the SARS-CoV-2 delta variant and household transmission: Role of vaccination, anti-spike IgG and neutralizing activity", *J. Infect. Chemother.* In press, available online 11 February 2022, https://www.sciencedirect.com/science/article/pii/S1341321X22000435.

[59] R. Gharpure et al., "Multistate Outbreak of SARS-CoV-2 Infections, Including Vaccine Breakthrough Infections, Associated with Large Public Gatherings, United States", *Emerg. Infect. Dis.* 28 (2022) 35-43, https://wwwnc.cdc.gov/eid/article/28/1/21-2220_article.

[60] M. Bergwerk et al., "Covid-19 Breakthrough Infections in Vaccinated Health Care Workers", *New Eng. J. Med.* (2021), https://www.nejm.org/doi/10.1056/NEJMoa2109072.

[61] I. Kroidl et al., "Vaccine breakthrough infection and onward transmission of SARS-CoV-2 Beta (B.1.351) variant, Bavaria, Germany, February to March 2021", *Eurosurveillance* 26 (2021) 1-4, https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.30.2100673.

[62] J. Liu et al., "SARS-CoV-2 transmission dynamics and immune responses in a household of vaccinated persons", *Clin. Inf. Dis.* (2022) ciac029 (Accepted manuscript), https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciac029/6509064.

[63] ""The vaccine isn't providing significant benefit at two doses against the risk of transmission, as compared to someone unvaccinated," [Ontario Chief Medical Officer of Health] Moore said. "We have to reassess the value of the passports in the coming weeks and months."" – CTV News, "Ontario needs to 'reassess the value' of COVID-19 vaccine passport system, top doctor says", 3 February 2022, https://toronto.ctvnews.ca/ontario-needs-to-reassess-the-value-of-covid-19-vaccine-passport-system-top-doctor-says-1.5765973; Alternative link: https://archive.ph/2oN8I.

In sum, the fact that vaccine products injected via intramuscular routes are physiologically incapable of preventing infection and transmission of respiratory illnesses is a "medical reason for [me] not to be vaccinated".

2e (iv): Autopsies have provided histopathological evidence of grave dangers of COVID-19 vaccine products

The German pathologist Prof. Arne Burkhardt has performed autopsies on at least 17 people who died within days to months after being injected with a COVID-19 vaccine product. Prof. Burkhardt states his findings and conclusions as follows:[64]

> **"Histopathologic studies: findings**
>
> Histopathologic findings of a similar nature were detected in organs of 14 of the 15 deceased. Most frequently afflicted were the heart (14 of 15 cases) and the lung (13 of 15 cases). Pathologic alterations were furthermore observed in the liver (2 cases), thyroid gland (Hashimoto's thyroiditis, 2 cases), salivary glands (Sjögren`s Syndrome; 2 cases) and brain (2 cases).
>
> A number of salient aspects dominated in all affected tissues of all cases:
>
> 1. inflammatory events in small blood vessels (endothelitis), characterized by an abundance of Tlymphocytes and sequestered, dead endothelial cells within the vessel lumen;
> 2. the extensive perivascular accumulation of T-lymphocytes;
> 3. a massive lymphocytic infiltration of surrounding non-lymphatic organs or tissue with Tlymphocytes.
>
> Lymphocytic infiltration occasionally occurred in combination with intense lymphocytic activation and follicle formation. Where these were present, they were usually accompanied by tissue destruction.
>
> This combination of multifocal, T-lymphocyte-dominated pathology that clearly reflects the process of immunological self-attack is without precedent. Because vaccination was the single common denominator between all cases, there can be no doubt that it was the trigger of self-destruction in these deceased individuals.
>
> **Conclusion**
>
> Histopathologic analysis show clear evidence of vaccine-induced autoimmune-like pathology in multiple organs. That myriad adverse events deriving from such auto-attack processes must be expected to very frequently occur in all individuals, particularly following booster injections, is self-evident."

[64] S. Bhakdi and A. Burkhardt, "On COVID vaccines: Why they cannot work, and irrefutable evidence of their causative role in deaths after vaccination", Doctors for Covid Ethics, 10 December 2021: https://doctors4covidethics.org/wp-content/uploads/2021/12/end-covax.pdf, at Tab 15.

Additionally, Prof. Michael Palmer has shown and interpreted images of histopathology slides from Prof. Bukrhardt's autopsies in a public presentation at the link here: https://www.bitchute.com/video/R6O8768RoWxm/.

In a separate study,[65] the Chief Medical Examiner of the State of Connecticut (Prof. James Gill)[66] and co-authors present their "results of autopsies for two teenage boys who were found dead in bed 3 and 4 days after receiving the second dose of the Pfizer-BioNTech COVID-19 vaccine." Gill et al. state that "[b]oth teenage boys had similar clinical presentations with no obvious cardiac symptoms" and make the following conclusions:

> "Conclusions.– The myocardial injury seen in these post-vaccine hearts is different from typical myocarditis and has an appearance most closely resembling a catecholamine-mediated stress (toxic) cardiomyopathy. Understanding that these instances are different from typical myocarditis and that cytokine storm has a known feedback loop with catecholamines may help guide screening and therapy."

Gill et al. also cite another histopathological study[67] of patients with myocarditis shortly following COVID-19 vaccination as follows:

> "Two adults (ages 42 and 45 years) with "myocarditis" diagnosed histologically (one at autopsy and one by biopsy) following SARS-COV-2 mRNA vaccinations were recently reported.41 One occurred 10 days after receiving the first Pfizer-BioNTech COVID-19 vaccine dose and the other occurred 14 days after receiving the second mRNA-1273 (Moderna) dose. Histologically, both were described as "fulminant" myocarditis with "multifocal cardiomyocyte damage associated with mixed inflammatory infiltration." In addition to areas of myocyte necrosis associated with the inflammatory infiltrate, the photomicrographs demonstrate ischemic changes distinct from the inflammation similar to our findings."

F. Sessa et al. conducted a systematic review entitled "Autopsy Findings and Causality Relationship between Death and COVID-19 Vaccination: A Systematic Review". The Abstract of that paper is as follows:[68]

> "Abstract: The current challenge worldwide is the administration of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. Considering that the COVID-19 vaccination represents the best possibility to resolve this pandemic, this systematic review aims to clarify the major aspects of fatal adverse effects related to COVID-19 vaccines, with the goal of advancing our knowledge, supporting decisions, or suggesting changes in policies at local, regional, and global levels. Moreover, this review aims to provide key recommendations to improve awareness of vaccine safety. All studies published up to 2 December 2021 were

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[65] J.R. Gill et al., "Autopsy Histopathologic Cardiac Findings in Two Adolescents Following the Second COVID-19 Vaccine Dose", Archives of Pathology & Laboratory Medicine, College of American Pathologists (2022) doi: 10.5858/arpa.2021-0435-SA.

[66] "James R. Gill, MD" , https://medicine.yale.edu/profile/james_gill/.

[67] A.K. Verma et al., "Correspondence: Myocarditis after Covid-19 mRNA Vaccination", *New England Journal of Medicine*, 385 (2021) 1332-1334, https://www.nejm.org/doi/10.1056/NEJMc2109975.

[68] F. Sessa et al., "Autopsy Findings and Causality Relationship between Death and COVID-19 Vaccination: A Systematic Review", *J. Clin. Med.* 10 (2021) 5876, https://www.mdpi.com/2077-0383/10/24/5876/htm.

> searched using the following keywords: "COVID-19 Vaccine", "SARS-CoV-2 Vaccine", "COVID-19 Vaccination", "SARS-CoV-2 Vaccination", and "Autopsy" or "Post-mortem". We included 17 papers published with fatal cases with post-mortem investigations. A total of 38 cases were analyzed: 22 cases were related to ChAdOx1 nCoV-19 administration, 10 cases to BNT162b2, 4 cases to mRNA-1273, and 2 cases to Ad26.COV2.S. Based on these data, autopsy is very useful to define the main characteristics of the so-called vaccine-induced immune thrombotic thrombocytopenia (VITT) after ChAdOx1 nCoV-19 vaccination: recurrent findings were intracranial hemorrhage and diffused microthrombi located in multiple areas. Moreover, it is fundamental to provide evidence about myocarditis related to the BNT162B2 vaccine. Finally, based on the discussed data, we suggest several key recommendations to improve awareness of vaccine safety." [Emphasis added.]

Regarding causality, the Sessa et al. paper states:

> "Based on the discussed data, a causality relationship between vaccine administration and death was demonstrated in 13 cases of ChAdOx1 nCOV-19 (AstraZeneca) vaccination, while it was excluded in the other 6 cases; in two cases the relationship was classified as "very likely", and in the last one as "unlikely". As concerns BNT162B2, of the ten cases reported in the literature, the causality relationship was established in one case, while in another case it was defined as "possible". Finally, the causality relationship was established in one case of mRNA-1273 vaccination and classified as "possible" in the two cases related to the Ad26.COV2.S (Janssen) vaccine. As recently noted in a review published by Sharifian-Dorche et al. [36], other severe adverse effects have been described related to other authorized vaccines." [Emphasis added.]

One of the studies reviewed by Sessa et al. is a case report by S. Choi et al. of "Myocarditis-induced Sudden Death after BNT162b2 mRNA COVID-19 Vaccination in Korea: Case Report Focusing on Histopathological Findings". BNT162b2 refers to the Pfizer-BioNTech vaccine product. The Abstract of the Choi et al. paper is as follows:[69]

> "We present autopsy findings of a 22-year-old man who developed chest pain 5 days after the first dose of the BNT162b2 mRNA vaccine and died 7 hours later. Histological examination of the heart revealed isolated atrial myocarditis, with neutrophil and histiocyte predominance. Immunohistochemical C4d staining revealed scattered single-cell necrosis of myocytes which was not accompanied by inflammatory infiltrates. Extensive contraction band necrosis was observed in the atria and ventricles. There was no evidence of microthrombosis or infection in the heart and other organs. The primary cause of death was determined to be myocarditis, causally-associated with the BNT162b2 vaccine." [Emphasis added.]

Sessa et al. also reviewed the case report by Verma et al. cited above (at footnote 64) and found a causality relationship to have been established between vaccination with the Moderna COVID-19

[69] S. Choi et al., "Myocarditis-induced Sudden Death after BNT162b2 mRNA COVID-19 Vaccination in Korea: Case Report Focusing on Histopathological Findings", *J. Kor. Med. Sci.* 36 (2021) e286, https://jkms.org/pdf/10.3346/jkms.2021.36.e286.

vaccine and the death of a 42 year-old male from myocarditis which developed within two weeks of the vaccination.[70] In Verma et al.'s words:

> "Patient 2, a 42-year-old man, presented with dyspnea and chest pain 2 weeks after mRNA-1273 vaccination (second dose). He did not report a viral prodrome, and a PCR test was negative for SARS-CoV-2 (Table S1). He had tachycardia and a fever, and his electrocardiogram showed diffuse ST-segment elevation (Fig. S1). A transthoracic echocardiogram showed global biventricular dysfunction (ejection fraction, 15%), normal ventricular dimensions, and left ventricular hypertrophy. Coronary angiography revealed no coronary artery disease. Cardiogenic shock developed in the patient, and he died 3 days after presentation. An autopsy revealed biventricular myocarditis (Figure 1B and Figs. S5 and S6). An inflammatory infiltrate admixed with macrophages, T-cells, eosinophils, and B cells was observed, a finding similar to that in Patient 1.
>
> In these two adult cases of histologically confirmed, fulminant myocarditis that had developed within 2 weeks after Covid-19 vaccination, a direct causal relationship cannot be definitively established because we did not perform testing for viral genomes or autoantibodies in the tissue specimens. However, no other causes were identified by PCR assay or serologic examination."

There is thus significant histopathological evidence of grave dangers associated with the COVID-19 vaccine products, including "clear evidence of vaccine-induced autoimmune-like pathology in multiple organs (…) expected to very frequently occur in all individuals" and established causality relationships between COVID-19 vaccination and death. The evidence from autopsies cited in this section eminently constitutes a "medical reason for [me] not to be vaccinated".

2e (v) Active and passive surveillance data show serious harms, including death, associated with COVID-19 vaccine products

"Active surveillance" refers to monitoring for adverse events (AEs) potentially caused by a medical product within a clinical trial, where participants in both placebo and treatment groups are actively followed for some time after the injections. Active surveillance in the Pfizer trials showed a 1.2% (262 of 21,926 participants) rate of severe AEs in the treatment group and a 0.7% (150 of 21,921 participants) rate of severe AEs in the placebo group,[71] and a serious adverse event to at least one of 1005 participants in the treatment group of Pfizer's adolescent (12-15 year old) trial, although Pfizer failed to report this AE.[72]

"Passive surveillance" refers to spontaneous reports made by patients, their families or contacts, or the medical professionals that see them. Passive surveillance systems are known to suffer from a high-degree of under-reporting, such that AE rates in passive surveillance systems are typically assumed to be

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[70] See Table 1 of Sessa et al. (2021).

[71] S.J. Thomas et al., Supplement to: "Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine through 6 months", *New Eng. J. Med.* 385 (2021) 1761-73, https://www.nejm.org/doi/full/10.1056/nejmoa2110345.

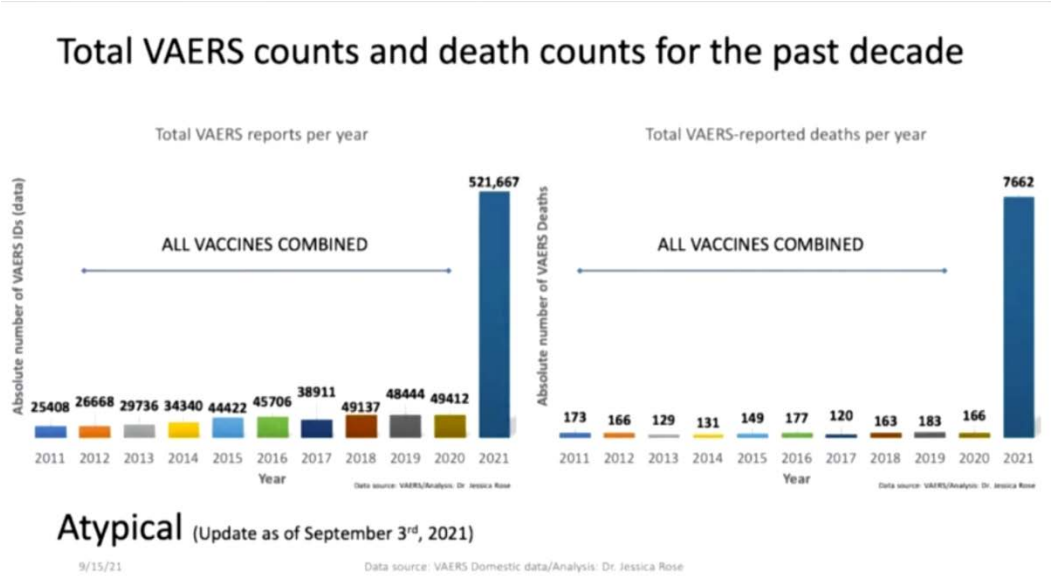
[72] Canadian Covid Care Alliance (CCCA), "The Pfizer Inoculations for Covid-19: More Harm than Good" (2021): https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf, slides 24-25, at Tab 10.

lower than the true rates of AEs in the general population.[73]

US Vaccine Adverse Event Reporting System (VAERS)

A prominent example of a passive surveillance system is the Vaccine Adverse Event Reporting System (VAERS) of the U.S. Department of Health & Human Services.[74] Healthcare workers in the United States are required by law to report adverse events following vaccination to VAERS.[75] As noted in the VAERS user guide, "VAERS staff follow-up on all serious and other selected adverse event reports to obtain additional medical, laboratory, and/or autopsy records to help understand the concern raised" and "reports of serious events are of greatest concern and receive the most careful scrutiny by VAERS staff."[76]

The figure below, from Dr. Jessica Rose's submission to the U.S. Food and Drug Administration (FDA),[77] illustrates the magnitude of harm and death potentially associated with the COVID-19 vaccines. As can be seen, by Sep. 3, 2021, there were already more adverse events and deaths reported to VAERS for the year 2021 than the respective totals summed over all of the preceding decade. The adverse events reported to VAERS include cardiac events such as heart inflammation (myocarditis and pericarditis) or infarction, irregular menstruation, rashes, dizziness and falling, sudden unexpected death, and many other symptoms.

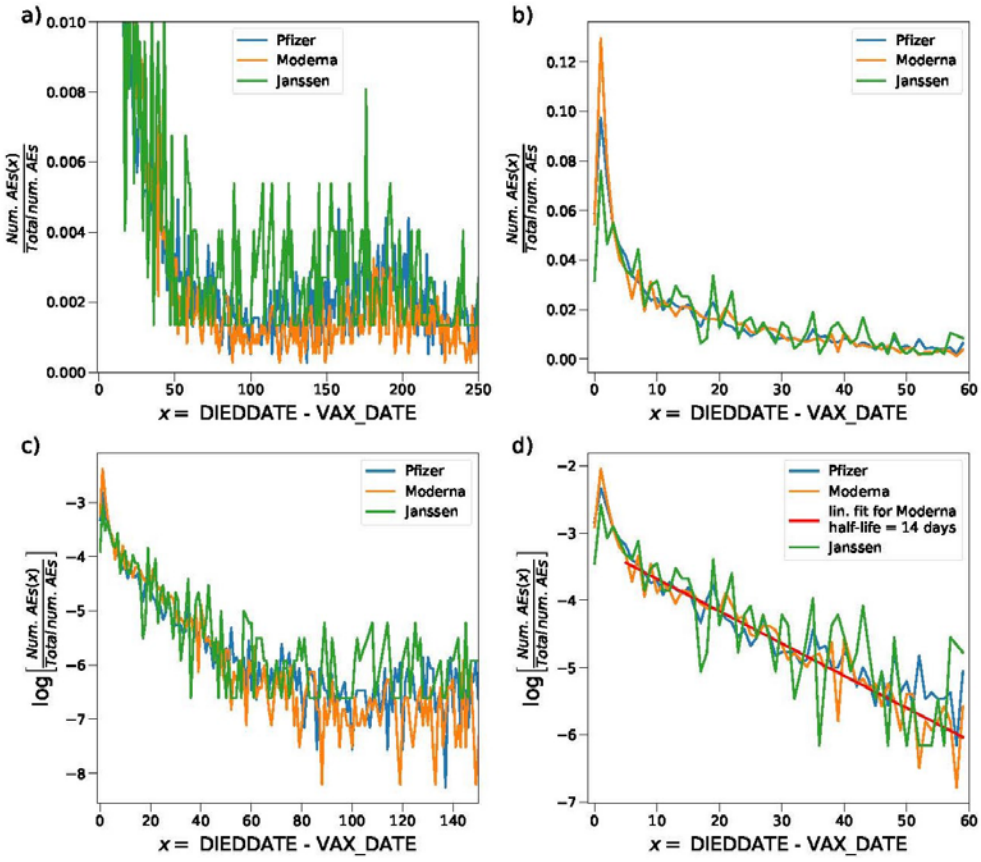


[73] VAERS user guide, September 2021, https://vaers.hhs.gov/docs/VAERSDataUseGuide_en_September2021.pdf; See also: VAERS, "Guide to interpreting VAERS data" (no date), https://vaers.hhs.gov/data/dataguide.html.
[74] VAERS, https://vaers.hhs.gov/.
[75] 42 USC 300aa-25; and see: https://vaers.hhs.gov/faq.html and https://vaers.hhs.gov/esubhelp.html.
[76] VAERS user guide, September 2021, https://vaers.hhs.gov/docs/VAERSDataUseGuide_en_September2021.pdf.
[77] J. Rose, Submission to the Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER), 167th Meeting of the Vaccines and Related Biological Products Committee, 17 September 2021, published by the Association of American Physicians and Surgeons: https://rumble.com/vmzze8-dr.-jessica-rose-more-vaers-death-reports-in-2021-than-last-10-years-combin.html; FDA transcript: https://www.fda.gov/media/154871/download.

In a recent study of the adverse events reported to VAERS following COVID-19 vaccination,[78] Hickey and Rancourt showed (figure labeled "Figure S4" below) that the distribution of the number of days between injection and death (or onset of serious symptoms) has a robust pattern comprised of a sharp peak from 0 to 5 days post-injection, followed by an exponential decay with a half-life of approximately 2 weeks extending from approximately 5 to 60 days post-injection. They state:

> "The observed exponential decay implies a causal link between death (or AE) and injection, up to ~60 days. Accidental deaths would have a uniform (constant) distribution versus time since injection (versus "x"), mathematically corresponding to an infinite decay time."

Figure S4. Histograms showing the share of VAERS deaths occurring x days after vaccination, for each manufacturer separately. y-axes are linear on the top row and logarithmic on the bottom row. In the plots in the left column (a and c), deaths at all x values are included in the calculation (but the plots are truncated for better visualization), whereas in the right column (b and d), only deaths for which x < 60 were used. The y-axis in (a) was also truncated for better visualization. Note: The exponential fit (d) gives a half-life equal to 14 days, as indicated.



Furthermore, the observed exponential decay up to approximately 60 days cannot be due to a time-dependent under-reporting bias. This can be seen from the following examination of the distribution of

[78] J. Hickey and D.G. Rancourt, "Nature of the Toxicity of the COVID-19 Vaccines in the USA", OCLA Report 2022-1 (ver. 1) (2022), https://ocla.ca/wp-content/uploads/2022/02/OCLA-Report-2022-1-v1.pdf, at Tab 17.

the time to symptom onset of patients that were hospitalized with Guillain-Barré Syndrome (GBS) in the USA following influenza vaccination.

US law requires healthcare workers to report incidents of GBS to VAERS up to at least 42 days following injection with a flu vaccine.[79] As can be seen in the figure below, the distribution of number of days between injection and onset of GBS following injection with an influenza vaccine has an exponential decay that extends up to about 60 days post-injection, with a half-life of approximately 2 weeks, similar to the decay pattern shown in Figure S4, above. The same distribution of number of days between injection and onset of GBS is also shown for the COVID-19 vaccines in the figure below, for comparison, and it again exhibits the same exponential decay pattern.

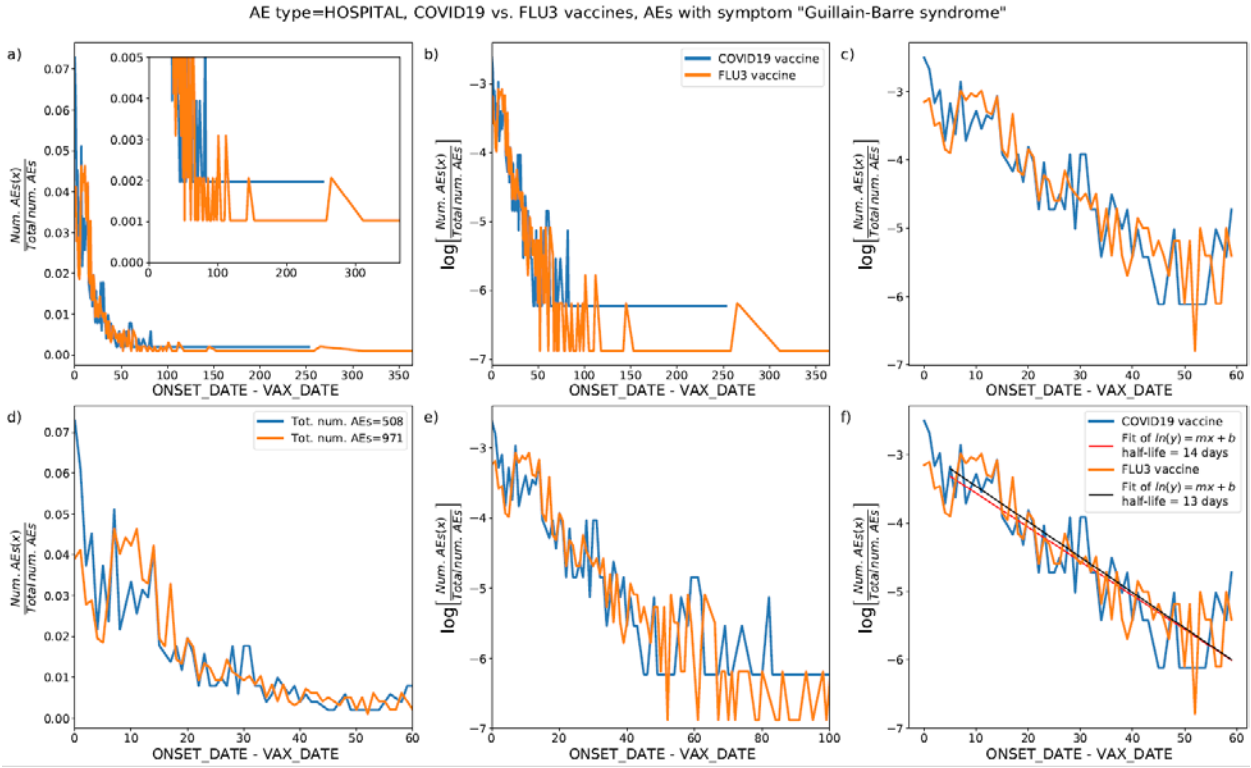


Figure 2: Histograms showing the share of VAERS hospitalizations occurring *x* days after vaccination, for COVID-19 vaccines (blue, data for 2021) and trivalent influenza virus vaccine[80] ("FLU3", orange, data for 1990-2020). y-axes are linear in panels (a) and (d) and the axes are truncated to allow examination of different parts of the distribution. y-axes are logarithmic in panels (b, c, e, and f)) and the axes are again truncated to allow examination of different parts of the distribution. In panels (c) and (f), only hospitalizations for which $x < 60$ were used. Note: The exponential fit (panel f) gives a half-life equal to 14 days (COVID-19) and 13 days (FLU3), as indicated. Figure created by J. Hickey using the VAERS data for 1990-2021 downloaded from: https://vaers.hhs.gov/data.html.

[79] "VAERS Table of Reportable Events Following Vaccination", https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf; also see: https://vaers.hhs.gov/faq.html.

[80] Trivalent influenza virus vaccine ("FLU3") is the influenza vaccine with the most adverse event reports in VAERS from 1990-2020 (84,704 reports).

The VAERS data therefore demonstrates a causal link between COVID-19 vaccination and death or life-threatening adverse events, hospitalizations, or adverse events causing disability up to (at least) 60 days following injection.

Table 1, below, lists the number of deaths reported to VAERS following vaccination with a COVID-19 vaccine (between Dec. 11, 2020, and Dec. 31, 2021) and following vaccination with an influenza vaccine (between Jul. 1, 1990 and Jun. 30, 2019), for various intervals (number of days, *x*) between vaccination and death.

Num. days ("x") between vax and death	**Col A: Num. VAERS deaths post COVID-19 vax (2020-12-11 to 2021-12-31)**	**Col A / Num. COVID-19 doses admin. (2020-12-11 to 2021-12-31)***	**Col A / Num. COVID-19 doses distrib. (2020-12-11 to 2021-12-31)****	**Col B: Num. VAERS deaths post influenza vax (1990-07-01 to 2019-06-30)**	**Col B / Num. influenza doses distrib. (1990-07-01 to 2019-06-30)*****
$x < 1000$	8334	164	135	756	2.6
$x < 60$	5518	101	89.7	629	2.2
$x < 5$	1859	36.5	30.2	319	1.1

Table 1: Deaths reported to VAERS post COVID-19 and influenza vaccination, and deaths per dose. All values times 10^{-7}. *Num. COVID-19 doses admin. (2020-12-11 to 2021-12-31)=509,307,789;[81] **Num. COVID-19 doses distrib. (2020-12-11 to 2021-12-31)=615,262,365;[82] ***Num. influenza doses distrib. (1990-07-01 to 2019-06-30)=2,910,700,000.[83]

Table 1 also shows the number of VAERS deaths divided by the number of doses of vaccine. For the COVID-19 vaccines, the US Centers for Disease Control and Prevention (CDC) provides the number of doses that were distributed by the manufacturers ("doses distributed") and the number of doses that were actually injected into people ("doses administered"). For the influenza vaccines, the CDC only provides the number of doses distributed. However, the number of distributed doses of influenza vaccine is a good proxy for the number of administered doses of influenza vaccine, as can be seen from a 2010 publication by the Center for Infectious Disease Research and Policy, Office of the Vice-President for Research, University of Minnesota:

> "[The CDC] said about 123 million people received the seasonal flu vaccine through May 2010, an increase from the previous estimate of 118.8 million. (…)The CDC cautioned that the seasonal flu vaccine coverage is an overestimate, because the reported coverage level of 123 million exceeds the 114 million doses of seasonal vaccine that were distributed. In its early estimate the CDC had said that respondent confusion over the two types of flu vaccines might have contributed to some overreporting."[84]

Table 1 therefore allows a comparison of the per dose lethality of the COVID-19 vaccines vs. the influenza vaccines used from 1990 to 2019. As can be seen from the table, the COVID-19 vaccines are approximately 27 times more lethal, on a per-dose basis, than the influenza vaccines, using the deaths

[81] Data downloaded on Jan. 12, 2022, from: CDC, "COVID-19 Vaccinations in the United States,Jurisdiction", 3 March 2022, https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-States-Jurisdi/unsk-b7fc.
[82] *Ibid.*
[83] Data downloaded on Mar. 4, 2022, from: CDC, "Historical Reference of Seasonal Influenza Vaccine Doses Distributed", 4 August 2021, https://www.cdc.gov/flu/prevent/vaccine-supply-historical.htm.
[84] L. Schnirring, "CDC confirms record doses of flu vaccine were given", CIDRAP, University of Minnesota, 8 October 2010, https://www.cidrap.umn.edu/news-perspective/2010/10/cdc-confirms-record-doses-flu-vaccine-were-given, at Tab 18.

that occurred within 5 days following injection (numerator) and the number of doses distributed as a proxy for the number of doses administered (denominator), for both COVID-19 and influenza vaccines.

To conclude this discussion of the VAERS data, I refer to the January 2022 article by M. Oster et al. in the *Journal of the American Medical Association* entitled "Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US from December 2020 to August 2021" as a prominent example of a study in which this data has been used to demonstrate harm following injection with a COVID-19 vaccine.[85]

In the Oster et al. study, authors from the CDC and other institutions identified VAERS reports coded (by VAERS staff) with the Medical Dictionary for Regulatory Activities preferred terms of myocarditis or pericarditis, then verified that the identified reports met the CDC's case definition for probable or confirmed myocarditis, then further confirmed the identified cases through histopathological or cardiac magnetic resonance imaging analyses. The authors found that the cases of myocarditis within a 7-day risk interval following injection with a COVID-19 vaccine product were more than 100 times higher than would be normally expected for males aged 12-15, 30 times higher than normal for males aged 18-24, 11 times higher than normal for males aged 30-39, and so on. The authors also state that the actual rates of myocarditis post-vaccination are likely higher than estimated:

> "Furthermore, as a passive system, VAERS data are subject to reporting biases in that both underreporting and overreporting are possible.(ref) Given the high verification rate of reports of myocarditis to VAERS after mRNA-based COVID-19 vaccination, underreporting is more likely. Therefore, the actual rates of myocarditis per million doses of vaccine are likely higher than estimated."[86] [Emphasis added.]

Pfizer's passive surveillance reporting data

Vaccine product manufacturers also collect reports of AEs following injection. For example, litigation in the USA has produced documents showing that Pfizer maintains a "safety database" containing "cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment."[87]

Pfizer's document states:[88]

> "Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy

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[85] M.E. Oster et al., "Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021", *J. Amer. Med. Assoc.* 327 (2022) 331-340, https://jamanetwork.com/journals/jama/fullarticle/2788346.
[86] *Ibid.*
[87] Pfizer, "5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received through 28-Feb-2021", FDA-CBER-2021-5683-0000054, published by Public Health and Medical Professionals for Transparency: https://phmpt.org/pfizers-documents/, at Tab 19.
[88] *Ibid.* pg. 6.

> (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries."

The adverse events in Pfizer's database, reported at System Organ Class (SOC) classification level of the MedDRA symptom classification system,[89] include: cardiac disorders, gastrointestinal disorders, general disorders and administration site conditions, infections and infestations, injury, poisoning and procedural complications, musculoskeletal and connective tissue disorders, nervous system disorders, respiratory, thoracic and mediastinal disorders, and skin and subcutaneous tissue disorders.[90]

A graph from Pfizer's document showing the breakdown of the SOC-level symptom occurrences is included below.[91] As can be seen, tens of thousands of serious AEs were reported to Pfizer by Feb. 28, 2021. As of that date (Feb. 28, 2021), 75,236,003 doses of COVID-19 vaccines had been administered,[92] while as of Mar. 4, 2022, a total of 554,532,208 doses of COVID-19 vaccines had been administered.[93] This means that the AE reports in Pfizer's document only pertain to a small portion of the full vaccination campaign (a time period during which less than 13.6% of all COVID-19 vaccine doses were administered).[94]

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[89] MedDRA, "Introductory Guide MedDRA Version 24.1", September 2021, https://admin.meddra.org/sites/default/files/guidance/file/000594_intguide_%2024_1.pdf.

[90] *Ibid.* pgs. 8-9.

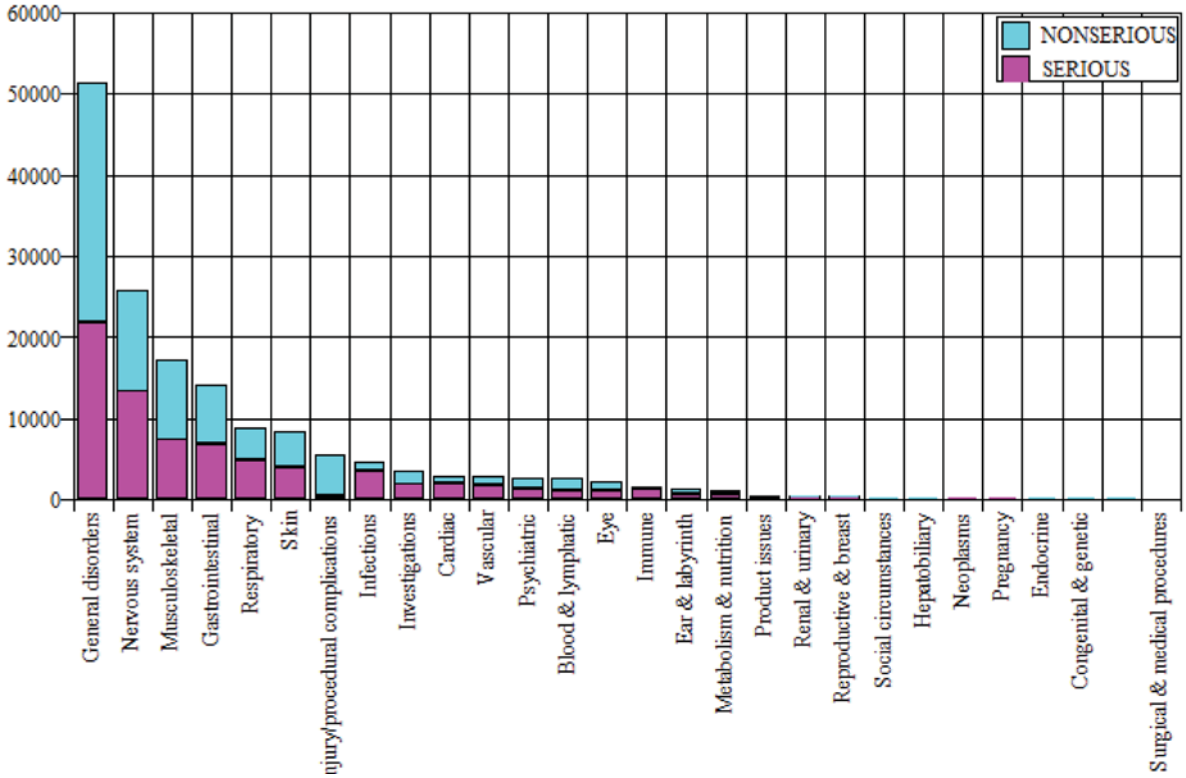
[91] Pfizer, "5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received through 28-Feb-2021", FDA-CBER-2021-5683-0000054, published by Public Health and Medical Professionals for Transparency: https://phmpt.org/pfizers-documents/, at Tab 19.

[92] Data downloaded on Jan. 12, 2022, from: CDC, "COVID-19 Vaccinations in the United States,Jurisdiction", 3 March 2022, https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-States-Jurisdi/unsk-b7fc.

[93] CDC, "COVID-19 Vaccinations in the United States", Accessed Mar. 4, 2022: https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.

[94] Symptoms classified under the SOC "General disorders and administration site conditions" can relate to specific serious dangers known to be associated with the COVID-19 vaccine products. For example, if MedDRA's "Primary SOC" is used to classify the symptom "Chest pain" (a so-called "Preferred Term" in MedDRA's classification scheme), then "Chest pain" will be classified under "General disorders and administration site conditions", although "Chest pain" can also be classified under the SOCs "Cardiac disorders" and "Respiratory, thoracic, and mediastinal disorders" [See: Academic and Clinical Central Office for Research and Development, NHS Lothian (UK), "MedDRA coding for Adverse Event (AE) Logs", https://www.accord.scot/sites/default/files/MedDRA%20Coding%20to%20SOC%20Level%20for%20AE%20Logs.ppsx.] The Preferred Term "Chest pain" is often associated with heart inflammation (myocarditis or pericarditis) in the VAERS database. The multiplicity inherent in the MedDRA classification system when relating a low-level Preferred Term to a high-level SOC could explain why there are so many "Serious" events classified as "General disorders" in Pfizer's "Figure 1. Total Number of BNT162b2 AEs…".

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness



Public health agencies also publish data on adverse events received through passive reporting. For example, Ontario Public Health (PHO) has been regularly updating its "Adverse Events Following Immunization (AEFIs) for COVID-19" reports since the autumn of 2021.[95] The version of this document covering the period Dec. 13, 2020, to Feb. 20, 2022, states that the reporting system used by PHO has received 19,035 AEFI reports, 1,052 of which are serious, and 690 of which are reports of myocarditis or pericarditis.

Additionally, passive and active surveillance data reveal a wide array of serious adverse events following injection with a COVID-19 vaccine, including serious cardiac, neurological, pulmonary, reproductive system, cerebral, and allergic problems, and more. However, little is currently known about the risk factors for serious adverse events following COVID-19 vaccination. Research on risk factors is required to understand who will suffer serious adverse events following vaccination with a COVID-19 vaccine product.[96] The current lack of knowledge of the risk factors for serious adverse events following injection with a COVID-19 vaccine make it in-effect impossible to provide informed consent.

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[95] Public Health Ontario, "Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to February 20, 2022", https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-aefi-report.pdf?sc_lang=en.

[96] C. Brazete et al., "Thrombotic events and COVID-19 vaccines", *Int. J. Tub. Lung. Dis.* 25 (2021) 701-707, https://doi.org/10.5588/ijtld.21.0298; J. Park et al., "COVID-19 vaccine-related interstitial lung disease: a case study", *Thorax* 77 (2021) 9-10, https://thorax.bmj.com/content/77/1/102.abstract; R. Joshi et al., "Higher

In sum, active and passive surveillance data show serious harms and death associated with the COVID-19 vaccine products: this is a "medical reason for [me] not to be vaccinated".

2e (vi) There are more than one thousand peer-reviewed articles providing evidence of harm from COVID-19 vaccine products

More than 1000 peer-reviewed scientific articles showing evidence of harm from COVID-19 vaccine products have been published.[97]

These peer-reviewed articles are listed in Box 1 below, and include many case studies involving adverse events (including deaths) occurring shortly after vaccination such as blood clotting and thrombosis, myocarditis, anaphylaxis, Bell's palsy, Guillain-Barré syndrome, and more.

Box 1: Over 1000 peer-reviewed articles showing evidence of harm from COVID-19 vaccine products

1. Cerebral venous thrombosis after COVID-19 vaccination in the UK: a multicentre cohort study: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01608-1/
2. Vaccine-induced immune thrombotic thrombocytopenia with disseminated intravascular coagulation and death after ChAdOx1 nCoV-19 vaccination: https://www.sciencedirect.com/science/article/pii/S1052305721003414
3. Fatal cerebral hemorrhage after COVID-19 vaccine: https://pubmed.ncbi.nlm.nih.gov/33928772/
4. Myocarditis after mRNA vaccination against SARS-CoV-2, a case series: https://www.sciencedirect.com/science/article/pii/S2666602221000409
5. Three cases of acute venous thromboembolism in women after vaccination against COVID-19: https://www.sciencedirect.com/science/article/pii/S2213333X21003929
6. Acute thrombosis of the coronary tree after vaccination against COVID-19: https://www.sciencedirect.com/science/article/abs/pii/S1936879821003988
7. US case reports of cerebral venous sinus thrombosis with thrombocytopenia after vaccination with Ad26.COV2.S (against covid-19), March 2 to April 21, 2020: https://pubmed.ncbi.nlm.nih.gov/33929487/
8. Portal vein thrombosis associated with ChAdOx1 nCov-19 vaccine: https://www.thelancet.com/journals/langas/article/PIIS2468-1253(21)00197-7/
9. Management of cerebral and splanchnic vein thrombosis associated with thrombocytopenia in subjects previously vaccinated with Vaxzevria (AstraZeneca): position statement of the Italian Society for the Study of Hemostasis and Thrombosis (SISET): https://pubmed.ncbi.nlm.nih.gov/33871350/
10. Vaccine-induced immune thrombotic thrombocytopenia and cerebral venous sinus thrombosis after vaccination with COVID-19; a systematic review: https://www.sciencedirect.com/science/article/pii/S0022510X21003014
11. Thrombosis with thrombocytopenia syndrome associated with COVID-19 vaccines: https://www.sciencedirect.com/science/article/abs/pii/S0735675721004381
12. Covid-19 vaccine-induced thrombosis and thrombocytopenia: a commentary on an important and practical clinical dilemma: https://www.sciencedirect.com/science/article/abs/pii/S0033062021000505
13. Thrombosis with thrombocytopenia syndrome associated with COVID-19 viral vector vaccines: https://www.sciencedirect.com/science/article/abs/pii/S0953620521001904
14. COVID-19 vaccine-induced immune-immune thrombotic thrombocytopenia: an emerging cause of splanchnic vein thrombosis: https://www.sciencedirect.com/science/article/pii/S1665268121000557
15. The roles of platelets in COVID-19-associated coagulopathy and vaccine-induced immune thrombotic immune thrombocytopenia (covid): https://www.sciencedirect.com/science/article/pii/S1050173821000967
16. Roots of autoimmunity of thrombotic events after COVID-19 vaccination: https://www.sciencedirect.com/science/article/abs/pii/S1568997221002160

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The large number of journal articles and the factual and interpretive content of all those articles showing evidence of harm from COVID-19 vaccine products constitute a "medical reason for [me] not to be vaccinated".

2e (vii) There is a significantly increased risk of dangerous heart inflammation following injection with a COVID-19 vaccine product, especially for younger males, and this danger is heightened for those who engage in strenuous physical activity

It has now been clearly established that there is a significant increase in the risk of myocarditis following injection with a COVID-19 vaccine, particularly for younger males[98] (please also read and consider Section 3d of these submissions, and the references therein, in relation to this submission).

In light of this established fact, it is relevant that there were many more cases of young athletes collapsing or dying in 2021 than in previous years, as reported in the slide below from the Canadian Covid Care Alliance:[99]

[98] M.E. Oster et al., "Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021", *J. Amer. Med. Assoc.* 327 (2022) 331-340, https://jamanetwork.com/journals/jama/fullarticle/2788346; and see the references cited in Section 3d of these submissions.

[99] Canadian Covid Care Alliance (CCCA), "The Pfizer Inoculations for Covid-19: More Harm than Good" (2021): https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf, slide 37, at Tab 10.

There are plausible hypotheses as to why mRNA COVID-19 vaccine products could cause cardiac problems that would be more likely to manifest the more the heart is exposed to a high level of cardio-vascular demand (such as during strenuous sports activity).[100,101]

In particular, it is now undisputed that "the risk of myocarditis after receiving mRNA-based COVID-19 vaccines was increased across multiple age and sex strata and was highest after the second vaccination dose in adolescent males and young men",[102] and that myocarditis is a serious risk for athletes:

> "For patients with myocarditis, the American Heart Association and the American College of Cardiology guidelines advise that patients should be instructed to refrain from competitive sports for 3 to 6 months, and that documentation of a normal electrocardiogram result,

[100] J.R. Gill et al., "Autopsy Histopathologic Cardiac Findings in Two Adolescents Following the Second COVID-19 Vaccine Dose", Archives of Pathology & Laboratory Medicine, College of American Pathologists (2022) doi: 10.5858/arpa.2021-0435-SA.
[101] K. Kadkhoda, "Post RNA-based COVID vaccines myocarditis: Proposed mechanisms", *Vaccine* 40 (2022) 406-407, https://www.sciencedirect.com/science/article/pii/S0264410X21015942.
[102] M.E. Oster et al., "Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021", *J. Amer. Med. Assoc.* 327 (2022) 331-340, https://jamanetwork.com/journals/jama/fullarticle/2788346.

> ambulatory rhythm monitoring, and an exercise test should be obtained prior to resumption of sports.(ref)"[103]

I regularly (multiple times per week) engage in strenuous physical activity, including cross-country skiing, running, and soccer, depending on the season. Since elementary school, through high school, university, and afterwards until now, I have always participated in sports that entail a high degree of cardiovascular demand, and sport participation has been and continues to be an important way for me to socially connect with others and to build my social circle, as well as to manage and release stress.

I am, therefore, someone who regularly places a high demand on my cardiovascular system for fitness, social, and stress management reasons. The increased risk to me of cardiac problems including sudden collapse or death following injection with a COVID-19 vaccine product is a "medical reason for [me] not to be vaccinated".

2e (viii): Natural immunity provides robust and sufficient protection against respiratory illnesses

Breathing animals and respiratory viruses have co-existed on Earth for hundreds of millions of years. In this time, animals have developed complex immune systems that respond to infections adaptively in order to protect against future infection by the same or similar pathogens. Regarding respiratory-system pathogens, this is accomplished using secretory IgA (sIgA) antibodies associated with the mucus membranes of the respiratory system (see Section 2e (iii), above). Therefore, it should be assumed that the body's natural immune response against any currently-circulating respiratory pathogen provides protection against future similar infections.

In a recent article in *Nature Communications*,[104] researchers published their findings of cross-reactive immune responses in people who were exposed to SARS-CoV-2. Exposed household contacts who remained PCR-negative following exposure had higher frequencies of memory T cells specific for spike, nucleocapsid, membrane, envelope and ORF1 SARS-CoV-2 epitopes that cross-react with human endemic coronaviruses than exposed household contacts who converted to PCR-positive following contact. The T cells are likely to have been derived from other human coronaviruses pre-dating SARS-CoV-2. This finding strongly suggests that there is robust natural immunity against SARS-CoV-2.

Additionally, scientific studies have attempted to gather evidence about the body's natural immune system response to COVID-19 by measuring levels of bloodstream (serum) IgG antibodies and bone-marrow plasma cells (BMPCs) in patients who had recently received a positive COVID-19 test, and found that these immune system components continued to be present many months following the positive test.[105] Although serum IgG and BMPCs do not protect against infection by respiratory pathogens (see Section 2e (iii), above), these results are not inconsistent with an adaptive immune system response to protect against respiratory pathogen infection.

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[103] *Ibid.*

[104] R. Kundu et al. "Cross-reactive memory T cells associate with protection against SARS-CoV-2 infection in COVID-19 contacts", *Nature Comm.* 13 (2022) 1-8, https://www.nature.com/articles/s41467-021-27674-x.

[105] J.S. Turner et al., "SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans", *Nature* 595 (2021) 421; V.J. Hall et al., "SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study (SIREN)", *The Lancet* 397 (2021) 17-23.

The presumption, based on both evolutionary arguments and the body of scientific knowledge about animal and human immunology, of robust and sufficient natural immunity following infection by any currently-circulating respiratory pathogens is a "medical reason for [me] not to be vaccinated".

2e (ix): It is a fundamental principle of medicine that individual assessment of risk is a personal and confidential choice, and the decision to receive or not receive a medical intervention must be made with free and informed consent

It is established in Canadian law that the application of a medical treatment without the patient's consent constitutes assault ("battery"). The Supreme Court of Canada has stated this on multiple occasions, for example:

> "That there is a right to choose how one's body will be dealt with, even in the context of beneficial medical treatment, has long been recognized by the common law. To impose medical treatment on one who refuses it constitutes battery, and our common law has recognized the right to demand that medical treatment which would extend life be withheld or withdrawn."[106]

> "The law has long recognized that the human body ought to be protected from interference by others. At common law, for example, any medical procedure carried out on a person without that person's consent is an assault."[107]

> "The well-known statement of Cardozo J. in *Schloendorff v. Society of New York Hospital*[4], at pp. 129-30 and at p. 93 respectively, that 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages' cannot be taken beyond the compass of its words to support an action of battery where there has been consent to the very surgical procedure carried out upon a patient but there has been a breach of the duty of disclosure of attendant risks. In my opinion, actions of battery in respect of surgical or other medical treatment should be confined to cases where surgery or treatment has been performed or given to which there has been no consent at all or where, emergency situations aside, surgery or treatment has been performed or given beyond that to which there was consent."[108]

> "It seems to me that had the patient herself, Mrs. Yule, made such statements to the dentist, he would not have proceeded, and would not have been justified in proceeding, without making an examination of her teeth and advising and consulting with her; then, if she desired and

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[106] Sopinka J. (writing for the majority) in *Rodriguez v. British Columbia (Attorney General)*, 1993 CanLII 75 (SCC), at pg. 588, https://canlii.ca/t/1frz0.
[107] Dickson C.J. (concurring reasons in a per curiam decision) in *R. v. Morgentaler*, 1988 CanLII 90 (SCC), at pg. 53, https://canlii.ca/t/1ftjt.
[108] Laskin C.J. (writing for a unanimous court) in *Reibl v. Hughes*, 1980 CanLII 23 (SCC), at pgs. 890-891, https://canlii.ca/t/1mjvr.

requested that her teeth or any of them be extracted, the dentist would be justified in proceeding to do so.

> Force to the person is rendered lawful by consent in such matters as surgical operations. The fact is common enough; indeed authorities are silent or nearly so, because it is common and obvious. Taking out a man's tooth without his consent would be an aggravated assault and battery. With consent it is lawfully done every day. [Pollock on Torts, 14th ed., p. 124.]"[109]

> "The term "informed consent", frequently used in American cases, reflects the fact that although there is, generally, prior consent by a patient to proposed surgery or therapy, this does not immunize a surgeon or physician from liability for battery or for negligence if he has failed in a duty to disclose risks of the surgery or treatment, known or which should be known to him, and which are unknown to the patient. The underlying principle is the right of a patient to decide what, if anything, should be done with his body: see *Parmley v. Parmley* and *Yule*[2], at pp. 645-46. (I leave aside any question of emergency or of mental incompetency and, also, situations where the operation or treatment performed or given is different from that to which the patient consented.) It follows, therefore, that a patient's consent, whether to surgery or to therapy, will give protection to his surgeon or physician only if the patient has been sufficiently informed to enable him to make a choice whether or not to submit to the surgery or therapy."[110]

It is also established that, in the context of assault, consent given under coercion or duress (including "fear, threats, … or the exercise of authority") is not legally effective:

> "To be legally effective, consent must be freely given. Therefore, even if the complainant consented, or her conduct raises a reasonable doubt about her non-consent, circumstances may arise which call into question what factors prompted her apparent consent. The Code defines a series of conditions under which the law will deem an absence of consent in cases of assault, notwithstanding the complainant's ostensible consent or participation. As enumerated in s. 265(3), these include submission by reason of force, fear, threats, fraud or the exercise of authority, and codify the longstanding common law rule that consent given under fear or duress is ineffective: see G. Williams, Textbook of Criminal Law (2nd ed. 1983), at pp. 551-61."[111] [Emphasis added.]

Canadian medical professional bodies also recognize that consent to a medical procedure can only be legally and ethically effective in the absence of coercion or duress.

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[109] *Parmley v. Parmley*, 1945 CanLII 13 (SCC), [1945] SCR 635, https://canlii.ca/t/21v4g, at pg. 645.
[110] *Hopp v. Lepp*, 1980 CanLII 14 (SCC), [1980] 2 SCR 192, https://canlii.ca/t/1mjv6, at pg. 196.
[111] *R. v. Ewanchuk*, 1999 CanLII 711 (SCC), [1999] 1 SCR 330, https://canlii.ca/t/1fqpm, at para. 36.

The Canadian Medical Protective Association (CMPA) states this clearly in its document "Consent: A guide for Canadian physicians", as quoted below.[112] The CMPA is a not-for-profit founded in 1901 that represents more than 100,000 physicians in Canada (approximately 95% of Canadian physicians),[113] and which provides legal defence, liability protection, and risk-management education for physicians in Canada.[114] From the CMPA's guide for physicians:

> "**Voluntary consent**
>
> Patients must always be free to consent to or refuse treatment, and be free of any suggestion of duress or coercion. Consent obtained under any suggestion of compulsion either by the actions or words of the physician or others may be no consent at all and therefore may be successfully repudiated. In this context physicians must keep clearly in mind there may be circumstances when the initiative to consult a physician was not the patient's, but was rather that of a third party, a friend, an employer, or even a police officer. Under such circumstances the physician may be well aware that the patient is only very reluctantly following the course of action suggested or insisted upon by a third person. Then, physicians should be more than usually careful to assure themselves patients are in full agreement with what has been suggested, that there has been no coercion and that the will of other persons has not been imposed on the patient." [Emphasis added.]

Threat of loss of livelihood and social status[115] constitutes coercion. This coercion has been applied to me via removal of my pay and benefits, career advancement opportunities, access to my work environment including social and professional connections with my colleagues, and the threat of termination of my employment.

The said coercion was communicated to me in the Nov. 19, 2021, email from the Bank of Canada's Human Resources Dept. to me, in which my employer stated:

> "Please note that you will be expected to comply with the Bank's mandatory COVID-19 Vaccination Policy. To the extent that you remain non-compliant, you will be placed on leave without pay or benefits as of November, 22, 2021; your employment may ultimately be terminated if you remain non-compliant after the leave period.
>
> As discussed, your access to the Bank's system will be suspended. You will also be sent a prepaid courier box for the purpose of collecting your Bank assets. This will be sent to the home address the Bank has on file for you. If this address is not up-to-date, please provide me with the correct

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[112] "Consent: A guide for Canadian physicians", Fourth Edition: May 2006 / Updated April 2021, https://www.cmpa-acpm.ca/en/advice-publications/handbooks/consent-a-guide-for-canadian-physicians, at Tab 20.

[113] C. Crosbie et al., "Open Access College complaints against resident physicians in Canada: a retrospective analysis of Canadian Medical Protective Association data from 2013 to 2017", *Can. Med. Assoc. J. Open*, 10 (2022) E35-E42, https://doi.org/10.9778/cmajo.20210026. Note that Lisa A. Calder, the CEO of the CMPA, is a co-author of this article.

[114] CMPA, "Who we are", (no date), https://www.cmpa-acpm.ca/en/about/who-we-are.

[115] That the removal of employment constitutes a loss "not only of salary but of benefits and prestige as well" was found to be the case in the labour arbitration of a Bank of Canada employee in *Bank of Canada v Laflèche*, 2013 CanLII 13137 (CA LA), https://canlii.ca/t/fwkk7, at para. 33.

> address Please provide me with a personal email address so that I may contact you during your leave, if and when required As well, you cannot come onsite and your building pass has been disabled.
>
> Should you decide to comply with the Bank`s policy, please provide the dates you will be receiving, or have received, your first and second doses Once you have your second dose please use the attached form to attest that you are fully vaccinated. Once I receive this completed form from you, your system access will be restored, your Bank assets will be returned to you, and you will be reintegrated to work as soon as possible. You will be removed from leave without pay and benefits the day following your second dose."

[redacted]

That the Bank's Policy and decision to deny me accommodation and place me on unpaid leave without health benefits is coercive is also demonstrated by the fact that the Deputy Prime Minister of Canada Chrystia Freeland referred to leave without pay as a "compliance measure" in her Oct. 29, 2021, letter to Bank of Canada Governor Tiff Macklem, in which she instructed him to implement a mandatory vaccination policy for the Bank's staff:

> "The Bank of Canada (BOC) is expected to ensure that its vaccination requirements (and those of any wholly-owned subsidiaries) are fully aligned with the requirements of the policy by November 30, 2021. Specifically, this includes, but is not limited to, ensuring that employees attest to their vaccination status no later than November 30, 2021. Compliance measures, including leave without pay, should be underway by as early as December 15, 2021." [Emphasis added.][116]

If coercing me to receive injections of a COVID-19 vaccine was not an intent of the Policy, then my leave from work would have been paid (not unpaid), and the leave would not have been referred to as a "compliance measure". Here, the term "compliance measure" clearly means a materially significant measure that is applied to me with the goal of obtaining my acceptance of a medical procedure that I would not otherwise accept. [redacted]

I submit that the MD evaluating my appeal has a fundamental professional duty as a medical doctor to acknowledge that it is not possible for me to give free and informed consent to receive the COVID-19 injections in the context of the coercion applied to me by my employer, the Bank of Canada, and by the Government of Canada including the Deputy Prime Minister herself.

The impossibility for me to give free and informed consent to the COVID-19 injections due to the coercion exerted on me, and the palpable coercive actions of the Government, of my employer and of all professionals who contribute to induce me to receive an unwanted medical intervention having

[116] Letter from C. Freeland to T. Macklem attached to email of Oct. 29, 2021, from Department of Finance Canada to T. Macklem, at Tab 31.

proven risk of serious injury or death, constitutes a "medical reason for [me] not to be vaccinated".

Section 3: Evaluation of the religious and human rights (age & sex) aspects of my accommodation request

This section concerns the evaluation of the religious and human rights (age & sex) aspects of my accommodation request.

3a: Procedure used to evaluate request

An internal committee of the Bank evaluated the religious and human rights (age & sex) aspects of my request for accommodation. As part of this process, the Bank hired "external legal experts" to "provide advice on accommodation requests under the COVID-19 Vaccination Policy."[117]

I asked to see the evaluations of my accommodation request, but the Bank of Canada refused to provide them to me, stating that: "[W]e are not in a position to release the third party legal advice relating to your request. That said, we can advise that the committee reviewing the request felt that the information that you have submitted to date does not establish a sufficient connection between your request and a religious belief."[118]

3b: Test for granting a religious accommodation

An appropriate statement of the test for granting a religious accommodation to COVID-19 vaccination under the *Canadian Human Rights Act* is as expressed in the Treasury Board of Canada Secretariat's document "Managers' Toolkit for the Implementation of the Policy on COVID-19 Vaccination for the Core Public Administration including the Royal Canadian Mounted Police":

> "Religion
>
> 37. How does a manager decide whether to approve accommodation for religion?
>
> • The manager must be satisfied that the employee holds a sincere religious belief that prevents them from being fully vaccinated.
>
> • The requirement is to focus on the sincerity of the individual belief rooted in religion, not whether it is recognized by other members of the same religion.
>
> o The belief must be religious in nature (not a personal, moral belief), and the employee must explain the nature of the belief and why it prevents vaccination.
>
> o The manager can request more information if the explanation provided is not sufficient.

[117] Email from [redacted] to J. Hickey of Dec. 6, 2021, at Tab 21.
[118] Email from [redacted] to J. Hickey of Nov. 29, 2021, at Tab 21.

o The validity of the belief itself must not be challenged by the manager;

o They must determine only if the belief is sincerely held by the employee." [119] [Emphasis in original.]

The Treasury Board of Canada Secretariat's test stated above is a concise and accurate expression of the main elements of the test developed in the Canadian case law regarding duty to accommodate for religious reasons in an employment context.[120]

The test is stated in more detail by the Ontario Human Rights Commission in the context of discrimination based on "creed", below, and the same test applies regarding discrimination based on religion under the *Canadian Human Rights Act*:

> "9.5 The legal test
>
> Section 11 of the Code prohibits discrimination that results from requirements, qualifications or factors that may appear neutral but have an adverse effect on people identified by Code grounds.[282] This is known as "constructive" or "adverse effect" discrimination (see section 7.8 above). Organizations have a duty to accommodate people up to the point of undue hardship, where a person faces adverse effect discrimination based on their creed. (…)
>
> 9.5.1 Establishing adverse effect discrimination
>
> A person must first establish a prima facie claim of discrimination before the duty to accommodate is triggered. In the context of creed, this requires showing that a person has been adversely affected by a requirement, qualification or factor in a Code social area, at least in part based on their sincerely held creed belief (see section 9.5.3 for more on "sincerely held belief").[283]
>
> Not every adverse impact on a person's creed may be discriminatory under the Code. Interference with creed practices or beliefs that are only marginally significant for, or peripherally connected to, a person's creed may not necessarily receive protection.[284] Examples include:
>
> - Taking part in volunteer activities at church,[285] or other social and communal activities connected to a religion or creed[286]
> - Accessing religious and cultural programming[287]
> - Attending a land claim selection meeting[288]

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[119] Treasury Board of Canada Secretariat, "Managers' Toolkit for the Implementation of the Policy on COVID-19 Vaccination for the Core Public Administration including the Royal Canadian Mounted Police", Version 1.0, 8 October 2021, at Tab 22.

[120] See: Ontario Human Rights Commission, "Policy on Preventing Discrimination Based on Creed", section 9.5, https://www.ohrc.on.ca/en/policy-preventing-discrimination-based-creed/9-duty-accommodate; *Ont. Human Rights Comm. v. Simpsons-Sears*, 1985 CanLII 18 (SCC) ["*O'Malley*"], https://canlii.ca/t/1ftxz; *British Columbia (Public Service Employee Relations Commission) v. BCGSEU*, 1999 CanLII 652 (SCC) ["*Meiorin*"], https://canlii.ca/t/1fqk1; J. Koshan, "Under the Influence: Discrimination under Human Rights Legislation and Section 15 of the *Charter*", Can. J. Hum. Rights, 3 (2014) 115-142.

- Expressing aspects of one's religious identity in ways that are neither required nor perceived as necessary to "establish a connection with the divine" or the "subject or object of one's spiritual faith."[289]

Objective evidence may be required to show that a requirement, rule or practice actually adversely affects a person based on their sincerely held creed belief.[290] (…)

9.5.2 Bona fide requirement defence

Section 11 of the Code allows an organization to show that the requirement, qualification or factor that results in discrimination is reasonable and bona fide (legitimate). However, to do this, the organization must first show that the needs of the person (including the "needs of the group"[292] they belong to) cannot be accommodated without creating undue hardship.

The Supreme Court of Canada has set out a framework for examining whether the bona fide requirement defence has been met.[293] If prima facie discrimination or discrimination on its face is found to exist, a respondent must establish on a balance of probabilities that the standard, factor, requirement or rule:

1. Was adopted for a purpose or goal that is rationally connected to the function being performed (such as a job, being a tenant, or taking part in the service)
2. Was adopted in good faith, in the belief that it is necessary to fulfill the purpose or goal, and
3. Is reasonably necessary to accomplish its purpose or goal, in the sense that it is impossible to accommodate the claimant without undue hardship.[294]

Ultimately, the person who wants to justify a discriminatory requirement, rule or standard must show that accommodation was incorporated into the standard to the point of undue hardship.[295] This means the requirement was designed or changed to include as many people as possible, and that any remaining individual needs were accommodated, short of undue hardship.[296]

Some of the factors to consider during the analysis include:[297]

- Whether the accommodation provider investigated alternative approaches that do not have a discriminatory effect
- Reasons why viable alternatives were not put in place
- The ability to have differing standards that reflect group or individual differences and capabilities
- Whether the accommodation provider can meet their legitimate objectives in a less discriminatory way
- Whether the standard is properly designed to make sure the desired qualification is met without placing undue burden on the people it applies to
- Whether other parties who are obliged to assist in the search for accommodation have fulfilled their roles.

9.5.3 Sincerely held creed belief

Section 11 of the Code protects people from adverse effect discrimination based on their personal religious or creed beliefs, practices or observances, provided they are sincerely held[298] and connected to a religion or creed.

As per the legal test for the duty to accommodate set out above, organizations have a duty to accommodate people's sincerely held creed beliefs.

While protection under section 11 of the Code requires that an adversely affected belief or practice be creed-based,[299] it is not necessary for someone to show that the belief, practice or observance is:

- An "essential" element of the creed[300]
- Required or recognized as valid by religious officials or "official" creed teachings[301]
- Consistent with the beliefs, practices or observances of others of the same faith.[302]

Organizations have a duty to accommodate both obligatory and voluntary expressions of faith, as long as they are sincerely held. It is the creed-based, "religious or spiritual essence of an action, not any mandatory or perceived-as-mandatory nature of its observance, that attracts protection."[303] (…)

Sincerity of belief means honesty of belief.[306] Sincerity of belief should generally be accepted in good faith unless there are evident reasons for believing otherwise. Where warranted, inquiry into a person's sincerity of belief should be as limited as possible (see section 9.5.3 below).[307] An inquiry only needs to establish that an asserted creed belief "is in good faith, neither fictitious nor capricious, and that it is not an artifice."[308] In many cases, this will be unnecessary or relatively easy to show. However, in other cases, evidence may be required, usually from the person asserting the right, to establish that a person's claim is sincere.

Where there is reason to question someone's sincerity,[309] the credibility of a person's accommodation request is an important factor in establishing sincerity of belief. The consistency of a person's current practices with their asserted creed accommodation may need to be examined to establish sincerity of belief.[310] This may require evidence from the accommodation-seeker about their current belief and practice at the time of the accommodation request.[311]

While inconsistent adherence to a creed practice in the past or present may suggest a lack of sincere belief, it does not necessarily do so. "A sincere believer may occasionally lapse, her beliefs may change over time or her belief may permit exceptions to the practice in particular situations." [312] The context of the inconsistency must be examined. For example, while it may be extremely hard for a person to sacrifice or compromise

their religious or creed-based beliefs, they may have a more compelling need in some contexts that leads them to make that compromise – for instance, the need to keep a job or to maintain access to a service. Sometimes, a departure from usual practice indicates "strength of belief," which the Supreme Court has said is a separate issue from "sincerity of belief." [313]

(…)

> Organizations should be careful not to impose their own standards and viewpoints of what authentic or sincere creed adherence looks like.[316] For example, not all religious or creed traditions require an exclusive commitment. [317]"[121]

3c: My religious belief prevents injection with a COVID-19 vaccine product

In my accommodation request letter, I stated the following:

> "I am a scientist with B.Sc., M.Sc., and Ph.D. degrees in Physics, and I have carefully considered the scientific literature regarding the risks posed to me by COVID-19 and by the COVID-19 vaccines. Having done so, I have come to the deep personal conviction that the right choice for my health is for me not to take a COVID-19 vaccine. From my analysis of the available evidence, I have also come to the deep conviction that the government should not be recommending these vaccines for young and healthy individuals; I therefore object, as a matter of conscience, to participating in the government's vaccination program. Due to these deep personal convictions, I request an accommodation on the basis of freedom of conscience and religion. My personal conviction is informed by:
>
> - The values imparted to me from my upbringing as a member of the Catholic Church and as a student in Catholic elementary and middle school in Ontario. These include the values expressed in the philosophy of Saint Thomas Aquinas, who believed that "conscience is the consideration of a specific case in light of one's moral knowledge" and "the binding character of conscience, whether erring or not, means that acting against conscience is always evil."[ref in original]
>
> - A family tragedy: my father died as a result of an adverse event from a pharmaceutical product. I am therefore acutely aware that there are risks associated with pharmaceutical products, and take this into account in developing my personal convictions and health choices."[122]

My religious belief is that "conscience is the consideration of a specific case in light of one's moral knowledge" and "the binding character of conscience, whether erring or not, means that acting against conscience is always evil."[123]

My belief is directly rooted in the philosophy and teachings of Saint Thomas Aquinas,[124] which form an integral part of the Christian religious doctrine.[125] My belief is also rooted in the *Catechism of the*

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[121] Ontario Human Rights Commission, *supra*; Koshan, *supra*.
[122] Accommodation Request Letter of J. Hickey, at Tab 2.
[123] *Ibid.*
[124] T. Hoffman, "Conscience and *Synderesis*", in *The Oxford Handbook of Aquinas* (Davies, Brian, ed.), Oxford University Press, New York (2012).
[125] "(…) the Church declared the teaching of Thomas [Aquinas] to be her own and that Doctor, honored with the special praises of the Pontiffs, the master and patron of Catholic schools." *Fausto Appentente Die*, Encyclical of Pope Benedict XV, 1921, https://www.vatican.va/content/benedict-xv/en/encyclicals/documents/hf_ben-xv_enc_29061921_fausto-appetente-die.html; "In a recent apostolic letter confirming the statutes of Canon Law, We declared that the guide to be followed in the higher studies by young men training for the priesthood was Thomas Aquinas. (…) We propose to comment briefly in this Letter on the sanctity and doctrine of Thomas Aquinas

Catholic Church, which is “a text which contains the fundamental Christian truths formulated in a way that facilitates their understanding”.[126] From the *Catechism*:

> “Article 6
>
> MORAL CONSCIENCE
>
> 1776 "Deep within his conscience man discovers a law which he has not laid upon himself but which he must obey. Its voice, ever calling him to love and to do what is good and to avoid evil, sounds in his heart at the right moment.... For man has in his heart a law inscribed by God.... His conscience is man's most secret core and his sanctuary. There he is alone with God whose voice echoes in his depths."47
>
> I. The Judgment of Conscience
>
> 1777 Moral conscience,48 present at the heart of the person, enjoins him at the appropriate moment to do good and to avoid evil. It also judges particular choices, approving those that are good and denouncing those that are evil.49 It bears witness to the authority of truth in reference to the supreme Good to which the human person is drawn, and it welcomes the commandments. When he listens to his conscience, the prudent man can hear God speaking.
>
> 1778 Conscience is a judgment of reason whereby the human person recognizes the moral quality of a concrete act that he is going to perform, is in the process of performing, or has already completed. In all he says and does, man is obliged to follow faithfully what he knows to be just and right. It is by the judgment of his conscience that man perceives and recognizes the prescriptions of the divine law:
>
> Conscience is a law of the mind; yet [Christians] would not grant that it is nothing more; I mean that it was not a dictate, nor conveyed the notion of responsibility, of duty, of a threat and a promise.... [Conscience] is a messenger of him, who, both in nature and in grace, speaks to us behind a veil, and teaches and rules us by his representatives. Conscience is the aboriginal Vicar of Christ.50
>
> 1779 It is important for every person to be sufficiently present to himself in order to hear and follow the voice of his conscience. This requirement of interiority is all the more necessary as life often distracts us from any reflection, self-examination or introspection:
>
> Return to your conscience, question it.... Turn inward, brethren, and in everything you do, see God as your witness.51

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and to show what profitable instruction may be derived therefrom by priests, by seminarians especially, and, not least, by all Christian people. (…) Our greatly regretted Predecessor Benedict XV (…) is to be praised for having promulgated the Code of Canon Law in which ‘the system, philosophy and principles of the Angelic Doctor’ are unreservedly sanctioned. (…) Again, if we are to avoid the errors which are the source and fountain-head of all the miseries of our time, the teaching of Aquinas must be adhered to more religiously than ever.”, *Studiorum Ducem* on St. Thomas Aquinas, Encyclical of Pope Pius XI, 1923, https://www.papalencyclicals.net/pius11/p11studi.htm.

[126] United States Conference of Catholic Bishops, “Frequently asked questions about the Catechism”, https://www.usccb.org/committees/subcommittee-catechism/faq-about-catechism.

1780 The dignity of the human person implies and requires uprightness of moral conscience. Conscience includes the perception of the principles of morality (synderesis); their application in the given circumstances by practical discernment of reasons and goods; and finally judgment about concrete acts yet to be performed or already performed. the truth about the moral good, stated in the law of reason, is recognized practically and concretely by the prudent judgment of conscience. We call that man prudent who chooses in conformity with this judgment.

1781 Conscience enables one to assume responsibility for the acts performed. If man commits evil, the just judgment of conscience can remain within him as the witness to the universal truth of the good, at the same time as the evil of his particular choice. the verdict of the judgment of conscience remains a pledge of hope and mercy. In attesting to the fault committed, it calls to mind the forgiveness that must be asked, the good that must still be practiced, and the virtue that must be constantly cultivated with the grace of God:

We shall . . . reassure our hearts before him whenever our hearts condemn us; for God is greater than our hearts, and he knows everything.52

1782 Man has the right to act in conscience and in freedom so as personally to make moral decisions. "He must not be forced to act contrary to his conscience. Nor must he be prevented from acting according to his conscience, especially in religious matters."53

II. The Formation of Conscience

1783 Conscience must be informed and moral judgment enlightened. A well-formed conscience is upright and truthful. It formulates its judgments according to reason, in conformity with the true good willed by the wisdom of the Creator. the education of conscience is indispensable for human beings who are subjected to negative influences and tempted by sin to prefer their own judgment and to reject authoritative teachings.

1784 The education of the conscience is a lifelong task. From the earliest years, it awakens the child to the knowledge and practice of the interior law recognized by conscience. Prudent education teaches virtue; it prevents or cures fear, selfishness and pride, resentment arising from guilt, and feelings of complacency, born of human weakness and faults. the education of the conscience guarantees freedom and engenders peace of heart.

1785 In the formation of conscience the Word of God is the light for our path,54 we must assimilate it in faith and prayer and put it into practice. We must also examine our conscience before the Lord's Cross. We are assisted by the gifts of the Holy Spirit, aided by the witness or advice of others and guided by the authoritative teaching of the Church.55

III. To Choose in Accord With Conscience

1786 Faced with a moral choice, conscience can make either a right judgment in accordance with reason and the divine law or, on the contrary, an erroneous judgment that departs from them.

1787 Man is sometimes confronted by situations that make moral judgments less assured and decision difficult. But he must always seriously seek what is right and good and discern the will of God expressed in divine law.

1788 To this purpose, man strives to interpret the data of experience and the signs of the times assisted by the virtue of prudence, by the advice of competent people, and by the help of the Holy Spirit and his gifts.

1789 Some rules apply in every case:

- One may never do evil so that good may result from it;

- the Golden Rule: "Whatever you wish that men would do to you, do so to them."56

- charity always proceeds by way of respect for one's neighbor and his conscience: "Thus sinning against your brethren and wounding their conscience . . . you sin against Christ."57 Therefore "it is right not to . . . do anything that makes your brother stumble."58

IV. Erroneous Judgment

1790 A human being must always obey the certain judgment of his conscience. If he were deliberately to act against it, he would condemn himself. Yet it can happen that moral conscience remains in ignorance and makes erroneous judgments about acts to be performed or already committed.

1791 This ignorance can often be imputed to personal responsibility. This is the case when a man "takes little trouble to find out what is true and good, or when conscience is by degrees almost blinded through the habit of committing sin."59 In such cases, the person is culpable for the evil he commits.

1792 Ignorance of Christ and his Gospel, bad example given by others, enslavement to one's passions, assertion of a mistaken notion of autonomy of conscience, rejection of the Church's authority and her teaching, lack of conversion and of charity: these can be at the source of errors of judgment in moral conduct.

1793 If - on the contrary - the ignorance is invincible, or the moral subject is not responsible for his erroneous judgment, the evil committed by the person cannot be imputed to him. It remains no less an evil, a privation, a disorder. One must therefore work to correct the errors of moral conscience.

1794 A good and pure conscience is enlightened by true faith, for charity proceeds at the same time "from a pure heart and a good conscience and sincere faith."60

The more a correct conscience prevails, the more do persons and groups turn aside from blind choice and try to be guided by objective standards of moral conduct.61

IN BRIEF

1795 "Conscience is man's most secret core, and his sanctuary. There he is alone with God whose voice echoes in his depths" (GS 16).

1796 Conscience is a judgment of reason by which the human person recognizes the moral quality of a concrete act.

> 1797 For the man who has committed evil, the verdict of his conscience remains a pledge of conversion and of hope.
>
> 1798 A well-formed conscience is upright and truthful. It formulates its judgments according to reason, in conformity with the true good willed by the wisdom of the Creator. Everyone must avail himself of the means to form his conscience.
>
> 1799 Faced with a moral choice, conscience can make either a right judgment in accordance with reason and the divine law or, on the contrary, an erroneous judgment that departs from them.
>
> 1800 A human being must always obey the certain judgment of his conscience.
>
> 1801 Conscience can remain in ignorance or make erroneous judgments. Such ignorance and errors are not always free of guilt.
>
> 1802 The Word of God is a light for our path. We must assimilate it in faith and prayer and put it into practice. This is how moral conscience is formed."[127]

As I stated in my Accommodation Request Letter: "I have come to the deep personal conviction that the right choice for my health is for me not to take a COVID-19 vaccine. From my analysis of the available evidence, I have also come to the deep conviction that the government should not be recommending these vaccines for young and healthy individuals; I therefore object, as a matter of conscience, to participating in the government's vaccination program."[128]

My conscience thus informs me not to receive injections of a COVID-19 vaccine product. My religious belief prevents me from acting against my conscience, and therefore prevents me from receiving injections of a COVID-19 vaccine product. My religious belief is sincere and it is rooted in religion. I hereby swear that all my statements in this regard are truthful. Please inform me if you require an affidavit or in-person sworn testimony to make your decision on this or any other points in my submissions.

I further submit that "deeply held personal convictions… connected to an individual's spiritual faith and integrally linked to one's self-definition" is the essence of religion, as expressed by the Supreme Court of Canada:

> "In essence, religion is about freely and deeply held personal convictions or beliefs connected to an individual's spiritual faith and integrally linked to one's self-definition and spiritual fulfilment, the practices of which allow individuals to foster a connection with the divine or with the subject or object of that spiritual faith."[129]

I further submit that it is the religious or spiritual essence of an action, not any mandatory or perceived-as-mandatory nature of its observance, that attracts protection:

> "… freedom of religion consists of the freedom to undertake practices and harbour beliefs, having a nexus with religion, in which an individual demonstrates he or she sincerely believes or

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[127] Catechism of the Catholic Church, https://www.vatican.va/archive/ENG0015/_INDEX.HTM.
[128] Accommodation Request Letter of J. Hickey, at Tab 2.
[129] *Syndicat Northcrest v. Amselem*, 2004 SCC 47 (CanLII), at para. 39, https://canlii.ca/t/1hddh.

> is sincerely undertaking in order to connect with the divine or as a function of his or her spiritual faith, irrespective of whether a particular practice or belief is required by official religious dogma or is in conformity with the position of religious officials."[130] [Emphasis added.]

> "[Freedom of religion] encompasses objective as well as personal notions of religious belief, "obligation", precept, "commandment", custom or ritual. Consequently, both obligatory as well as voluntary expressions of faith should be protected under the Quebec (and the Canadian) Charter. It is the religious or spiritual essence of an action, not any mandatory or perceived-as-mandatory nature of its observance, that attracts protection. An inquiry into the mandatory nature of an alleged religious practice is not only inappropriate, it is plagued with difficulties. Indeed, the Ontario Court of Appeal quite correctly noted this in R. v. Laws (1998), 1998 CanLII 7157 (ON CA), 165 D.L.R. (4th) 301, at p. 314:
>
> > There was no basis on which the trial judge could distinguish between a requirement of a particular faith and a chosen religious practice. Freedom of religion under the Charter surely extends beyond obligatory doctrine."[131] [Emphasis added.]

I further submit that it is inappropriate to require expert opinions in the context of a freedom of religion claim, since the focus of a freedom of religion inquiry is not on what others view the claimant's religious obligations as being, but what the claimant views these personal religious "obligations" to be:

> "A claimant may choose to adduce expert evidence to demonstrate that his or her belief is consistent with the practices and beliefs of other adherents of the faith. While such evidence may be relevant to a demonstration of sincerity, it is not necessary. Since the focus of the inquiry is not on what others view the claimant's religious obligations as being, but rather what the claimant views these personal religious "obligations" to be, it is inappropriate to require expert opinions to show sincerity of belief. An "expert" or an authority on religious law is not the surrogate for an individual's affirmation of what his or her religious beliefs are. Religious belief is intensely personal and can easily vary from one individual to another. Requiring proof of the established practices of a religion to gauge the sincerity of belief diminishes the very freedom we seek to protect."[132] [Emphasis added.]

I further submit that it is possible for the Bank to accommodate me without undue hardship or unreasonable inconvenience or disruption to the Bank or its operations, by allowing me to continue working from home without receiving the COVID-19 injections (see Section 3e of these submissions, below, on this point).

3d: Discrimination based on age and sex: Higher risk of myocarditis/pericarditis in males aged 30-39 than in females or males over forty

As I stated in my Accommodation Request Letter:

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[130] *Ibid.*, at para. 46.
[131] *Ibid.*, at para. 47.
[132] *Ibid.*, at para. 54.

"Human Rights (Age and Sex)

The Bank's policy discriminates against me on the basis of age and sex, because it forces me to expose myself to a higher risk of a dangerous adverse health event (heart inflammation) than females and those older than me, in order to obtain the same employment opportunity of continuing my work at the Bank.

Public Health Ontario's publication "Weekly surveillance summary: adverse events following immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to October 17, 2021" [reference in original] shows that heart inflammation (myocarditis or pericarditis) events after two doses of an mRNA (Pfizer or Moderna) vaccine occur:

1. 3.7 times more frequently in males than in females
2. 1.8 times more frequently in males aged 30-39 (my age group) than in females aged 12-17
3. 1.4 times more frequently in males aged 30-39 than in females aged 18-24
4. 3.8 times more frequently in males aged 30-39 than in females aged 25-29
5. 1.6 times more frequently in males aged 30-39 than in females aged 30-39
6. 9.8 times more frequently in males aged 30-39 than in females aged 40-49
7. 3.3 times more frequently in males aged 30-39 than in females aged 50-59
8. 7.2 times more frequently in males aged 30-39 than in females aged 60-69
9. 10.4 times more frequently in males aged 30-39 than in females aged 70-79
10. 6.6 times more frequently in males aged 30-39 than in females aged 80+
11. 2.1 times more frequently in males aged 30-39 than in males aged 40-49
12. 3.4 times more frequently in males aged 30-39 than in males aged 50-59
13. 3.3 times more frequently in males aged 30-39 than in males aged 60-69
14. 3.1 times more frequently in males aged 30-39 than in males aged 70-79
15. 4.5 times more frequently in males aged 30-39 than in males aged 80+

Males aged 30-39 (my age group) are therefore clearly at a higher risk of developing heart inflammation following two doses of an mRNA vaccine than females or men older than 40. This discriminates against me, because it forces me to expose myself to greater health risk (of a dangerous adverse event following vaccine dosage) than members of other identifiable groups in order to continue working. This discrimination can be remedied without undue hardship to the Bank by allowing me to continue working from home without taking a vaccine."[133]

[133] Accommodation Request Letter of J. Hickey, at Tab 2.

Additional data and analyses published by government-employed scientists and in peer-reviewed journals only confirms and strengthens my argument, as follows:

1. A Jan. 25, 2022, article in the *Journal of the American Medical Association* (also discussed in further detail in Section 2e (v) of these submissions, above) found that the rate of myocarditis incidents following a second dose of an mRNA vaccine is at least 11 times greater than the normal rate of myocarditis for my age group and sex, and that underreporting is "likely" such that "the actual rates of myocarditis per million doses of vaccine are likely higher than estimated."[134] The study also found that the rate of myocarditis post-injection was higher for my males aged 30-39 than for females or for males over forty. This is shown in Table 2 of that paper:

Table 2. Reports to VAERS After mRNA-Based COVID-19 Vaccination That Met the CDC's Case Definition for Myocarditis Within a 7-Day Risk Interval per Million Doses of Vaccine Administered

	Reported cases of myocarditis within a 7-d risk interval per million doses of vaccine administered (95% CI)[a]				Expected cases of myocarditis in a 7-d risk interval per million doses (95% CI)[c]
	Vaccination with BNT162b2		Vaccination with mRNA-1273[b]		
	First dose	Second dose	First dose	Second dose	
Males					
Age group, y					
12-15	7.06 (4.88-10.23)	70.73 (61.68-81.11)			0.53 (0.40-0.70)
16-17	7.26 (4.45-11.86)	105.86 (91.65-122.27)			1.34 (1.05-1.72)
18-24	3.82 (2.40-6.06)	52.43 (45.56-60.33)	10.73 (7.50-15.34)	56.31 (47.08-67.34)	1.76 (1.58,1.98)
25-29	1.74 (0.78-3.87)	17.28 (13.02-22.93)	4.88 (2.70-8.80)	24.18 (17.93-32.61)	1.45 (1.21-1.74)
30-39	0.54 (0.20-1.44)	7.10 (5.26-9.57)	3.00 (1.81-4.97)	7.93 (5.61-11.21)	0.63 (0.54.0.73)
40-49	0.55 (0.21-1.48)	3.50 (2.28-5.36)	0.59 (0.19-1.82)	4.27 (2.69-6.78)	0.78 (0.67-0.90)
50-64	0.42 (0.17-1.01)	0.68 (0.33-1.43)	0.62 (0.28-1.39)	0.85 (0.41-1.79)	0.77 (0.68-0.86)
≥65	0.19 (0.05-0.76)	0.32 (0.10-1.00)	0.18 (0.05-0.72)	0.51 (0.21-1.23)	
Females					
Age group, y					
12-15	0.49 (0.12-1.98)	6.35 (4.05-9.96)			0.17 (0.11-0.29)
16-17	0.84 (0.21-3.37)	10.98 (7.16-16.84)			0.42 (0.27-0.66)
18-24	0.18 (0.03-1.31)	4.12 (2.60-6.54)	0.96 (0.31-2.96)	6.87 (4.27-11.05)	0.38 (0.30-0.49)
25-29	0.26 (0.04-1.84)	2.23 (1.07-4.69)	0.41 (0.06-2.94)	8.22 (5.03-13.41)	0.48 (0.35-0.65)
30-39	0.72 (0.32-1.60)	1.02 (0.49-2.14)	0.74 (0.28-1.98)	0.68 (0.22-2.10)	0.47 (0.39-0.57)
40-49	0.24 (0.06-0.97)	1.73 (0.98-3.05)	0.18 (0.02-1.25)	1.89 (0.98-3.63)	0.89 (0.77-1.04)
50-64	0.37 (0.15-0.88)	0.51 (0.23-1.14)	0.65 (0.31-1.36)	0.43 (0.16-1.15)	1.00 (0.89-1.13)
≥65	0.08 (0.01-0.54)	0.35 (0.13-0.92)		0.26 (0.08-0.81)	

Abbreviations: CDC, US Centers for Disease Control and Prevention; VAERS, Vaccine Adverse Event Reporting System.

[a] Of 1453 cases of myocarditis with known vaccination dose and time to symptom onset, 1267 had symptom onset within the 7-day risk interval.

[b] The observed estimates were not calculated for the strata with 0 cases of myocarditis. In addition, the observed estimates were not calculated for the strata with cases of myocarditis after administration of mRNA-1273 in those younger than aged 18 years. The mRNA-1273 vaccine had not been authorized for use in the US in this age group.

[c] Estimated using data from the IBM MarketScan Commercial Research Database for 2017-2019. Rates were not calculated for those aged 65 years or older due to the limitations of the database.

[134] M.E. Oster et al., "Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021", *J. Amer. Med. Assoc.* 327 (2022) 331-340, https://jamanetwork.com/journals/jama/fullarticle/2788346.

2. A study by Public Health Ontario researchers posted to the medRxiv preprint repository on Dec. 5, 2021, reported increased rates of myocarditis/pericarditis for males aged 30-39 as compared to females and males over forty, as can be seen in Table 4 of that paper, below:[135]

Table 4. Observed vs. expected episodes of myocarditis/pericarditis using a 7-day risk window following dose 2 of COVID-19 mRNA vaccines among individuals receiving dose 2 on or after June 1, 2021, by age group, sex, and vaccine product

Age group (years)	Females			Males		
	Individuals with 2 doses	Expected*	Observed	Individuals with 2 doses	Expected*	Observed
			BNT162b2 – Dose 2			
12-17	331,016	0.1-0.1	**4**	338,234	0.4-0.5	**31**
18-24	255,580	0.3-0.3	**2**	245,430	0.9-1.0	**10**
25-29	196,378	0.2-0.3	**3**	190,586	0.5-0.6	**2**
30-39	404,704	0.5-0.6	**2**	369,721	1.1-1.3	**6**
40-49	404,785	0.5-0.7	0	350,902	1.0-1.1	1
50-59	460,742	0.8-1.0	0	420,927	1.2-1.4	1
60-69	441,965	1.0-1.2	0	392,472	1.3-1.5	**3**
70-79	368,666	1.0-1.3	1	319,305	1.2-1.5	**3**
≥80	193,578	0.5-0.6	0	148,837	0.5-0.7	0
			mRNA-1273 – Dose 2			
12-17**	-	-	-	-	-	-
18-24	170,317	0.2-0.2	**7**	179,866	0.6-0.7	**55**
25-29	133,420	0.1-0.2	0	151,079	0.4-0.5	**12**
30-39	266,347	0.3-0.4	**5**	292,548	0.9-1.0	**15**
40-49	261,699	0.4-0.4	**2**	274,340	0.8-0.9	**5**
50-59	292,890	0.5-0.6	**1**	311,910	0.9-1.0	**2**
60-69	247,723	0.6-0.7	0	249,489	0.8-0.9	**2**
70-79	139,124	0.4-0.5	0	128,971	0.5-0.6	**1**
≥80	66,729	0.2-0.2	0	47,684	0.2-0.2	0

*The expected range is estimated from the confidence intervals around the mean background rate from 2015-2019.
**Estimates were not provided for individuals aged 12-17 for mRNA-1273 because this product was not used for this age group in Ontario.
Bold results indicate where the observed number was greater than the upper confidence limit of the expected number.

[135] S.A. Buchan et al., "Epidemiology of myocarditis and pericarditis following mRNA vaccines in Ontario, Canada: by vaccine product, schedule and interval", medRxiv, 5 December 2021, https://www.medrxiv.org/content/10.1101/2021.12.02.21267156v1, at Tab 23.

3. Similar rates of myocarditis by age and sex group post-COVID-19-vaccination were found in the United States in the study of Bozkurt *et al.* Tables 1 and 2 from that study are included below:[136]

Table 1. Expected Versus Observed Number of Myocarditis/Pericarditis Cases in 7-Day Risk Window After Dose 2 of mRNA Covid-19 Vaccination*

	Females			Males		
Age groups	Doses administered	Expected*,†	Observed*	Doses administered	Expected*,†	Observed*
12–17 y	2 189 726	0–2	19	2 039 871	0–4	128
18–24 y	5 237 262	1–6	23	4 337 287	1–8	219
25–29 y	4 151 975	0–5	7	3 625 574	1–7	59
30–39 y	9 356 296	2–18	11	8 311 301	2–16	61
40–49 y	9 927 773	2–19	18	8 577 766	2–16	34
50–64 y	18 696 450	4–36	18	16 255 927	3–31	18
65+ y	21 708 975	4–42	10	18 041 547	3–35	11

COVID-19 indicates coronavirus disease 2019.

*Preliminary myocarditis/pericarditis reports to US Vaccine Adverse Event Reporting System after dose-2 mRNA vaccination, expected vs observed number of cases using 7-day risk window with data through June 11, 2021. Includes total preliminary reports identified by Centers for Disease Control and Prevention Advisory Committee on Immunization Practices through Vaccine Adverse Event Reporting System database searches for reports with myocarditis/pericarditis codes and prescreened Vaccine Adverse Event Reporting System reports with signs and symptoms consistent with myocarditis/pericarditis. Observed cases may include probable and confirmed cases by Centers for Disease Control and Prevention. Adapted from Centers for Disease Control and Prevention[5] with permission. Copyright ©2021, Centers for Disease Control and Prevention.

†Based on US population–based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines and expected counts among females 12 to 29 years of age adjusted for lower prevalence relative to males by factor of 1.73.[6] Adapted from Centers for Disease Control and Prevention[5] with permission. Copyright ©2021, Centers for Disease Control and Prevention.

Table 2. Crude Reporting Rates of Myocarditis/Pericarditis Cases per Million Doses After mRNA COVID-19 Vaccination

	Female rates per million doses			Male rates per million doses		
Age groups	All doses	Dose 1	Dose 2	All doses	Dose 1	Dose 2
12–17 y	4.2	1.1	9.1	32.4	9.8	66.7
18–24 y	3.6	1.5	5.5	30.7	8.7	56.3
25–29 y	2.0	0.8	2.6	12.2	4.5	20.4
30–39 y	1.8	1.4	1.8	6.9	2.0	10.0
40–49 y	2.0	0.9	2.8	3.5	1.0	5.1
50–64 y	1.6	1.0	1.8	1.9	1.0	2.3
65+ y	1.1	0.6	1.2	1.2	0.7	1.4

Preliminary myocarditis/pericarditis crude reporting rates per million mRNA vaccine doses administered by sex and dose number to US Vaccine Adverse Event Reporting System following mRNA COVID-19 vaccination with no restrictions on post-vaccination observation time, data through June 11, 2021. Adapted from Centers for Disease Control and Prevention[5] with permission. Copyright ©2021, Centers for Disease Control and Prevention. COVID-19 indicates coronavirus disease 2019.

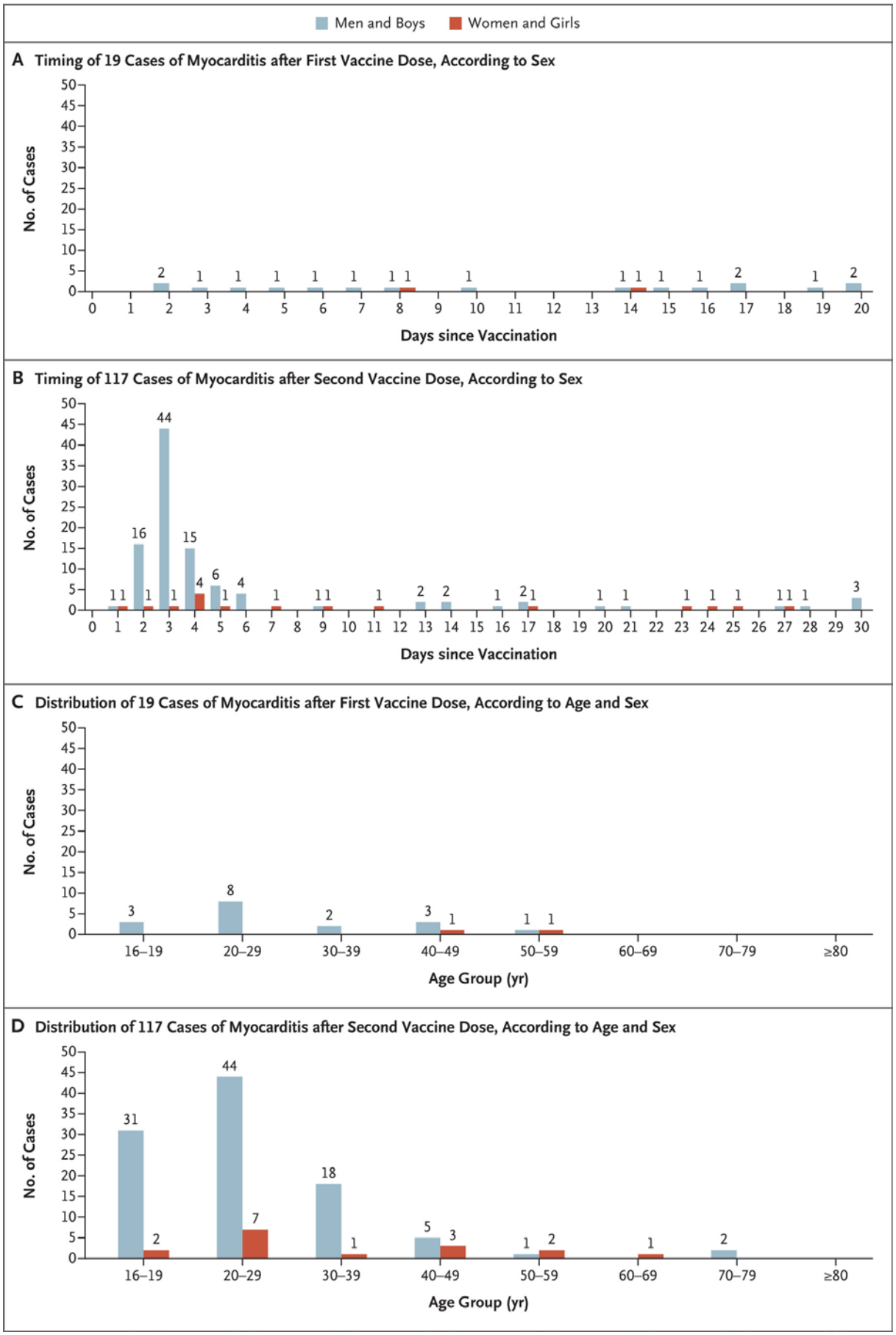
[136] B. Bozkurt et al., "Myocarditis With COVID-19 mRNA Vaccines", *Circulation* 144 (2021) 471-484, https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.056135.

4. A large study from the UK entitled "Risk of myocarditis following sequential COVID-19 vaccinations by age and sex" was posted to the medRxiv preprint repository on Dec. 25, 2021, and states that "[a]ssociations were strongest in males younger than 40 years for all vaccine types…" as quoted below:

> "ABSTRACT
>
> In an updated self-controlled case series analysis of 42,200,614 people aged 13 years or more, we evaluate the association between COVID-19 vaccination and myocarditis, stratified by age and sex, including 10,978,507 people receiving a third vaccine dose. Myocarditis risk was increased during 1-28 days following a third dose of BNT162b2 (IRR 2.02, 95%CI 1.40, 2.91). Associations were strongest in males younger than 40 years for all vaccine types with an additional 3 (95%CI 1, 5) and 12 (95% CI 1,17) events per million estimated in the 1-28 days following a first dose of BNT162b2 and mRNA-1273, respectively; 14 (95%CI 8, 17), 12 (95%CI 1, 7) and 101 (95%CI 95, 104) additional events following a second dose of ChAdOx1, BNT162b2 and mRNA-1273, respectively; and 13 (95%CI 7, 15) additional events following a third dose of BNT162b2, compared with 7 (95%CI 2, 11) additional events following COVID-19 infection. An association between COVID-19 infection and myocarditis was observed in all ages for both sexes but was substantially higher in those older than 40 years. These findings have important implications for public health and vaccination policy."[137]

5. The increased risk to my age and sex group (males aged 30-39) compared to females and males over forty is visually portrayed in panel "D" of the following figure, from the article "Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Israel" published in the *New England Journal of Medicine*:[138]

[137] M. Patone et al., "Risk of myocarditis following sequential COVID-19 vaccinations by age and sex", medRxiv, 25 December 2021, https://www.medrxiv.org/content/10.1101/2021.12.23.21268276v1, at Tab 24.
[138] D. Mevorach et al., "Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Israel", *New Eng. J. Med.* 385 (2021) 2140-2149, https://www.nejm.org/doi/full/10.1056/nejmoa2109730.


Men and Boys
Women and Girls
A Timing of 19 Cases of Myocarditis after First Vaccine Dose, According to Sex
No. of Cases
Days since Vaccination
B Timing of 117 Cases of Myocarditis after Second Vaccine Dose, According to Sex
No. of Cases
Days since Vaccination
C Distribution of 19 Cases of Myocarditis after First Vaccine Dose, According to Age and Sex
No. of Cases
16–19
20–29
30–39
40–49
50–59
60–69
70–79
≥80
Age Group (yr)
D Distribution of 117 Cases of Myocarditis after Second Vaccine Dose, According to Age and Sex
No. of Cases
16–19
20–29
30–39
40–49
50–59
60–69
70–79
≥80
Age Group (yr)

There are thus clearly higher risks of dangerous heart inflammation following COVID-19 vaccine injection in my age and sex group (males aged 30-39) than in females and in males over forty.

I submit that the increased danger of dangerous heart inflammation to me as compared to other identifiable groups (females and males over forty) discriminates against me, because it forces me to expose myself to greater health risk in order to continue working. This discrimination can be remedied without undue hardship or unreasonable inconvenience or disruption to the Bank or its operations, by allowing me to continue working from home without receiving a COVID-19 injection.

3e: No undue hardship: All of my work can be done remotely and was done so since March 2020

The Bank will experience no undue hardship or unreasonable inconvenience or disruption in allowing me to work from home while the COVID-19 Vaccination Policy is in place.

The great majority of Bank staff have worked entirely from home from March 2020 to present. This includes most (if not all) of my departmental colleagues and colleagues in other analytical departments at the Bank, such as the Financial Stability Department, the International Economic Analysis Department, the Banking and Payments Department, the Currency Department, and the Financial Markets Department.

The fact that a large proportion of the Bank's staff have worked entirely from home for two years (from March 13, 2020, to present), without any significant disruption to the Bank's operations, proves that the Bank will experience no undue hardship in allowing me to continue working from home while the COVID-19 Vaccination Policy is in place.

In fact, in 2.5 years of work at the Bank of Canada, there has never been any task asked of me that could not have been done remotely. I am a data scientist, and my work is theoretical, and can be done entirely from home, using electronic communication. I worked entirely from home from March 13, 2020, until I was placed on unpaid leave on November 22, 2021.

Furthermore, the Bank has announced that the return of staff to the office will take place under a "Hybrid Model", where all work will be capable of being done from home, including meetings.[139] [redacted]

There can be no doubt that allowing me to work from home while the Bank's COVID-19 Vaccination Policy is in place would impose no undue hardship on the Bank of Canada.

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[139] [redacted] Bank of Canada job posting for the position of "Senior Data Management Specialist", downloaded 22 February 2022, at Tab 27.

[redacted]

Section 4: Illegality of the Policy and of the Bank's decision to deny accommodation

4a: The Policy and decision to deny accommodation violate the *Canadian Charter of Rights and Freedoms*

This section contains my submissions that the Bank of Canada's COVID-19 Vaccination Policy (the "Policy") and its decision to deny my accommodation request (the "decision") violate my rights under the *Canadian Charter of Rights and Freedoms*.[141]

4a (i): The Policy and decision are government action

The Bank of Canada (the "Bank") is a federal Crown corporation[142] created and governed by the *Bank of Canada Act*,[143] an Act of Parliament.

The Bank was directed by the Federal Government of Canada to implement a policy requiring all employees to receive injections of a COVID-19 vaccine product. The Bank accordingly created its COVID-19 Vaccination Policy (the "Policy"), which came into effect on Oct. 6, 2021.

That the Bank was directed by the Federal Government to implement its Policy is evident from the statements of [redacted], Senior Employee Relations Specialist at the Bank of Canada, in a Nov. 18, 2021, meeting on Microsoft Teams, in which [redacted] said to me:

> "The mandate from the federal government was that each Crown corporation create their own policies that are in alignment with the guidelines that all employees be vaccinated, the duty to accommodate, and all of that.
>
> (…)
>
> Our mandate from the Federal Government was to create our own policies based on the guidelines that all employees be vaccinated, and if they cannot be vaccinated due to medical reasons or protected grounds, that the employer set out to explore its duty to accommodate, and our policy is aligned with those requirements.
>
> (…)
>
> Crown corporations have their own regulations and laws, but we are bound by Federal Government guidelines, and that's why I explained that the Treasury Board guidelines don't apply to us, but we were mandated to create policies that were aligned with the Federal Government's requirements as to vaccination within the workplace."

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[141] *Canadian Charter of Rights and Freedoms*, Part 1 of the *Constitution Act*, 1982, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11, https://laws-lois.justice.gc.ca/eng/const/page-12.html ["*Charter*" from here on].
[142] Government of Canada, "List of Crown Corporations", https://www.canada.ca/en/treasury-board-secretariat/services/guidance-crown-corporations/list-crown-corporations.html.
[143] *Bank of Canada Act* (R.S.C., 1985, c. B-2), https://laws-lois.justice.gc.ca/eng/acts/b-2/.

(…)

people who are not vaccinated by [Nov. 22, 2021] are all being moved to leave without pay until either they are fully vaccinated or until we have more direction from the Federal Government if someone decides to refuse to comply. (…) So if somebody refuses to comply with the policy, if they say 'No, I'm not going to get vaccinated', then they are moved on leave without pay until further notice, and what we're waiting for is further direction from the Federal Government as to what the next steps will be for individuals who are in that scenario."[144] [Emphasis added.]

I wrote to [redacted] on Nov. 22, 2021, to recap in writing the important points from our Nov. 18, 2021, meeting, and stated the following:

"- You informed me that the Bank was mandated by the Federal Government to create a vaccination policy requiring all employees to be vaccinated, except for cases in which specific employees cannot be vaccinated, in which cases those employees must be accommodated under human rights legislation. You told me that even though Crown corporations have their own regulations and laws, the Bank is bound by the Federal Government's mandate to create and apply this(the Bank's) vaccination policy.

- You informed me that the Bank will follow further direction from the Federal Government (expected in 4-6 months) regarding what to do about the status of employees on unpaid leave under the vaccination policy, such as terminating these employees, returning them to work, or prolonging their period of leave."[145]

[redacted] responded by email on Nov. 23, 2021, by quoting my statements from my Nov. 22, 2021, email and adding [redacted] replies directly below my statements, in green text:

"- You informed me that the Bank was mandated by the Federal Government to create a vaccination policy requiring all employees to be vaccinated, except for cases in which specific employees cannot be vaccinated, in which cases those employees must be accommodated under human rights legislation. You told me that even though Crown corporations have their own regulations and laws, the Bank is bound by the Federal Government's mandate to create and apply this(the Bank's) vaccination policy. I rather explained that Bank implemented its own vaccination policy based on direction from the Federal Government indicating that it would be mandatory for Crown corporations and other federal entities. To date, the Federal government has issued a direction to Crown corporations to implement a vaccine mandate for all employees.

- You informed me that the Bank will follow further direction from the Federal Government (expected in 4-6 months) regarding what to do about the status of employees on unpaid leave under the vaccination policy, such as terminating these employees, returning them to work, or prolonging their period of leave. You are correct that the Bank expects further direction as the situation evolves. I did not specify any other potential outcome other than termination, as indicated in the Bank's communication on this topic with you to date. The Bank will review the

[144] Statements made by [redacted] to J. Hickey in Microsoft Teams meeting of Nov. 18, 2021.
[145] Email of J. Hickey to [redacted] of Nov. 22, 2021, at Tab 28.

> situation periodically and will make its own determinations based on all relevant consideration."[146] [Emphasis added.]

The above statements by [redacted] demonstrate that the Bank of Canada is following the Federal Government's direction in implementing its COVID-19 Vaccination Policy; that the Bank is acting for the Government, as an agent of the Government.

That the Bank was directed by the Federal Government to implement its (the Bank's) Policy and that it complied with the Federal Government's direction is also evident from the text of the Bank's Policy:

> "Context
>
> The Bank is committed to protecting the health and safety of all of its employees and others in its workplaces. In the context of the COVID-19 pandemic that was declared by the World Health Organization, the mandates issued by the federal government, and direction provided by public health authorities, special health and safety measures are necessary to protect the health and safety of Bank employees and prevent the spread of COVID-19, and to ensure that the Bank's operations can continue, given its critical role to the Canadian economy in challenging economic times.
>
> Policy Statement
>
> The objective of this policy is to reduce the risk of transmission of COVID-19 in order to protect the health and safety of the employees of the Bank, and to protect the general public health of all Canadians by mandating all employees to be fully vaccinated against COVID-19 and its variants.
>
> Scope
>
> The Government of Canada has provided notice that it intends to require all federal public service employees, employees of federal Crown corporations and employees in the federally regulated air, rail, and marine transportation sectors to be fully vaccinated. This policy reflects the approach outlined by the Government and the recommendations of public health authorities. It applies to all Bank employees, regardless of their role at the Bank." [Emphasis added.]

[redacted]

[146] Email of [redacted] to J. Hickey of Nov. 23, 2021, at Tab 5.

That the Bank was directed by the Federal Government to implement its Policy is also evident from a letter sent on Oct. 29, 2021, from Deputy Prime Minister and Minister of Finance Chrystia Freeland to Bank of Canada Governor Tiff Macklem, which states:

> "The new *Policy on COVID-19 Vaccination for the Core Public Administration, Including the Royal Canadian Mounted Police* stipulates that all employees must be vaccinated. As announced on October 6, 2021, the Government of Canada expects all other federal institutions outside the core public administration, including Crown corporations, to align with the policy.
>
> The Bank of Canada (BOC) is expected to ensure that its vaccination requirements (and those of any wholly-owned subsidiaries) are fully aligned with the requirements of the policy by November 30, 2021. Specifically, this includes, but is not limited to, ensuring that employees attest to their vaccination status no later than November 30, 2021. Compliance measures, including leave without pay, should be underway by as early as December 15, 2021.
>
> (…)
>
> Vaccination requirements should apply to all employees, officers, and directors.
>
> (…)
>
> Thank you in advance for paying close personal attention to the material attached and for taking the necessary measures for the BOC to align with the policy."[149]

On Nov. 2, 2021, Mr. Matthew Meagher, Senior Legal Counsel for the Bank, responded to Deputy Prime Minister Freeland's Oct. 29, 2021, letter, stating:

[149] Letter from C. Freeland to T. Macklem attached to email of Oct. 29, 2021, from Department of Finance Canada to T. Macklem, at Tab 31.

> "I am writing with respect to the October 29 letter to the Bank of Canada from Deputy Prime Minister Freeland, which indicated that Crown corporations will be required to report to you on the implementation of their Covid-19 vaccination policies.
>
> The Bank has already implemented its mandatory vaccination policy for employees, directors and officers. Attestations of vaccination status were required to be submitted prior to November 1, and those individuals who are not fully vaccinated and who do not qualify for an exemption under human rights legislation will be placed on leave without pay effective November 22. The Bank has engaged a third party service provider to conduct audits of all attestations that were submitted.
>
> If you are ready to do so, I would appreciate it if you would be able to provide us with guidance in terms of the format and content of the reports that you are looking to receive. We'd also be interested in any guidance that you might be able to provide on the reports for directors, if you have that available."[150]

Mr. Meagher's response to the Deputy Prime Minister's Oct. 29, 2021, letter demonstrates that the Bank was following the Federal Government's direction and acting as an agent of the Federal Government regarding the Bank's implementation of its mandatory vaccination policy.

The Government of Canada has also announced that it will be amending the *Canada Labour Code* to require vaccination in federally-regulated workplaces including federal Crown corporations:

> "Today the Minister of Labour, Seamus O'Regan Jr., announced that the Government of Canada will propose regulations under Part II of the Canada Labour Code to make vaccination mandatory in federally regulated workplaces.
>
> (…)
>
> Mandatory vaccination requirements are already in place for the public sector, employees working in the federally regulated air, rail, and marine transportation sectors, and travelers on these modes of transportation. The new regulations would ensure that employees in all other federally regulated industries, such as road transportation, telecommunications, and banking, are also vaccinated.
>
> (…)
>
> Quick facts
>
> - The federally regulated sector is comprised of workplaces from a broad range of industries, including interprovincial air, rail, road, and marine transportation, pipelines, banks, postal and courier services, among others.
> - There are approximately 18,500 employers in federally regulated industries, including federal Crown corporations, which together employ 955,000 people (about 6% of all employees in Canada). The vast majority (87%) of these people work in companies with 100 or more employees. These figures exclude the federal public service. Including the

[150] Email of M. Meagher to J. Wright of Nov. 2, 2021, at Tab 31.

> federal public service, there are approximately 19,000 employers and 1,300,000 employees (about 8.5% of all employees in Canada)."[151] [Emphasis added.]

Furthermore, the Minister of Labour, the Hon. Seamus O'Regan, was given the following mandate by the Prime Minister of Canada on Dec. 16, 2021:[152]

> "As Minister of Labour, your immediate priorities are to work with federally regulated workplaces to ensure that COVID-19 vaccinations are enforced for those workers and to advance amendments to the Canada Labour Code to provide 10 paid days of sick leave for all federally regulated workers. (…)
>
> To realize these objectives, I ask that you achieve results for Canadians by delivering the following commitments.
>
> Continue to work with federally regulated workplaces to ensure that COVID-19 vaccination is enforced. (…)"

I have also requested, pursuant to federal Access to Information law, the documents held by the Bank of Canada that would "specify the nature of the government's directive or request to the Bank of Canada to develop a vaccination policy, and what the government expects the Bank's policy to accomplish". I submitted a first such request by letter dated Nov. 17, 2021, and received a final response dated Mar. 9, 2022. However, none of the records provided to me by the Bank's Access to Information and Privacy Office were dated prior to Oct. 6, 2021, the date on which the Bank announced its Policy. Yet such records must exist, because there must have been communication between the Federal Government and the Bank regarding the development or elaboration of, or planning for, the Bank's Policy and what it was required or expected to achieve before the finalized Policy was announced and took effect on Oct. 6, 2021.

In response to my inquiry as to why none of the access to information records were dated prior to Oct. 6, 2021, the Bank's Access to Information and Privacy Analyst, [redacted], wrote:

> "[W]e have performed a thorough search for records and you are being provided with everything that is relevant based on the text of your request. Please be advised, should you wish to submit another Access to Information request using different parameters, we would be happy to assist you again."[153] [Emphasis added.]

Accordingly, I will submit a new and revised access request with the same overall goal as my Nov. 17, 2021, request. I am therefore still waiting to receive records dated prior to Oct. 6, 2021, that would "specify the nature of the government's directive or request to the Bank of Canada to develop a vaccination policy, and what the government expects the Bank's policy to accomplish".

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[151] Employment and Social Development Canada, "Government of Canada will require employees in all federally regulated workplaces to be vaccinated against COVID-19", 7 December 2021, https://www.canada.ca/en/employment-social-development/news/2021/12/government-of-canada-will-require-employees-in-all-federally-regulated-workplaces-to-be-vaccinated-against-covid-19.html, at Tab 32.
[152] Prime Minister of Canada, "Minister of Labour Mandate Letter", 16 December 2021, https://pm.gc.ca/en/mandate-letters/2021/12/16/minister-labour-mandate-letter.
[153] Email from [redacted] to J. Hickey of Mar. 9, 2022, at Tab 33.

In conclusion, the Bank was directed by the Federal Government to implement its COVID-19 Vaccination Policy, and followed the directives. As such, the Policy and the Bank's decisions pursuant to the Policy constitute government action that is subject to the *Canadian Charter of Rights and Freedoms*.

Additionally, as noted above in this section, the Federal Government is implementing amendments to the *Canada Labour Code* to require vaccination in federally-regulated workplaces including Crown corporations. The fact that statutory amendments (which have not yet been enacted) are needed to implement mandatory vaccination in federally-regulated workplaces, which include the Bank of Canada, implies that the Federal Government did not have any authority to require the Bank to implement mandatory vaccination of its staff, in that the Government generally does not advance unneeded laws.

The Federal Government, via the Prime Minister's Aug. 13, 2021, announcement that the "Government of Canada expects that Crown corporations and other employers in the federally regulated sector will (…) require vaccination for their employees"[154] and via the Deputy Prime Minister's Oct. 29, 2021, letter to the Bank of Canada Governor,[155] infringed or denied my *Charter* rights irrespective of whether the Federal Government had the legal authority to force the Bank of Canada to follow its "expectation" regarding mandatory vaccination of the Bank's staff. Furthermore, the Bank, as my employer, had a duty to protect me against this *Charter* infringement, rather than enact the infringement.

Also, the Bank's Policy states that it "applies to all employees, regardless of their role at the Bank." The Policy surpasses any obligation the Bank has to provide a safe workplace for its employees, since the vaccination requirement extends to remote-working employees or employees who are capable of doing 100% of their work from home and who do not need to have any physical contact with co-workers. If the Bank is not bound to follow the Federal Government's direction in this matter, then it does not have jurisdiction or authority to implement this broad medical and public health policy that surpasses its workplace safety obligations and exceeds any contractual agreement with me as an employee.

4a (ii): Freedom of conscience and religion

As explained in my Accommodation Request Letter[156] and repeated in Section 3c of these submissions, I hold a deep conviction that receiving injections of a COVID-19 vaccine product is not the right choice for my health, and I object as a matter of conscience to participating in the Government of Canada's vaccination campaign.

I also (see Section 3c of these submissions) hold the religious belief that "conscience is the consideration of a specific case in light of one's moral knowledge" and "the binding character of conscience, whether erring or not, means that acting against conscience is always evil", and my religious belief prevents me from receiving a COVID-19 vaccine injection, since to do so would be to act against my conscience.

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[154] Treasury Board Secretariat, "Government of Canada to require vaccination of federal workforce and federally regulated transportation sector", 13 August 2021, https://www.canada.ca/en/treasury-board-secretariat/news/2021/08/government-of-canada-to-require-vaccination-of-federal-workforce-and-federally-regulated-transportation-sector.html, at Tab 34.

[155] Letter from C. Freeland to T. Macklem attached to email of Oct. 29, 2021, from Department of Finance Canada to T. Macklem, at Tab 31.

[156] Accommodation Request Letter of J. Hickey, at Tab 2.

Freedom of conscience and religion are fundamental freedoms guaranteed by the *Canadian Charter of Rights and Freedoms*, section 2(a):

> "Fundamental freedoms
>
> 2 Everyone has the following fundamental freedoms:
>
> (a) freedom of conscience and religion;"[157]

Freedom of conscience

Freedom of conscience is a right in and of itself, separate from freedom of religion:

> "[W]hile a careful review of legislative intent supports the conclusion that freedom of conscience was deliberately included in the *Charter* as a distinct freedom, the relationship between freedom of conscience and freedom of religion remains unclear."[158] [Emphasis added.]

> "It seems to me, therefore, that in a free and democratic society 'freedom of conscience and religion' should be broadly construed to extend to conscientiously held beliefs, whether grounded in religion or in a secular morality. Indeed, as a matter of statutory interpretation, 'conscience' and 'religion' should not be treated as tautologous[159] if capable of independent, although related, meaning."[160]

> "Freedom means that, subject to such limitations as are necessary to protect public safety, order, health, or morals or the fundamental rights and freedoms of others, no one is to be forced to act in a way contrary to his beliefs or his conscience."[161] [Emphasis added.]

> "In order to define religious freedom, we must first ask ourselves what we mean by 'religion'. While it is perhaps not possible to define religion precisely, some outer definition is useful since only beliefs, convictions and practices rooted in religion, as opposed to those that are secular, socially based or conscientiously held, are protected by the guarantee of freedom of religion."[162] [Emphasis added.]

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[157] *Charter*, *supra*, s. 2(a).
[158] J. Downie and F. Baylis, "A Test for Freedom of Conscience under the Canadian Charter of Rights and Freedoms: Regulating and Litigating Conscientious Refusals in Health Care", *McGill J. Law Health* 11 (2017) S1-S29, https://canlii.ca/t/6xx. [See Section II for a review of the legislative history surrounding freedom of conscience in the *Charter*.]
[159] Note that "tautology" is defined as: "Needless repetition of the same sense in different words; redundancy" by the American Heritage Dictionary of the English Language, Fifth Edition (2016), https://www.thefreedictionary.com/tautology.
[160] Wilson J. in *R. v. Morgentaler*, 1988 CanLII 90 (SCC), https://canlii.ca/t/1ftjt.
[161] Dickson J. in *R. v. Big M Drug Mart Ltd.*, 1985 CanLII 69 (SCC), at para. 95, https://canlii.ca/t/1fv2b.
[162] *Syndicat Northcrest v. Amselem*, 2004 SCC 47 (CanLII), at para. 39, https://canlii.ca/t/1hddh.

> "[Four of the intervenors (the Catholic Civil Rights League, the Faith and Freedom Alliance, the Protection of Conscience Project, and the Catholic Health Alliance of Canada)] would have the Court direct the legislature to provide robust protection for those who decline to support or participate in physician-assisted dying for reasons of conscience or religion.
>
> (…)
>
> However, we note – as did Beetz J. in addressing the topic of physician participation in abortion in *Morgentaler* – that a physician's decision to participate in assisted dying is a matter of conscience and, in some cases, of religious belief."[163] [Emphasis added.]

> "It seems, therefore, that freedom of conscience is broader than freedom of religion. The latter relates more to religious views derived from established religious institutions, whereas the former is aimed at protecting views based on strongly held moral ideas of right and wrong, not necessarily founded on any organized religious principles. These are serious matters of conscience. Consequently the appellant is not limited to challenging the oath or affirmation on the basis of a belief grounded in religion in order to rely on freedom of conscience under paragraph 2(a) of the Charter. For example, a secular conscientious objection to service in the military might well fall within the ambit of freedom of conscience, though not religion. However, as Madam Justice Wilson indicated, "conscience" and "religion" have related meanings in that they both describe the location of profound moral and ethical beliefs, as distinguished from political or other beliefs which are protected by paragraph 2(b)."[164] [Emphasis added.]

> "In sum, a review of legislative intent supports the conclusion that freedom of conscience was deliberately kept as a distinct freedom in the Charter and was not considered to be adequately protected through freedom of religion. Indeed, its purpose appears to have been specifically to offer those without religious convictions a freedom analogous to the freedom granted to those with religious convictions."[165]

As a September 2021 report by the *Cardus* charity states, "[t]o date, there has been only one court decision in Canada that has relied exclusively on the guarantee of freedom of conscience in the *Charter*."[166] That judgment is the 2002 Federal Trial Court decision in *Maurice v. Canada (Attorney General)*, in which a prison inmate challenged, on the basis of freedom of conscience, the Correctional Service of Canada (the "CSC")'s decision to deny him a vegetarian diet. The judge stated:

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[163] *Carter v. Canada (Attorney General)*, 2015 SCC 5 (CanLII), at paras. 130-132, https://canlii.ca/t/gg5z4.
[164] *Roach v. Canada (Minister of State for Multiculturalism and Citizenship)*, 1994 CanLII 3453 (FCA), https://canlii.ca/t/4nm5, leave to appeal to Supreme Court of Canada denied.
[165] J. Downie and F. Baylis, "A Test for Freedom of Conscience under the Canadian Charter of Rights and Freedoms: Regulating and Litigating Conscientious Refusals in Health Care", *McGill J. Law Health* 11 (2017) S1-S29, https://canlii.ca/t/6xx. [See Section II for a review of the legislative history surrounding freedom of conscience in the *Charter*.]
[166] Cardus, "Our Inner Guide: Protecting Freedom of Conscience", 27 September 2021, https://content.cardus.ca/documents/download/6532.

> "[8] Thus, while the CSC has recognized its legal duty to facilitate the religious freedoms outlined in the *Charter*, freedom of conscience has effectively been ignored. Section 2(a) of the *Charter* affords the fundamental freedom of both religion *and* conscience, yet by the CSC's policy, inmates with conscientiously held beliefs may be denied expression of their "conscience". In my opinion the CSC's approach is inconsistent. The CSC cannot incorporate s.2(a) of the *Charter* in a piecemeal manner; both freedoms are to be recognized.
>
> [9] Vegetarianism is a dietary choice, which is founded in a belief that consumption of animal products is morally wrong. Motivation for practising vegetarianism may vary, but, in my opinion, its underlying belief system may fall under an expression of "conscience".
>
> [10] In *R. v. Big M Drug Mart Ltd.,* 1985 CanLII 69 (SCC), [1985] 1 S.C.R. 295, at 346, Dickson J. stated that the rights associated with freedom of individual conscience are central to basic beliefs about human worth and dignity, and that every individual should be free to hold and manifest whatever beliefs and opinions his or her conscience dictates. Justice Dickson further articulated the broad scope of s.2(a) as follows:
>
> > Freedom means that, subject to such limitations as are necessary to protect public safety, order, health, or morals or the fundamental rights and freedoms of others, no one is to be forced to act in a way contrary to his beliefs or his conscience.
>
> [11] Therefore, in my opinion, just as the entitlement for a religious diet may be found in s. 2(a) of the *Charter*, a similar entitlement for a vegetarian diet exists based on the right to freedom of conscience."[167] [Underline emphasis added, italic emphasis in "religion *and* conscience" is in the original.]

No Canadian court has elaborated a test to be used in evaluating a claim of freedom of conscience beyond the analysis made in *Maurice*. However, several proposals have been made in the academic literature.[168] The test proposed by Manley-Casimir is as follows:

> "The essential requirements of the proposed test are threefold. First, that the claim advanced in the case reflects an individual refusing to comply with state action on the basis of a deeply held personal position. Second, there must be a preponderance of evidence that the claimant's position is authentic and coherent -- that it represents a moral or political commitment justified by reason rather than faith. And third, there must also be a preponderance of evidence that the claimant has either demonstrably held this position over time as a consistent principle of individual integrity, or, as a result of significant personal reflection and introspection, has recognized the existential force of a personal imperative. 'Existential force' implies the recognition of the unconditional ontological gravity of the matter at hand for the individual.

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[167] *Maurice v. Canada (Attorney General)*, 2002 FCT 69 (CanLII), at paras. 8-11, https://canlii.ca/t/lnk. [Note: This case was not appealed to the Supreme Court of Canada and has not been cited by any Canadian appellate court including the Supreme Court of Canada.]

[168] Downie and Baylis, *supra*; M. Manley-Casimir, "The Meaning of 'Freedom of Conscience' in the Canadian Charter of Rights and Freedoms: A Polyvocal Cultural Analysis", LL.M. thesis, University of British Columbia, 2004, https://open.library.ubc.ca/soa/cIRcle/collections/ubctheses/831/items/1.0077582.

> Assuming that these three requirements are met by the case in question, the Court would arguably be justified in upholding the right to 'freedom of conscience' under s. 2(a).”[169]

The Canadian government, through the Bank of Canada’s COVID-19 Vaccination Policy, is requiring me to receive injections of a medical product. I refuse to comply with this state action on the basis of my deeply held conviction that the right choice for my health is for me not to take a COVID-19 vaccine and that the government should not be recommending these vaccines for young and healthy individuals, such that I object, as a matter of conscience, to participating in the government's vaccination program.

In addition, I have developed a firm belief based on available adverse event data that injection of a COVID-19 vaccine product can cause death and serious injury, and that it already has caused many deaths (see Table 1 in Section 2e (v) of these submissions and the scientific research article that I co-authored entitled “Nature of the toxicity of the COVID-19 vaccines in the USA”[170]).

There is a preponderance of evidence that my position is authentic and coherent, and it represents a moral commitment amply supported by reason and scientific information. I have developed this position beginning with the first scientific articles and data that emerged regarding the COVID-19 vaccines, and my position is the result of significant personal reflection and introspection. I have recognized the existential force of my personal imperative not to receive injections of a COVID-19 vaccine product, and I recognize the unconditional ontological gravity of not receiving the injections.

I submit that for the above reasons, the Bank’s Policy and decision to deny me accommodation infringe or deny my *Charter* right of freedom of conscience.

Freedom of religion

The Supreme Court of Canada has defined freedom of religion as follows:

> “46 To summarize up to this point, our Court’s past decisions and the basic principles underlying freedom of religion support the view that freedom of religion consists of the freedom to undertake practices and harbour beliefs, having a nexus with religion, in which an individual demonstrates he or she sincerely believes or is sincerely undertaking in order to connect with the divine or as a function of his or her spiritual faith, irrespective of whether a particular practice or belief is required by official religious dogma or is in conformity with the position of religious officials.”[171] [Emphasis added.]

In evaluating whether freedom of religion is engaged the Court has followed the steps outlined below:

> “65 As outlined above, the first step in successfully advancing a claim that an individual’s freedom of religion has been infringed is for a claimant to demonstrate that he or she sincerely believes in a practice or belief that has a nexus with religion. The second step is to

[169] *Ibid.*, M. Manley-Casimir.
[170] J. Hickey and D. Rancourt, “Nature of the toxicity of the COVID-19 vaccines in the USA”, OCLA Research Report 2022-1 (ver. 1) (2022), https://ocla.ca/wp-content/uploads/2022/02/OCLA-Report-2022-1-v1.pdf, at Tab 17.
[171] *Syndicat Northcrest v. Amselem*, 2004 SCC 47 (CanLII), at para. 46, https://canlii.ca/t/1hddh.

> then demonstrate that the impugned conduct of a third party interferes with the individual's ability to act in accordance with that practice or belief in a manner that is non-trivial."[172]

As I have explained in Section 3 of these submissions, I hold the religious belief that "conscience is the consideration of a specific case in light of one's moral knowledge" and "the binding character of conscience, whether erring or not, means that acting against conscience is always evil", and that my religious belief is rooted in the philosophy of Saint Thomas Aquinas and the doctrine of the Christian religion. I hereby swear that all my statements in this regard are truthful. Please inform me if you require an affidavit or in-person sworn testimony to make your decision on this or any other points in my submissions.

As I have also explained in Section 3 of these submissions, the Bank of Canada's COVID-19 Vaccination Policy infringes on my freedom of religion because it requires me to act against my conscience by receiving injections of a COVID-19 vaccine product.

I submit that for the above reasons and the reasons expressed in Section 3 of these submissions, the Bank's Policy and decision to deny me accommodation violate the *Charter* right of freedom of religion.

4a (iii): Life, Liberty, and Security of the Person

Section 7 of the *Charter* is as follows:

> "Life, liberty and security of person
>
> 7 Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice."[173]

Mandatory vaccination violates my right to life, liberty, and security of the person

It is clear and obvious that imposing on a non-consenting individual a medical procedure with known risks as severe as death violates the individual's s. 7 right under the *Charter.*

Canadian case law contains explicit statements to this effect, as follows:

> "I agree with the Chief Justice and with Beetz J. that the right to 'security of the person' under s. 7 of the *Charter* protects both the physical and psychological integrity of the individual. State enforced medical or surgical treatment comes readily to mind as an obvious invasion of physical integrity."[174] [Emphasis added.]

> "[66] In *St. Peter's Health System v. CUPE, Local 778*, supra, Arbitrator Charney undertakes a detailed review of authorities provided to him and finds that prior to balancing the interests of the employer and the employees one must look at any common law rights issues and s.7 of the

[172] *Ibid.*, para 65.
[173] *Charter*, supra, s. 7.
[174] Wilson J. in *R. v. Morgentaler*, 1988 CanLII 90 (SCC), at pg. 173, https://canlii.ca/t/1ftjt.

Charter as to whether it is permissible to enforce a mandatory medical treatment. Arbitrator Charney concludes:

> '…suspending employees (non-disciplinary) for refusing to undergo medical treatment is a violation of their common law sec. 7 charter rights. Virtually all the court cases, including Supreme Court of Canada and Ontario Court of Appeal, find that enforced medical treatment, and I point out that this is not a medical examination but treatment, is an assault if there is no consent.'"[175] [Emphasis added.]

"[41] In the Standing Court Martial of Ex-Sergeant Kipling, whose breach of command resulted in severe disciplinary proceedings, the Chief Military Judge found that the forced vaccination program did violate section 7 of the *Charter*, in that the accused's right to life, liberty, and security of the person was infringed. At page 2 of the minutes of the proceedings of the Standing Court Martial:

> Non-consensual vaccination under the threat of disciplinary proceedings amounts to an invasion of the bodily integrity and personal autonomy of a person. [emphasis added]

[42] The plaintiff points out that the issue before the court in *Kipling* was the application of section 7 in connection with a positive law which imposed mandatory vaccination and did not involve the accused's interaction with the judicial system."[176] [Emphasis added in para. 41 at "the Chief Military Judge found…".]

"That there is a right to choose how one's body will be dealt with, even in the context of beneficial medical treatment, has long been recognized by the common law. To impose medical treatment on one who refuses it constitutes battery, and our common law has recognized the right to demand that medical treatment which would extend life be withheld or withdrawn."[177] [Emphasis added.]

"[198] There is a strong consensus among common law countries regarding the right to refuse medical treatment, even if this leads to death. (…)

[199] In Canada, this was recognized by the Ontario Court of Appeal in the *Malette* case. (…) The court stated:

> A competent adult is generally entitled to reject a specific treatment or all treatment, or to select an alternate form of treatment, even if the decision may entail risks as serious as death and may appear mistaken in the eyes of the medical profession or of the community. Regardless of the doctor's opinion, it is the patient who has the final say on whether to undergo the treatment. . . . The doctrine of informed consent is plainly intended to ensure the freedom of individuals to make choices concerning their medical

[175] *Electrical Safety Authority v Power Workers' Union*, 2022 CanLII 343 (ON LA), https://canlii.ca/t/jlnm8.
[176] *Duplessis v. Canada*, 2000 CanLII 16541 (FC), https://canlii.ca/t/42cc.
[177] *Rodriguez v. British Columbia (Attorney General)*, 1993 CanLII 75 (SCC), at pg. 588, https://canlii.ca/t/1frz0.

> care. For this freedom to be meaningful, people must have the right to make choices that accord with their own values regardless of how unwise or foolish those choices may appear to others . . . .
>
> . . .
>
> The state's interest in preserving the life or health of a competent patient must generally give way to the patient's stronger interest in directing the course of her own life. . . . Recognition of the right to reject medical treatment cannot, in my opinion, be said to depreciate the interest of the state in life or in the sanctity of life. Individual free choice and self-determination are themselves fundamental constituents of life. To deny individuals freedom of choice with respect to their health care can only lessen, and not enhance, the value of life. [Emphasis added; pp. 424 and 429-30.]
>
> *Malette* was endorsed by the majority opinion in *Rodriguez v. British Columbia (Attorney General)*, 1993 CanLII 75 (SCC), [1993] 3 S.C.R. 519, at p. 598."[178] [Emphasis added.]

The right to life

The right to life is engaged "where the law or state action imposes death or an increased risk of death on a person, either directly or indirectly":

> "This Court has most recently invoked the right to life in *Chaoulli v. Quebec (Attorney General)*, 2005 SCC 35, [2005] 1 S.C.R. 791, where evidence showed that the lack of timely health care could result in death (paras. 38 and 50, per Deschamps J.; para. 123, per McLachlin C.J. and Major J.; and paras. 191 and 200, per Binnie and LeBel JJ.), and in *PHS*, where the clients of Insite were deprived of potentially lifesaving medical care (para. 91). In each case, the right was only engaged by the threat of death. In short, the case law suggests that the right to life is engaged where the law or state action imposes death or an increased risk of death on a person, either directly or indirectly. Conversely, concerns about autonomy and quality of life have traditionally been treated as liberty and security rights. We see no reason to alter that approach in this case."[179]

In my case, the state action is a mandatory vaccination policy imposed by my employer, under direction of the Federal Government, and the accompanying coercive action including denying me an accommodation to continue working, removing my pay and health benefits, and threatening me with termination of employment.

The COVID-19 vaccines are known to have caused deaths (see section 2e of these submissions).

One may argue that the Policy does not "directly" impose an increased risk of death on me, because I have the choice to accept losing my job and remain uninjected. However, the Policy does impose an

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[178] Binnie J. (dissenting) in *A.C. v. Manitoba (Director of Child and Family Services)*, 2009 SCC 30 (CanLII), at paras. 198-199, https://canlii.ca/t/24432.

[179] *Carter v. Canada (Attorney General)*, 2015 SCC 5 (CanLII), at para. 62, https://canlii.ca/t/gg5z4.

increased risk of death on me, because the threat of job loss is a significant coercive measure that is applied to me with the goal of convincing me to accept the injections.

To "impose" means:

> "1. To establish or apply as compulsory; levy: *impose a tax.*
>
> 2. To bring about by authority or force; force to prevail: *impose a peace settlement.*
>
> (…)"[180]

The state action of implementing a mandatory vaccination policy, and the Bank's participation in this policy, establishes vaccination as compulsory and brings it about by authority or forces it to prevail (using coercion) and therefore directly imposes an increased risk of death on me.

The injection into my body directly imposes a definitive, significant and quantifiable risk of death demonstrably caused by the injection (see section 2e of these submissions) whereas any postulated benefit from the injection relies on a hypothetical scenario that I have no prior immunity, will by chance be exposed and infected, and will die from the infection rather than recover. This further presupposes that the vaccine would have protected me from the specific variant or mutation of the pathogen presumed by chance to have infected me in the said hypothetical scenario. Meanwhile the vaccine formulation has not changed one iota since the vaccine was first rolled out, while thousands of mutations and many "variants" of the presumed pathogen have been reported.[181]

Accordingly, the Bank's Policy and decision to deny me accommodation violate my right to life under s. 7 of the *Charter*, and have no logical or moral basis.

<u>The right to liberty</u>

The right to liberty is engaged when "state compulsions or prohibitions affect important and fundamental life choices":

> "The liberty interest protected by s. 7 of the Charter is no longer restricted to mere freedom from physical restraint. Members of this Court have found that <u>"liberty" is engaged where state compulsions or prohibitions affect important and fundamental life choices.</u> (…) <u>In our free and democratic society, individuals are entitled to make decisions of fundamental importance free from state interference.</u> In *B. (R.) v. Children's Aid Society of Metropolitan Toronto*, 1995 CanLII 115 (SCC), [1995] 1 S.C.R. 315, at para. 80, La Forest J., with whom L'Heureux-Dubé, Gonthier and McLachlin JJ. agreed, emphasized that the liberty interest protected by s. 7 must be interpreted broadly and in accordance with the principles and values underlying the Charter as a whole and that it protects an individual's personal autonomy:
>
> > . . . liberty does not mean mere freedom from physical restraint. In a free and democratic society, the individual must be left room for personal autonomy to live his or

[180] "Impose", American Heritage Dictionary of the English Language, 5th Ed. (2016), https://www.thefreedictionary.com/impose.
[181] M. Ciotti et al., "The COVID-19 pandemic: viral variants and vaccine efficacy", *Crit. Rev. Clin. Lab. Sci.* 59 (2022) 66-75, https://doi.org/10.1080/10408363.2021.1979462.

> her own life and to make decisions that are of fundamental personal importance."[182] [Emphasis added.]

The right to liberty is deprived when the state interferes with fundamentally important and personal medical decision-making:

> "[30] Turning to s. 7 of the Charter, which protects life, liberty and security of the person, the trial judge found that the prohibition impacted all three interests. The prohibition on seeking physician-assisted dying deprived individuals of liberty, which encompasses "the right to non-interference by the state with fundamentally important and personal medical decision-making" (para. 1302). In addition, it also impinged on Ms. Taylor's security of the person by restricting her control over her bodily integrity. While the trial judge rejected a "qualitative" approach to the right to life, concluding that the right to life is only engaged by a threat of death, she concluded that Ms. Taylor's right to life was engaged insofar as the prohibition might force her to take her life earlier than she otherwise would if she had access to a physician-assisted death."[183]

An individual's choices of which medical treatments to receive or not receive are, without doubt, profoundly personal and fundamental life choices. The state action in my case interferes with my decision whether or not to receive an injection of a COVID-19 vaccine product and violates my right to liberty under s. 7 of the *Charter*.

The right to security of the person

The right to security of the person is engaged when state action invades the "physical and psychological integrity of the individual" and includes state action causing "stigmatization", "loss of privacy", and "stress and anxiety resulting from (…) possible disruption of family, social life and work, legal costs, uncertainty as to outcome and sanction". Furthermore, "enforced medical or surgical treatment [is] an obvious invasion of physical integrity":

> "I agree with the Chief Justice and with Beetz J. that the right to 'security of the person' under s. 7 of the *Charter* protects both the physical and psychological integrity of the individual. State enforced medical or surgical treatment comes readily to mind as an obvious invasion of physical integrity. Lamer J. held in *Mills v. The Queen*, 1986 CanLII 17 (SCC), [1986] 1 S.C.R. 863, that the right to security of the person entitled a person to be protected against psychological trauma as well -- in that case the psychological trauma resulting from delays in the trial process under s. 11(b) of the *Charter*. He found that psychological trauma could take the form of 'stigmatization of the accused, loss of privacy, stress and anxiety resulting from a multitude of factors, including possible disruption of family, social life and work, legal costs, uncertainty as to outcome and sanction'."[184]

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[182] *Blencoe v. British Columbia (Human Rights Commission)*, 2000 SCC 44 (CanLII), at para. 49, https://canlii.ca/t/525t.
[183] *Carter v. Canada (Attorney General)*, 2015 SCC 5 (CanLII), at para. 30, https://canlii.ca/t/gg5z4.
[184] Wilson J. in *R. v. Morgentaler*, 1988 CanLII 90 (SCC), at pg. 173, https://canlii.ca/t/1ftjt.

Security of the person includes control over one's bodily integrity:

> "122 In Rodriguez v. British Columbia (Attorney General), 1993 CanLII 75 (SCC), [1993] 3 S.C.R. 519, Sopinka J., writing for the majority, held that security of the person encompasses "a notion of personal autonomy involving, at the very least, control over one's bodily integrity free from state interference and freedom from state-imposed psychological and emotional stress" (pp. 587-88). The prohibition against private insurance in this case results in psychological and emotional stress and a loss of control by an individual over her own health."[185] [Emphasis added.]

> "[67] The law has long protected patient autonomy in medical decision-making. In A.C. v. Manitoba (Director of Child and Family Services), 2009 SCC 30, [2009] 2 S.C.R. 181, a majority of this Court, per Abella J. (the dissent not disagreeing on this point), endorsed the "tenacious relevance in our legal system of the principle that competent individuals are — and should be — free to make decisions about their bodily integrity" (para. 39). This right to "decide one's own fate" entitles adults to direct the course of their own medical care (para. 40): it is this principle that underlies the concept of "informed consent" and is protected by s. 7's guarantee of liberty and security of the person (para. 100; see also R. v. Parker (2000), 2000 CanLII 5762 (ON CA), 49 O.R. (3d) 481 (C.A.)). As noted in Fleming v. Reid (1991), 1991 CanLII 2728 (ON CA), 4 O.R. (3d) 74 (C.A.), the right of medical self-determination is not vitiated by the fact that serious risks or consequences, including death, may flow from the patient's decision. It is this same principle that is at work in the cases dealing with the right to refuse consent to medical treatment, or to demand that treatment be withdrawn or discontinued: see, e.g., Ciarlariello v. Schacter, 1993 CanLII 138 (SCC), [1993] 2 S.C.R. 119; Malette v. Shulman (1990), 1990 CanLII 6868 (ON CA), 72 O.R. (2d) 417 (C.A.); and Nancy B. v. Hôtel-Dieu de Québec (1992), 1992 CanLII 8511 (QC CS), 86 D.L.R. (4th) 385 (Que. Sup. Ct.)."[186] [Emphasis added.]

The State action of coercing me to receive injections of a medical product that I do not want interfere with my personal autonomy and bodily integrity and deprives me of my right to security of the person.

In *R. v. Morgentaler*, the Supreme Court of Canada found that forcing a woman by threat of criminal sanction not to receive an abortion was an interference with her body and thus a violation of security of the person:

> "At the most basic, physical and emotional level, every pregnant woman is told by the section that she cannot submit to a generally safe medical procedure that might be of clear benefit to her unless she meets criteria entirely unrelated to her own priorities and aspirations. Not only does the removal of decision-making power threaten women in a physical sense; the indecision of knowing whether an abortion will be granted inflicts emotional stress. Section 251 clearly interferes with a woman's bodily integrity in both a physical and emotional sense. Forcing a woman, by threat of criminal sanction, to carry a foetus to term unless she meets certain criteria unrelated to her own priorities and aspirations, is a profound interference with a woman's body

[185] *Chaoulli v. Quebec (Attorney General)*, 2005 SCC 35 (CanLII), at para. 122, https://canlii.ca/t/1kxrh.
[186] *Carter v. Canada (Attorney General)*, 2015 SCC 5 (CanLII), at para. 67, https://canlii.ca/t/gg5z4.

> and thus a violation of security of the person. Section 251, therefore, is required by the Charter to comport with the principles of fundamental justice."[187]

In my case, I am being forced by threat of loss of livelihood, social status, social connections and career opportunities to receive injections of a medical product that I do not want. This violates my right to security of the person. The injection is designed to interfere with my body's natural immune response to the outside world, and is designed to use my body's cells to fabricate spike proteins, which are demonstrated to be toxic,[188] in an unknown amount, by an *in vivo* reaction that is not controlled.

In its Nov. 19, 2021, email communicating its decision to deny me an accommodation, place me on unpaid leave, remove my health benefits, and that it may in the future terminate my employment, the Bank of Canada offered psychological counselling:

> "I also wish to remind you that as a Bank employee you have access to the Employee Assistance and Family Program (EFAP) which is a confidential counselling and information service. Should you wish to avail yourself of their services, they can be reached at [phone number]."[189]

The Bank's offer of psychological counselling in-effect acknowledges that the Policy and decision to deny me accommodation could cause me psychological stress or trauma, which abrogates my right to security of the person.

In sum, the Bank of Canada's Policy requiring injections of a medical product and its decision denying exemption to the injections "interfere with, or deprive me of" my life, liberty, and security of the person, violating my rights under s. 7 of the *Charter*.

4a (iv): s. 1 of the *Charter* does not apply

Section 1 of the *Charter* states:

> "Rights and freedoms in Canada
>
> 1 The Canadian Charter of Rights and Freedoms guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society."[190]

A limit on a *Charter* right must therefore be reasonable and demonstrably justified, and the onus for justification is on the government.[191]

Furthermore, as the Chief Justice of Canada Brian Dickson stated in *R. v. Oakes*, in evaluating whether a rights-limiting measure is permissible under s. 1, the Court must be guided by the values and principles

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[187] R. v. Morgentaler, 1988 CanLII 90 (SCC), at pgs. 56-57, https://canlii.ca/t/1ftjt.
[188] M. Moghaddar et al., "Severity, Pathogenicity and Transmissibility of Delta and Lambda Variants of SARS-CoV-2, Toxicity of Spike Protein and Possibilities for Future Prevention of COVID-19", *Microorganisms*, 9 (2021) 2167, https://www.mdpi.com/2076-2607/9/10/2167.
[189] Email of [redacted] to J. Hickey of Nov. 19, 2021, at Tab 3.
[190] *Charter*, supra, s. 1.
[191] *R. v. Oakes*, 1986 CanLII 46 (SCC), https://canlii.ca/t/1ftv6.

essential to a free and democratic society. These values are the ultimate standard against which any state imposition must be measured:

> "64. A second contextual element of interpretation of s. 1 is provided by the words "free and democratic society". Inclusion of these words as the final standard of justification for limits on rights and freedoms refers the Court to the very purpose for which the *Charter* was originally entrenched in the Constitution: Canadian society is to be free and democratic. The Court must be guided by the values and principles essential to a free and democratic society which I believe embody, to name but a few, respect for the inherent dignity of the human person, commitment to social justice and equality, accommodation of a wide variety of beliefs, respect for cultural and group identity, and faith in social and political institutions which enhance the participation of individuals and groups in society. The underlying values and principles of a free and democratic society are the genesis of the rights and freedoms guaranteed by the *Charter* and the ultimate standard against which a limit on a right or freedom must be shown, despite its effect, to be reasonable and demonstrably justified."[192] [Emphasis added.]

The barrier that the state must overcome in order to impose measures that infringe on the basic rights of individuals is therefore very high, and egregiously invasive or authoritarian measures that are *prima facie* contrary to the values and principles of a free and democratic society, such as compulsory medical procedures, will be extremely difficult to justify.

The applicable test is known as the *Oakes* test, which can be stated as follows:

> "1. Is the legislative goal pressing and substantial? i.e., is the objective sufficiently important to justify limiting a Charter right?
>
> 2. Is there proportionality between the objective and the means used to achieve it?
>
> The second branch of the test has three elements:
>
> a. "Rational Connection": the limit must be rationally connected to the objective. There must be a causal link between the impugned measure and the pressing and substantial objective;
> b. "Minimal Impairment": the limit must impair the right or freedom no more than is reasonably necessary to accomplish the objective. The government will be required to show that there are no less rights-impairing means of achieving the objective "in a real and substantial manner" (Carter v. Canada (Attorney General), [2015] 1 S.C.R. 331, at paragraph 102; citing Hutterian Brethren, [2009] 2 S.C.R. 567, at paragraph 55);
> c. "Final Balancing": there must be proportionality between the deleterious and salutary effects of the law (Carter, supra, at paragraph 122; JTI-Macdonald, supra, at paragraph 45)."[193]

[192] Dickson C.J. in *R. v. Oakes*, 1986 CanLII 46 (SCC), at para. 64, https://canlii.ca/t/1ftv6.
[193] Government of Canada, "Section 1 – Reasonable limits", https://www.justice.gc.ca/eng/csj-sjc/rfc-dlc/ccrf-ccdl/check/art1.html.

Oakes Part 1: Is the legislative goal pressing and substantial?

Under Part 1 of the *Oakes* test, the purpose of the law or infringing measure must be:

- "of significant importance and consistent with the principles integral to a free and democratic society (Vriend, supra; Figueroa v. Canada (A.G.), [2003] 1 S.C.R. 912);
- the objective of the specific infringing measure or omission, which may not always be the same as the objective of the legislation as a whole (RJR-MacDonald, supra; Vriend, supra, at paragraphs 110-11; M. v. H., supra, at paragraph 82; Hislop, supra, at paragraph 45; Alliance du personnel professionel et technique de la santé et des services sociaux v. Quebec, [2018] 1 S.C.R. 464 at paragraphs 45-47);
- specific rather than general; overly abstract or idealized objectives are suspect. However, it may be helpful to articulate a broader overarching objective in addition to narrower sub-objectives (Frank v. Canada, [2019] 1 S.C.R. 3 at paragraphs 46-58; Sauvé v. Canada (Chief Electoral Officer), [2002] 3 S.C.R. 519; JTI-Macdonald, supra, at paragraph 38; Health Services and Support - Facilities Subsector Bargaining Assn. v. British Columbia, [2007] 2 S.C.R. 391, at paragraph 146);
- the real or actual objective (Tetreault-Gadoury v. Canada (Employment and Immigration Commission, [1991] 2 S.C.R. 22);
- the objective of the impugned measure at the time the measure was adopted (R. v. Big M Drug Mart Ltd., [1985] 1 S.C.R. 295; R. v. Zundel, [1992] 2 S.C.R. 731 at paragraph 45). A shift in purpose is not permissible, but a shift in emphasis over time may be permitted (Butler, supra, at pages 495-46; see also R. v. Malmo-Levine, [2003] 3 S.C.R. 571, at paragraph 65)." [194]

The Bank of Canada's COVID-19 Vaccination Policy states:

> "Policy Statement
>
> The objective of this policy is to reduce the risk of transmission of COVID-19 in order to protect the health and safety of the employees of the Bank, and to protect the general public health of all Canadians by mandating all employees to be fully vaccinated against COVID-19 and its variants."[195]

The Bank's Policy thus has two objects:

1. to reduce the risk of transmission of COVID-19 in order to protect the health and safety of the employees of the Bank; and
2. to reduce the risk of transmission of COVID-19 in order to protect the general public health of all Canadians by mandating all employees to be fully vaccinated against COVID-19 and its variants.

Part 1 of the *Oakes* test has not been met. There has been no medical emergency affecting Canada that is of a magnitude sufficient to justify the measure of mandatory vaccination.[196]

In the alternative, if there ever was a pressing and substantial goal, it no longer exists, since provinces and territories across the country are removing public health measures, including vaccine mandates for

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[194] *Ibid*.
[195] Bank of Canada COVID-19 Vaccination Policy, at Tab 1.
[196] See Section 2e (i) of these submissions.

public-sector employees, vaccine passports to enter public spaces, facemask mandates for the general public, and social distancing requirements.

For example, there are many public-sector workplaces in Canada in which the government employer never imposed or no longer imposes vaccine mandates. Indeed, public-sector employers in most of Canada's provinces and territories do not impose vaccination on employees, as listed below:

Ontario

- "Ontario government workers will no longer be required to provide proof of vaccination or undergo regular testing to go to work as of April 4 [2022], an internal announcement reveals. The Government of Ontario includes ministries, agencies and Crown Corporations, and has a workforce of more than 60,000 public servants called the Ontario Public Service, or OPS."[197]
- "The [Toronto District School Board] also said that trustees also voted to rescind the mandatory vaccination policy for employee [sic] as of March 14 [2022], in line with direction from the Ontario government. That will pave the way for the return of the 100 permanent staff and 643 occasional staff that were placed on leave in November after failing to comply with the terms of the policy."[198]

Quebec

- "Quebec health-care employees will no longer have to be fully vaccinated to work in the health system, the government announced Wednesday [November 3, 2021]."[199]
- "Even though the [Quebec] government tried to impose vaccination on healthcare workers (before backing down due to fear of a worker shortage), imposing vaccination on the whole public sector was never on the table."[200]
- "Quebec will not require its public servants to be vaccinated".[201]
- "Vaccines won't be mandatory for teachers, school staff as Quebec COVID-19 situation improves"[202]

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[197] R. Williams, "Ontario government workers will no longer need to be vaccinated as of April 4", *Toronto Star*, 3 March 2022, https://archive.ph/lBT2F.

[198] C. Fox, "'They aren't medical experts:' Premier Ford warns boards not to maintain mask mandate in schools", *CP24*, 11 March 2022, https://www.cp24.com/news/they-aren-t-medical-experts-premier-ford-warns-boards-not-to-maintain-mask-mandate-in-schools-1.5815459; https://archive.ph/St55Q.

[199] CBC News, "Quebec backs down again on mandatory vaccination in health network", 3 November 2021, https://www.cbc.ca/news/canada/montreal/mandatory-vaccination-new-health-workers-1.6235760; https://archive.ph/cF2MK.

[200] M. Vastel, "Vaccination obligatoire: l'étonnante timidité de Québec, d'ordinaire plus ferme", *Le Devoir*, 26 January 2022, (Free translation), https://www.ledevoir.com/politique/664842/analyse-l-etonnante-timidite-de-quebec-d-ordinaire-plus-ferme; https://archive.ph/X1fGQ.

[201] O. Bossé, "Québec n'obligera pas ses fonctionnaires à se faire vacciner", *Le Soleil*, 13 August 2021, (Free translation), https://www.lesoleil.com/2021/08/13/quebec-nobligera-pas-ses-fonctionnaires-a-se-faire-vacciner-3a415426fad3e17514a8f222eafc575f; https://archive.ph/BW7by.

[202] CBC News, "Vaccines won't be mandatory for teachers, school staff as Quebec COVID-19 situation improves", 27 October 2021, https://www.cbc.ca/news/canada/montreal/covid-19-vaccination-schools-outbreaks-mandatory-1.6226937; https://archive.ph/EwM3s.

Alberta

- "Effective March 10 [2022] at 4 p.m., Alberta Health Services (AHS) will no longer require proof of COVID-19 vaccination or regular rapid testing of its current workers."[203]

Saskatchewan

- "The City of Saskatoon and City of Regina confirmed Wednesday they will no longer require proof of vaccination or negative tests for employees. Regina police spokesperson Elizabeth Popowich said the organization will no longer require proof of vaccination or negative testing at the start of shifts."[204]
- "The Saskatchewan Health Authority is ending a vaccine and testing mandate for employees — the same mandate that multiple sources say the SHA was directed to not actually enforce."[205]

Manitoba

- "Health-care workers, teachers and other front-line workers will no longer need to be vaccinated against COVID-19 or receive repeated testing, the Manitoba government announced Thursday. Manitoba's chief public health officer Dr. Brent Roussin said the requirement, which took effect in October, is being lifted as of March 1 [2022]."[206]
- "Manitoba Health reminds Manitobans new public health orders have come into effect today [March 1, 2022] that remove all remaining proof of vaccination requirements for public places. Proof of vaccination and testing requirements for designated public sector employees, including education, child-care and health-care workers, have also ended."[207]

Nova Scotia

- "Public sector employees in non-high risk areas who refused to be vaccinated under Nova Scotia's COVID-19 mandates can return to the job when all remaining public health restrictions are lifted. Colton LeBlanc, the minister responsible for the Public Service Commission, confirmed following a cabinet meeting today that 84 civil servants can go back

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[203] rdnewsNOW, "AHS mandatory vaccination policy lifted", 8 March 2022, https://rdnewsnow.com/2022/03/08/ahs-mandatory-vaccination-policy-lifted/; https://archive.ph/Wl04g.
[204] J. Simes, "Sask. cities, organizations removing employee proof of vaccination requirement", *Regina Leader Post*, 16 February 2022, https://leaderpost.com/news/saskatchewan/sask-cities-organizations-removing-employee-proof-of-vaccination-requirement; https://archive.ph/pBLRO.
[205] Z. Vescera, "COVID-19: SHA ending vaccine, testing mandate for employees", *Saskatoon StarPhoenix*, 11 February 2022, https://thestarphoenix.com/news/saskatchewan/covid-19-sha-ending-vaccine-testing-mandate-for-employees; https://archive.ph/nXEIp.
[206] R. Stelter, "Manitoba to end requirement for front-line workers to have COVID-19 vaccine or test", *Winnipeg Sun*, 24 February 2022, https://winnipegsun.com/news/news-news/manitoba-to-end-requirement-for-front-line-workers-to-have-covid-19-vaccine-or-test; https://archive.ph/yFeqB; https://archive.ph/jizjw.
[207] Government of Manitoba, "Public Health Orders Remove Proof of Vaccination Requirements", *Media Bulletin – Manitoba*, 1 March 2022, https://news.gov.mb.ca/news/?archive=&item=53597; https://archive.ph/xqyF5.

to work March 21 [2022] when restrictions including the indoor mask requirement for public spaces are dropped."[208]

Yukon

- "Government employees [in the Yukon] will no longer have to be vaccinated, as of April 4 [2022]."[209]

The absence of vaccine mandates in the public-sector workplaces in most of Canada's provinces and territories (making up at least 82% of the Canadian population) proves that there is no pressing and substantial need for the draconian measure of mandatory vaccination.

Furthermore, the objective of "[protecting] the general public health of all Canadians" is not specific, and is an overly abstract or idealized objective. It is also beyond the mandate of the Bank of Canada, and outside of the jurisdiction of the Federal Government (see Section 4b of these submissions, below).

Furthermore, as Chief Justice Dickson stated in *R. v. Oakes*:

> "The underlying values and principles of a free and democratic society are (…) the ultimate standard against which a limit on a right or freedom must be shown, despite its effect, to be reasonable and demonstrably justified."[210] [Emphasis added.]

That the government would compel an individual to be injected with a biopharmaceutical product that carries a risk of death in order to maintain one's livelihood and social connections is repugnant and offensive to the principles integral to a free and democratic society. This is the ultimate standard against which the vaccine mandate must be measured.

If the high degree of repugnance inherent in the government's coercive action needs illustration, then I refer to the following judicial history in North America, as described in the 1986 Supreme Court of Canada case *E. (Mrs.) v. Eve*:

> "56. The American experience in this area cannot be understood without reference to the interest in the eugenic sterilization of the mentally incompetent manifested in that country early in this century. Eugenics theory, founded upon the rearticulation of the Mendelian theories of inheritance, developed from the premise that physical, mental and even moral deficiencies have a genetic basis. In the early part of this century, many social reformers advocated eugenic sterilization as a panacea for most of the troubles that had been created by "misfits" in society. This general attitude, coupled with the evolution of surgical sterilization techniques, provoked the widespread adoption of enabling legislation. In time, over thirty states en- acted statutes providing for the compulsory sterilization of the mentally retarded; see Sherlock and Sherlock, "Sterilizing the Retarded: Constitutional, Statutory and Policy Alternatives," 60 *N.C.L.Rev.* 943 (1982), at p. 944.

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[208] The Canadian Press, "Nova Scotia government workers who refused COVID-19 vaccine can return to work March 21", *CTV News*, 10 March 2022, https://atlantic.ctvnews.ca/nova-scotia-government-workers-who-refused-covid-19-vaccine-can-return-to-work-march-21-1.5814211; https://archive.ph/zxEaz.
[209] CBC News, "Yukon plans to drop COVID-19 vaccination requirement for gov't staff, mask mandate", 2 March 2022, https://www.cbc.ca/news/canada/north/yukon-covid-update-mar-2-1.6369911; https://archive.ph/x7jd5.
[210] Dickson C.J. in *R. v. Oakes*, 1986 CanLII 46 (SCC), at para. 64, https://canlii.ca/t/1ftv6.

57. The constitutionality of such statutes arose before the United States Supreme Court in the landmark case of *Buck v. Bell*, 274 U.S. 200 (1927). Carrie Buck, a mildly retarded woman, was the daughter of a similarly afflicted woman and had herself given birth to an allegedly retarded child. A majority of the court sanctioned her sterilization despite claims that such a course violated substantive and procedural due process as well as the equal protection rights of the handicapped. The case constituted the high water mark of eugenic theory, as the strong judgment of Holmes J. attests. He sets the tone at p. 207:

> We have seen more than once that the public welfare may call upon the best citizens for their lives. It would be strange if it could not call upon those who already sap the strength of the State for these lesser sacrifices, often not felt to be such by those concerned, in order to prevent our being swamped with incompetence. It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. <u>The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. ... Three generations of imbeciles are enough.</u>

58. During the 1930s researchers and biologists began to denounce the sweeping generalizations concerning heredity in relation to mental and physical disorders. (…)"[211]
[Emphasis added.]

<u>*Oakes* Part 2: Is there proportionality between the objective and the means used to achieve it?</u>

Since there is no pressing and substantial crisis (no medical emergency affecting Canada that is of a magnitude sufficient to justify the measure of mandatory vaccination), Part 2 of the *Oakes* test is not met.

In the alternative, the Policy and decision to deny accommodation fail Part 2 of the *Oakes* test, as follows:

Rational Connection

In order to pass the second part of the *Oakes* test, the limit caused by the government's action must be rationally connected to the objective of the action. There must be a causal link between the impugned measure and the pressing and substantial objective

Furthermore, when the imposed measure can cause death, the connection between the measure and its objective must be based on empirical evidence and must be unambiguous:

> "131 In order not to be arbitrary, the limit on life, liberty and security requires not only a theoretical connection between the limit and the legislative goal, but a real connection on the facts. The onus of showing lack of connection in this sense rests with the claimant. The question in every case is whether the measure is arbitrary in the sense of bearing no real

[211] *E. (Mrs.) v. Eve*, 1986 CanLII 36 (SCC), at paras. 56-58, https://canlii.ca/t/1ftqt.

> relation to the goal and hence being manifestly unfair. The more serious the impingement on the person's liberty and security, the more clear must be the connection. Where the individual's very life may be at stake, the reasonable person would expect a clear connection, in theory and in fact, between the measure that puts life at risk and the legislative goals."[212] [Emphasis added.]

There is no rational connection between the objects of the Policy and the imposition of mandatory vaccination, because:

- There has been no medical emergency affecting Canada that is of a magnitude sufficient to justify the measure.[213]
- There is no reliable evidence that the COVID-19 vaccine products provide any health benefit.[214] Therefore, even if there were or had been a significant medical emergency in Canada that can unambiguously be attributed to a respiratory virus, there is no reason to believe (no reliable scientific evidence) that the COVID-19 vaccines would protect against infection, transmission, or any other consequence of infection.
- Vaccine products injected via intramuscular routes are in-effect physiologically incapable of preventing infection and transmission of respiratory illnesses.[215] Therefore, even if there were or had been a significant medical emergency in Canada that can unambiguously be attributed to a respiratory virus, there is no scientific basis in immunology for believing that a product injected intra-muscularly could protect against infection and transmission of the said respiratory virus.
- There are many scientific studies showing that the COVID-19 vaccines do not protect against infection and transmission.[216] The proposed measure (injection with a COVID-19 vaccine product) has been proven to carry a risk of death; therefore, the connection between the measure and its objective must be based on empirical evidence and must be unambiguous. However, there is no conclusive empirical evidence that the COVID-19 vaccine products prevent transmission and infection; rather, the empirical evidence in fact demonstrates that they do not prevent transmission and infection.
- It is absurd to impose a medical treatment that is intended to modify the subject's immune system (or bodily or health characteristics) with the objective of protecting co-workers, in the event that the subject cannot be accommodated by working from home. Why not then force dietary pills or an exercise regime to prevent accidents at work? Since psychological stress is a major determinant of susceptibility to viral respiratory disease infection and serious illness,[217]

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[212] McLachlin C.J. and Major J. (joint reasons concurring in the result) in *Chaoulli v. Quebec (Attorney General)*, 2005 SCC 35 (CanLII), at para. 131, https://canlii.ca/t/1kxrh.
[213] See Section 2e (i) of these submissions.
[214] See Section 2e (ii) of these submissions.
[215] See Section 2e (iii) of these submissions.
[216] See the bulleted list at the end of Section 2e (iii) of these submissions.
[217] G.E. Miller and S. Cohen, "Infectious disease and psychoneuroimmunology", in *Human Psychoneuroimmunology* (K. Vedhara et al., *eds*.), Oxford University Press (Oxford, 2005); S. Cohen et al., "Psychological Stress and Disease", *JAMA*, 298 (2007) 1685-1687, https://jamanetwork.com/journals/jama/article-abstract/209083; S. Cohen et al.,

why not enforce regular psychiatric interventions, including medication? Since the second known determinant is social isolation,[218] why not force employees to marry and socialize to a sufficient recommended degree?

- It is absurd to force an employee to accept a lethal risk from a definitive intervention (injection) for a hypothetical benefit to the society at large. Otherwise, why not force healthy lifestyles or prescription medication or therapies against identified risk factors such as out-of-norm body weight, genetic factors, psychological characteristics, and so on, to reduce pressure on medical resources in order to better save lives and concentrate on extending quality of life?
- In my case, as a remote-working employee, the object of "[reducing] the risk of transmission of COVID-19 in order to protect the health and safety of the employees of the Bank" cannot be met because it is impossible to transmit a biological disease via the Internet. As such, the measure is arbitrary because the sought outcome cannot be achieved.

The forced injections are clearly a totalitarian measure, antithetical to freedom, and incompatible with a democratic society. The policy has no rational connection with any objective that is admissible to be achieved in this way in a free and democratic society.

Minimal Impairment

The Policy and decision to deny accommodation force me to be vaccinated instead of allowing me to work from home, as I did from March 13, 2020, to November 22, 2021. Allowing me to work from home would be a less rights-impairing means of achieving the objective of protecting the Bank's staff (accepting, for argument's sake, that there is something significant against which the Bank's staff needs protecting). Allowing me to continue working from home would impose no undue hardship or unreasonable inconvenience or disruption on the Bank or its operations, as explained in Section 3e of these submissions.

Regarding the objective of protecting the general public health of Canadians, it is important to note that there are many economic sectors in Canadian society that do not require COVID-19 vaccination, including public-sector workplaces in most Canadian provinces and territories,[219] being an employee or a client in restaurants and other entertainment and recreation venues in most provinces and territories, being an employee or a client in most private-sector workplaces, being a passenger on municipal public transit or inter-provincial buses, and so on.

There are thus many economic sectors involving in-person social contact where vaccination is not mandatory. It is inconceivable that force-vaccinating Bank of Canada staff (who are entirely capable of working from home, as has been amply demonstrated from March 2020 to present) is a necessary, proportional, and minimally-invasive public health measure when society can get by without force-vaccinating in-person workers and clients in the healthcare, education, recreation and food services,

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"Social Ties and Susceptibility to the Common Cold", *JAMA*, 277 (1997) 1940-1944, https://jamanetwork.com/journals/jama/article-abstract/417085.

[218] *Ibid.*

[219] See the list of provincial public-sector workplaces without vaccine mandates in the sub-section entitled "*Oakes* Part 1: Is the legislative goal pressing and substantial?", above.

etc., sectors of the economy. In this actual societal context, the policy is not minimal, and is in-effect arbitrary.

My employer cannot impose a potentially deadly medical injection on me to protect members of the public at large. A lesser measure would be to request that I self-quarantine if it is proven that I have a virulent transmissible disease.

Additionally, allowing me to benefit from natural immunity would be a less rights-impairing means of achieving the objective of protecting the general public health of all Canadians than forcing me to be vaccinated without any regard for my actual immunity status.

Final Balancing

The deleterious effects of the Policy and decision to deny accommodation grossly outweigh any salutary effects, which are hypothetical and insignificant compared to normal accepted risks in a free and democratic society.

The deleterious effect of the Policy and decision are enormous: proven risk to me of injury or death from taking the vaccine on the one hand, or loss of livelihood, social status, social connections, health benefits, pension contributions, and so forth, from not taking the vaccine, on the other hand.

Furthermore, the internal harm of the injections, to organs, tissues, and metabolic and other physiological systems in the human body is virtually unknown, and pathology results from some individuals who have died implies that it must be large, at least for some individuals.[220] The permanence or cumulative nature of this harm, and the variability from individual to individual are egregiously under-determined, unknown, and unstudied, for a novel molecular therapy applied to billions of individuals.

The salutary effects of the Policy and decision are either non-existent or insignificant. This is illustrated by the fact that almost all economic sectors in our society (including many in which face-to-face contact frequently occurs) do not require COVID-19 vaccination, as described directly above in the section on *Minimal Impairment*. The said sectors can carry on business without forcing vaccination on their workers and clients, that is, without benefiting from any of the purported salutary effects of forced vaccination. The fact that those sectors can get by without forced vaccination demonstrates that any salutary effects of forced vaccination are insignificant and unnecessary.

4a (v): The infringement of my rights to life, liberty, and security of the person was not in accordance with the principles of fundamental justice

In addition to obviously violating my rights to life, liberty, and security of the person, the vaccine mandate applied to me also violates my right not to be deprived of life, liberty, and security of the person except in accordance with the principles of fundamental justice.

[220] See Section 2e (iv) of these submissions.

Characteristics of "principles of fundamental justice"

In *Re BC Motor Vehicle Act*, the Supreme Court stated that "[t]he principles of fundamental justice are to be found in the basic tenets of our legal system. They do not lie in the realm of general public policy but in the inherent domain of the judiciary as guardian of the justice system."[221]

In *Canada (Attorney General) v. Federation of Law Societies of Canada*, the Supreme Court set out three criteria that must be met for a principle to be recognized as a principle of fundamental justice:

> "Principles of fundamental justice have three characteristics. They must be legal principles, there must be 'significant societal consensus' that they are 'fundamental to the way in which the legal system ought fairly to operate' and they must be sufficiently precise so as 'to yield a manageable standard against which to measure deprivations of life, liberty or security of the person': *R. v. Malmo-Levine*, 2003 SCC 74, [2003] 3 S.C.R. 571, at para. 113, per Gonthier and Binnie JJ.; *R. v. D.B.*, 2008 SCC 25, [2008] 2 S.C.R. 3, at para. 46, per Abella J.; *R. v. Anderson*, 2014 SCC 41, [2014] 2 S.C.R. 167, at para. 29, per Moldaver J."[222]

Arbitrariness, overbreadth, and gross disproportionality

My submissions in Section 4a (iv) show that the government action in my case is arbitrary, overbroad, and grossly disproportionate.

Accordance with the contract of employment

It is a principle of fundamental justice that an employer cannot infringe on an employee's life, liberty, and security interests in a manner that is not in accordance with the contract of employment.[223] This principle meets the three criteria for recognition as a principle of fundamental justice: it is a legal principle; it is sufficiently precise; and it is deeply embedded in our legal order, specifically in the law of employment.

My contract of employment with the Bank of Canada does not place any requirement on me to undertake any medical procedures such as vaccination;[224] therefore, the Bank's Policy and decision to deny accommodation and place me on unpaid leave violate my contract of employment. Consequently, the vaccine mandate infringes on my rights to life, liberty, and security of the person in a manner that is not in accordance with my contract of employment.

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[221] *Re BC Motor Vehicle Act*, [1985] 2 SCR 486, https://canlii.ca/t/dln.
[222] *Canada (Attorney General) v. Federation of Law Societies of Canada*, [2015] S.C.J. No. 7, at para. 87, https://canlii.ca/t/gg977.
[223] H. Stewart, "Assn. of Justice Counsel: The Section 7 Liberty Interest in the Context of Employment", *The Supreme Court Law Review: Osgoode's Annual Constitutional Cases Conference*, 88 (2019) 295-303, https://digitalcommons.osgoode.yorku.ca/sclr/vol88/iss1/13.
[224] "Terms and Conditions of Employment for Regular, Term and Short-term Employees of the Bank of Canada", at Tab 35.

Procedural fairness

The principles of fundamental justice referred to in s. 7 of the *Charter* include procedural fairness:

> "[221] The more difficult step in the s. 7 analysis generally is to identify the principle of fundamental justice that is said to be breached. In the present case, the principles of fundamental justice at issue are both procedural and substantive.
>
> (…)
>
> [224] The principles of fundamental justice also include, of course, procedural fairness whose content varies with the context of the case and the interests at stake. In *Morgentaler*, the procedures set out by the legislature to allow women access to legal abortions were held to be deficient because they caused undue delay and were unavailable to many women. In the present case, the procedures in the CFSA are deficient because they do not afford a young person the opportunity to rebut the very presumption upon which the court's authority to act in the best interests of the young person rests — the presumption that she is incapable of making that decision for herself. (…)"[225] [Emphasis added.]

In having my request for accommodation under the Bank's COVID-19 Vaccination Policy denied and being placed on unpaid leave without benefits, I have not received a fair procedure because:

- I was not informed of the identities of the individuals who decided not to grant me an accommodation under the Bank's Policy or who recommended that I not receive an accommodation; and
- I was not informed of the reasons why I was not granted an accommodation for religious and human rights (age & sex) reasons.

Therefore, the s. 7 violation caused by the implementation of the vaccine mandate was not procedurally fair and was not in accordance with the principle of fundamental justice.

"Principles of fundamental justice" clause in s. 7 does not impose any onus on the claimant

The clause "except in accordance with the principles of fundamental justice" cannot, in the case of an imposed biopharmaceutical injection that can cause death, be interpreted to mean that my s. 7 rights are violated *only if* I can demonstrate that the government has imposed the injection in a way that does not conform with certain legalistic criteria. As Dickson J. wrote in *R. v. Big M Drug Mart Ltd.*:

> "116. This Court has already, in some measure, set out the basic approach to be taken in interpreting the *Charter*. In *Hunter v. Southam Inc.*, 1984 CanLII 33 (SCC), [1984] 2 S.C.R. 145, this Court expressed the view that the proper approach to the definition of the rights and freedoms guaranteed by the *Charter* was a purposive one. The meaning of a right or freedom guaranteed by the *Charter* was to be ascertained by an analysis of the purpose of such a

[225] Binnie J. in *A.C. v. Manitoba (Director of Child and Family Services)*, 2009 SCC 30 (CanLII), at paras. 221-224, https://canlii.ca/t/24432.

> guarantee; it was to be understood, in other words, in the light of the interests it was meant to protect.
>
> 117. In my view this analysis is to be undertaken, and the purpose of the right or freedom in question is to be sought by reference to the character and the larger objects of the *Charter* itself, to the language chosen to articulate the specific right or freedom, to the historical origins of the concepts enshrined, and where applicable, to the meaning and purpose of the other specific rights and freedoms with which it is associated within the text of the *Charter*. The interpretation should be, as the judgment in *Southam* emphasizes, a generous rather than a legalistic one, aimed at fulfilling the purpose of the guarantee and securing for individuals the full benefit of the *Charter*'s protection. At the same time it is important not to overshoot the actual purpose of the right or freedom in question, but to recall that the *Charter* was not enacted in a vacuum, and must therefore, as this Court's decision in *Law Society of Upper Canada v. Skapinker*, 1984 CanLII 3 (SCC), [1984] 1 S.C.R. 357, illustrates, be placed in its proper linguistic, philosophic and historical contexts."[226] [Emphasis added in para. 117.]

Otherwise, the government could, via an onus placed on me in s. 7, escape or circumvent its s. 1 onus to demonstrably justify the imposition of a measure (mandatory injection with a product that can cause death) that *prima facie* egregiously infringes my rights to life, liberty, and security of the person. This would be incompatible with the principles underlying the *Charter*.

4b: The Policy and decision are *ultra vires*

With regards to the objective of "[protecting] the general public health of all Canadians by mandating all employees to be fully vaccinated against COVID-19 and its variants", the Bank of Canada's Policy and decision denying me accommodation are *ultra vires* because:

1. It is not within the Bank's mandate to protect public health;
2. Public health falls under provincial, not federal, jurisdiction.

The Bank of Canada's mandate is contained in the Bank's enabling act, the *Bank of Canada Act*.[227] The *Bank of Canada Act* makes no mention of health care or public health, and makes no provision for the Bank of Canada to have any role whatsoever with regard "the general public health of all Canadians". Therefore, the Policy and the decision to place me on unpaid leave without benefits are *ultra vires* of the Bank's mandate.

Health care, including public health policy, falls squarely under provincial jurisdiction under the Canadian constitution:

> "Exclusive Powers of Provincial Legislatures
>
> Subjects of exclusive Provincial Legislation

[226] *R. v. Big M Drug Mart Ltd.,* 1985 CanLII 69 (SCC), at paras. 116-117, https://canlii.ca/t/1fv2b.
[227] *Bank of Canada Act* (R.S.C., 1985, c. B-2), https://laws-lois.justice.gc.ca/eng/acts/b-2/.

> 92 In each Province the Legislature may exclusively make Laws in relation to Matters coming within the Classes of Subjects next hereinafter enumerated; that is to say,
>
> (…)
>
> 7. The Establishment, Maintenance, and Management of Hospitals, Asylums, Charities, and Eleemosynary Institutions in and for the Province, other than Marine Hospitals."[228]

That public health policy falls squarely under provincial jurisdiction has been recognized throughout the COVID era: each province has its own Chief Medical Officer of Health or equivalent that sets provincial health policy, and each province has independently decided its own public health policy, without being legally bound by the federal government.

The only way the federal government could claim jurisdiction over public health policy is via the so-called "Peace, Order, and Good Government" (POGG) power contained in s. 91 of the *Constitution Act, 1867*.[229] However, the federal government's POGG power only applies to matters of national concern:[230]

> "23. It is necessary then to consider the national dimensions or national concern doctrine (as it is now generally referred to) of the federal peace, order and good government power as a possible basis for the constitutional validity of s. 4(1) of the Act, as applied to the control of dumping in provincial marine waters.
>
> (…)
>
> 33. From this survey of the opinion expressed in this Court concerning the national concern doctrine of the federal peace, order and good government power I draw the following conclusions as to what now appears to be firmly established:
>
> 1. The national concern doctrine is separate and distinct from the national emergency doctrine of the peace, order and good government power, which is chiefly distinguishable by the fact that it provides a constitutional basis for what is necessarily legislation of a temporary nature;
>
> 2. The national concern doctrine applies to both new matters which did not exist at Confederation and to matters which, although originally matters of a local or private nature in a province, have since, in the absence of national emergency, become matters of national concern;
>
> 3. <u>For a matter to qualify as a matter of national concern in either sense it must have a singleness, distinctiveness and indivisibility that clearly distinguishes it from matters of provincial concern and a scale of impact on provincial jurisdiction that is reconcilable with the fundamental distribution of legislative power under the Constitution</u>;
>
> 4. In determining whether a matter has attained the required degree of singleness, distinctiveness and indivisibility that clearly distinguishes it from matters of provincial concern it

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[228] *Constitution Act, 1867*, 30 & 31 Victoria, c. 3 (U.K.), https://laws-lois.justice.gc.ca/eng/const/FullText.html.
[229] M. Butler and M. Tiedemann, "The Federal Role in Health and Health Care", Library of Parliament, Publication No. 2011-91-E (2013), https://lop.parl.ca/sites/PublicWebsite/default/en_CA/ResearchPublications/201191E.
[230] *R. v. Crown Zellerbach Canada Ltd.*, 1988 CanLII 63 (SCC), at paras. 23 and 33, https://canlii.ca/t/1fthr.

> is relevant to consider what would be the effect on extra-provincial interests of a provincial failure to deal effectively with the control or regulation of the intra-provincial aspects of the matter." [Emphasis added.]

Therefore, the federal government can only claim jurisdiction to impose a public health policy on the residents of provinces if the matter has a "singleness, distinctiveness and indivisibility that clearly distinguishes it from matters of provincial concern". Requiring that a certain class of residents of a province (in this case federal government and Crown corporation employees) be vaccinated is not a matter that is singular, distinctive, special, or incapable of being handled by each province independently ("indivisible"), since the provinces have independently chosen to impose (and in most cases, by now, revoke) or not to impose COVID-19 vaccination mandates on:

- certain provincially-regulated employees such as health care workers and university and college professors,
- post-secondary students,
- clients of various businesses, via the provincial "vaccine passports",
- attendees of certain residences, such as retirement homes,
- etc.

Furthermore, Quebec has legislation in place that allows the provincial government to impose vaccination on all of its residents:

> "123. Notwithstanding any provision to the contrary, while the public health emergency is in effect, the Government or the Minister, if he or she has been so empowered, may, without delay and without further formality, to protect the health of the population,
>
> (1) order compulsory vaccination of the entire population or any part of it against smallpox or any other contagious disease seriously threatening the health of the population and, if necessary, prepare a list of persons or groups who require priority vaccination;"[231] [Emphasis added.]

Alberta also had similar legislation allowing imposition of vaccination, although it was repealed recently.[232]

In Ontario, the Medical Officer of Health has the power to exclude persons from workplaces affected by an outbreak of a contagious disease if they are unvaccinated against the contagion:

> "It is not disputed that the Hospital's decision to exclude persons from the workplace during a declared outbreak in the Hospital, unless those persons had been vaccinated 14 days prior or had commenced taking Tamiflu, was the Hospital's attempt to implement the direction of the Medical Officer of Health (MOH) for Simcoe Muskoka. The Health Protection and Promotion Act (HPPA) provides that a MOH may respond to an outbreak of a communicable disease at a hospital if the "disease presents a risk to the health of persons in the public hospital" by making an order directed

[231] Public Health Act, S-2.2, Quebec, (Updated to 31 October 2021), https://www.legisquebec.gouv.qc.ca/en/document/cs/S-2.2.
[232] Global News, "COVID-19: Alberta 'will not revisit' mandatory vaccination: Kenney", 8 January 2022, https://globalnews.ca/news/8496569/covid-19-alberta-will-not-revisit-mandatory-vaccination-kenney/. Alternate link: https://archive.ph/Gn7aH.

> to the administrator of the hospital "in order to decrease or eliminate the risks to health associated with the outbreak." (see ss. 29.2(2)). The administrator of the hospital "shall ensure that actions provided for in the order are implemented." (ss. 29.2(4)) Influenza is a communicable disease listed in the applicable regulation. (R.R.O. 558/91)"[233]

Therefore, the provinces have the power to impose vaccination on their residents, should they choose to do so.

In conclusion, with regards to the objective of "[protecting] the general public health of all Canadians by mandating all employees to be fully vaccinated against COVID-19 and its variants", the federal government's directive to the Bank of Canada compelling it to create a vaccination policy for its staff is *ultra vires* the federal government's jurisdiction.

4c: Administrative (non-disciplinary) suspensions cannot be unpaid

The Policy and decision to deny me accommodation and unilaterally place me on unpaid leave with no health benefits is also illegal because it has been established at the Supreme Court of Canada that administrative suspensions cannot be unpaid.

The Supreme Court of Canada in *Cabiakman* stated:

> "62 This residual power to suspend for administrative reasons because of acts of which the employee has been accused is an integral part of any contract of employment, but it is limited and must be exercised in accordance with the following requirements: (1) the action taken must be necessary to protect legitimate business interests; (2) the employer must be guided by good faith and the duty to act fairly in deciding to impose an administrative suspension; (3) the temporary interruption of the employee's performance of the work must be imposed for a relatively short period that is or can be fixed, or else it would be little different from a resiliation or dismissal pure and simple; and (4) the suspension must, other than in exceptional circumstances that do not apply here, be with pay."[234] [Emphasis added.]

The above paragraph from *Cabiakman* also states that the suspension must only be "for a relatively short period that is or can be fixed". However, I have already been on unpaid leave for almost four months, and there is no defined end date to my period of unpaid leave.

Confirming the principles expressed in *Cabiakman*, the Supreme Court of Canada in *Potter* emphasized the requirement that non-disciplinary, administrative leave must be with pay:

> "[87] In *Cabiakman*, this Court addressed, albeit in the civil law context, the scope of an employer's authority to impose an administrative suspension on an employee against whom criminal charges have been laid. The Court defined the employer's "residual power" to suspend as follows:

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[233] *Muskoka Algonquin Healthcare v Ontario Nurses' Association*, 2015 CanLII 32027 (ON LA), https://canlii.ca/t/gjfgn.

[234] *Cabiakman v. Industrial Alliance Life Insurance Co.*, 2004 SCC 55 (CanLII), at para. 62, https://canlii.ca/t/1hmp7.

> This residual power to suspend for administrative reasons because of acts of which the employee has been accused is an integral part of any contract of employment, but it is limited and must be exercised in accordance with the following requirements: (1) the action taken must be necessary to protect legitimate business interests; (2) the employer must be guided by good faith and the duty to act fairly in deciding to impose an administrative suspension; (3) the temporary interruption of the employee's performance of the work must be imposed for a relatively short period that is or can be fixed, or else it would be little different from a resiliation or dismissal pure and simple; and (4) the suspension must, other than in exceptional circumstances that do not apply here, be with pay. [para. 62]

In *Cabiakman*, the employee, a sales manager, had been charged with conspiracy to extort money from his securities broker, and after pleading not guilty to the offence, was suspended by his employer without pay pending resolution of the charges. The suspension was found to have been justified, as the employer had imposed it for legitimate business reasons relating to the company's image and reputation. However, the employer could not justify its decision not to pay the employee during the suspension period: ". . . in the context of a suspension that at all times remained administrative in nature, there was no reason to refuse to pay the salary of an employee who remained available to work" (para. 79; see also paras. 76-78 and 80).

(…)

[93] Although the tests from *Reininger* and *Cabiakman* were developed in the contexts of different legal systems, they both incorporate principles from the collective bargaining context and are, as a result, quite similar. For the determination of whether a suspension is justified, both tests focus on the need for legitimate business reasons, good faith and a minimal impact in terms of duration. (Incidentally, the test from *Reininger*, unlike the one from *Cabiakman*, does not address the requirement that the employee be paid, given that in the former case, the issue was analyzed through the lens of a disciplinary suspension, which means that it was assumed that the employee would not be paid.)

(…)

[95] Although *Devlin* did not involve a suspension pending the resolution of criminal charges, these factors, like the ones considered in *Cabiakman* and in *Reininger*, focus on a need for legitimate business reasons, good faith, and minimization of the duration of the suspension. As in *Cabiakman*, the *Devlin* factors also emphasize the importance of the employee's being paid during the suspension period. In my view, the additional factors in the test from *Devlin* are consistent with the approach taken in *Cabiakman* and *Reininger*, and they help answer the fundamental question whether the suspension was reasonable and justified." [235] [Emphasis added.]

It has also been found, in an Ontario labour arbitration, that it is unreasonable to place employees on unpaid leave for declining a COVID-19 vaccination:

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[235] *Potter v. New Brunswick Legal Aid Services Commission*, 2015 SCC 10 (CanLII), at para. 87, https://canlii.ca/t/ggkhh.

> [5] After carefully considering the parties' submissions, I find that the ESA's current Vaccination Policy is unreasonable to the extent that employees may be disciplined or discharged for failing to get fully vaccinated. It is also currently unreasonable to place employees on an administrative leave without pay if they do not get fully vaccinated.
>
> (…)
>
> "[66] In *St. Peter's Health System v. CUPE, Local 778*, supra, Arbitrator Charney undertakes a detailed review of authorities provided to him and finds that prior to balancing the interests of the employer and the employees one must look at any common law rights issues and s.7 of the *Charter* as to whether it is permissible to enforce a mandatory medical treatment. Arbitrator Charney concludes:
>
> > '…suspending employees (non-disciplinary) for refusing to undergo medical treatment is a violation of their common law sec. 7 charter rights. Virtually all the court cases, including Supreme Court of Canada and Ontario Court of Appeal, find that enforced medical treatment, and I point out that this is not a medical examination but treatment, is an assault if there is no consent.'"[236] [Emphasis added.]

My departmental colleagues have continued to work entirely from home, with no requirement to attend the Bank's offices on-site, throughout the entire period that I have been on unpaid leave (Nov. 22, 2021, to present). There is no reason that the Bank could not have allowed me to continue working from home during that time, like the rest of my colleagues.

Accordingly, I ask to be removed from unpaid leave status and permitted to continue working from home (as I did from March 2020 to November 2021), to be paid my regular salary for the period during which the Bank unilaterally placed me on unpaid leave, and to be compensated for the lost health benefits and any other compensation during the unpaid-leave period.

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[236] *Electrical Safety Authority v Power Workers' Union*, 2022 CanLII 343 (ON LA), at paras. 5 and 66, https://canlii.ca/t/jlnm8.

Section 5: Conclusion

In conclusion, I ask the Bank of Canada to respect my personal choice not to receive injections of a COVID-19 vaccine product, to accommodate me by allowing me to continue working from home while the Bank's COVID-19 Vaccination Policy is in place, and to compensate me for lost pay, benefits, and any other compensation lost during the period of unpaid leave.

ALL OF WHICH IS RESPECTFULLY SUBMITTED, this 16th day of March, 2022

Joseph Hickey, BSc, MSc, PhD
Data Scientist
Digital Economy and Advanced Analytics Division
Canadian Economic Analysis Department
Bank of Canada

COVID-19 Vaccination Policy

Date

EFFECTIVE DATE: October 6, 2021

Context

The Bank is committed to protecting the health and safety of all of its employees and others in its workplaces. In the context of the COVID-19 pandemic that was declared by the World Health Organization, the mandates issued by the federal government, and direction provided by public health authorities, special health and safety measures are necessary to protect the health and safety of Bank employees and prevent the spread of COVID-19, and to ensure that the Bank's operations can continue, given its critical role to the Canadian economy in challenging economic times.

Policy Statement

The objective of this policy is to reduce the risk of transmission of COVID-19 in order to protect the health and safety of the employees of the Bank, and to protect the general public health of all Canadians by mandating all employees to be fully vaccinated against COVID-19 and its variants.

Scope

The Government of Canada has provided notice that it intends to require all federal public service employees, employees of federal Crown corporations and employees in the federally regulated air, rail, and marine transportation sectors to be fully vaccinated. This policy reflects the approach outlined by the Government and the recommendations of public health authorities. It applies to all Bank employees, regardless of their role at the Bank.

Accountabilities

Employees

- Get fully vaccinated against COVID-19 as soon as possible, and at a minimum, by the deadlines established by this policy.
- Adhere to and respect any accommodation measures put in place on legitimate human rights grounds.

Employee Relations

- Provide direction and guidance to employees with respect to the vaccination mandate.
- Manage the process to support leaders dealing with employees who are not compliant with the requirements of this policy.
- Manage requests for accommodation, provide guidance and work with the employee and their leader with respect to the implementation of accommodation measures.

Leaders

- Reinforce with employees the requirements of this policy and encourage compliance.
- Provide employees with guidance as to the requirements of this policy.
- Work with Employee Relations to manage and respond to any requests for accommodation and address issues of non-compliance.

Mandatory Policy Requirements

a. The Bank will take all reasonable precautions to protect its employees and other individuals in its workplace from the risk of transmission of COVID-19.
b. Bank employees are required to be fully vaccinated against COVID-19 and its variants. Employees must attest to and provide proof of one of the following:

   [1] That they have been fully vaccinated against COVID-19 or will be fully vaccinated by November 22, 2021; or

   [2] A legitimate medical, religious or other human-rights based reason for not being vaccinated against COVID-19.

c. All contractors, visitors and other individuals entering Bank premises will be required to provide satisfactory proof of full vaccination prior to admission.
d. To the extent that the Bank determines that, based on public health advice, fully vaccinated status requires one or more vaccine booster shots, employees may be required to provide subsequent attestation to the fact that they have received the necessary booster shots. Employees will be provided with advance notice of any booster requirement that is implemented.
e. Information on the vaccination status of employees will be kept separate from other employee information and protected from unauthorized disclosure. The information will only be retained by the Bank or its delegated third party for as long as is required to administer pandemic health measures, and will only be accessed by those employees of the Bank or its contractors who have a need to access the information for those purposes.

f. The Bank is committed to respecting its accommodation obligations under the *Canadian Human Rights Act (CHRA)*. Where an individual cannot receive a COVID-19 vaccine due to protected grounds under the *CHRA*, such as medical, religious or other protected reasons, and where the individual requires workplace accommodation as a result, the Bank will accommodate that employee to the point of undue hardship. Accommodation measures may include COVID-19 testing at regular intervals, observation of enhanced health and safety protocols, modifications to job duties or re-assignment to other duties, and/or other measures as appropriate.
g. Employees who opt not to get fully vaccinated as required by this policy and who do not have a requirement for accommodation will be placed on special leave without pay or benefits (COVID-19 Leave of Absence Without Pay or Benefits) as of November 22, 2021. The status of employees on COVID-19 leave will be reviewed regularly.
h. The duration of the COVID-19 leave may be limited by the Bank at its discretion, taking into account factors such as the public health environment, the risk to other individuals in the workplace, the impact on the Bank's operations and any other considerations relevant to the objectives of this policy. If an employee has not complied with this policy by the time that their COVID-19 leave comes to an end, their employment may be terminated at the discretion of the Bank without further notice or severance entitlement. Employees on COVID-19 leave will be provided with a reasonable opportunity to comply with the policy before their COVID-19 leave is ended.
i. All employee attestations of vaccination status will be subject to verification by the Bank or its delegated third-party, at its sole discretion, and employees will be required to provide official proof of vaccination in accordance with the documentation available in the province where they were vaccinated.
j. Failure to provide official proof of vaccination upon request after attesting to fully vaccinated status will be considered a serious breach of this policy and the *Code of Business Conduct and Ethics*. Any employee who makes a false attestation or who misrepresents their vaccination status will be subject to serious disciplinary measures, including termination of employment.

Review and Modification of Policy

The Bank will review the Policy on a regular basis and reserves the right to modify its contents at any time, based on current available public health information and any legislative, judicial or regulatory direction.

Employee Attestation

You are required to provide your attestation in this online form.

Content Type(s): Governance materials, Policies
Subject(s): Health and safety, Coronavirus disease (COVID-19)
Source(s): Corporate Administration, Human Resources (HR)

By Email

November 12, 2021

[redacted], Senior Employee Relations Specialist
Human Resources Department, Bank of Canada
[redacted]

Re: Request for accommodation with respect to the Bank of Canada's COVID-19 Vaccination Policy

Dear [redacted],

With respect to the Bank's COVID-19 Vaccination Policy, I request accommodation for the following reasons:

Medical

I, like the great majority of my departmental colleagues, have been working 100% from home since March 2020 (20 months). My department will continue to be on 100% telework until at least February 2022, and once called back to the office, will be working under a new "hybrid" model, where all work will be capable of being done from home, including meetings. My department will also be allowing employees six weeks per year of a "work from anywhere" (in the world) arrangement, highlighting that all work can be done remotely.

There is no medical reason to require me to be vaccinated while I am working from home. There is also no reason that the status quo of full telework cannot be maintained for employees who choose not to be vaccinated. Therefore, I request to be accommodated by continuing to work from home, as I have been doing since March 2020. This accommodation presents no undue hardship to the Bank, because it would simply be a continuation of the work arrangement I have had for the past 20 months.

The Bank's vaccination policy is arbitrary. For example, the Bank has arbitrarily decided not to provide an option of testing for employees who choose not to be vaccinated. In contrast, the vaccination policies of various employers operating in federally-regulated industries, such as the Bank of Montreal, Rogers, Telus, and Canada Life reportedly allow the alternative of rapid testing for employees who choose not to take a vaccine.[1] It is noteworthy that many such employees have a high degree of face-to-face interaction with the public, which is in stark contrast to my work environment at the Bank of Canada, where I can do all of my work from home, and where even at head office there is very little, if any, interaction with the public. I also note that Telus's media release about its vaccination policy states that "unvaccinated team members will continue to work from home,"[2] which is the accommodation that I

[1] "Canada Life, Rogers join growing list of companies requiring COVID-19 vaccination or rapid tests for employees", 23 August 2021, *Globe & Mail*: https://www.theglobeandmail.com/business/article-canada-life-rogers-join-growing-list-of-companies-requiring-covid-19/.

[2] "TELUS prioritizes the health and safety of team members and customers by introducing Covid-19 vaccination policy", 31 August 2021, TELUS.com (media release): https://www.telus.com/en/about/news-and-events/media-releases/telus-prioritizes-the-health-and-safety-of-team-members-and-customers-by-introducing-covid-19-vaccination-policy.

am requesting. Additionally, the Quebec and Ontario governments have announced that they will not require vaccination for workers in their provincial healthcare systems.[3] If testing of non-vaccinated employees is sufficient for the entire Quebec healthcare system (the hub of transmission of most infections in that province), how can testing not be sufficient for any other workplace in Canada?

I am concerned about the known and unknown medical risks of COVID-19 vaccines. Administration of the AstraZeneca vaccine was halted in Canada after several people died due to lethal blood clots caused by the vaccine.[4,5,6] Although the potential dangers were well-known internationally as early as March 11, 2021, and use of the AstraZeneca vaccine had already been halted in at least nine European countries,[7] Canadian provinces continued to administer hundreds of thousands of doses before finally discontinuing use of the AstraZeneca vaccine in mid-May because of the associated health risks.[8,9] The currently-available COVID-19 vaccines have also been associated with many serious adverse health events.[10] Due to the risks of heart inflammation (myocarditis and pericarditis), Germany, France, Norway, Denmark, Sweden, Iceland, and Finland have paused or are no longer recommending the Moderna vaccine for younger people,[11,12,13,14] and Ontario is no longer recommending Moderna for

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[3] "Quebec scraps vaccine mandates for health care workers, Ontario won't require them", 3 November 2021, *Globe & Mail*: https://www.theglobeandmail.com/canada/article-ontario-expands-booster-shots-to-people-70-and-older-wont-be-mandatory/.

[4] "Quebec confirms 1st death related to rare AstraZeneca-linked blood clots, emphasizes benefits outweigh risks", 27 April 2021, *CBC News*: https://www.cbc.ca/news/canada/montreal/az-vaccine-death-quebec-1.6003957.

[5] "Edmonton woman who died of vaccine-induced blood clot was turned away from ER, friend says", 6 May 2021, *CBC News*: https://www.cbc.ca/news/canada/edmonton/edmonton-covid-astrazeneca-vaccine-blood-clot-death-1.6015535.

[6] "Ontario confirms first blood clot death in man who received AstraZeneca COVID-19 vaccine", 25 May 2021, *CTV News*: https://toronto.ctvnews.ca/ontario-confirms-first-blood-clot-death-in-man-who-received-astrazeneca-covid-19-vaccine-1.5442160.

[7] "Covid-19: European countries suspend use of Oxford-AstraZeneca vaccine after reports of blood clots", 11 March 2021, *British Medical Journal* 372:n699: https://www.bmj.com/content/372/bmj.n699.

[8] "Ontario Pauses Administration of AstraZeneca Vaccine", 11 May 2021, Government of Ontario: https://news.ontario.ca/en/statement/1000103/ontario-pauses-administration-of-astrazeneca-vaccine.

[9] "Quebec halts 1st doses of AstraZeneca vaccine, keeps future supply for 2nd only", 13 May 2021, *CBC News*: https://www.cbc.ca/news/canada/montreal/astrazeneca-vaccine-quebec-1.6025187.

[10] "Weekly surveillance summary: adverse events following immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to October 17, 2021", Public Health Ontario: https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-aefi-report.pdf?la=en.

[11] "Germany, France Restrict Moderna's Covid Vaccine For Under-30s Over Rare Heart Risk—Despite Surging Cases", 10 November 2021, *Forbes*: https://www.forbes.com/sites/roberthart/2021/11/10/germany-france-restrict-modernas-covid-vaccine-for-under-30s-over-rare-heart-risk-despite-surging-cases/?sh=cdfd6ed2a8a6.

[12] ["On Wednesday Sweden said it would halt the use of the mRNA shot among those under 30 and Denmark paused its rollout for children and teenagers under 18. Norway advised men younger than 30 to opt for the Pfizer jab instead. Finland has since followed suit, announcing on Thursday that men born in 1991 and later will subsequently be given the Pfizer jab."], "Scandinavian countries limit use of Moderna jab among young people", 7 October 2021, *The Telegraph*: https://www.telegraph.co.uk/global-health/science-and-disease/scandinavian-countries-limit-use-moderna-jab-among-young-people/.

[13] "Iceland Joins Nordic Peers in Halting Moderna Covid Vaccinations" 8 October 2021, *BNN Bloomberg*: https://www.bnnbloomberg.ca/iceland-joins-nordic-peers-in-halting-moderna-covid-vaccinations-1.1663781.

[14] "Sweden extends pause of Moderna vaccine for younger age group", 21 October 2021, *Reuters*: https://www.reuters.com/world/europe/sweden-extends-pause-moderna-covid-vaccine-younger-age-groups-2021-10-21/.

males aged 18-24.[15] These decisions by governments to stop administering or recommending COVID-19 vaccines demonstrate that my concerns about the medical risks associated with COVID-19 vaccines are legitimate.

Religious

I am a scientist with B.Sc., M.Sc., and Ph.D. degrees in Physics, and I have carefully considered the scientific literature regarding the risks posed to me by COVID-19 and by the COVID-19 vaccines. Having done so, I have come to the deep personal conviction that the right choice for my health is for me not to take a COVID-19 vaccine. From my analysis of the available evidence, I have also come to the deep conviction that the government should not be recommending these vaccines for young and healthy individuals; I therefore object, as a matter of conscience, to participating in the government's vaccination program. Due to these deep personal convictions, I request an accommodation on the basis of freedom of conscience and religion.

My personal conviction is informed by:

- The values imparted to me from my upbringing as a member of the Catholic Church and as a student in Catholic elementary and middle school in Ontario. These include the values expressed in the philosophy of Saint Thomas Aquinas, who believed that "conscience is the consideration of a specific case in light of one's moral knowledge" and "the binding character of conscience, whether erring or not, means that acting against conscience is always evil."[16]
- A family tragedy: my father died as a result of an adverse event from a pharmaceutical product. I am therefore acutely aware that there are risks associated with pharmaceutical products, and take this into account in developing my personal convictions and health choices.

Human Rights (Age and Sex)

The Bank's policy discriminates against me on the basis of age and sex, because it forces me to expose myself to a higher risk of a dangerous adverse health event (heart inflammation) than females and those older than me, in order to obtain the same employment opportunity of continuing my work at the Bank.

Public Health Ontario's publication "Weekly surveillance summary: adverse events following immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to October 17, 2021"[17] shows that heart inflammation (myocarditis or pericarditis) events after two doses of an mRNA (Pfizer or Moderna) vaccine occur:

- 3.7 times more frequently in males than in females
- 1.8 times more frequently in males aged 30-39 (my age group) than in females aged 12-17
- 1.4 times more frequently in males aged 30-39 than in females aged 18-24
- 3.8 times more frequently in males aged 30-39 than in females aged 25-29

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[15] "Ontario Recommends the use of Pfizer-BioNTech COVID-19 Vaccine for Individuals Aged 18-24 Years Old", 29 September 2021, Government of Ontario: https://news.ontario.ca/en/statement/1000907/ontario-recommends-the-use-of-pfizer-biontech-covid-19-vaccine-for-individuals-aged-18-24-years-old.

[16] Hoffman, Tobias. "Conscience and *Synderesis*", in *The Oxford Handbook of Aquinas* (Davies, Brian, ed.), Oxford University Press, New York (2012).

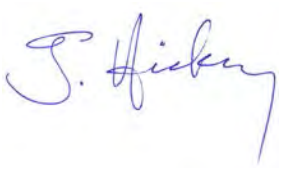
[17] See footnote 10, above, Table A3.

- 1.6 times more frequently in males aged 30-39 than in females aged 30-39
- 9.8 times more frequently in males aged 30-39 than in females aged 40-49
- 3.3 times more frequently in males aged 30-39 than in females aged 50-59
- 7.2 times more frequently in males aged 30-39 than in females aged 60-69
- 10.4 times more frequently in males aged 30-39 than in females aged 70-79
- 6.6 times more frequently in males aged 30-39 than in females aged 80+
- 2.1 times more frequently in males aged 30-39 than in males aged 40-49
- 3.4 times more frequently in males aged 30-39 than in males aged 50-59
- 3.3 times more frequently in males aged 30-39 than in males aged 60-69
- 3.1 times more frequently in males aged 30-39 than in males aged 70-79
- 4.5 times more frequently in males aged 30-39 than in males aged 80+

Males aged 30-39 (my age group) are therefore clearly at a higher risk of developing heart inflammation following two doses of an mRNA vaccine than females or men older than 40. This discriminates against me, because it forces me to expose myself to greater health risk (of a dangerous adverse event following vaccine dosage) than members of other identifiable groups in order to continue working. This discrimination can be remedied without undue hardship to the Bank by allowing me to continue working from home without taking a vaccine.

For all of the above reasons, I request to be accommodated by being permitted to continue working from home until the Bank's COVID vaccination policy is no longer in place.

Sincerely,



Joseph Hickey, PhD
Data Scientist
Bank of Canada

Gmail [redacted]

FW: Private

Joseph Hickey <JHickey@bank-banque-canada.ca> Fri, Nov 19, 2021 at 5:28 PM
To: Joseph Hickey [redacted]

Category/Catégorie: Protected A/Protégé A

From: [redacted]@bank-banque-canada.ca>
Sent: November 19, 2021 5:26 PM
To: Joseph Hickey <JHickey@bank-banque-canada.ca>
Subject: Private

Category/Catégorie: Protected A/Protégé A

Hi Joseph,

This is a follow up to our discussion on November 18, 2021 and is in response to your request for an accommodation based on medical, religious, sex and age grounds. Having reviewed your request in consultation with third party experts, the Bank has determined that you have not established that your request meets the threshold for a medical, religious, sex and age based accommodation. Should you wish to submit additional information for the Bank to consider further to your initial accommodation based on religious, sex and age request, please do so to my attention at your earliest convenience. Should you wish additional information in order to submit additional information for the medical third party`s review based on that ground, please send a note using the following email and their representative will contact you to that end.

[redacted]

Please note that you will be expected to comply with the Bank's mandatory COVID-19 Vaccination Policy. To the extent that you remain non-compliant, you will be placed on leave without pay or benefits as of November, 22, 2021; your employment may ultimately be terminated if you remain non-compliant after the leave period.

As discussed, your access to the Bank's system will be suspended. You will also be sent a pre-paid courier box for the purpose of collecting your Bank assets. This will be sent to the home address the Bank has on file for you. If this address is not up-to-date, please provide me with the

correct address. Please provide me with a personal email address so that I may contact you during your leave, if and when required As well, you cannot come onsite and your building pass has been disabled.

Should you decide to comply with the Bank`s policy, please provide the dates you will be receiving, or have received, your first and second doses. Once you have your second dose please use the attached form to attest that you are fully vaccinated. Once I receive this completed form from you, your system access will be restored, your Bank assets will be returned to you, and you will be reintegrated to work as soon as possible. You will be removed from leave without pay and benefits the day following your second dose. However, please note that you will be required to work remotely for a 14 day period following the second dose, which is required to be considered fully vaccinated. Upon restoration of your system access, you will also be required to update your vaccine status using the Bank's Service Now Attestation Tool.

I also wish to remind you that as a Bank employee you have access to the Employee Assistance and Family Program (EFAP) which is a confidential counselling and information service. Should you wish to avail yourself of their services, they can be reached at [redacted].

Please let me know if you have any further questions.

Thank you,

[redacted]

[redacted] [redacted]
Senior Employee Relations Specialist
Spécialiste principal des relations avec les employés
Human Resources| Ressources humaines
Bank of Canada |Banque du Canada
234 rue Wellington Street, Ottawa, ON K1A 0G9
[redacted]
[redacted]
[redacted]

BANK OF CANADA
BANQUE DU CANADA

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La version française suit le texte anglais.

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3 attachments

image002.png
2K

image004.png
8K

Vaccination Attestation Form (Return from LWOP) - BIL.pdf
196K

Gmail Joseph Hickey [redacted]

Your Appeal

Joseph Hickey [redacted] Tue, Dec 14, 2021 at 9:56 PM
To: [redacted]@rcgtconsulting.com>
Cc [redacted]@bank-banque-canada.ca>

Dear [redacted],

Thank you for your email sent at 3:54 PM today (below).

Your email of today was a fresh email that did not carry forward any of our prior correspondence. Therefore, to keep the record up to date, I am appending all of our prior email correspondence below your Dec. 14 email in this email string.

In my email to you of Dec. 7 (below, directly following your Dec. 14 email), I recapped the main points we discussed in our phone conversation earlier that day (Dec. 7).

In particular, I wrote:

> "You told me that there is no set deadline for me to submit my appeal. I said that I intend to appeal and will do so as soon as possible."

Accordingly, I am preparing my appeal submission, which will contain further documentation beyond my initial accommodation request. It will take more time (weeks) to complete, and I will send it to you as soon as it is ready.

I trust this is acceptable.

Sincerely,
Joseph

--
Joseph Hickey, PhD
[redacted]

On Tue, Dec 14, 2021 at 3:54 PM [redacted]@rcgtconsulting.com> wrote:

> Hello Dr Hickey,
>
> I am following up with you today from our last dialogue to see if there is any update to your medical accommodation request appeal.
>
> Would you like to attach any further documentation, or should I forward your original application to a separate physician for review?
>
> Please let me know your intentions, and do not hesitate to reply or contact me if needed.
>
> Thank you,
>
> [redacted]

Senior Case Manager & Project Lead in Service Operations

[redacted]

[redacted]

Raymond Chabot Grant Thornton | RCGT Consulting

From Status Quo to Status Go

---------- Forwarded message ---------
From: **Joseph Hickey** [redacted]
Date: Tue, Dec 7, 2021 at 6:51 PM
Subject: Re: Procedure re: appeal of decision, Bank of Canada vaccination policy
To: [redacted]@rcgtconsulting.com>
Cc: [redacted]@bank-banque-canada.ca [redacted]

Dear [redacted],

Thank you for the phone call earlier today. I would like to recap a few points from our conversation.

Regarding requests by Bank of Canada employees for accommodations under the Bank's COVID-19 Vaccination Policy:

- You told me that the mandate given to RCGT by the Bank of Canada was: to validate whether or not there is a medical reason for the person requesting accommodation not to be vaccinated.

- You told me that RCGT instructed its doctors to "form a medical opinion as to whether or not there's a reason not to be vaccinated" for each particular accommodation request. You also told me that RCGT did not give any additional or more specific instructions to its doctors regarding how to decide if there was a medical reason not to be vaccinated, such as a specific list of contraindicated medical conditions.

- You told me that the written documents about the procedure for evaluating accommodation requests and for appealing the decisions on these requests are proprietary to RCGT and cannot be shared with me for that reason.

- You told me that I can attach additional documents to my appeal, such as the Treasury Board of Canada's guidelines for implementing its COVID-19 vaccination policy.

- As an example of medical reasons that were submitted in accommodation requests by other Bank employees, you pointed me to a document on the Government of Ontario's website at the link <https://health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/medical_exemptions_to_vaccination.pdf> entitled "Medical Exemptions to COVID-19 Vaccination" and dated Sep. 14, 2021, which includes a table entitled "Table 1: Summary of conditions and/or adverse events following immunization (AEFI) that may qualify for a medical exemption to COVID-19 vaccination".

- You told me that the evaluations made by RCGT's doctors are generally based on the information in documents such as the above-noted Government of Ontario publication, or similar publications by the Government of Canada or the World Health Organization. However, you told me that it is not necessary for a Bank employee to have one of the conditions listed in Table 1 of the Government of Ontario document in order to receive an accommodation.

- You told me that there is no set deadline for me to submit my appeal. I said that I intend to appeal and will do so as soon as possible.

- You told me that my appeal will be evaluated by a different medical doctor than the doctor who first evaluated my request. You said that the second doctor will follow the same procedure as the first doctor and make a new evaluation of "whether or not there is a medical reason not to be vaccinated".

Sincerely,
Joseph

--
Joseph Hickey, PhD
[redacted]

On Mon, Dec 6, 2021 at 3:58 PM [redacted]@rcgtconsulting.com> wrote:

> Hello Mr Hickey,
>
> I am happy to answer all the questions I can on our call, and it looks like we both have some availability tomorrow December 7th. I will block off from 12-1pm for our meeting.
>
> You can call me at the number listed below in my signature, and If I have not heard from you, I will call within the time block as well.
>
> Thank you,
>
> [redacted]
>
> Senior Case Manager & Project Lead in Service Operations
>
> [redacted]
>
> [redacted]
>
> [redacted]
>
> [redacted]
>
> [redacted]
>
> **From:** Joseph Hickey [redacted]
> **Sent:** December 6, 2021 3:53 PM
> **To:** [redacted]@rcgtconsulting.com>
> **Cc:** [redacted]@bank-banque-canada.ca
> **Subject:** Re: Procedure re: appeal of decision, Bank of Canada vaccination policy

Dear [redacted]

Thank you for your email. I am available to speak by phone on Tuesday (Dec. 7) between 11:00-14:00, or Wednesday (Dec. 8) between 10:00-12:00 or 14:00-17:00. Please let me know what time works for you.

As I mentioned in my previous email, I wish to appeal the decision, and I want to make sure I will have a fair and open process in the appeal. Therefore, I would like to know the details of the process. In particular:

- Will there be a new decision-maker on appeal?
- Is there a timeline for the appeal?
- Do you have any written documents about the appeal process that you can provide me?

Sincerely,
Joseph

On Fri, Dec 3, 2021 at 2:43 PM [redacted]@rcgtconsulting.com> wrote:

> Hello Joseph Hickey,
>
> I would be happy to discuss the process with you and would like to schedule a call.
>
> I am available until 330pm today, or Monday between 9-10am, and 2-4pm. If that does not work, please send me your availability and Id be happy to try to accommodate.
>
> Thanks you
>
> [redacted]
>
> ---
>
> **From:** Joseph Hickey [redacted]
> **Sent:** December 2, 2021 9:07 PM
> **To:** [redacted]
> **Cc:** [redacted]@bank-banque-canada.ca; [redacted]@rcgtconsulting.com>
> **Subject:** Procedure re: appeal of decision, Bank of Canada vaccination policy
>
>
>
> Dear RCGT representative,
>
> I have received your letter sent by mail and dated Nov. 24, 2021, including an enclosed form entitled "Vaccine Exemption Medical Review Report - Bank of Canada".
>
> In your letter you indicated the following:

"Should you wish to appeal this decision, please contact RCGT at [redacted] and request to speak to a Case Manager within 10 business days of receiving this notice".

Please note that I wish to appeal this decision.

In order to prepare and submit my appeal, please tell me the details of the procedure you will be applying in this appeal process. In particular, please send me any documents that you have pertaining to the procedure that you will be applying in this appeal, and please also let me know who the decision-maker will be.

Sincerely,

--
Joseph Hickey, PhD
[redacted]

[redacted]

Gmail

Joseph Hickey [redacted]

FW: {External} Recap of Nov. 18 meeting re: request for accommodation, COVID-19 vaccination policy

[redacted]@bank-banque-canada.ca> Tue, Nov 23, 2021 at 12:27 PM
To: [redacted]

Category/Catégorie: Protected A/Protégé A

Dear Joseph,

Thank you for taking of your time to contact me and seek clarity regarding our recent discussion. I have included the Bank`s COVID-19 Vaccination Policy, as it addresses many of the comments below both in context and scope. I have also made a few clarifying comments below in green for your review.

Please do not hesitate to contact me if you have further questions.

Sincerely,

[redacted]

[redacted]
Senior Employee Relations Specialist
Spécialiste principal des relations avec les employés
Human Resources| Ressources humaines
Bank of Canada |Banque du Canada
234 rue Wellington Street, Ottawa, ON K1A 0G9
[redacted]

BANK OF CANADA
BANQUE DU CANADA

From: Joseph Hickey [redacted]
Sent: November 22, 2021 3:39 PM
To: [redacted]@bank-banque-canada.ca>
Subject: {External} Recap of Nov. 18 meeting re: request for accommodation, COVID-19 vaccination policy

Dear [redacted]

I'm following up on our meeting of Nov. 18 that took place on Microsoft Teams, regarding the Bank's decision on my request for an accommodation with respect to the Bank's COVID-19 vaccination policy. I will respond to your email of Nov. 19 separately. You have asked for my personal email address – please use [redacted] to contact me going forward.

I would like to recap a few of the points from our meeting of Nov. 18, as follows:

- In our meeting, you informed me that my request for an accommodation for medical, religious, and human rights (age and sex) reasons was reviewed by third party experts (individuals external to the Bank) and that based on their recommendations, the Bank has decided not to grant me an accommodation.

- You informed me that medical aspects of my request for accommodation were reviewed by individuals working for the firm Raymond Chabot Grant Thornton, and that the religious and human rights (age and sex) aspects of my request were reviewed by an internal committee at the Bank as well as by individuals external to the Bank.

- You informed me that I may request additional information from all the third party individuals and the Bank's internal committee about their reviews of my request for accommodation. I indicated that you could appeal the accommodation decision I informed you that you could submit additional information for the committee and third party review.

- You informed me that there is an internal process to appeal the Bank's decision to deny my request for accommodation. You informed me that this internal process requires me to make a submission to Raymond Chabot Grant Thornton by way of a dedicated email address and to the Bank's internal committee by way of an email to you. In the case of the request for medical accommodation, you can submit a request for reconsideration directly to Raymond Chabot Grant Thornton. For other types of accommodation, you can submit additional information to the Bank.

- You informed me that the Bank was mandated by the Federal Government to create a vaccination policy requiring all employees to be vaccinated, except for cases in which specific employees cannot be vaccinated, in which cases those employees must be accommodated under human rights legislation. You told me that even though Crown corporations have their own regulations and laws, the Bank is bound by the Federal Government's mandate to create and apply this (the Bank's) vaccination policy. I rather explained that Bank implemented its own vaccination policy based on direction from the Federal Government indicating that it would be mandatory for Crown corporations and other federal entities. To date, the Federal government has issued a direction to Crown corporations to implement a vaccine mandate for all employees.

- You informed me that the Bank will follow further direction from the Federal Government (expected in 4-6 months) regarding what to do about the status of employees on unpaid leave under the vaccination policy, such as terminating these employees, returning them to work, or prolonging their period of leave. You are correct that the Bank expects further direction as the situation evolves. I did not specify any other potential outcome other than termination, as indicated in the Bank's communication on this topic with you to date. The Bank will review the situation periodically and will make its own determinations based on all relevant consideration.

- You informed me that the Bank's vaccination policy makes no distinction based on where the employee works, whether on-site at a Bank workplace, from the employee's home, or elsewhere. For employees that are on 100% telework (i.e. working from home 100% of the time and not required to be physically on-site at a Bank workplace), you told me that the reason the policy requires these employees to be vaccinated is that the policy includes the objective of protecting the Canadian population as a whole, not only Bank employees and others who are physically present in the Bank's workplaces. You told me that the Bank's policy has this objective because protecting the health of all Canadians is part of the mandate given to the Bank (and other Crown corporations) by the Federal Government. I explained that the Bank`s Vaccination Policy is separate and distinct from upcoming proposed return to the office measures. The policy is consistent with the direction and objectives outlined by the federal government, and with Bank policy, which requires employees to be available to attend work at any time. The requirement is that all employees be fully vaccinated by November 22, 2021 and that accommodation request be reviewed and actioned should they have met required threshold. (Please refer to the attached policy for more details)

- You told me that the Bank constructed its vaccination policy to align with the policies of other Crown corporations, and that, in developing its policy, the Bank followed guidelines provided by the Federal Government that are similar to the guidelines the Treasury Board used to construct its vaccination policy. I explained that the Bank's Vaccination Policy was aligned with the mandate provided by the Federal Government.

Please let me know if any of the above is incorrect.

I also note that it has been announced (via an "Info Bytes" memo to employees dated Nov. 2, 2021) that many employees at the Bank, including my departmental colleagues, will not be required to physically come on-site to a Bank workplace until Feb. 7, 2022, at the earliest. I assume that the reason I am not being permitted to continue working from home until at least that date (Feb. 7, 2022) is because the Bank's policy has the objective of protecting the health of all Canadians, not only individuals physically present in Bank workplaces. Please let me know if this is incorrect. That is incorrect, it is expected that in-person events will increase as of December 1 as part of the Bank's staged return to work. As explained in previous communication, the reason you have been placed on leave without pay and without benefits, is that you are not compliant with the Bank`s mandatory Vaccination Policy, as of November 22, 2021.

Sincerely,
Joseph

--
Joseph Hickey, PhD
[redacted]

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La version française suit le texte anglais.

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l'expéditeur un message électronique pour l'aviser que vous avez éliminé de votre ordinateur toute copie du courriel reçu.

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3 attachments

image002.png
2K

image007.png
8K

COVID 19 Vaccination Policy.pdf
100K

Gmail [redacted]

Private - Accommodation Requests

Joseph Hickey [redacted] Thu, Feb 10, 2022 at 10:00 PM
To: [redacted]@bank-banque-canada.ca>

Dear [redacted]

Thank you for your email.

[redacted]

I plan to send you my appeal submission as soon as possible.

Sincerely,
Joseph

--
Joseph Hickey, PhD
[redacted]

On Thu, Feb 10, 2022 at 9:00 AM [redacted]@bank-banque-canada.ca> wrote:

Category/Catégorie: Protected A/Protégé A

Good morning Joseph,

Our records indicate that you have not yet submitted additional documentation to have your requests for religious and medical accommodations reconsidered in application of the Bank's Vaccination Policy, though you indicated your intention to do so in previous communications.

As a reminder, the process provides a means for you to engage in a confidential exchange with the Bank and its external service provider, as applicable, regarding your requests. To that end, you are welcome to submit additional information if you think that it would assist the Bank in evaluating your requests. We will communicate our decisions, per applicable process, once further information is received and reviewed. We will therefore endeavour to respond to your appeal as soon as possible and encourage you to do so as soon as possible should you continue to wish to proceed.

Thank you,

[redacted]

[redacted] [redacted]
Senior Employee Relations Specialist

Spécialiste principal des relations avec les employés

Human Resources| Ressources humaines

Bank of Canada |Banque du Canada

234 rue Wellington Street, Ottawa, ON K1A 0G9
[redacted]

[redacted]

[redacted]

BANK OF CANADA
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La version française suit le texte anglais.

Raymond Chabot Grant Thornton | RCGT Consulting

Case Number: [redacted]

Accommodation request: Denied

Date: 2021-11-24

Dear Joseph Hickey,

A physician representative from RCGT has completed the assessment of your request for medical accommodation under the Bank of Canada's COVID-19 vaccination policy.

In reviewing all evidence provided to support your request, it has been concluded that the request does not meet the requirements for a medical accommodation to be granted.

Should you wish to appeal this decision, please contact RCGT at [redacted] and request to speak to a Case Manager within 10 business days of receiving this notice.

Thank you,

[redacted]

Senior Case Manager & Project Lead in Service Operations

[redacted]

[redacted]

Raymond Chabot Grant Thornton | RCGT Consulting

From Status Quo to **Status Go**

Raymond Chabot Grant Thornton | RCGT Consulting

Numéro de dossier : [redacted]

Demande de mesures d'accommodement – Rejetée

Date : 2021-11-24

Monsieur Joseph Hickey,

Un médecin représentant de RCGT Consulting a terminé l'évaluation de votre demande de mesures d'accommodement pour des raisons médicales en vertu de la politique de vaccination contre la COVID-19 de la Banque du Canada.

Après l'examen des preuves à l'appui de votre demande, celle-ci a été refusée puisqu'elle ne répond pas aux critères liés aux mesures d'accommodement pour des raisons médicales.

Si vous souhaitez faire appel de cette décision, veuillez, dans les 10 jours ouvrables suivant la réception du présent avis, contacter RCGT Consulting par courriel à [redacted] et demander à parler à un gestionnaire de cas.

Merci,

[redacted]

Senior Case Manager & Project Lead in Service Operations

[redacted]

[redacted] | [redacted]

Raymond Chabot Grant Thornton | RCGT Consulting

From Status Quo to **Status Go**

Protected (when completed)

Vaccine Exemption Medical Review Report
Bank of Canada

Case #: [redacted] **Date & time of medical review:** 2021-11-13 10:00 (YYYY-MM-DD HH:MM)

Name of medical reviewer completing this assessment: Dr. [redacted]

1 CASE ASSESSMENT CONCLUSION	
Please select one of the following outcomes.	
In the opinion of the medical reviewer, has enough evidence been provided in order to grant vaccine exemption?	☐ **Yes, approve exemption** ☒ **No, deny exemption** ☐ **More information required for a full evaluation**

2 EXPLANATION OF ASSESSMENT OUTCOME

Please provide a brief summary and justification for the decision made in Section 1. If more information is required to complete the assessment, please indicate any recommendations for follow up actions including medical documentation required for reassessment.

This claimant requests an exemption to vaccination not on medical grounds, but mainly on grounds of principle, religion, and human rights. The only reference to medical issues in the claimant's letter are:

- **an opinion that there is no medical reason for vaccination if they are allowed to work at home with frequent testing for COVID, and**
- **concerns about vaccine side effects.**

The claimant did not provide any supportive medical information to suggest that they have a medical contraindication to COVID vaccines.

Decision – The criteria for a medical exemption for vaccination have not been met in this case. Given the information before me, the claimant would need a letter from a specialist with supporting documentation indicating why they cannot receive an mRNA-based vaccine.

It is not within my mandate as a medical reviewer to consider their non-medical reasons for requesting an exemption.

9 COMMENTS

Please use the following space for any additional comments on the case.

Medical Reviewer Signature

By signing this form, I confirm that I have given this case a fair assessment and believe that a reasonable outcome has been chosen based on the presented evidence.

[redacted] **2021-11-13**

Signature (YYYY-MM-DD)

Please upload the signed, dated and completed form to the applicable case file.

Analysis of all-cause mortality by week in Canada 2010-2021, by province, age and sex: There was no COVID-19 pandemic, and there is strong evidence of response-caused deaths in the most elderly and in young males

Denis G. Rancourt[1,*], Marine Baudin[2], Jérémie Mercier[2]

[1] Ontario Civil Liberties Association (ocla.ca) ; [2] Mercier Production (jeremie-mercier.com) ;
* denis.rancourt@alumni.utoronto.ca

Published at *denisrancourt.ca*

https://denisrancourt.ca/entries.php?id=104&name=2021_08_06_analysis_of_all_cause_mortality_by_week_in_canada_2010_2021_by_province_age_and_sex_there_was_no_covid_19_pandemic_and_there_is_strong_evidence_of_response_caused_deaths_in_the_most_elderly_and_in_young_males

6 August 2021

Abstract

We analyzed all-cause mortality by week (ACM/w) for Canada, and for the Canadian provinces, and by age group and sex, from January 2010 through March 2021; in comparison with data for other countries and their regions or counties.

We find that there is no extraordinary surge in yearly or seasonal mortality in Canada, which can be ascribed to a COVID-19 pandemic; and that several prominent features in the ACM/w in the COVID-19 period exhibit anomalous province-to-province heterogeneity that is irreconcilable with the known behaviour of epidemics of viral respiratory diseases (VRDs). We conclude that a pandemic did not occur.

In addition, our analysis of the ACM/w, by province, age and sex, allows us to highlight anomalies, occurring during the COVID-19 period, which provide strong evidence that:

- Among the most elderly (85+ years), many died from the immediate response to the pandemic that was announced by the WHO on 11 March 2020.
- Predominantly young males (0-44 years, and also 45-64 years) probably indirectly died from the sustained pandemic response, in the summer months of 2020, and into the fall and winter, starting in May 2020, especially in Alberta, significantly in Ontario and British Columbia, whereas not in Quebec.

Our study provides constraints on the mechanisms at play in VRD epidemics.

Index

1. Introduction

A viral respiratory disease (VRD) pandemic has two defining characteristics (Doshi 2008, 2011):

1. It occurs everywhere, irrespective of state or jurisdictional boundaries, presumably because there is no prior immunity.
2. It causes excess mortality far greater than that due to non-pandemic (seasonal) VRD epidemics.

In 2008, Doshi (2008) put it this way:

> One recent official US death toll projection(ref) suggested that the next pandemic will kill 6 to 56 times more Americans than the CDC currently estimates die in an average nonpandemic influenza season.(ref) The World Health Organization (WHO), in a “relatively conservative estimate,”(ref) predicted that the next influenza pandemic could claim 4 to 30 times more lives worldwide than a typical nonpandemic season.(ref)

One problem, in practice, is that VRD-classed mortality is difficult to quantify. The actual number of VRD-attributable deaths is always uncertain, especially when the deaths are counted in the context of a media-frenzy about “the pandemic”. This is as true today as it was when epidemiology was a nascent science; because a cause of death determination, with many co-factors, and in the absence of an analytical autopsy, is prone to human error, human bias, institutional bias, and even constructed bias as we have seen in the COVID period (Borger et al., 2021).

One solution is to avoid the problem altogether, by studying all-cause mortality (ACM) rather than VRD-classed mortality. A death is a death is a death.

In particular, if there is no discernable excess ACM during the presumed pandemic, above the trend in ACM, of the prior decade, say, then it is incorrect to conclude that a pandemic occurred.

The only alternatives are:

1. to believe that a pandemic occurred but that an extraordinary medical response prevented the presumably new pathogen from killing many people, in just the right amount as to bring the yearly ACM back to the decadal trend value; or
2. to believe that a pandemic occurred but that an extraordinary public-health response delayed the presumably new pathogen in its killing, in just the right amount as to bring the yearly ACM back to the decadal trend value, and then prevented future killing by an extraordinary mass vaccination campaign;

or some combination of the two, or their equivalents.

In science, there is a guiding principle regarding competing interpretations of the same data, called “Occam’s razor” (Gibbs, 1996):

> The most useful statement of the principle for scientists is: "when you have two competing theories that make exactly the same predictions, the simpler one is the better."

In this article, we ask whether a COVID-19 pandemic occurred in Canada, using the above criteria. Our application of Occam's razor, in this context, is supported by a multitude of studies showing that public-health measures are ineffective against a VRD, which we have reviewed in several other articles.[1]

2. Data

Statistics Canada (StatCan) is the national statistical office of the country. The all-cause mortality (ACM) data used in this article was retrieved from this database and is given by week (ACM/w) and covers the 2010-2021 period (StatCan, 2021). At the date of access, data were available from week-1 of 2010 (beginning of January) through week-17 of 2021 (end of April). In this article we present the data until week-12 of 2021 (end of March) because for later weeks the data for Canada are not consolidated and have the artifact of anomalously small mortality values.

The StatCan data are provided by:

- Provinces and territories
- Age group

[1] See: "COVID" section, Denis Rancourt's website: https://denisrancourt.ca/categories.php?id=1&name=covid (accessed on 5 August 2021).

    - 0-44 years-old
    - 45-64 years-old
    - 65-84 years-old
    - 85 years-old and over
- Sex
    - Males
    - Females

StatCan specifies that the ACM for 2020 and 2021 is provisional, and that the counts of deaths “have been rounded to a neighbouring multiple of 5 to meet the confidentiality requirements of the Statistics Act”.

3. Results / Interpretation

3.1 No detectable pandemic increase in the yearly and seasonal mortality

The all-cause mortality by week (ACM/w) for Canada, from January 2010 through March 2021, is shown in Figure 1a:

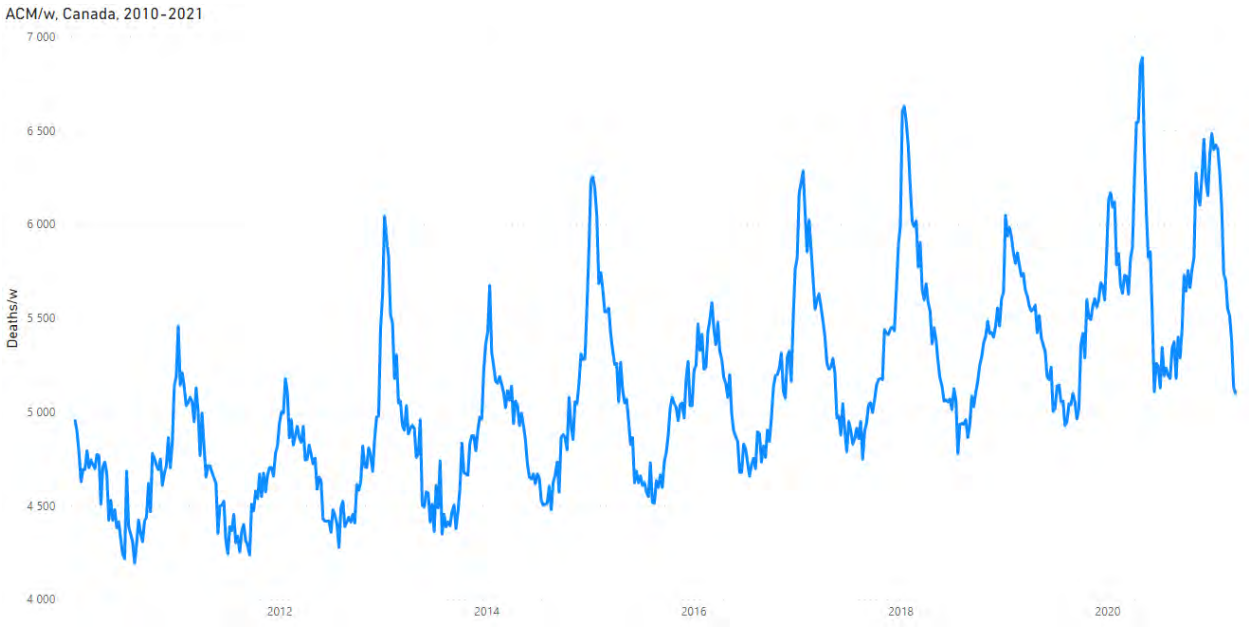

Figure 1a: All-cause mortality by week in Canada from 2010 to 2021. Data are displayed from January 2010 to March 2021. The y-scale is adjusted to show the region of interest. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

It is important to keep in mind that such graphs are represented using a region-of-interest y-scale. The same data on the full (starting at zero) y-scale is shown in Figure 1b:

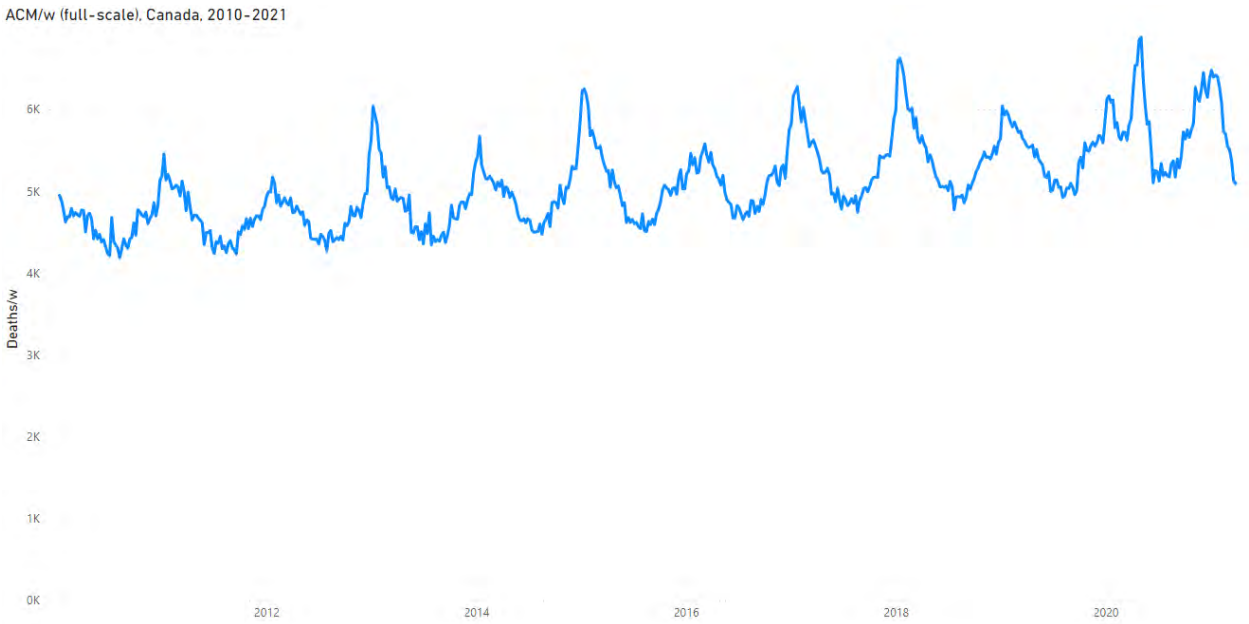

Figure 1b: All-cause mortality by week in Canada from 2010 to 2021. Data are displayed from January 2010 to March 2021. The y-scale is not adjusted to show only the region of interest; it starts from 0. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

In terms of the coarse-level main features (not intra-seasonal details), the usual seasonal pattern occurred in Canada since 2010 into March 2021, which is normally observed in all mid-latitude Northern hemisphere countries or jurisdictions, since 1900 or so where data has been collected.

The said usual seasonal pattern has these main features:

- winter highs and summer lows (here, of deaths per week, ACM/w)
    - o summer-low or trough values (deaths per week) that vary monotonically from summer to summer, typically linearly over the course of a decade (we refer to this monotonic variation as the “summer baseline trend”)

    - winter-high or maximum values (deaths per week) that vary erratically from winter season to winter season, in both magnitude and date (or week-number)
- winter-burden deaths (integrated above the summer baseline trend, over a “cycle-year”, from mid-summer to mid-summer) typically (since the 1960s) corresponding to between 5% and 15% of yearly mortality

We have analysed such patterns in ACM by time (day, week, month) for several jurisdictions, including jurisdictions in Canada, in two prior articles (Rancourt, 2020) (Rancourt, Baudin, Mercier, 2020).

Figure 1 shows that there was no excess yearly or seasonal mortality, above the usual values of the last decade for Canada, in either the 2019-2020 winter or the 2020-2021 winter (up to and including March 2021). This is confirmed by calculating ACM per year. We calculated ACM by “cycle-year”, where we define a cycle-year as occurring from week-31 (around the beginning of August) of calendar year N through to week-30 (around the end of July) of calendar year N+1. As such, for example, nominal cycle-year 2018 is centered on the winter of 2018-2019. This definition of cycle-year takes one from mid-summer-trough to the next mid-summer-trough in ACM/w, such as to capture the intrinsic seasonal structure of ACM/w, having winter highs and summer lows. The result is plotted in Figure 2:

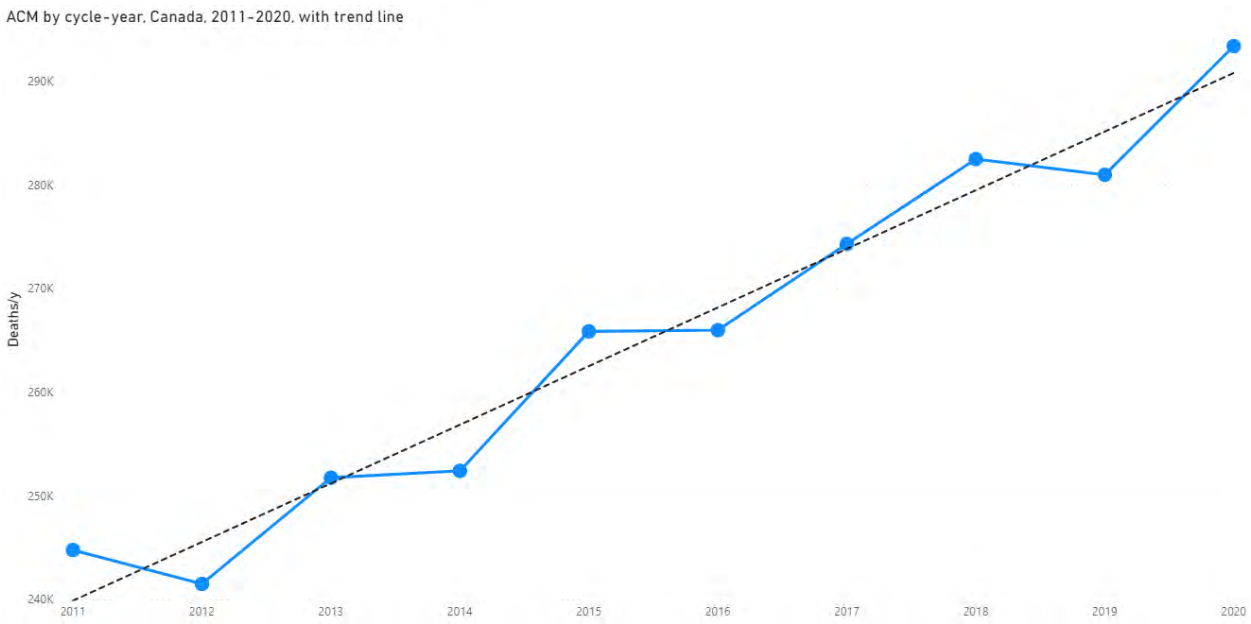

Figure 2: All-cause mortality by cycle-year for Canada, cycle-years 2011 to 2020, calculated as described above. The dashed line is a least-squares fitted straight line. The cycle-year starts on week-31 of a calendar year (beginning of August) and ends on week-30 of the next calendar year (end of July). Data for the calculation were retrieved from StatCan (StatCan, 2021), as described in section 2.

We conclude that there was no COVID-19 pandemic in Canada. It would be difficult to conclude otherwise. Either a pandemic causes a significant increase in deaths, or there was not a pandemic, barring the many unscientific false beliefs in effective public health interventions for VRDs.

Let us make this point further by showing the anomalous province-to-province intra-seasonal variations in ACM by time, which occur in the COVID or nominal-pandemic period (after 11 March 2020, the date the WHO proclaimed a pandemic).

3.2 Inter-jurisdictional uniformity of pre-COVID-period features in all-cause mortality by time, 2010-2019

The ACM/w 2010-2021 (through to March 2021) is plotted for several Canadian provinces, as follows.

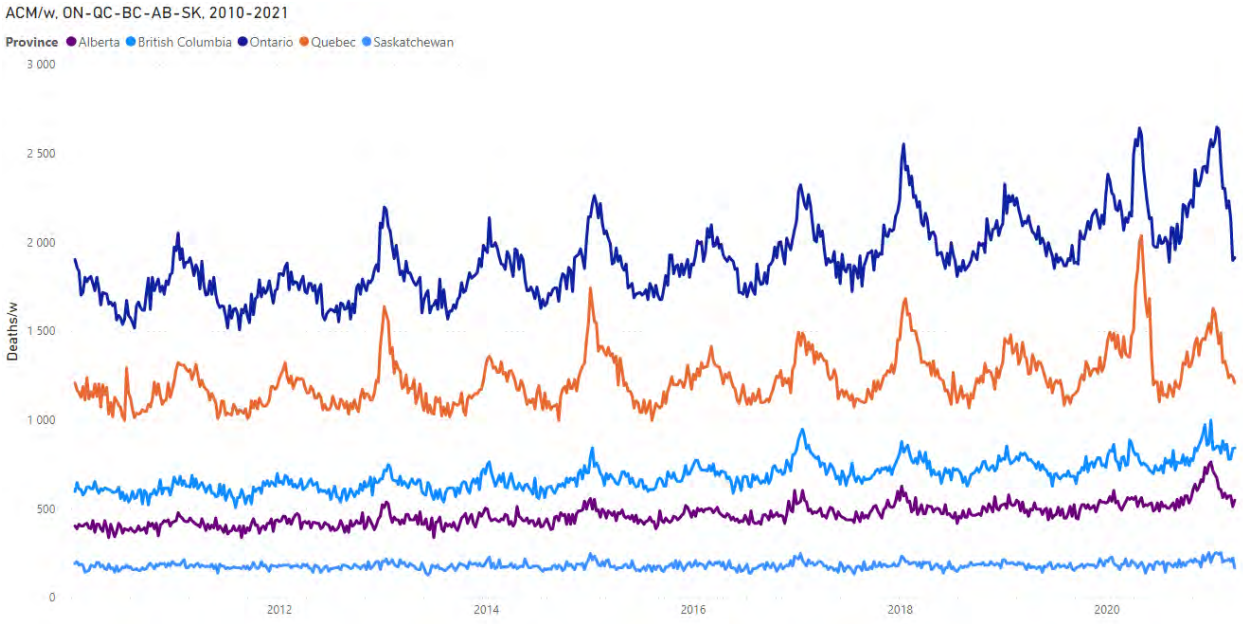

Figure 3a: All-cause mortality by week from 2010 to 2021 for, top to bottom, Ontario (ON), Quebec (QC), British Columbia (BC), Alberta (AB) and Saskatchewan (SK). Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

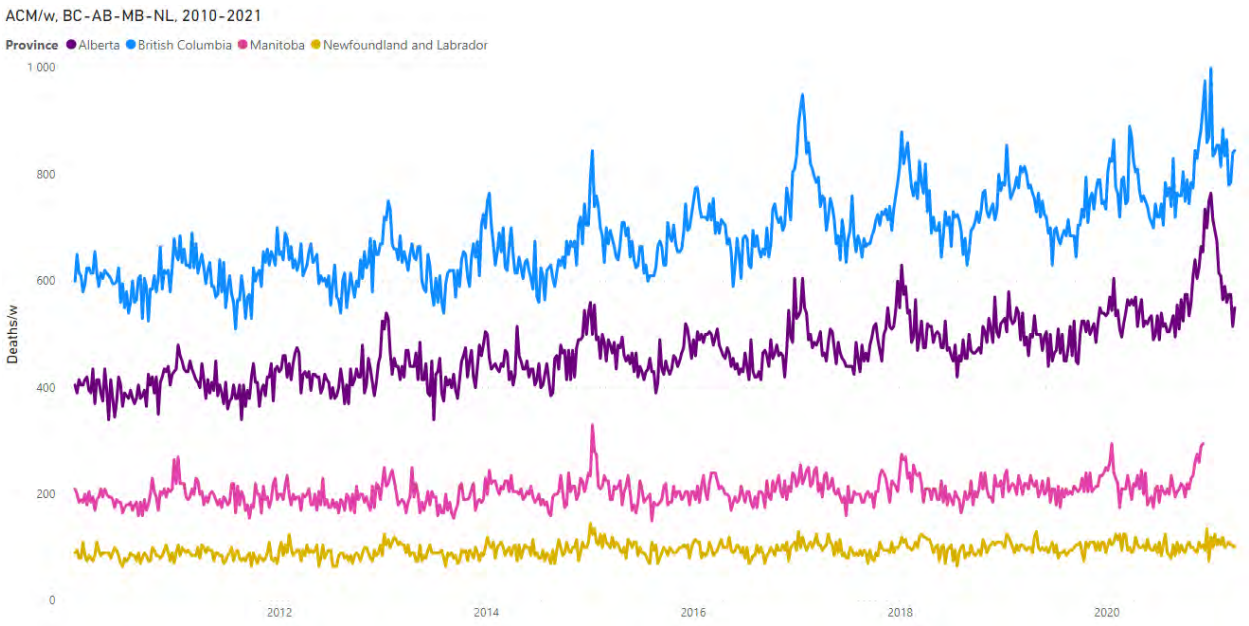

Figure 3b: All-cause mortality by week from 2010 to 2021 for, top to bottom, British Columbia (BC), Alberta (AB), Manitoba (MB) and Newfoundland and Labrador (NL). Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

The seasonal cycles of ACM/w are extraordinarily regular and display essentially identical winter-season features from province to province for a given winter, up to and including 2019. In other words, up to and including 2019, the seasonal patterns and intra-seasonal shapes of ACM/w are synchronous copies of each other, from province to province, while being scaled in whole-pattern magnitude approximately by provincial population. Plots of ACM/w, normalized by provincial population, are shown and compared in the Appendix.

We have observed such regularity, from jurisdiction to jurisdiction, and including from continent to continent, in all ACM-by-time data that we have examined for many jurisdictions (countries, regions, provinces, counties) in North America and Europe, over

the many decades of available data, for example (Rancourt, 2020) (Rancourt, Baudin, Mercier, 2020). Although there are small differences, the main first-level observation is the remarkable similarity in patterns, ratios of winter-to-winter magnitudes, and synchronicity, across all mid-latitude jurisdictions. We note that these robust data (ACM-by-time for North America and Europe, 20th and 21st centuries up to 2019) put into question two paradigms about VRDs (presumed to be the major cause of the seasonality of mortality in mid-latitude countries):

- that a specific VRD-causing virus/variant originates at a localized source and "spreads" across countries or continents by person to person contact or personal proximity ("source-spread" paradigm)
- that there are "pandemics" of VRDs, distinct from non-pandemic epidemics ("pandemic" paradigm)

Regarding the latter point, none of the 1957-1958 H2N2, 1968 H3N2, 2009 H1N1, or 2003 SARS pandemics are detected in ACM-by-time data, as meaningfully distinguished from non-pandemic seasonal epidemics. This is also the case if one analyses estimates of "influenza-classed mortality" rather than ACM (Doshi, 2008). The 1918 surges in ACM in both continents, by contrast, are very large, but constitute a special case involving mass bacterial infections, prior to the advent of antibiotics, killing solely young adults and infants, not the elderly, in societies and economies dramatically reorganized after the end of the First World War.

At the very least, ACM-by-time data imposes stringent real-world constraints on the theoretical or interpretational consequences of using these paradigms (source-spread, pandemic) to explain large-scale epidemiological observations.

Clearly for Canada, which is the size of a continent, Figures 3a & 3b (and see Appendix) show a remarkable regularity up to and including 2019: The provinces, East to West, have the same “fingerprints” of ACM/w. Detailed winter-season shapes, timing of features (synchronicity), and ratios of winter-to-winter magnitudes, are all essentially the same, province to province, 2010-2019, although the amplitudes of seasonal variation are smaller in the low-altitude (non-mountainous) maritime-climate provinces of the Canadian East coast (see below).

3.3 Inter-jurisdictional variations of COVID-period features in all-cause mortality by time

Although, as described above in section 3.1, “in terms of the coarse-level main features (not intra-seasonal details), the usual seasonal pattern occurred in Canada since 2010 into March 2021” (including the COVID-period), nonetheless there were significant anomalies in intra-seasonal features in the COVID-period, which we next examine, and which are relevant to whether a pandemic occurred.

As stated in the Introduction (section 1), a pandemic “occurs everywhere, irrespective of state or jurisdictional boundaries, presumably because there is no prior immunity”.

In particular:

- The pathogen presumed to cause the pandemic — a highly contagious pathogen of the VRD kind — will not stop at provincial borders in Canada.
- The presumed pathogen will not affect the similar populations in different provinces in dramatically different ways; such as killing young males in one province while killing only the elderly in another.
- The presumed pathogen itself, acting at the same time in March-April-May 2020 in two neighbouring similar provinces, for instance Ontario and Quebec, cannot be 2-3 times more deadly (per inhabitant) in Quebec than in Ontario.

We examine these propositions in the following figures.

First, the ACM/w for Canada is represented in an expanded view, from 2019 through March 2021, in order to define key features that occurred in the COVID-period:

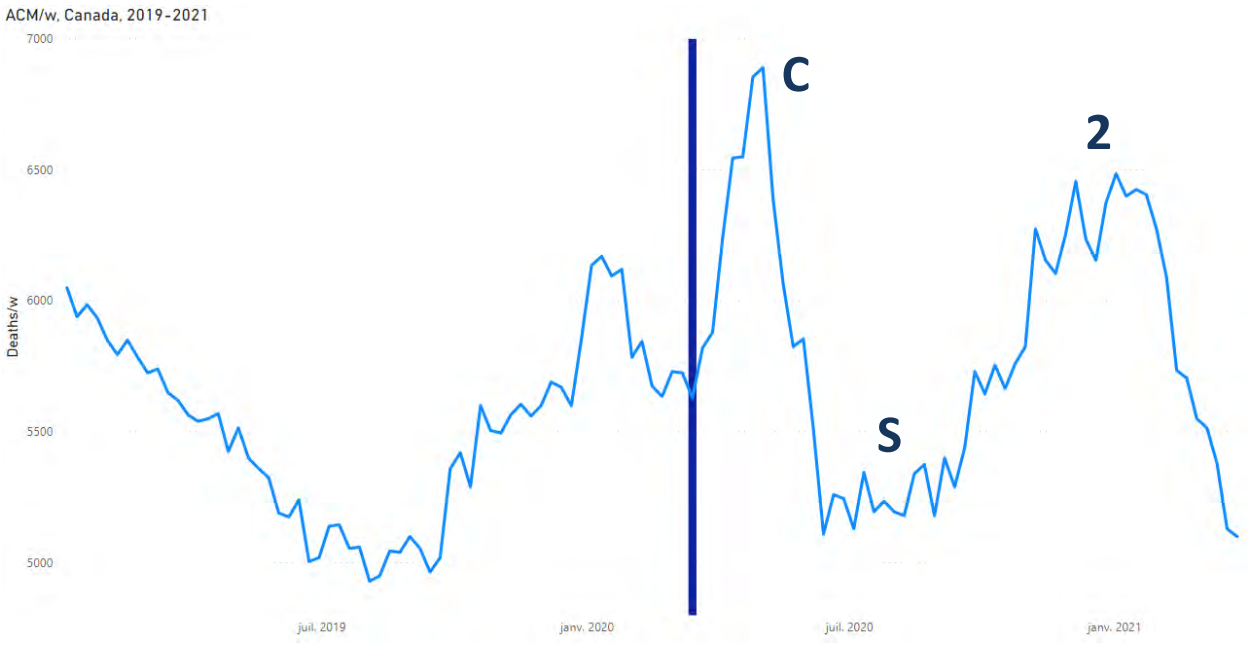

Figure 4: All-cause mortality by week in Canada from 2019 to 2021. Data are displayed from January 2019 to March 2021. The dark-blue vertical line represents the week of March 11 2020, when WHO declared the pandemic. The three features are labelled as: C = "covid-peak", S = summer 2020, 2 = 2020-2021 winter peak ("2nd wave"). Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

Here, the 11 March 2020 date of the WHO pronouncement of the pandemic is shown as the vertical line, "C" denotes the ACM-by-time feature that we have called the "covid-peak" (Rancourt, 2020) (Rancourt, Baudin, Mercier, 2020), "S" denotes the summer trough in mortality of 2020, and "2" denotes the 2020-2021 winter peak (usually referred to as "2nd wave").

The Canada ACM/w features "C" and "S" (Figure 4) are anomalous in their own right, as follows.

We have already written extensively about “C”, which is our so-called “covid-peak”, observed in many jurisdictions in mid-latitude Northern hemisphere countries (Rancourt, 2020) (Rancourt, Baudin, Mercier, 2020). It is anomalous in that:

- Everywhere that it occurs, it emerges synchronously immediately following the WHO’s 11 March 2020 pronouncement of the pandemic.
- Its initial rise is exceedingly sharp, with a base to inflection-point time of approximately 3 weeks (2 weeks in ACM by day, ACM/d, data for France).
- Such a large and sudden surge virtually never occurs so late in the seasonal cycle (after 11 March, in March, April, May), which is otherwise always a downslope from the mid-winter (January-February) highs.
- It is extremely heterogeneous by jurisdiction in its magnitude, not being present or barely detected in 34 of the 52 USA states, 6 of the 13 regions of metropolitan France, 7 of the 10 provinces of Canada, 18 of the 21 counties of Sweden, and so on, while being disproportionately large in specific jurisdictions such as New York City in the USA, the Paris region in France, Stockholm county in Sweden, and the province of Quebec in Canada.
- Where it occurs, the degree to which it extends late into the season (into May) is variable from jurisdiction to jurisdiction; ending in April 2020 in France, in May 2020 in Canada and the USA.

The Canada ACM/w feature “S” (Figure 4) is anomalous because its mean baseline magnitude (5.25K deaths/w) is anomalously larger than the summer-2019 mean baseline value (5.05K deaths/w), and significantly larger than the magnitude predicted

by the linear summer baseline trend values for the prior years, as can be ascertained from Figure 1.

This means that some net 200 excess deaths per week were occurring in Canada in the summer of 2020, in a season in which VRDs are not active. Below, we show that the main contributor to these excess summer deaths was deaths of young (0-44 years) males, an age where COVID-19 virtually does not cause deaths (Levin et al., 2020), occurring predominantly in Alberta, Ontario and British Columbia. Whereas, the opposite occurs in Canada for the 85+ years age group: The summer-2020 mean baseline magnitude (ACM/w) is significantly smaller than the 2010-2019 trend value for this age group (Figure 6a).

Figures 3a & 3b show the following points regarding the COVID-period:

- Only ON, QC and BC have significant “C”-features (“covid-peaks”). The other seven provinces do not have statistically detectable “C”-features.
- The “C”-feature in the QC data is very strong, intermediate in ON, and relatively weak in BC.
- Whereas AB, MB and SK did not have “C”-features, they have anomalously large “2”-features, compared to their prior winter-season mortalities since 2010, especially AB.

These observations are easier to make in y-scale expanded views of each province:

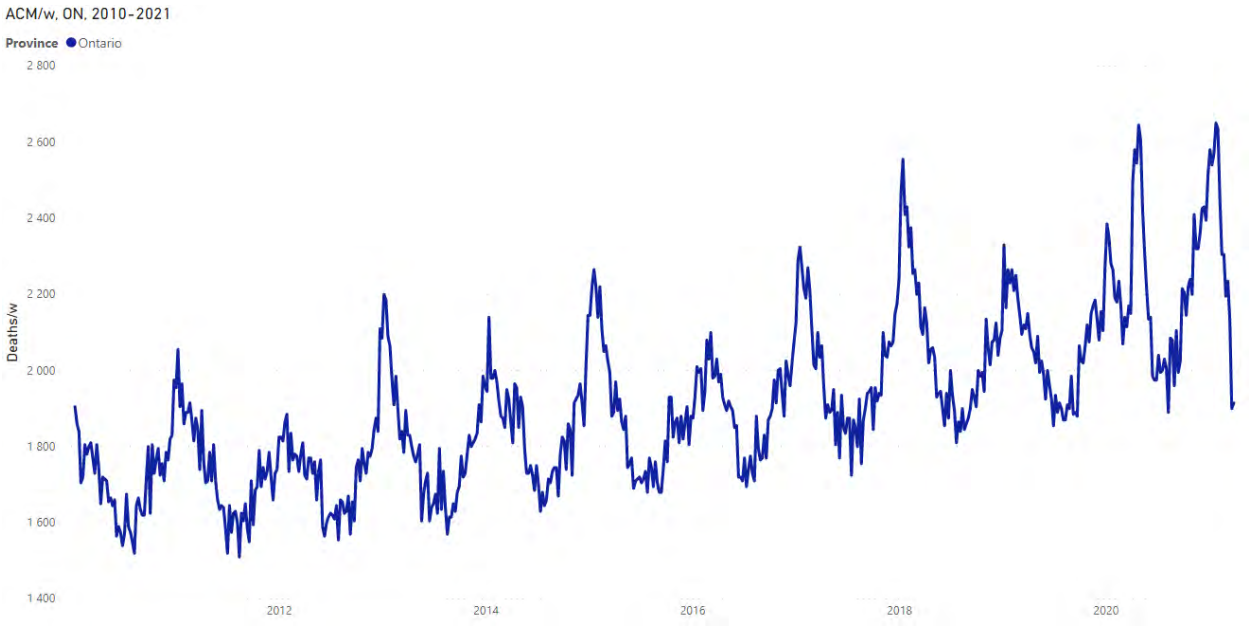

Figure 5-ON: All-cause mortality by week in Ontario from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

Figure 5-QC: All-cause mortality by week in Quebec from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

Figure 5-BC: All-cause mortality by week in British Columbia from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

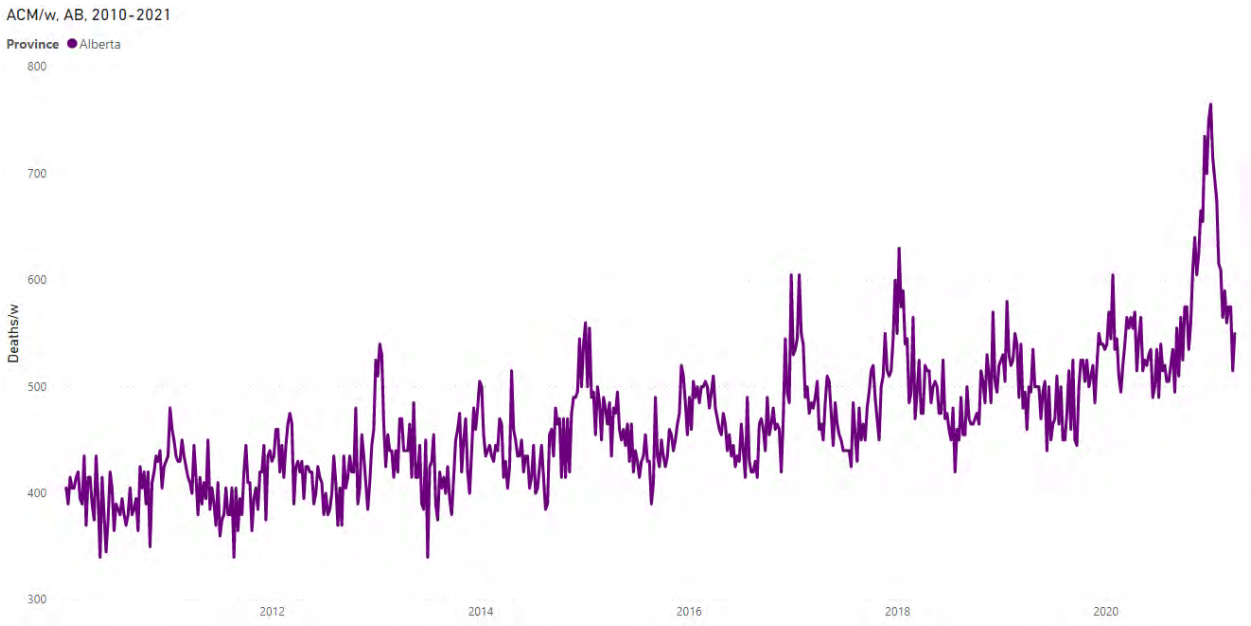

Figure 5-AB: All-cause mortality by week in Alberta from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

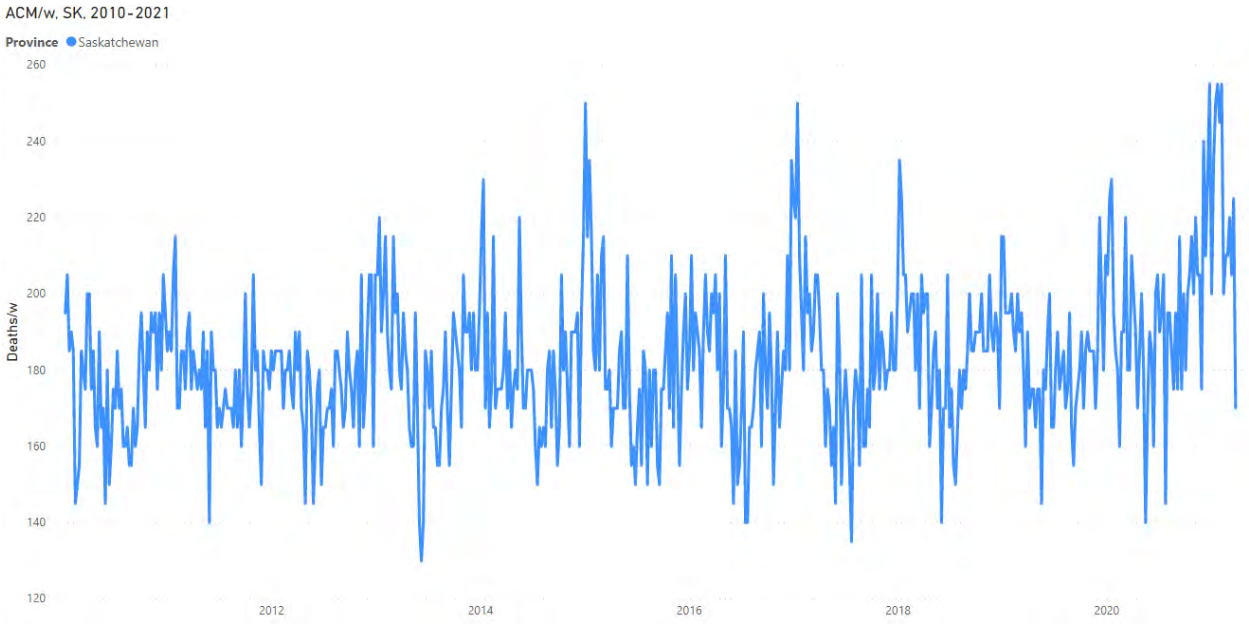

Figure 5-SK: All-cause mortality by week in Saskatchewan from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

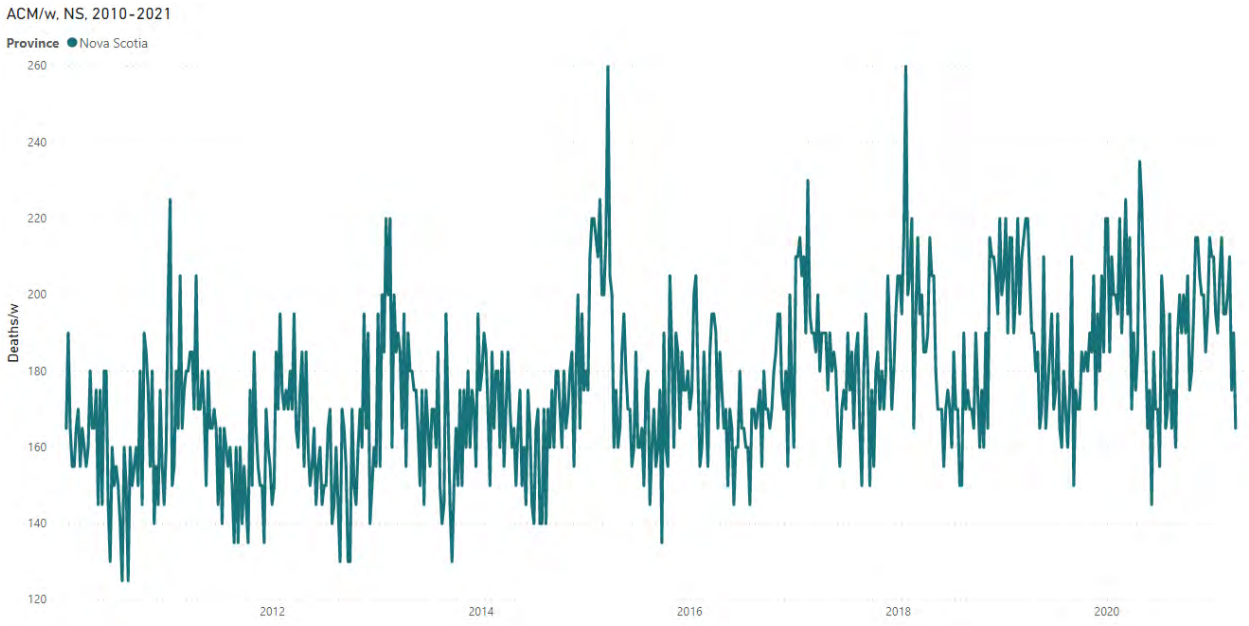

Figure 5-NS: All-cause mortality by week in Nova Scotia from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

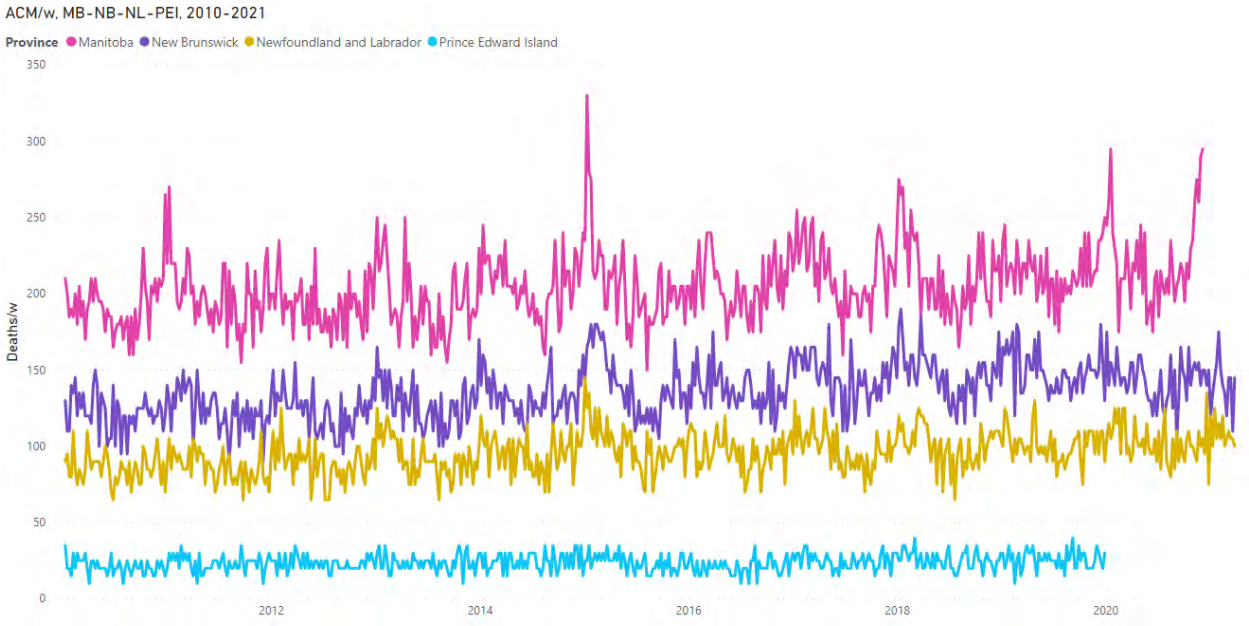

Figure 5-MB-NB-NL-PEI: All-cause mortality by week from 2010 to 2021 for, top to bottom, Manitoba (MB), New Brunswick (NB), Newfoundland and Labrador (NL) and Prince Edward Island (PEI). Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

Most notably:

- The “C”-feature (“covid-peak”) for Quebec is exceptionally large among all provinces. Among other factors, Quebec care-home workers are known to have abandoned their locked-in patients *en masse*, presumably out of fear, even leading to criminal investigations.[2]
- The “C”-feature (“covid-peak”) for Ontario is also unambiguously anomalous, as a large feature of this magnitude and shape this late in the winter-mortality

[2] "Montreal police, coroner investigating owner of seniors' residence where 31 died in less than 1 month" by Colin Harris · CBC News · Posted: Apr 12, 2020 12:56 PM ET | Last Updated: April 13, 2020 (accessed 6 August 2021). https://www.cbc.ca/news/canada/montreal/covid-19-private-seniors-home-dorval-chsld-herron-1.5530327

season. There was also large-scale care-home negligence in Ontario, documented in investigative media articles and a military report.[3]

- The “C”-feature (“covid-peak”) is present for British Columbia, indicating some measures-induced and treatment-induced deaths in care-homes and hospitals, but to a lesser degree than in Ontario and Quebec.
- The “2”-feature (“2nd wave”) is massive in Alberta, which is exceptional among all provinces. The peak is twice as high as any other winter peak for Alberta in the decade 2010-2020. Alberta also has an exceptionally high summer-2020 mortality, relative to its prior-decade trend of summer-trough mean magnitudes.
- Both Ontario and Saskatchewan also have high summer-2020 mortalities, relative to their respective prior-decade trends of summer-trough mean magnitudes, and unusually large “2”-features (“2nd waves”), but not to the degree observed for Alberta.
- Most East coast provinces (NS, NL, PEI, not NB) have small-amplitude seasonal cycles of ACM; and none for which there are data (NS, NL, NB) have ACM/w that exhibits any evidence of a COVID-19 pandemic or disruption, none whatsoever (data is missing for PEI).

[3] "Military report reveals what sector has long known: Ontario's nursing homes are in trouble" by Adam Carter · CBC News · Posted: May 27, 2020 4:00 AM ET | Last Updated: May 27, 2020 (accessed 6 August 2021). https://www.cbc.ca/news/canada/toronto/military-long-term-care-home-report-covid-ontario-1.5585844

3.4 Analysis of ACM/w by age group and by sex

The plots of ACM/w, from January 2010 through March 2021, for Canada, by age group (age at time of death), for the four age groups (0-44, 45-64, 65-84, 85+ years), are as follows.

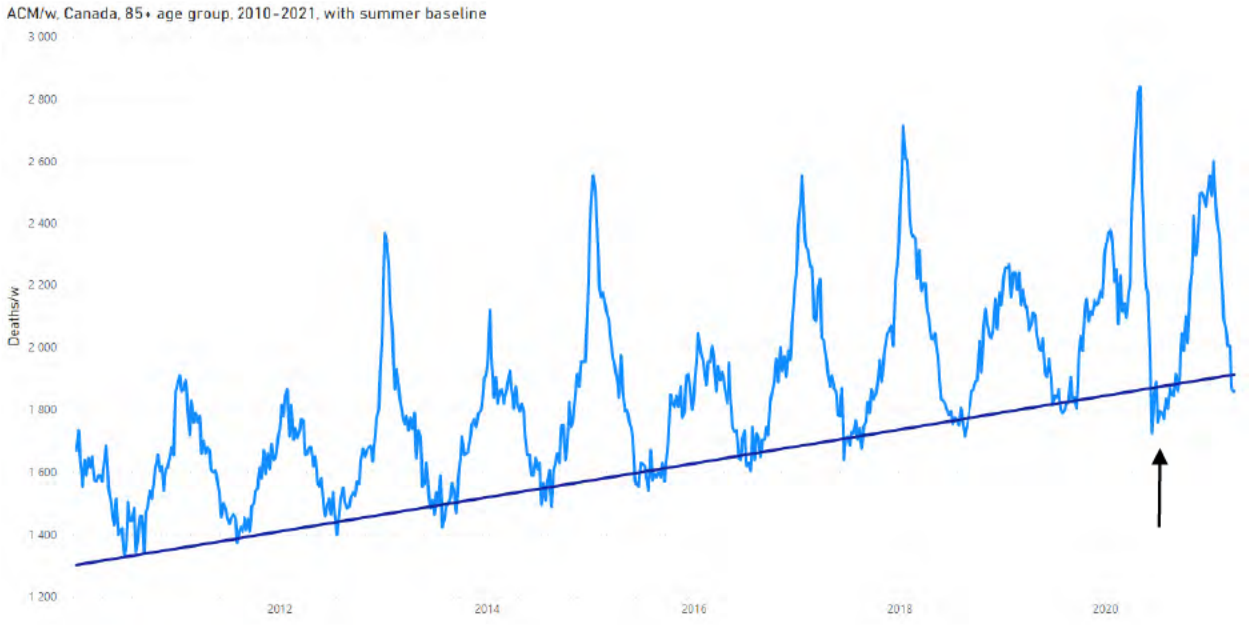

Figure 6a: All-cause mortality by week in Canada for the 85+ years age group, from 2010 to 2021. Data are displayed from January 2010 to March 2021. The linear trend-line is a least-squares fit to the summer troughs for summer-2013 through summer-2019, using the following summer trough weeks: 2013-weeks 24-37, 2014-weeks 28-33, 2015-weeks 25-38, 2016-weeks 24-34, 2017-weeks 24-33, 2018-weeks 27-35, 2019-weeks 26-38. The arrow indicates a feature discussed in the text. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

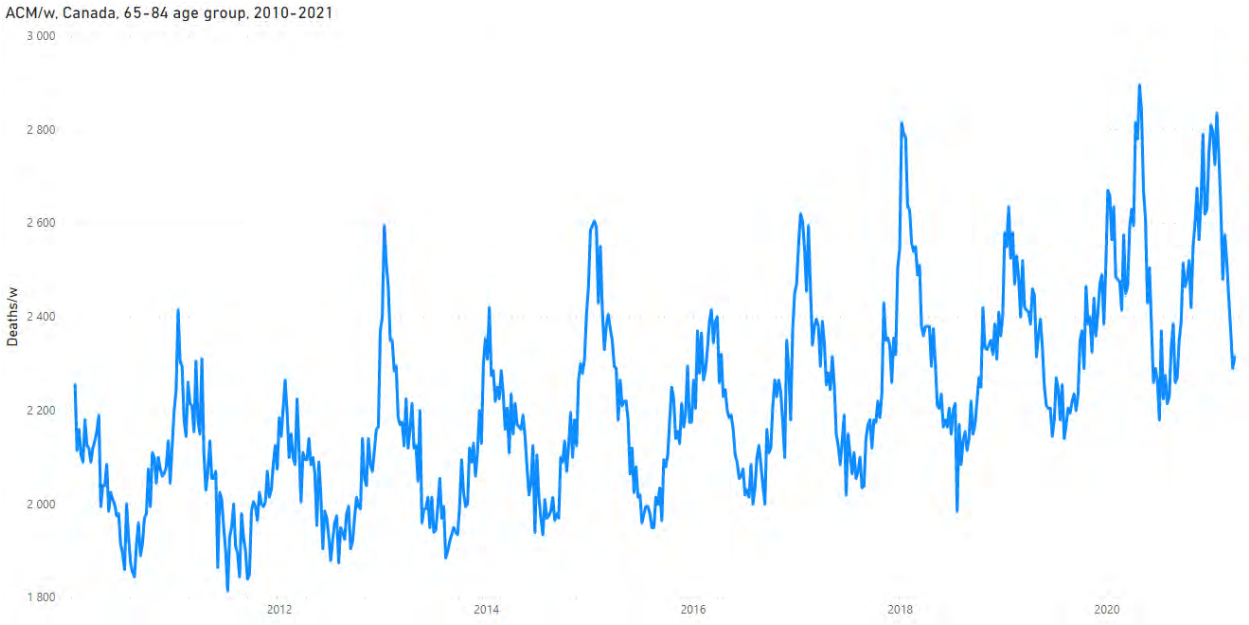

Figure 6b: All-cause mortality by week in Canada for the 65-84 years age group, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

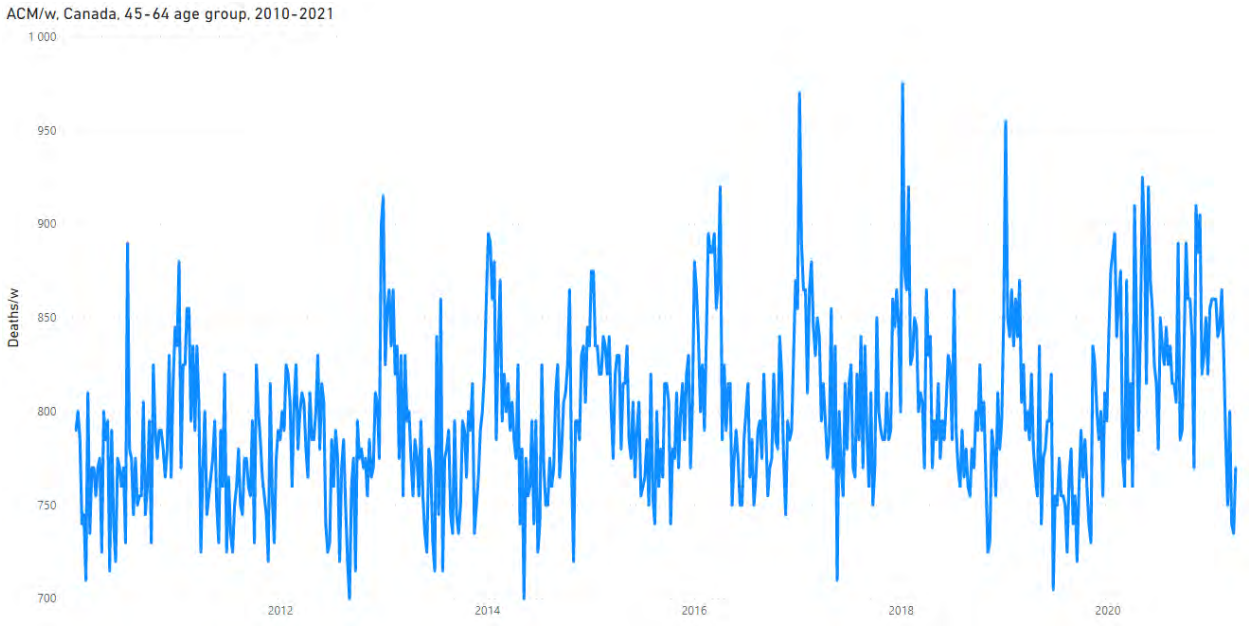

Figure 6c: All-cause mortality by week in Canada for the 45-64 years age group, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

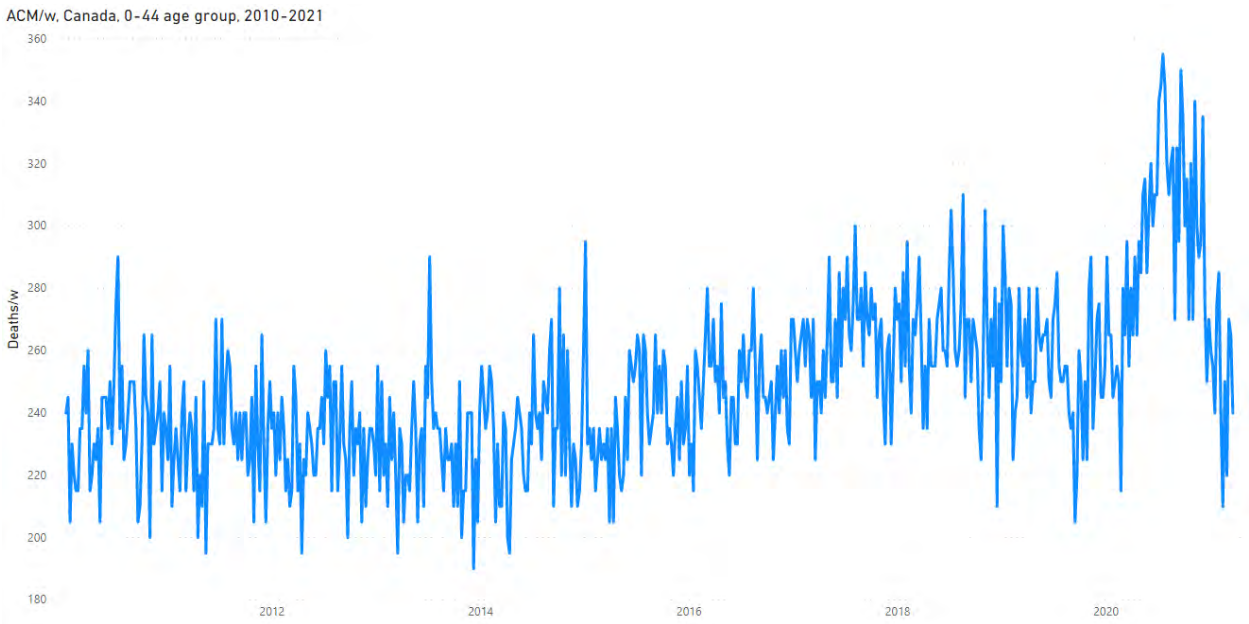

Figure 6d: All-cause mortality by week in Canada for the 0-44 years age group, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

Several observations can be made about the ACM/w data shown in Figures 6a through 6d, as follows:

- The amplitude (summer mean baseline value to winter maximum) of the seasonal variations in ACM/w, normalised by the summer mean baseline value, varies significantly with age, approximately as: near-zero for 0-44 years (no seasonal variation), 20% for 45-64 years, 30% for 65-84 years, and some 60% for 85+ years. The causes of increased winter deaths are more effective in the elderly, and all the more the older one gets.
- The patterns (“fingerprints”) of ACM/w are essentially identical for the 85+ and 65-84 years age groups, prior to the COVID-period (prior to 11 March 2020). See plots of direct comparisons in the Appendix. This suggests that the causes for

increased winter deaths, and their timing, are the same in the two age groups, normally, where only the magnitude for the age group is affected by increased generalized frailty in the most elderly. Stated differently: One age group does not die of different causes than the other, regarding the increased likelihood of death in the winter.

- The latter point, regarding virtually identical intra-season time-structures, for each given season in the two age groups of the most elderly, including in the COVID-period, suggests that the driver of increased winter deaths is synchronized by the same cause(s) for the two age groups, which precludes vitamin deficiency, cancer, heart attacks and strokes, acting alone, but does not preclude weather, sudden societal or economic or institutional changes, sudden geological events, or sudden appearances of high-concentrations of pathogens in the living environments.
- The “C”-feature (“covid-peak”) in the ACM/w of the 85+ years age group (Figure 6a) is anomalous, relative to known ACM by time data of the last many decades for European and North American jurisdictions. Its dramatic drop occurs in a mere 6 weeks (as does its rise), during the weeks of 2 May 2020 to 13 June 2020, to summer-2020 values that are significantly below the linear trend-line for mean summer-trough values for summers 2013 through 2019 (Figure 6a).
- As such, the “S”-feature in the ACM/w of the 85+ years age group (Figure 6a) is equally anomalous. Why would 85+ year olds in Canada become relatively impervious to dying in the summer of 2020, in mid pandemic, between the presumed first and second waves of death? Our interpretation is: The deaths of

many 85+ year olds were artificially accelerated, at a time when seasonal VRD transmission is low, so that their deaths were not spread out into the following summer and fall, as would normally be the case.

- Another large anomaly, which should be considered a national public health catastrophe of historic proportion but is virtually absent from the media and government-official pronouncements, is shown in Figure 6d, for the 0-44 years age group. Here, we see a significant increase in deaths, from a pre-COVID-period plateau value of approximately 260 deaths/w to a summer-2020 value of approximately 320 death/w, lasting at least 28 weeks, into the start of December 2020. The peak corresponds to approximately 2,000 excess deaths in this 0-44 years age group in Canada, following the WHO pronouncement of a pandemic.
- The latter deaths cannot be ascribed to COVID-19 because the presumed disease virtually does not kill in this age group, and there is little transmission of VRDs in summer months. A similar but lesser relative increase in summer-2020 deaths occurs in the 45-64 years age group (Figure 6c).

The COVID-period excess deaths in the younger age groups can be further explored by sex, and by province. Relevant plots of ACM/w are as follows, for the 0-44 years age group, first for Canada, then select provinces.

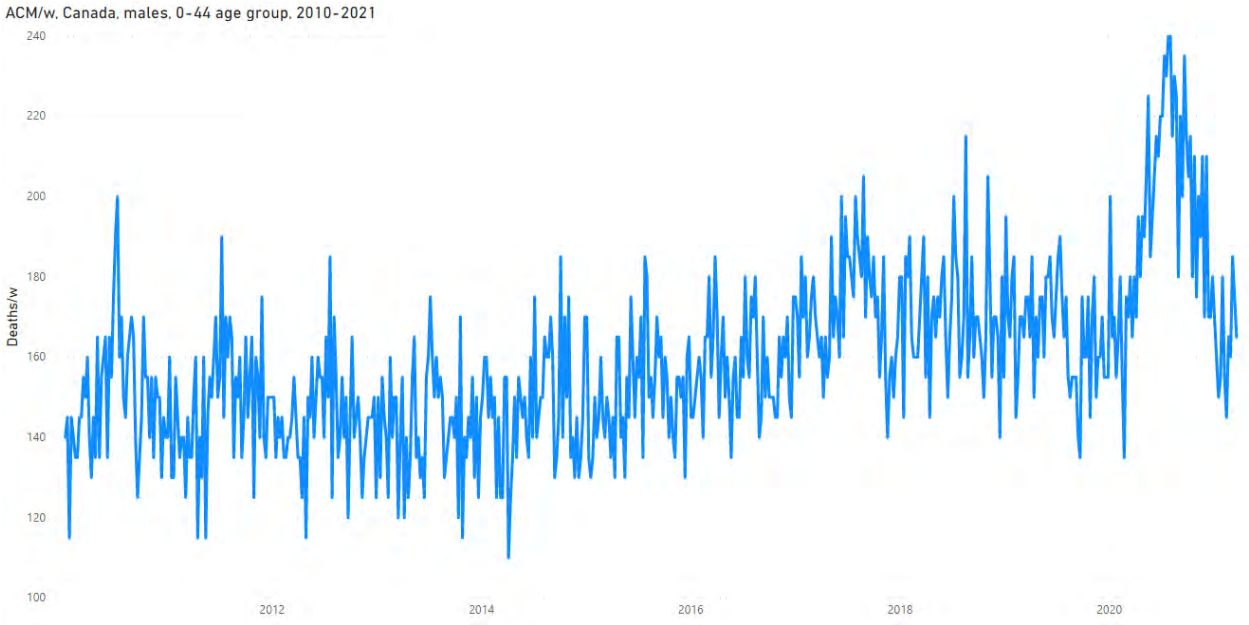

Figure 7a: All-cause mortality by week in Canada for males of the 0-44 years age group, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

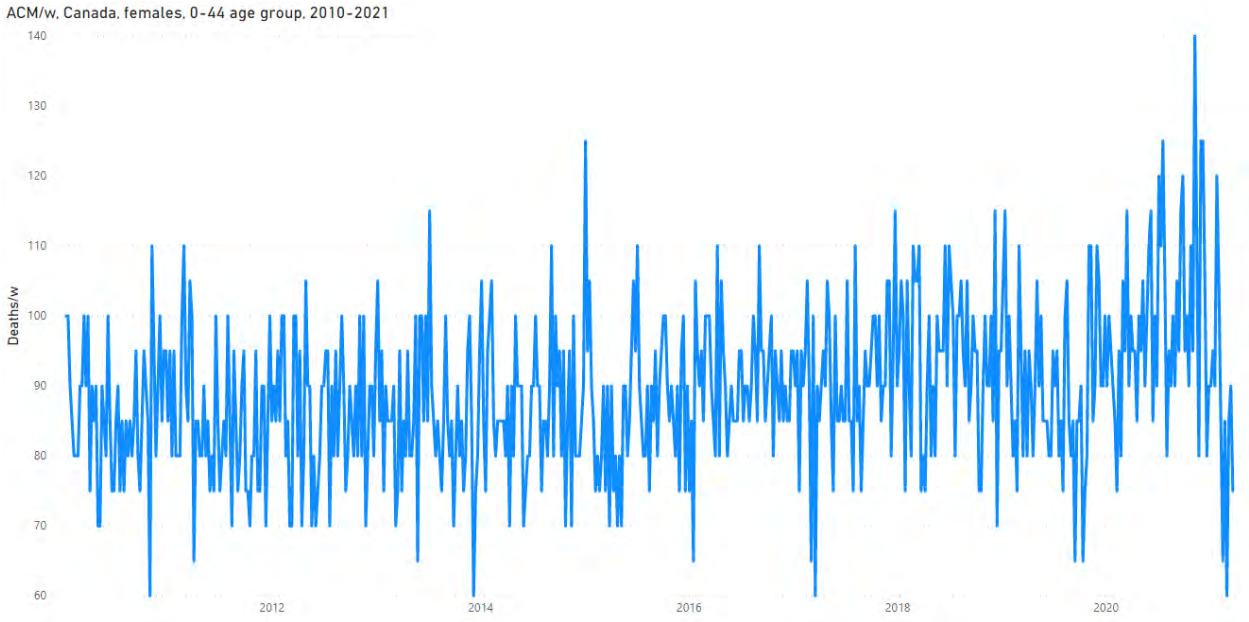

Figure 7b: All-cause mortality by week in Canada for females of the 0-44 years age group, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

Figures 7a & 7b show that, generally in the last decade, young Canadian males are almost twice (approximately 1.7 times) as likely to die of any cause compared to young Canadian females (0-44 years age group).

These figures (Figures 7a & 7b) also show that the excess summer-2020 deaths seen in this age group at the national level (Figure 6d) is almost entirely due to male deaths. This is also true for all the provinces that exhibit this feature in the 0-44 years age group. Virtually only males contribute to these excess deaths.

Next, we examine 0-44 years age group male deaths by province, as follows.

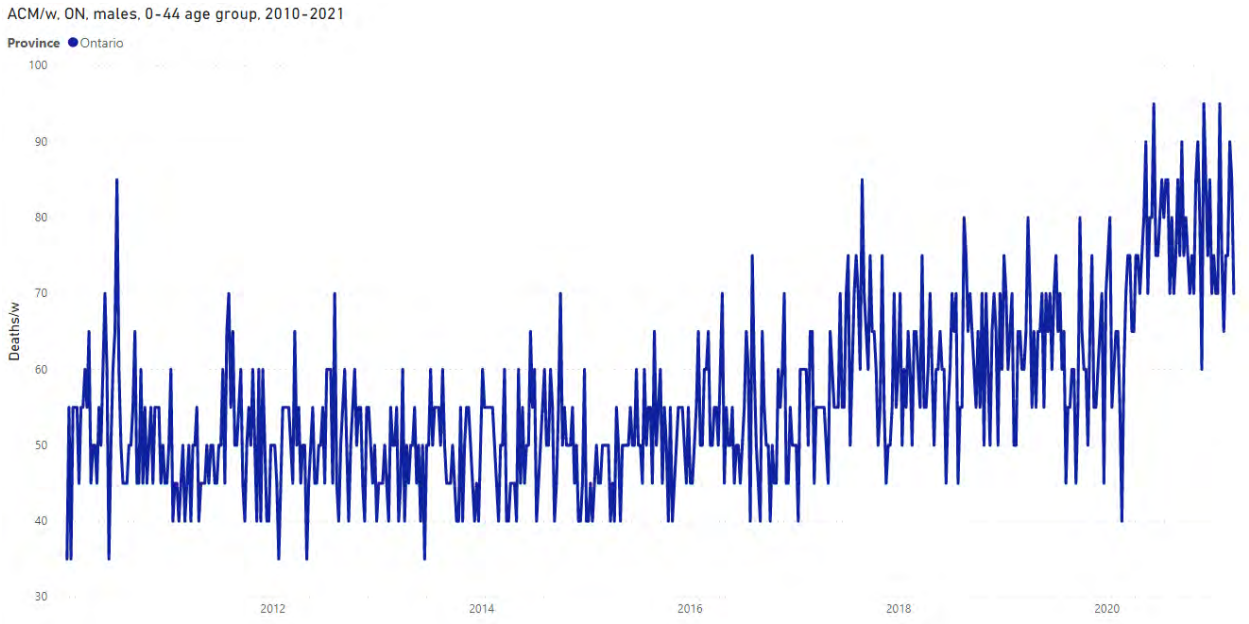

Figure 8-ON: All-cause mortality by week in Ontario for males of the 0-44 years age group, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

Figure 8-QC: All-cause mortality by week in Quebec for males of the 0-44 years age group, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

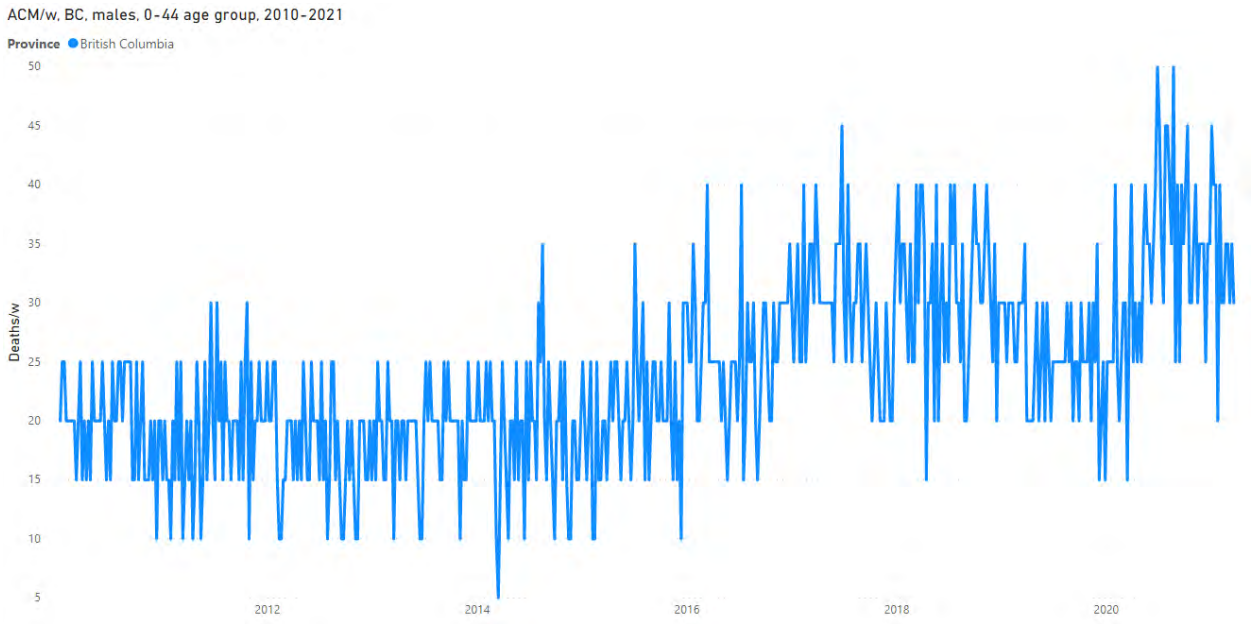

Figure 8-BC: All-cause mortality by week in British Columbia for males of the 0-44 years age group, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

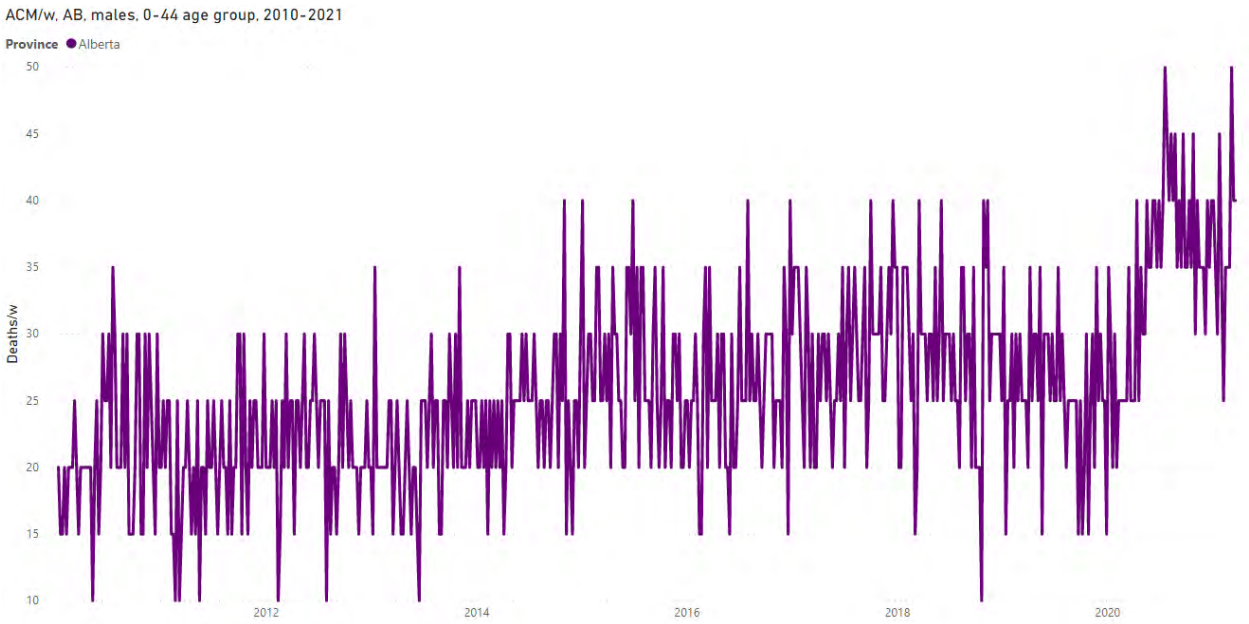

Figure 8-AB: All-cause mortality by week in Alberta for males of the 0-44 years age group, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

Figure 8-SK: All-cause mortality by week in Saskatchewan for males of the 0-44 years age group, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021), as described in section 2.

Thus we see that the phenomenon of excess 0-44 years age group male deaths is present in the large-population provinces, and in Saskatchewan and Manitoba (not shown), but exceptionally not present in Quebec.

Did the presumed SARS-CoV-2 virus decide not to act in this way in the province of Quebec, or is there another explanation? Our interpretation is that the excess deaths in males of the 0-44 years age group arise from the stress of the large-scale and continued societal and economic responses to the declared pandemic, and that the experienced stress in young men is lesser in Quebec because of significant cultural differences with Anglophone provinces, under conditions imposed by all provincial governments.

4. Discussion

4.1 Regarding pandemics

As noted above, the intra-seasonal and inter-seasonal time structures and the jurisdictional homogeneity in ACM by time, up to continental geographical scales for mid-latitudes, in unperturbed societies (unperturbed by sudden changes tied to world wars, or by sudden global “pandemic response” reorganizations), set constraints regarding the possible causes of the seasonal phenomenon having high winter death rates. Precluded causes are: vitamin deficiency, cancer, heart attacks and strokes,

acting alone. Not precluded causes include: weather, sudden societal or economic or institutional changes, sudden geological events, sudden appearances of high-concentrations of pathogens in the living environments, or combinations thereof.

We would argue for “sudden appearances of high-concentrations of pathogens in the living environments”. The stability-in-air of aerosol particles is known to be controlled by absolute humidity in mid-latitudes (e.g., see Rancourt, 2020b, and references therein). We imagine summer background population mixing, and faster dry-season population mixing, of continually arising mutations of pathogens that transmit by suspended aerosols (i.e., the entire ecology of VRD viruses), followed by sudden low-absolute-humidity-induced winter-time increases of concentrations (in the built environment - individual homes to public spaces) of aerosols bearing all such pathogens.

The infections from the multitude of co-acting VRD viruses would be accompanied by an array of opportunistic bacterial co-infections, aided by the dry-air stress on respiratory tract tissues.

We believe that the genome-centered view of single unique viral mutations/variants explaining seasonal structures in ACM by time is too narrow and over-emphasized. The contributions from weather and from the large array of co-acting pathogens must be more relevant than the “particular-special-new-mutation/variant virologist’s view”, otherwise pandemics would be observed in ACM by time data, and they are not.

Simply put, the pandemic paradigm is a beautiful theory, which is greatly pleasing to the genome jockeys, but it is not supported by hard epidemiological data, and it has a great potential to cloud public health thinking by directing focus on a presumed pathogen-specific disease rather than identifying and addressing all the important aspects of a health crisis or chronic-disease circumstances.

In Canada at least, in the present article we have shown that no additional yearly or seasonal integrated mortality occurs in the COVID-period (Figures 1 & 2). There was no COVID-19 pandemic in Canada, which can be detected in ACM by time. It would be a fantasy to believe that Canada avoided the COVID-19 pandemic deaths by its hurried, differing and unproven pandemic response, such as to exactly bring the resulting net yearly and seasonal mortalities in line with the trend of the last decade (Figure 2).

4.2 Regarding the “C”-feature (“covid-peak”) in ACM by time

The occurrence of dramatic jurisdiction-to-jurisdiction differences (jurisdictional heterogeneity) in the magnitude (relative to summer baseline) of the “C”-feature (“covid-peak”) in ACM/w by province in Canada is diametrically opposite to all pre-COVID-period ACM by time data that we have examined for many jurisdictions (countries, regions, provinces, counties) in North America and Europe, over the many decades of available data.

Whereas pre-COVID-period integrated winter-burden mortalities (above linear summer baseline trends), normalized by mean summer baseline mortality or by jurisdictional population, are always relatively constant between jurisdictions, the “covid-peak” feature varies widely between jurisdictions in a given country, or between countries, often being undetectable or borderline detectable, versus extreme “hot spot” jurisdictions.

For France, we calculate that, on the basis of region-level jurisdictional divisions, the standard deviation of the “covid-peak” integrated magnitude normalized by population divided by the mean (s.d./mean) is 3-fold greater than the standard deviation for integrated winter-burden magnitude (integrated above the linear trend of summer-trough minimums) normalized by population divided by the mean (s.d./mean) (article in preparation).

We argue that such jurisdictional heterogeneity cannot be due to a VRD epidemic in an unperturbed society, because such a phenomenon has never previously occurred in the many decades since reliable data is available for many jurisdictions. Only an unusually large perturbation of the society can produce such a phenomenon.

We believe that it is not a coincidence that all the “covid-peaks” — in jurisdictions where they occur on both continents — started their sharp and sudden surges immediately (within 1 week or so) after the WHO’s 11 March 2020 pronouncement of a pandemic. We believe that viruses did not suddenly everywhere act on cue in response to the

WHO memo, in those jurisdictions where the “covid-peak” feature occurs in ACM by time.

4.3 Regarding the summer-2020 level and the “2”-feature (“2nd wave”) in ACM by time

By-province heterogeneity is also present in the summer-2020 level and in the “2”-feature (“2nd wave”) in the COVID-period of ACM/w in Canada (esp. for Alberta, Figure 5-AB).

It is unlikely that a same pandemic-causing virus acted alone to produce significant excess deaths in the summer-2020 period, relative to the linear trend of summer baseline values, irrespective of the magnitude of the preceding “covid-peak”: Ontario (Figure 5-ON), British Columbia (Figure 5-BC) and Alberta (Figure 5-AB), but not noticeably in Quebec (Figure 5-QC), for instance.

It is possible that the excess deaths in the summer-2020 period were induced by the societal disruption of the pandemic response (more below), without being associated with any VRD, except secondarily *via* the so-called “dry tinder” effect following a large “covid-peak”.

More strikingly, the “2”-feature (“2nd wave”) peak for Alberta is massive, compared to any other province, whereas no noticeable “covid-peak” occurs in this province (Figure 5-AB). A pandemic-causing virus cannot decide not to produce a “1st wave” but only a “2nd wave” in one province of a continuously connected country having similar provincial populations. Nothing like this has ever been observed, to our knowledge.

We argue that the “2”-feature (“2nd wave”) peak, occurring during a winter-season of expected increased mortality, has varying province-wise magnitudes because of the province to province differences in pandemic response, and province to province differences in population resilience against the stress of the imposed measures.

In short, like with the “covid-peak”, such jurisdictional heterogeneity cannot be the result of the genome of a particular viral pathogen. Such epidemiological heterogeneity of presumed VRD mortality has not previously been observed in North America or Europe in many decades of reliable ACM by time data. VRD viruses of any mutation or variety do not recognize jurisdictional boundaries and do not act so widely differently on similar populations on continuous territories. The large features of the ACM by time data for the COVID-period can only be explained by appealing to additional causal factors beyond the limited purview of virology.

4.4 Regarding age group specifics in ACM by time

The ACM/w in Canada for the 85+ years age group (Figure 6a) allowed us to partly unravel the complex and unusual behaviour of mortality in the COVID-period. As mentioned above, the sharp drop in its “covid-peak” connects to a summer-2020 having anomalously small mortality for this age group (Figure 6a).

This is all the more surprising in that the summer-2020 mortality for all age groups is anomalously large (Figure 1). Cumulatively, all ages have an anomalously large summer-2020 mortality, whereas the 85+ years age group has an anomalously small summer-2020 mortality. Mortality of younger Canadians increased, in a season that does not normally carry many VRD infections, whereas less mortality occurred for the most aged Canadians.

In the ACM/w data for the 85+ years age group (Figure 6a), the “covid-peak” followed by an anomalously small summer-2020 mortality, may be a most compelling example of the so-called “dry tinder” effect, in which successive winter-season mortalities are argued to be anti-correlated because a harsh winter leaves fewer frail elderly to die in the following winter. Whereas this postulated winter-to-winter anti-correlation is not easily discerned, except in earlier times when mortalities were larger (see mid-1940s to mid-1950s for France, Figure 1 of Rancourt, Baudin, Mercier, 2020), here (Figure 6a) we demonstrate the effect, within an exceptional year, in current times.

Finally, there is the anomalous mass mortality of young males in Canada, especially in Alberta but not in Quebec, in summer-2020 and into the fall (Figure 7, all parts). This ignored and silent epidemic is most likely not due to any VRD, and merits an independent investigation in its own right.

4.5 Regarding causes of response-induced deaths

We seek to describe plausible mechanisms whereby sudden disruptions in society can induce deaths, or reduce deaths at later times, without necessarily significantly changing the yearly or seasonal death burden compared to a decadal trend, following (Rancourt, 2020) (Rancourt, Baudin, Mercier, 2020).

We propose that there are three large categories of such plausible mechanisms:

- Medical response, treatment and palliative protocols, adopted at the onset of the proclaimed and media-hyped pandemic.
- Pandemic response, public health measures, institutional protocols (esp. schools, care homes, and hospitals), economic upheaval, lockdowns, curfews, self-quarantine, etc.
- Policies of denial of medical treatment, such as refusal to admit elderly persons into hospital care, or transfers of patients out of hospital care.

In France, for example, as in many other countries, starting in March 2020 there were tremendous social and medical disruptions, not planned or previously applied. The national lockdown in-effect was a “stay-at-home” order, including not visiting the family physician, and to call the emergency services only in cases of breathing difficulty, which was by itself a dangerous recommendation as people presenting those symptoms were usually already in a late stage of disease, often admitted to hospital directly into the intensive care unit. This reckless protocol directed by health authorities concerned not only COVID-19, but generally all medical conditions since people were asked to stay at home, to not visit their general practitioners, nor to show up at hospitals (to avoid an unmanageable institutional burden). Another statement from the health authorities was that no treatment exists for COVID-19: people were told to take *Doliprane*® (acetaminophen) in case of symptoms; and healthcare professionals were denied using or attempting any medical protocol. This caused abandonment of medical care by the general population and by healthcare professionals, following the official recommendations. The official recommendations thereby may have promoted excessive and dangerous self-medication with over-the-counter substances such as *Doliprane*® and analogous drugs. Signatures of the unprecedented perturbation in the healthcare system include changes in specific drug usage and consumption in 2020, such as significant drops in the use of antibiotics and significant increases in the use of psychoactive drugs (Chaillot, 2020) (and our article in preparation). One specific example is the *Rivotril*® drug (clonazepam) in its injectable form, which by decree[4] could exceptionally by used from 23 March to 15 April 2020 without marketing authorization to

[4] Décret N° 2020-293 Du 23 Mars 2020 Prescrivant Les Mesures Générales Nécessaires Pour Faire Face à l’épidémie de Covid-19 Dans Le Cadre de l’état d’urgence Sanitaire.; 2020. https://www.legifrance.gouv.fr/loda/id/LEGIARTI000041767762/2020-03-29/

terminate patients affected or likely to be affected by SARS-CoV-2 if their health status justified it, and which showed an increase of more than 200% in April 2020 compared to the mean over January 2017 to February 2020 (Chaillot, 2020).

In the USA, the early over-use of mechanical ventilators is a well-studied aspect of deadly COVID-19 medical responses (Richardson et al., 2020).

In addition, and in Canada, the unprecedented strict mass quarantine and isolation of both sick and healthy elderly people, together and separately, would have caused the deaths of many of them, and is probably a main cause of the “covid-peak” event in Canada, where a great majority of COVID-19-assigned deaths occurred in care homes for the elderly (Clarke, 2021):

> During the first wave of the pandemic (March through August 2020), residents of nursing and seniors’ homes accounted for more than 80% of all reported COVID-19 deaths (ref). […] By mid-December (partway through the second wave that lasted from September 2020 through February 2021), there were about 44,000 cases and 9,200 deaths in nursing and seniors’ homes (ref). As of early March 2021, reports indicated that nursing and seniors’ homes continued to account for the greatest proportion of outbreak-related cases and deaths, representing about 7% of all cases and more than 50% of all deaths (refs).

By the said mass quarantine in care homes and establishments, Canadian provincial institutions isolated vulnerable elderly persons from their families, limited movements within establishments, often confining individuals to their rooms or beds for days and

weeks if not months, reduced the staff and allowed staff to be absent, forced staff to adopt extreme measures such as masks, shields and gloves, which can induce a measure of fear or terror, created a general atmosphere of danger, and prevented air circulation by locking doors and windows, and by preventing ingoing and outgoing traffic except for essential services (Campbell, 2020; Comas-Herrera, Fernandez, *et al.*, 2020; Wu, 2020).

This would have both: retained the pathogen-bearing aerosol particles suspended in the air without their evacuation (Morawska and Milton, 2020); and induced psychological stress in the residents.

Psychological stress is known:

i. to be a major factor causing diseases, including immune response dysfunction, depression, cardiovascular disease and cancer (Cohen, Janicki-Deverts and Miller, 2007),
ii. to be a dominant factor in making an individual susceptible to viral respiratory diseases, in terms of intensity of the infection (Cohen, Tyrrell and Smith, 1991), and
iii. to have more deleterious effects in elderly persons than in younger persons (Prenderville *et al.*, 2015).

Furthermore, social isolation itself, in addition to individual psychological stress, is known to have an added impact on the said susceptibility to viral respiratory disease (Cohen *et al.*, 1997).

Furthermore, there is a longer term “abandonment of life” phenomenon that occurs with imposed extended isolations of elderly persons, the so-called “*glissement*” syndrome (or “slipping away syndrome” or “geriatric failure to thrive”), which is analogous to depression (Robertson and Montagnini, 2004; Clegg *et al.*, 2013; Steptoe *et al.*, 2013; Ong, Uchino and Wethington, 2016).

The suddenly applied national policy of forced quarantine and the psychological stress it generated on fragile elderly people would have been a contributor in the decrease of efficiency of immune system response to a viral respiratory disease (Comas-Herrera, Zalakaín, *et al.*, 2020) and this is a probable explanation for much of the mortality in the “covid-peak” and in the “2nd wave”. The same mechanism would operate in any setting (facility, group home, home, hospital) where persons with health vulnerabilities are isolated and susceptible to psychological stress.

Whereas care homes are institutional environments that are extremely susceptible to epidemics, whereas VRD epidemics in care homes are common and this is well known (Utsumi et al., 2010), and whereas the best recommendation to prevent the spread of a VRD epidemic in a care home is vigilant and early diagnosis of cases of clinically ill infected individuals followed by rapid effective treatment and isolation/distancing of

those individuals (Loeb et al., 2000) (Bowles et al., 2003), therefore it is important to note that the opposite was done in Canadian care homes: no surveillance for emergent clinical infections, no treatment or search for treatment, no targeted removal/distancing or isolation of the clinically ill infected individuals, and universal lockdown of all residents. Even antibiotic treatment of bacterial co-infections may have been in-effect denied, as appears to have been the case in France (as mentioned above).

Rancourt recently summarized the situation this way:[5]

> The mechanism that made care homes and institutions for sick and elderly persons into killing fields includes the following elements (refs):
>
> - infection seeding by hospital transfers into the care homes
> - universal lockdowns of the care homes
> - denied specialized medical treatment to the residents of the care homes
> - reduced staffing and staff abandonment in the care homes, and negligence
> - collateral effects of the universal lockdown of the care homes: extreme social isolation, psychological stress, reduced aerosol-exhaust ventilation, lost oversight of the institutions by family-members

We can add the use of *Rivotril*® (in France), which would have terminated some elderly patients with breathing difficulties, and other changes in treatment practices (see above).

[5] "The Great VIRAL Debate: Dr Rancourt's Closing Statement" by Denis Rancourt, *Off-Guardian* (10 November 2020) (Accessed on 6 August 2021). https://off-guardian.org/2020/11/10/the-great-viral-debate-dr-rancourts-closing-statement/

4.6 Would there have been fewer deaths?

Although we have shown that there was no pandemic, nonetheless, there are year to year variations in mortality in non-pandemic years, and a valid question remains: Would fewer immediate and later deaths have resulted in the absence of the pandemic response?

We conclude that the answer is “yes”. The “covid-peak” was palpably induced by the pandemic response, at a time in the long-term seasonal cycle when there is always a decline in ACM by time. It was followed by an anomalously small mortality for the 85+ years age group, showing that deaths were accelerated in this age group. Likewise, the mortality of young males (0-44 years) has a large increase in the summer-2020, and into the fall, a phenomenon never before seen, which cannot be due to a VRD pathogen.

5. Concluding comments: Missing self-evaluation

We proved that there was no pandemic in the COVID-period in Canada, if the concept of a pandemic means anything. We showed strong evidence that the pandemic response was so aggressive and ill-advised as to have large negative health consequences, identified in ACM by time.

Although there was no pandemic, our analysis of the ACM by time data suggests that the pandemic response in Canada was a reckless and deadly fiasco. Had there been a particularly virulent pathogen, this level of government and institutional negligence, based on the international trend in attitudes and on political motives, would not have been possible.

There is no concrete evidence that the provincial and federal governments have learned any lesson from what was a massive public health blunder. On the contrary, there is every sign that governments continue to have a siloed approach based entirely on vaccine programs and ineffective personal hygiene regulations, while ignoring the science relevant to what actually occurred in Canadian care homes, and while avoiding strategies to start to address what actually occurred, and is occurring.

A first and immediate step should be to trash the pandemic-response methods that were implemented after the WHO's declaration of a pandemic, and to develop expertise-based national skepticism about such declarations and their accompanying recommendations.

We hope that our analysis will be useful to public health policy reviewers, and that the needed serious in-depth critical review of the government and medical responses will be undertaken, one way or another. We further hope that this will be done with transparency and accountability, and that it will include broad consultations.

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Appendix: ACM/w normalized by population, and comparisons

In this appendix, we show various plots of ACM/w, normalized by population, and various plots comparing ACM/w data, by province, and by age group.

Statistics Canada (StatCan) is the national statistical office of the country. The all-cause mortality (ACM) and the population (pop) data used in this appendix were retrieved from the StatCan database. The following table shows the characteristics of the data:

Data	**Geography**	**Period**	**Frequency**	**Source**
ACM	Canada Province Territory	2010-2021*	Weekly	StatCan, 2021
Population	Canada Province Territory	1971-2020	Annual	StatCan, 2020

* At the date of access, data were available from week-1 of 2010 (beginning of January) to week-17 of 2021 (end of April). In the following figures, we show the data until week-12 of 2021 (end of March), because the data are not consolidated in later weeks, which gives a large artifact (anomalous drop in mortality).

Moreover, data can be retrieved by sex (males/females) or by age group. For the population data, the age groups are year by year from 0 to 99 years-old, and the last group is 100 years-old and over. For the ACM data, the age groups are as follows:

- 0-44 years-old
- 45-64 years-old
- 65-84 years-old
- 85 years-old and over

The population is estimated on July 1st of each year. The ACM/w of one calendar year has been normalized by the population of that calendar year (ACM/pop/w). The only exception is the year 2021, as there are no population estimates for that year, the ACM/w has been normalized by the population estimates for 2020.

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Appendix Figures

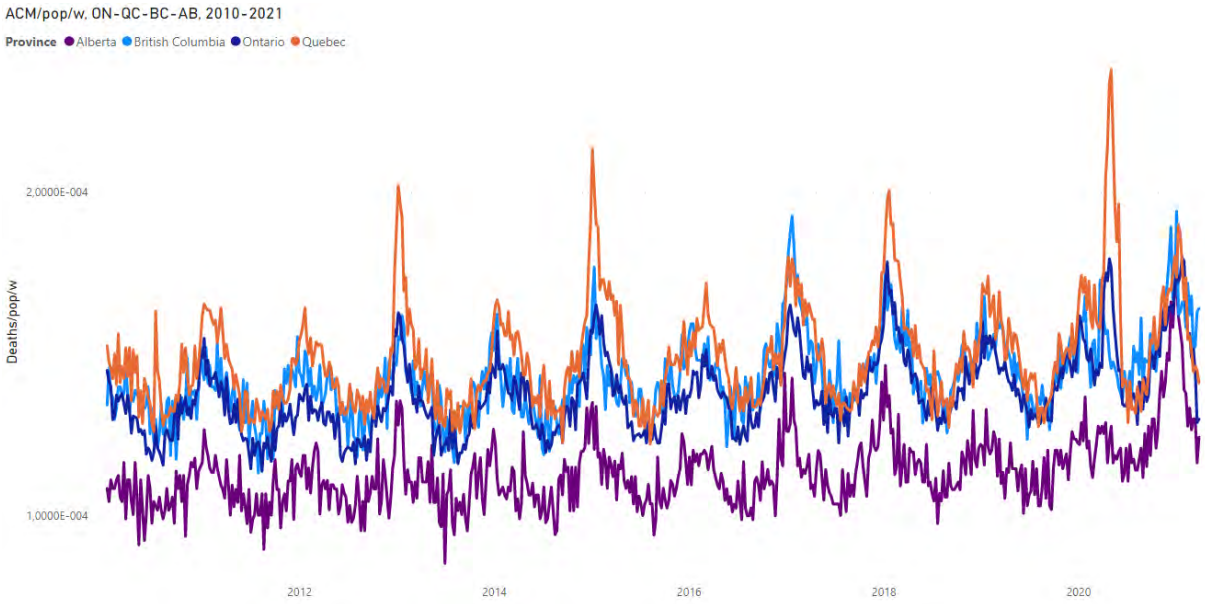

Figure A1: All-cause mortality by population by week in Ontario, Quebec, British Columbia and Alberta from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

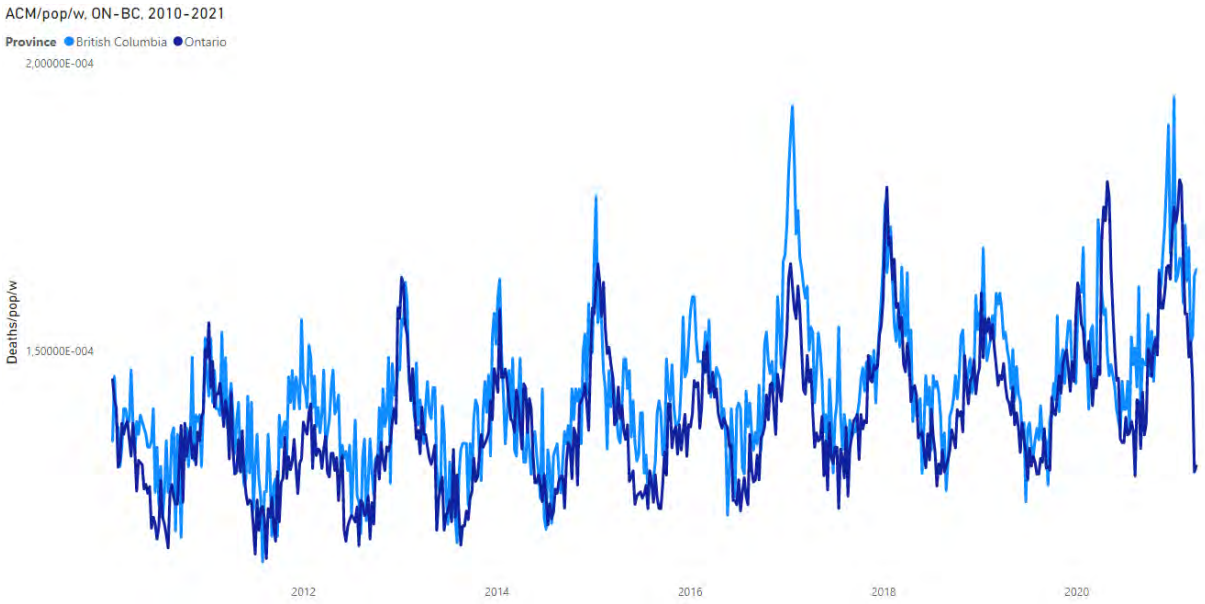

Figure A2: All-cause mortality by population by week in Ontario and British Columbia from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

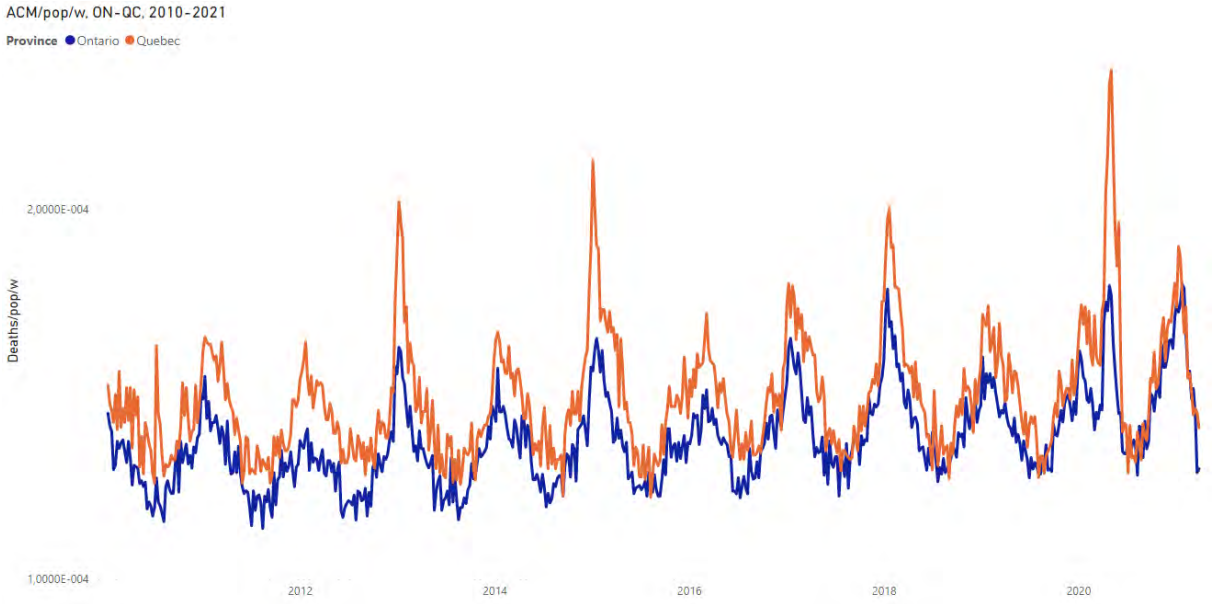

Figure A3: All-cause mortality by population by week in Ontario and Quebec from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

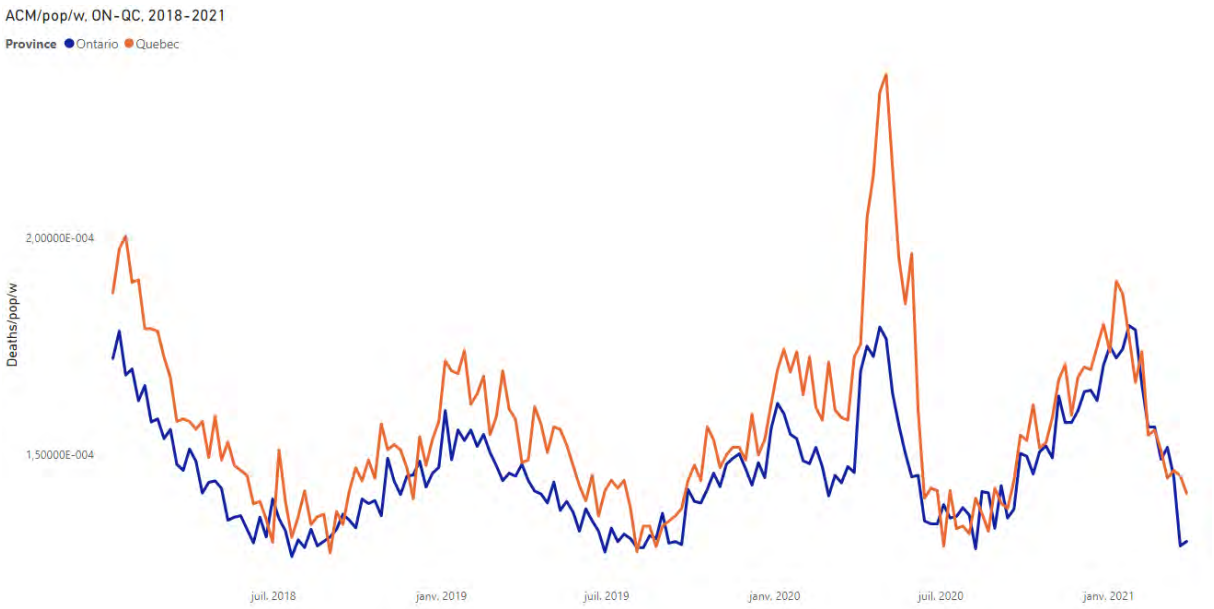

Figure A4: All-cause mortality by population by week in Ontario and Quebec from 2018 to 2021. Data are displayed from January 2018 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

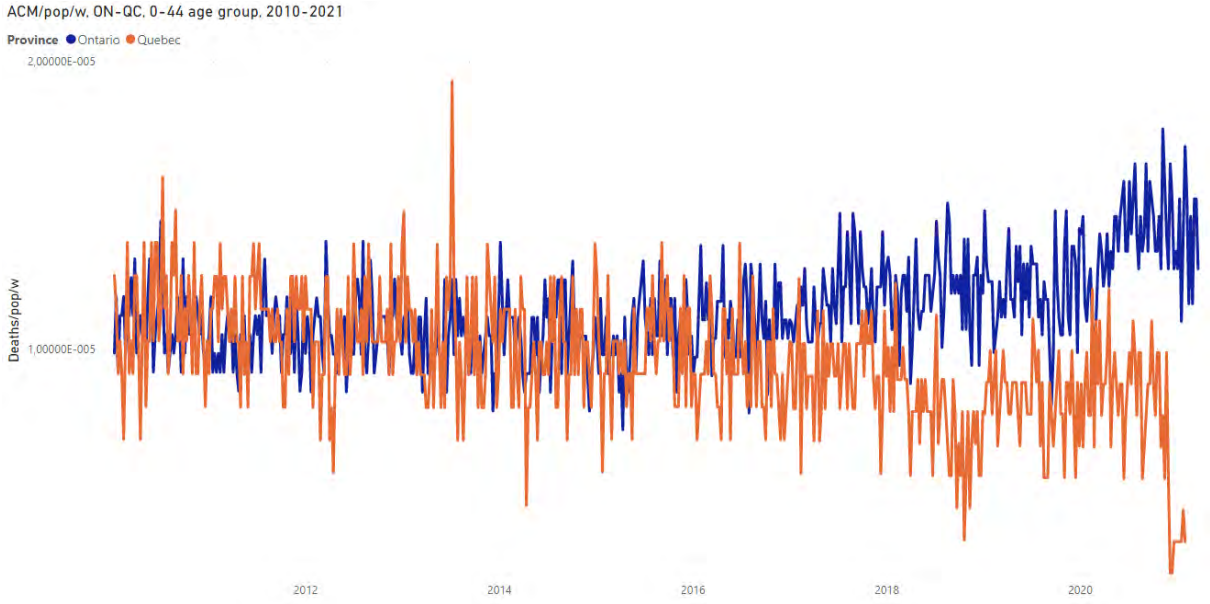

Figure A5: All-cause mortality by population by week in Ontario and Quebec for the 0-44 age group, both sexes, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

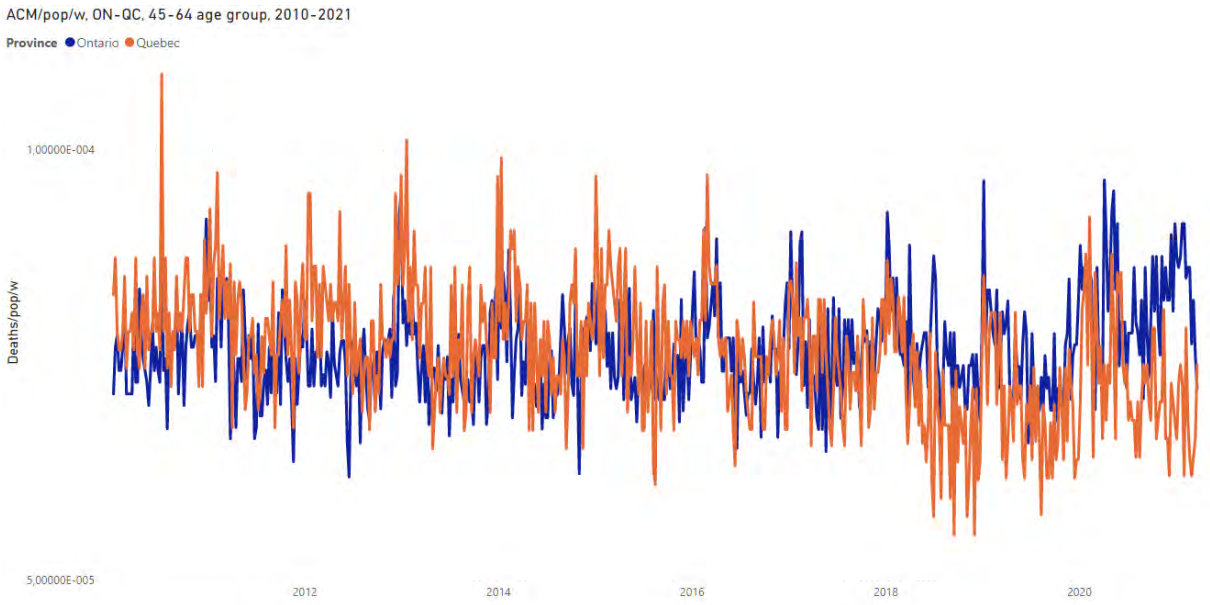

Figure A6: All-cause mortality by population by week in Ontario and Quebec for the 45-64 age group, both sexes, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

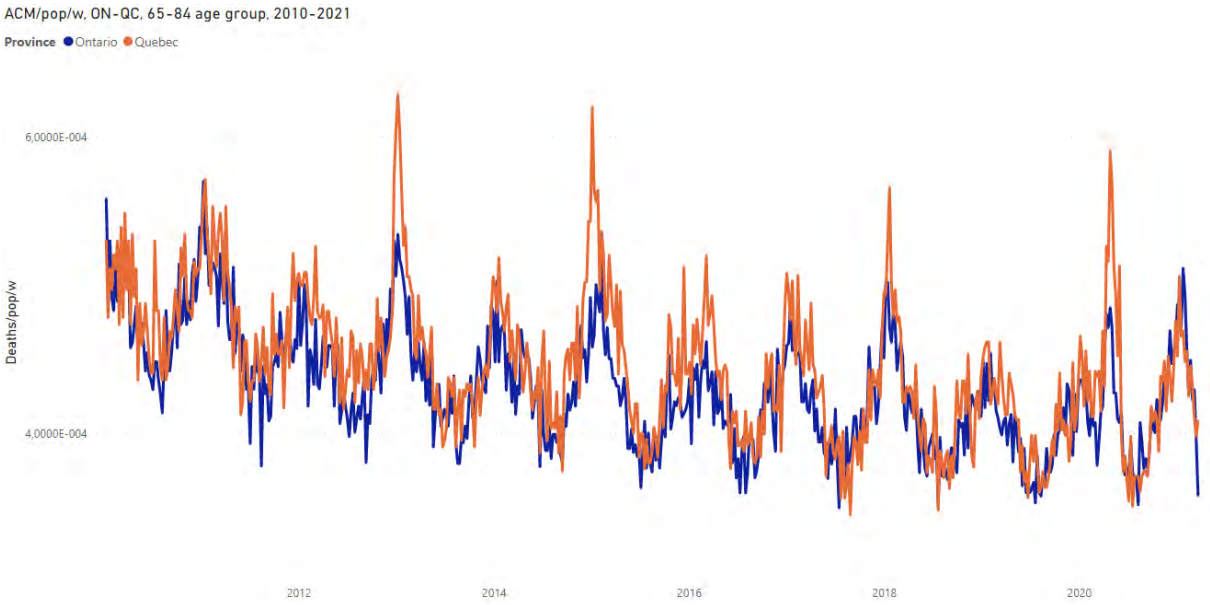

Figure A7: All-cause mortality by population by week in Ontario and Quebec for the 65-84 age group, both sexes, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

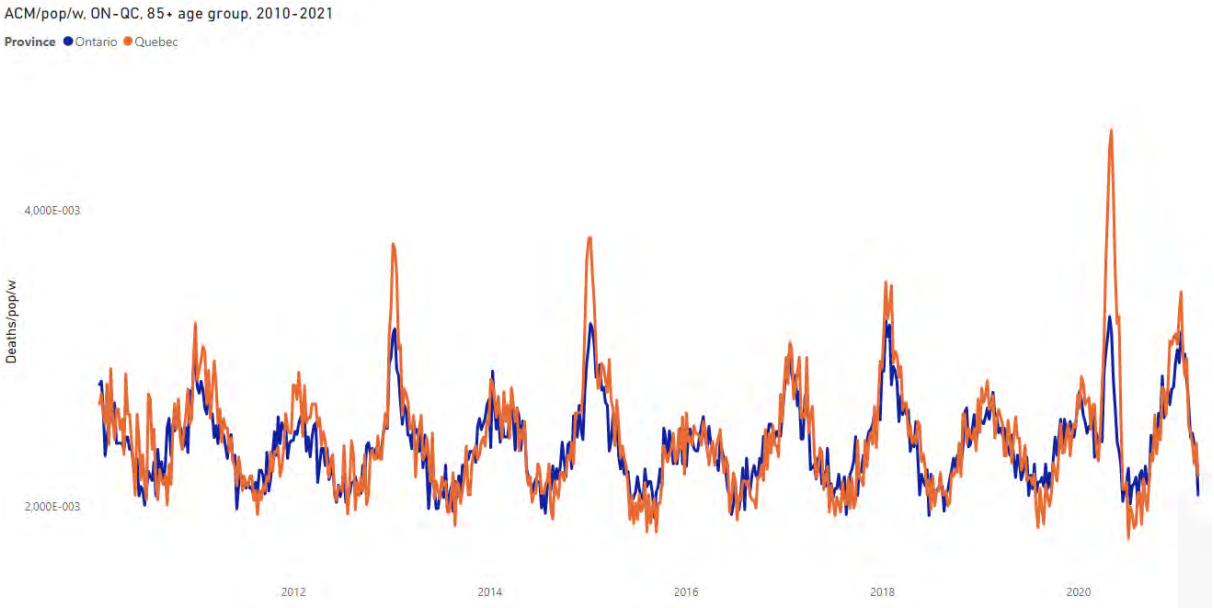

Figure A8: All-cause mortality by population by week in Ontario and Quebec for the 85+ age group, both sexes, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

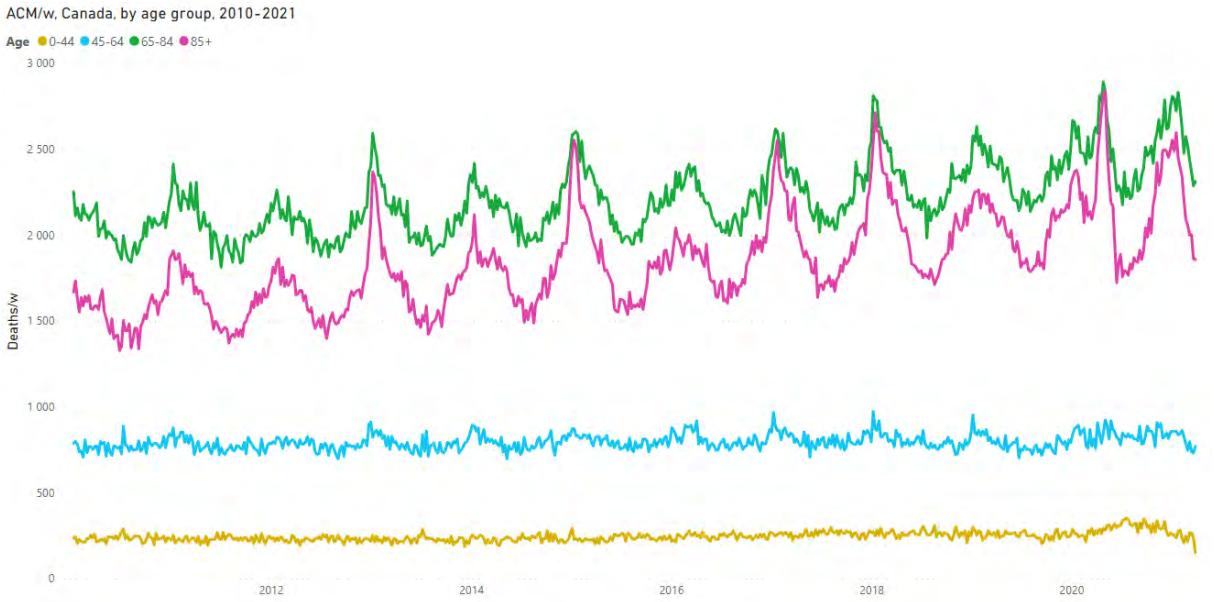

Figure A9: All-cause mortality by week in Canada by age group, both sexes, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021).

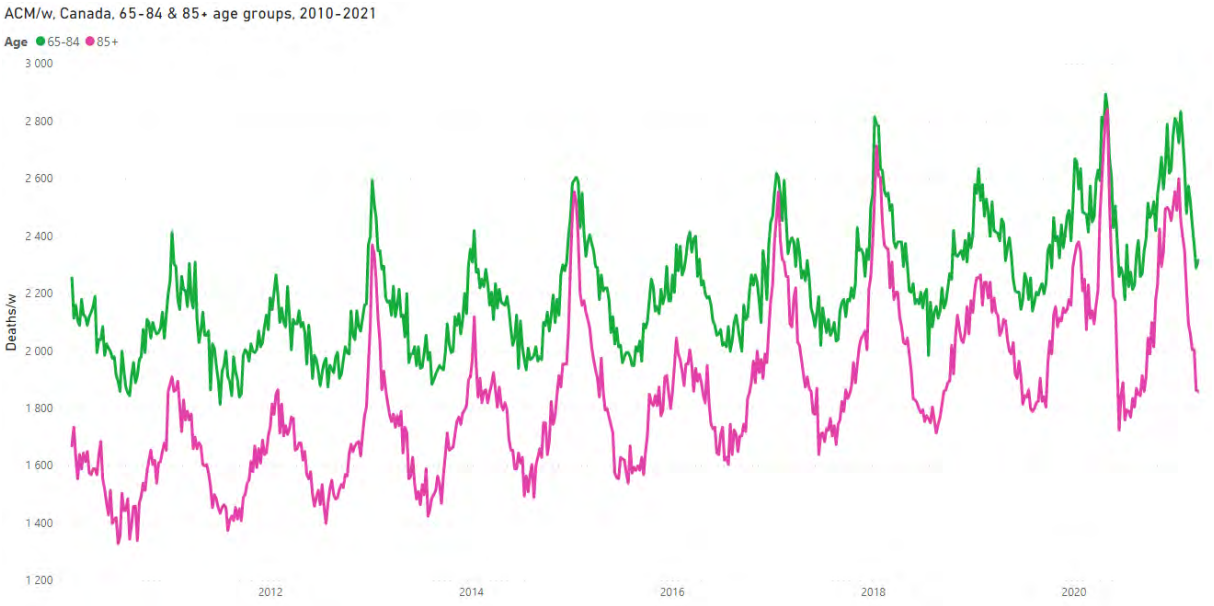

Figure A10: All-cause mortality by week in Canada for the 65-84 and 85+ age groups, both sexes, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2021).

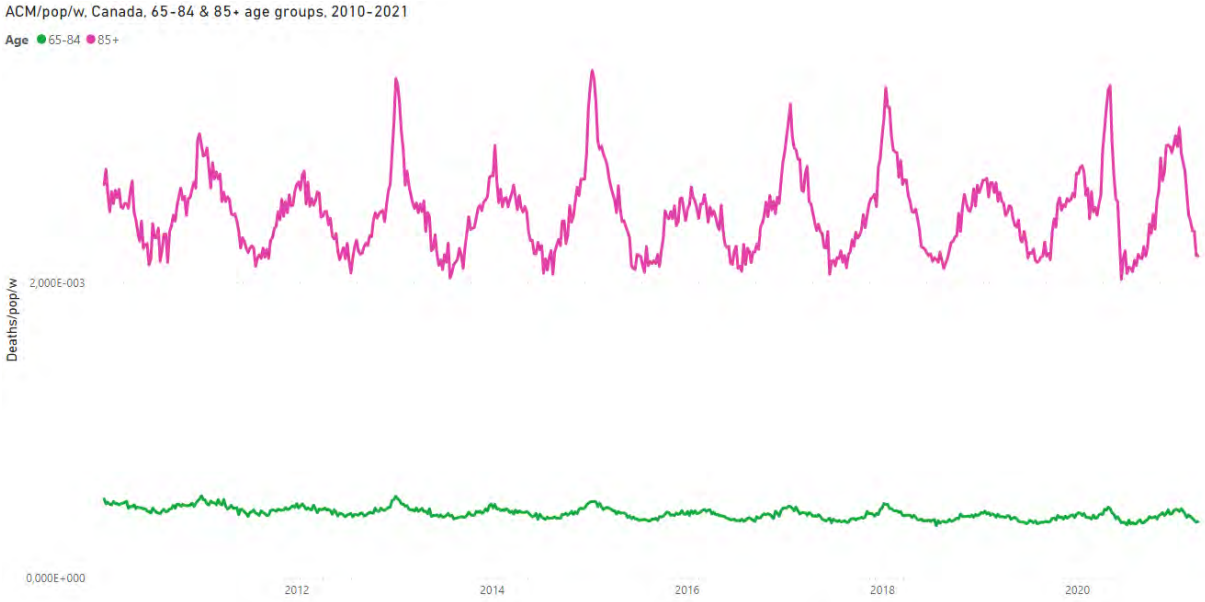

Figure A11: All-cause mortality by population by week in Canada for the 65-84 and 85+ age groups, both sexes, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

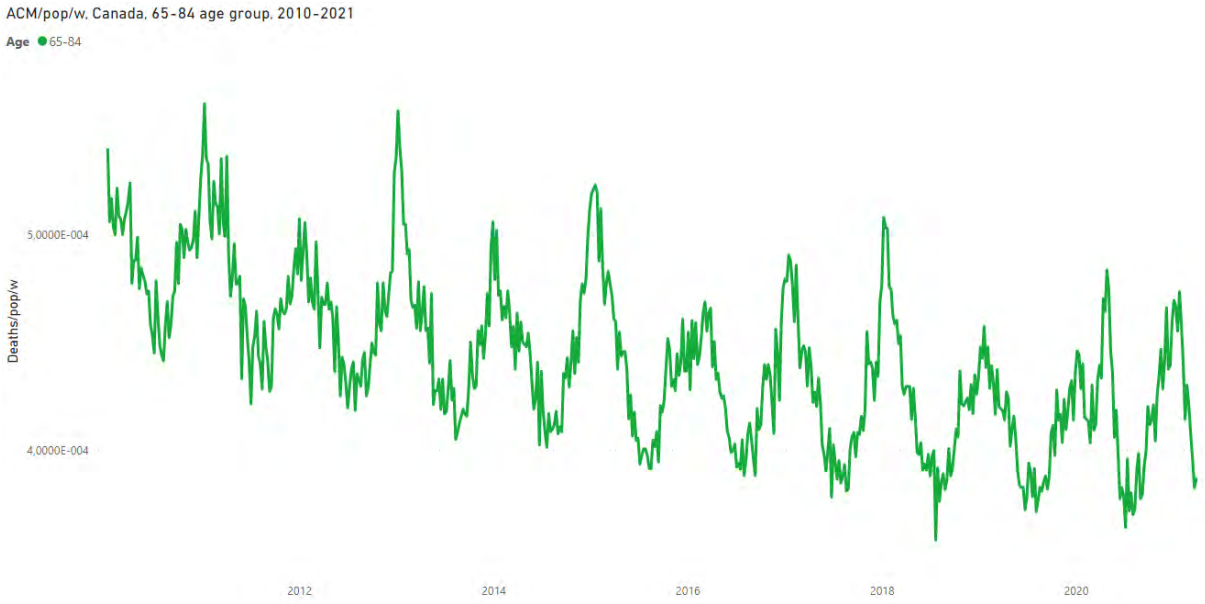

Figure A12: All-cause mortality by population by week in Canada for the 65-84 age group, both sexes, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

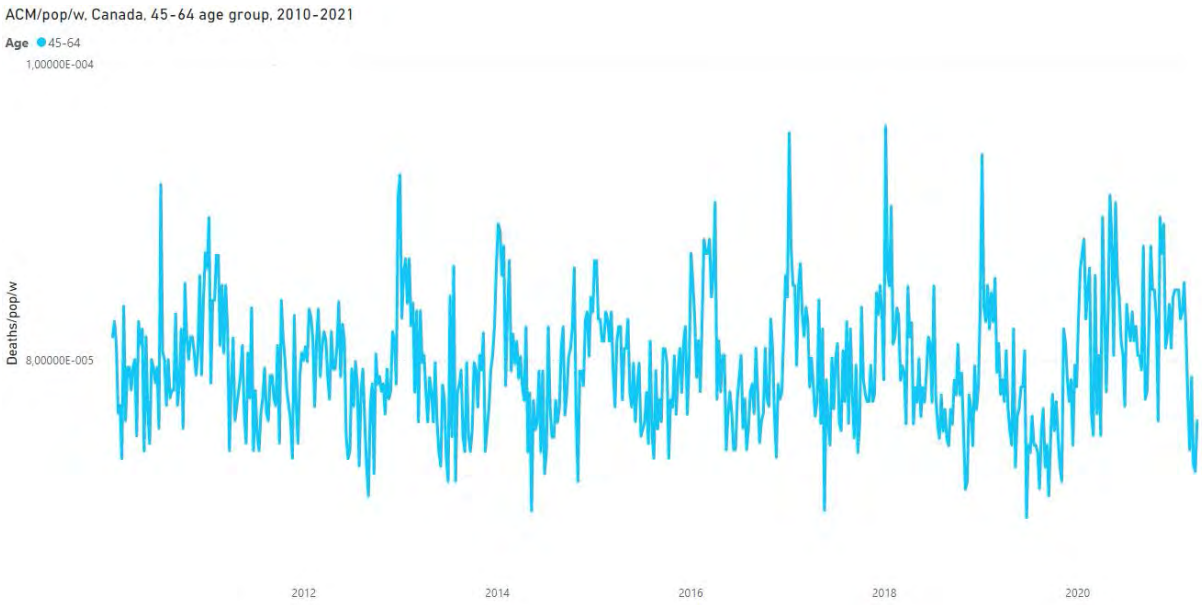

Figure A13: All-cause mortality by population by week in Canada for the 45-64 age group, both sexes, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

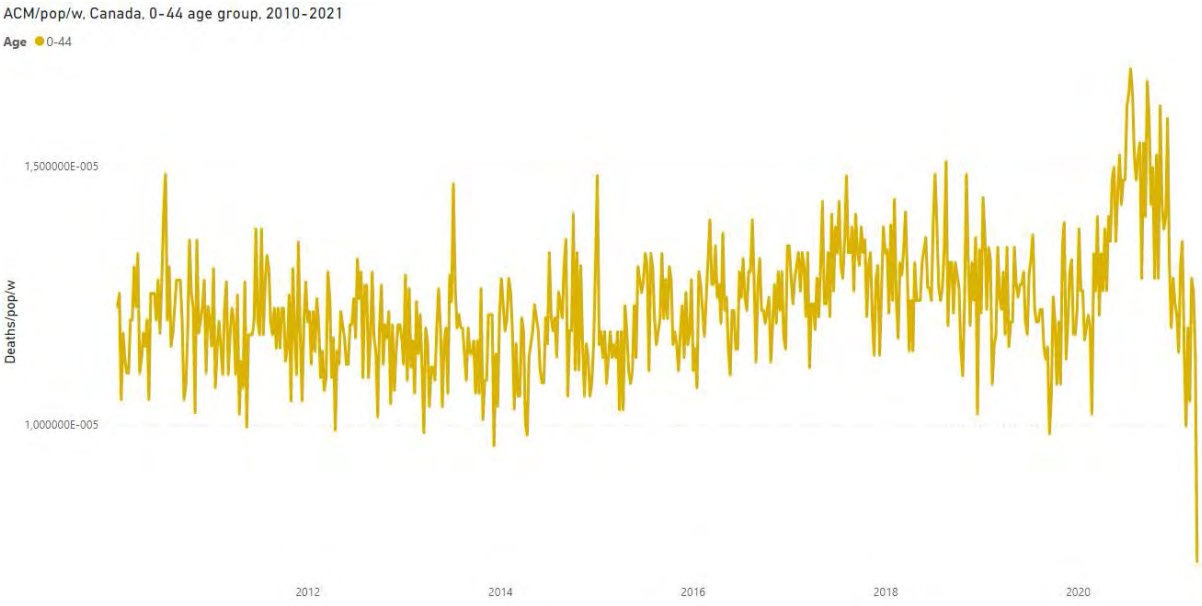

Figure A14: All-cause mortality by population by week in Canada for the 0-44 age group, both sexes, from 2010 to 2021. Data are displayed from January 2010 to March 2021. Data were retrieved from StatCan (StatCan, 2020 and 2021).

Nature of the COVID-era public health disaster in the USA, from all-cause mortality and socio-geo-economic and climatic data

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25 October 2021

Abstract

We investigate why the USA, unlike Canada and Western European countries, has a sustained exceedingly large mortality in the “COVID-era” occurring from March 2020 to present (October 2021). All-cause mortality by time is the most reliable data for detecting true catastrophic events causing death, and for gauging the population-level impact of any surge in deaths from any cause. The behaviour of the USA all-cause mortality by time (week, year), by age group, by sex, and by state is contrary to pandemic behaviour caused by a new respiratory disease virus for which there is no prior natural immunity in the population. Its seasonal structure (summer maxima), age-group distribution (young residents), and large state-wise heterogeneity are unprecedented and are opposite to viral respiratory disease behaviour, pandemic or not. We conclude that a pandemic did not occur. We infer that persistent chronic psychological stress induced by the long-lasting government-imposed societal and economic transformations during the COVID-era converted the existing societal (poverty), public-health (obesity) and hot-climate risk factors into deadly agents, largely acting together, with devastating population-level consequences against large pools of vulnerable and disadvantaged residents of the USA, far above preexisting pre-COVID-era mortality in those pools. We also find a large COVID-era USA pneumonia epidemic that is not mentioned in the media or significantly in the scientific literature, which was not adequately addressed. Many COVID-19-assigned deaths may be misdiagnosed bacterial pneumonia deaths. The massive vaccination campaign (380 M administered doses, 178 M fully vaccinated individuals, mainly January-August 2021 and March-August 2021, respectively) had no detectable mitigating effect, and may have contributed to making the younger population more vulnerable (35-64 years, summer-2021 mortality).

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Summary

We studied all-cause mortality (ACM) by time (week, year) 2013-2021 for the USA, resolved by state, or by age group, in relation to several socio-geo-economic and climatic variables (poverty, obesity, climatic temperature, population density, geographical region, and summer heatwaves).

We calculate “excess” mortality, by calendar-year or (summer to summer) cycle-year or selected ranges of weeks, as the week-by-week ACM above a summer baseline (SB) ACM, which has a monotonic and linear variation on the decadal timescale, 2013-2019, extrapolated into 2021.

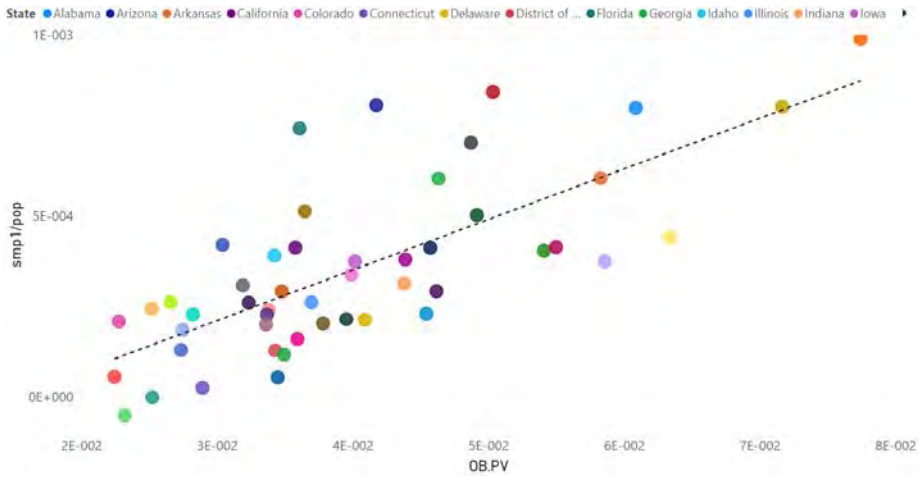
Unlike Canada and Western European countries, the USA has a dramatic anomalous increase in both ACM by year and “excess” ACM by year in 2020 and 2021, which started immediately following the World Health Organization (WHO) 11 March 2020 declaration of a pandemic. Nothing of this magnitude occurs in other nations. The USA’s yearly mortality in 2020-2021 is equal to (2020) and greater than (2021) the mortality by year occurring in its domestic population just after the Second World War.

Regarding geo-temporal variations in ACM by week (ACM/w) and in excess (above-SB) ACM by week (ACM-SB/w), we find that there are two distinct periods: the “COVID-era” (March 2020 to present), and the “pre-COVID-era” (prior to March 2020). Normal epidemiological variations occur in the pre-COVID-era, as has been observed for more than a century, in all mid-latitude Northern hemisphere jurisdictions having reliable data; whereas there is unprecedented state-wise jurisdictional and regional geographical heterogeneity in ACM by time in the COVID-era, which is contrary to theoretical pandemic behaviour caused by a new virus for which there is no prior natural immunity in the population.

COVID-era time-integrated seasonal and yearly features of ACM-SB/w significantly correlate with poverty (PV), obesity (OB), and climatic temperature (Tav), by state; and

differ by age group. The correlations account for the state-to-state heterogeneity, with notable outliers in one feature (March-June 2020) of the ACM-SB/w; and such correlations do not occur in pre-COVID-era cycle-year excess mortality. The co-associations of excess deaths with PV, OB and Tav occur only in the COVID-era. We show that normal (pre-COVID) excess (winter season) deaths — largely attributed to viral respiratory diseases occurring in the elderly — occur irrespective of PV, OB and climate, and that there is solely a correlation to age structure of the population in the state.

An example of a co-correlation is the relation between the summer-2020 excess mortality normalized by population (smp1/pop) and the product of OB and PV (OB.PV), state-by-state (see article for details):



A similar large excess of deaths occurred in the summer 2021, which is also strongly co-correlated with poverty, obesity and regional climate. In addition, we showed that these 2020 and 2021 summer mortalities and massive fall-winter-2020-2021 mortality, unlike with viral respiratory disease deaths, occur in younger people, over broad age categories.

In the correlations that we identified, the 2020 and 2021 summer excess (above-SB) mortalities extend to zero values for sufficiently small values of poverty, obesity or

summer temperatures, or their combinations, such as the product of poverty and obesity.

We also found, for example, that the onset of the COVID-era is associated with an increase in deaths of 15-34 year olds to a new plateau in ACM/w (approximately 400 more deaths per week), which does not return to normal over the period studied.

The behaviour of all-cause mortality in the COVID-era is irreconcilable with a pandemic caused by a new virus for which there is no prior natural immunity in the population.

On the contrary, we concluded that the COVID-era deaths are of two types:

- A large narrow peak (in ACM/w) occurring immediately after the WHO declaration of a pandemic apparently caused by the aggressive novel government and medical responses that were applied in certain specific state jurisdictions, against sick elderly populations (34 states do not significantly exhibit this feature).
- Summer-2020, fall-winter-2020-2021, and summer-2021 peaks and excesses (in ACM/w), which co-correlate with poverty, obesity and regional climate, presumably caused by chronic psychological stress induced by the government and medical responses, which massively disrupted lives and society, and affected broad age groups, as young as 15 year olds.

Therefore, a pandemic did not occur; but an unprecedented systemic aggression against large pools of vulnerable and disadvantaged residents of the USA did occur. We interpret that the persistent chronic psychological stress induced by the societal and economic transformation of the COVID-era converted the existing societal (poverty), public-health (obesity) and hot-climate risk factors into deadly agents, largely acting together, with devastating population-level consequences, far beyond the deaths that would have occurred from the pre-COVID-era background of preexisting risk factors.

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Table of abbreviations and definitions

Abbreviation	Name	Units	Description	Notes
85+	85+	People	Population estimate of people of 85 years old an over as of July 1st of the year	
85+/pop	85+ by population	%	Proportion of the people of 85 years old and older in the population	
ACM	All-cause mortality	Deaths	Total deaths from all causes (occurring in a defined period and for a defined place)	
ACM/w	All-cause mortality by week	Deaths/w	Total deaths from all causes occurring per week	
ACM/w/pop	ACM/w by population	Deaths/w/pop	Total deaths from all causes occurring per week normalized by population	
ACM/y	All-cause mortality by year	Deaths/y	Total deaths from all causes occurring per year	
ACM/y/pop	ACM/y by population	Deaths/y/pop	Total deaths from all causes occurring per year normalized by population	
ACM-SB	All-cause minus summer baseline mortality	Deaths	Difference between total deaths from all causes and deaths from all causes of the summer baseline	1
ACM-SB/w	ACM-SB by week	Deaths/w	Difference between total deaths from all causes and deaths from all causes of the summer baseline per week	
ACM-SB/w/pop	ACM-SB/w by population	Deaths/w/pop	Difference between total deaths from all causes and deaths from all causes of the summer baseline per week normalized by population ("Proportion of excess mortality per week")	
av	Average		Arithmetic mean of all the values of a data set	
(av-med)/av	Average minus median divided by average		Ratio between the difference between the average and the median and the average of the values of a data set	
av-sd	Average minus standard deviation		Difference between the average and the standard deviation of the values in a data set	

COVID-19	Coronavirus disease 2019	N/A	“Coronavirus disease 2019 is a contagious disease caused by severe acute respiratory syndrome coronavirus 2”	
cvp1	COVID-peak 1	Deaths	Integrated deaths of ACM-SB between week 11 of 2020 (week of March 9, 2020) and week 25 of 2020 (week of June 15, 2020), inclusively	2
cvp1/pop	COVID-peak 1 by population	Deaths/pop	COVID-peak 1 normalized by population	
cvp2	COVID-peak 2	Deaths	Integrated deaths of ACM-SB between week 40 of 2020 (week of September 28, 2020) and week 11 of 2021 (week of March 15, 2021), inclusively	3
cvp2/pop	COVID-peak 2 by population	Deaths/pop	COVID-peak 2 normalized by population	
med	Median		The 50th percentile of values in a data set	
neg-cor	Negative correlation			
OB	Obesity	%	Prevalence of self-reported obesity by state and territory (BRFSS (Behavioral Risk Factor Surveillance System), 2020)	
OB.PV	Obesity times poverty		Product of obesity and poverty	
pSB	Pneumonia summer baseline mortality	Deaths	Pneumonia assigned-deaths baseline trend	
Pneumonia-pSB	Pneumonia minus pneumonia summer baseline mortality	Deaths	Difference between total pneumonia-assigned deaths and summer baseline pneumonia-assigned deaths	
PIC	Pneumonia, Influenza and/or COVID-19 mortality	Deaths	Deaths from the following causes: pneumonia and/or influenza and/or COVID-19	
PIC-pSB	PIC minus pneumonia summer baseline mortality	Deaths	Difference between PIC-assigned deaths and summer baseline pneumonia-assigned deaths	
ACM-SB - PIC-pSB	ACM-SB minus PIC-pSB	Deaths	Difference between ACM-SB ("excess") and PIC-pSB ("PIC above pneumonia-baseline") deaths	

pop	Population	People	Resident population estimate for the states of the USA as of July 1st of the year	
popD	Population density	People/mile^2	Number of inhabitants per unit surface area (average population per square mile)	
pos-cor	Positive correlation			
PV	Poverty	%	Estimated percent of people of all ages in poverty	
SB	Summer baseline	Deaths	Linear baseline of mortality independent of winter mortality estimated from the summer trough weeks 26 to 37, inclusively, of summers 2013 to 2019, inclusively	
sd	Standard deviation		Measure of the amount of variation or dispersion of values in a data set	
sd/av	Standard deviation divided by average		Ratio between the standard deviation and the average of the values of a data set	
smp1	Summer-peak 1	Deaths	Integrated deaths of ACM-SB between week 26 of 2020 (week of June 22, 2020) and week 39 of 2020 (week of September 21, 2020), inclusively	4
smp1/pop	Summer-peak 1 by population	Deaths/pop	Summer-peak 1 divided by population	
smp2	Summer-peak 2	Deaths	Integrated deaths of ACM-SB between week 26 of 2021 (week of June 28, 2021) and week 37 of 2021 (week of September 13, 2021), inclusively	5
smp2/pop	Summer-peak 2 by population	Deaths/pop	Summer-peak 2 divided by population	
Tav	Average temperature	° F	Average daily average temperature, where an average daily temperature is the average between the max and min daily temperatures	
Tav 2020	Average temperature in 2020	° F	Average daily average temperature over the calendar-year 2020	
Tmax	Maximum temperature	° F	Average daily maximum temperature	
Tmax Jul-Aug 2020	Maximum temperature in July and August 2020	° F	Average daily maximum temperature over July and August 2020	

USA	United States of America	N/A	Here USA means continental USA, which are 49 states, including the District of Columbia and excluding Alaska and Hawaii	
WB	Winter burden	Deaths/y	Integrated deaths of ACM-SB between the week 31 of a year N and the week 30 of a year N+1, inclusively (which is the definition of a cycle-year)	6
WB/pop	Winter burden by population	Deaths/y/pop	Winter burden normalized by population	7

1 Also called "all-cause above-SB" or "excess" deaths in the text
2 Also called "March-June 2020 peak" or "covid peak" or "spring-2020 peak" or "spring-2020 excess mortality" in the text
3 Also called "fall-winter-2020-2021 excess mortality" in the text
4 Also called "summer-2020 excess mortality" in the text
5 Also called "summer-2021 excess mortality" in the text
6 If a year is placed in front, it means it's the WB of this cycle-year
7 If a year is placed in front, it means it's the WB/pop of this cycle-year
N/A stands for not applicable

1. Introduction

A small but growing number of researchers are recognizing that it is essential to examine all-cause mortality (ACM), and excess deaths from all causes compared with projections from historic trends, to make sense of the events surrounding COVID-19 (Jacobson and Jokela, 2021) (Kontopantelis et al., 2021) (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021) (Woolf et al., 2021).

In our prior analyses of ACM by time (by day, week, month, year) for many countries (and by province, state, region or county), we showed that the data in the COVID-era (March 2020 to present) is inconsistent with a viral respiratory disease pandemic, in that the mortality is highly heterogeneous between jurisdictions, with no anomalies in most places, and hot spots or hot regions with deaths that are synchronous with aggressive local or regional responses, both medical and governmental (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021).

The surges in all-cause deaths are highly localized geographically (by jurisdiction) and in time, which is contrary to pandemic behaviour; but is consistent with the surges being caused by the known government and medical responses (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021).

In particular, Canada shows no evidence of a pandemic, since ACM by year (ACM/y) in the COVID-era is squarely on the linear trend of the previous decade. In addition, the ACM by week (ACM/w) data for Canada shows large province-level heterogeneity of temporal and seasonal changes in ACM, by sex and by age group, that must be ascribed to the impacts of medical and governmental measures (Rancourt et al., 2021).

We have also extensively studied ACM by time (day, month, year) for France, at many jurisdictional levels (regions, departments, communes), in comparison to high-resolution

data for institutional occupancies and drug use (Rancourt et al., 2020) (and unpublished), and examined data for European countries, to various degrees of detail.

We reported on the USA in our prior articles about ACM, concentrating on the spectacular hot-spot anomalies that occurred in March through May 2020 (Rancourt, 2020) (Rancourt et al., 2020). Here, we extend our analysis for the USA, up to presently available data, and include socio-geo-economic and climatic data.

The ACM data for the USA in the COVID-era has shocking features, unlike anything else in the world. The USA is unique in this regard. Above-decadal-trend deaths in the COVID-era are massive. Nothing like this occurs in neighbouring Canada. Nothing like this occurs in Western European countries. Similar surges occur in Eastern European countries, but are not of the same large magnitudes as in the USA.

Our goal was to describe the most that can be rigorously inferred from ACM by time, jurisdiction, age group, and sex, in order to elucidate the nature of the massive excess mortality that occurred in the USA in the COVID-era, and delimit its likely causes, with an eye to known mechanisms of disease vulnerability (psychoneuroimmunology, and stress-immune-survival relationships for humans). Therefore, we examined socio-geo-economic data, including:

- Age structure of the population
- Population density
- Racial considerations
- Obesity
- Poverty (also median household income)
- Climatic temperatures
- Vaccination status (COVID-19 and flu vaccines)
- Antibiotic prescription rates

2. Data and methods

Table 1 describes data used in this work and the sources of the data.

Data	Country	Period	Time scale	Filters	Source
ACM	USA	2013-2021*	Week	State	CDC, 2021a
ACM	USA	2013-2021*	Week	Age group[1]	CDC, 2021a
ACM	USA	2020-2021**	Week	Age group[2], sex	CDC, 2021b
ACM	USA	1900-2020[§]	Year	Age group[3], sex	CDC, 2021a CDC, 2021c CDC, 2021d
ACM	USA	1900-1998	Year	Age group[3], sex	CDC, 2021c
ACM	USA	1968-2016	Year	Age group[4], sex	CDC, 2021d
Obesity	USA	2020	Year	State	CDC, 2021e
P-I-C	USA	2013-2021*	Week	-	CDC, 2021a
Population	USA	1900-2020[§§]	Year	Age group[3], sex	CDC, 2021c CDC, 2021d US Census Bureau, 2021b
Population	USA	1900-1997	Year	Age group[5], sex	CDC, 2021c
Population	USA	1968-2016	Year	Age group[4], sex	CDC, 2021d
Population	USA	2010-2020	Year	State	US Census

					Bureau, 2021a
Population	USA	2010-2020[#]	Year	State, age group[6], sex	US Census Bureau, 2021b
Density	USA	1910-2020[##]	Decade	State	US Census Bureau, 2021c
Poverty	USA	2019	Year	State	US Census Bureau, 2021d
Temperature	USA	1895-2021[***]	Month	State[7]	NOAA, 2021
Vaccines	USA	2020-2021[+]	Day	-	CDC, 2021f
ACM	Canada	2010-2021[++]	Week	-	StatCan, 2021

Table 1. Data retrieved. USA means continental USA, composed of 49 states, including the District of Columbia and excluding Alaska and Hawaii, unless otherwise stated in the text.
* At the date of access, data were available from week-40 of 2013 to week-40 of 2021. Usable data are until week-37 of 2021, due to insufficient data in later weeks, which gives a large artifact (anomalous drop in mortality, see Appendix). For the work on USA at the state level, we could add the missing weeks of 2013 (week-1 of 2013 to week-39 of 2020) thanks to a previously downloaded file (downloaded on June 24, 2020) from the same website (CDC, 2021a), which was including those weeks back then.
** At the date of access, data were available from week-1 of 2020 (week ending on January 4, 2020) to week-40 of 2021 (week ending on October 9, 2021). Usable data are until week-37 of 2021 (week ending on September 18, 2021), due to insufficient data in later weeks, which gives a large artifact (anomalous drop in mortality).
*** At the date of access, data were available until August 2021.
[§] These data are a combination of the data found in CDC 2021a, CDC 2021c and CDC 2021d.
[§§] These data are a combination of the data found in CDC 2021c, CDC 2021d and US Census Bureau 2021b.
[#] In our work, we use the population data of the year 2020 (census estimate).
[##] In our work, we use the population density data of the year 2020.
[+] At the date of access, data were available from December 14, 2020 (week-51 of 2020) to September 27, 2021 (week-39 of 2021).

[++] At the date of access, data were available from week-1 of 2010 (week ending on January 9, 2010) to week-30 of 2021 (week ending on July 31, 2021). Usable data are until week-20 of 2021 (week ending on May 22, 2021) due to not consolidated data in later weeks, which gives a large artifact (anomalous drop in mortality).
[1] 3 age groups: <18, 18-64, 65+
[2] 11 age groups: <1, 1-4, 5-14, 15-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75-84, 85+
[3] 12 age groups: <1, 1-4, 5-14, 15-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75-84, 85+, unknown
[4] 14 age groups: <1, 1-4, 5-9, 10-14, 15-19, 20-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75-84, 85+, not stated
[5] 19 age groups: <1, 1-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84, 85+
[6] 86 age groups: by 1 year age group, from 0 to 85+
[7] Temperatures are not available for the District of Columbia.

StatCan (2021) defines a death as “the permanent disappearance of all evidence of life at any time after a live birth has taken place” and excludes stillbirths. StatCan specifies that the ACM for 2020 and 2021 is provisional and subject to change, and that the counts of deaths “have been rounded to a neighbouring multiple of 5 to meet the confidentiality requirements of the Statistics Act”.

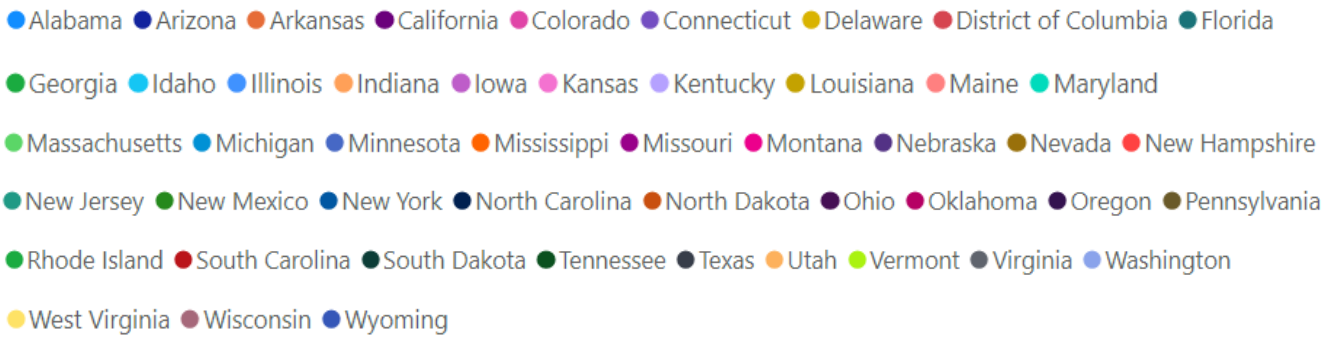
According to CDC (CDC, 2021a):

- “[…] pneumonia, influenza and/or COVID-19 (PIC) deaths are identified based on ICD-10 multiple cause of death codes.”
- “NCHS Mortality Surveillance System data are presented by the week the death occurred at the national, state, and HHS Region levels, based on the state of residence of the decedent.”
- “Not all deaths are reported within a week of death therefore data for earlier weeks are continually revised and the proportion of deaths due to P&I or PIC may increase or decrease as new and updated death certificate data are received by NCHS.”
- “The COVID-19 death counts reported by NCHS and presented here are provisional and will not match counts in other sources, such as media reports or numbers from county health departments. COVID-19 deaths may be classified or defined differently in various reporting and surveillance systems. **Death counts reported by NCHS include deaths that have COVID-19 listed as a cause of**

death and may include laboratory confirmed COVID-19 deaths and clinically confirmed COVID-19 deaths. Provisional death counts reported by NCHS track approximately 1-2 weeks behind other published data sources on the number of COVID-19 deaths in the U.S. These reasons may partly account for differences between NCHS reported death counts and death counts reported in other sources."

- "In previous seasons, the NCHS surveillance data were used to calculate the percent of all deaths occurring each week that had pneumonia and/or influenza (P&I) listed as a cause of death. Because of the ongoing COVID-19 pandemic, COVID-19 coded deaths were added to P&I to create the PIC (pneumonia, influenza, and/or COVID-19) classification. **PIC includes all deaths with pneumonia, influenza, and/or COVID-19 listed on the death certificate**. Because many influenza deaths and many COVID-19 deaths have pneumonia included on the death certificate, P&I no longer measures the impact of influenza in the same way that it has in the past. This is because the proportion of pneumonia deaths associated with influenza is now influenced by COVID-19-related pneumonia. The PIC percentage and the number of influenza and number of COVID-19 deaths will be presented in order to help better understand the impact of these viruses on mortality and the relative contribution of each virus to PIC mortality."

For all the scatter plots presented in this article, the following colour-code is applied for the 49 continental states of the USA (including District of Columbia, excluding Alaska and Hawaii).



The main points of our methodology are as follows.

We work with all-cause mortality (ACM), deaths from all causes, in order to avoid the uncertainty and bias in attributing a cause of death, in this context of COVID-19 in which cause of death is not simple nor obvious. ACM data is available by jurisdiction (state, country, county), by age group, by race, by sex, and by time (day, week, year). We can normalize group-specific ACM totals by the respective populations of the relevant groups, in order to allow comparisons between jurisdictions or different groups, on a per-population basis.

Generally, in jurisdictions that exhibit seasonal winter maximums of mortality, the bottom-values of mortality in the summer troughs follow a straight-line trend on a decadal or shorter timescale. We call this trend-line the “summer baseline” (SB), and we use it to count above-SB deaths, when we wish to thus quantify “excess deaths”.

In other words, we are following our previous methodology in which we argued that mortality by time (day, week, month) is best analyzed using a SB, and winter burden (WB) deaths above the SB, over a (natural) cycle-year from summer to following summer, rather than use assumed underlying sinusoidal seasonal variations of any presumed component(s), since such sinusoidal theoretical curves fail to represent the data or any of its inferred principle components (e.g., Simonsen et al., 1997). Although the summer trough mortality values follow a linear local trend by time (in normal, pre-COVID-era, circumstances), above-SB features have significant randomness in their season to season variations, suggesting that summer baseline mortality is representative of “stable” mortality not influenced by the many different and seasonally variable winter-time life-threatening health challenges (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021).

SB estimation at the state level

The linear summer baseline (SB) is a least-squares fit to the summer troughs for summer-2013 through summer-2019, using the summer trough weeks 27 to 36,

included, for all the states of the continental USA, except for Alabama and Wisconsin for summer-2014 and summer-2015, respectively, and corrected by 1 % (see below). For Alabama, only the weeks [30-32] were used for summer-2014 as drops in data are seen for weeks [27-29] and weeks [33-36] of 2014 (see Appendix). For Wisconsin, only the weeks [27-29] and [33-36] were used for summer-2015 as a drop in data is seen for weeks [30-32] of 2015 (see Appendix). We corrected the SB by 1 % so as to lower the SB and make it match the bottoms of the summer troughs. We also estimated the SB taking different summer periods, from the shortest to the largest: weeks [30-32], weeks [29-33], weeks [28-35] and weeks [27-36], to determine our 1 % correction. We found that the larger the period, the better the estimate of the SB slope, but also the higher the estimate of the SB intercept, as the last weeks towards the previous winter season and the first weeks towards the next winter season are included. We thus decided to estimate the SB with the largest summer period (weeks [26-37]) and lower the intercept by 1 % (no correction leading to a too high intercept and a correction factor of 2 % leading to a too low intercept). The SB is so estimated between the weeks 26 and 37 (inclusively) of each summer of the pre-COVID-era (summers 2013 to 2019), which corresponds to the weeks laying from the beginning of July to the beginning of September.

SB estimation at the national level

- For work involving the states, the SB estimate of the USA is a sum of the SB estimates of each individual state.
- For work not involving the states, the SB is a least-squares fit to the summer troughs for summer-2014 through summer-2019, using the summer trough weeks 27 to 36, included, for the whole USA (including Alaska and Hawaii) with no correction, since none was needed.

In the same way that we thus quantify a winter burden of deaths in a given cycle-year, we can also quantify an excess (above-SB) of deaths over any period of time, such as over a period that captures any prominent features in ACM by time. We defined such periods of interest occurring in the COVID-era: a spring-2020 peak (cvp1),

summer-2020 (smp1), the fall-winter-2020-2021 maximum (cvp2), and summer-2021 (smp2), as specified in the text.

3. Results, analysis and discussion

3.1. All-cause mortality per year, USA, 1900-2020

We start by examining ACM/y (per calendar-year) in the USA, for the years 1900 through 2020. This is shown in Figure 1.

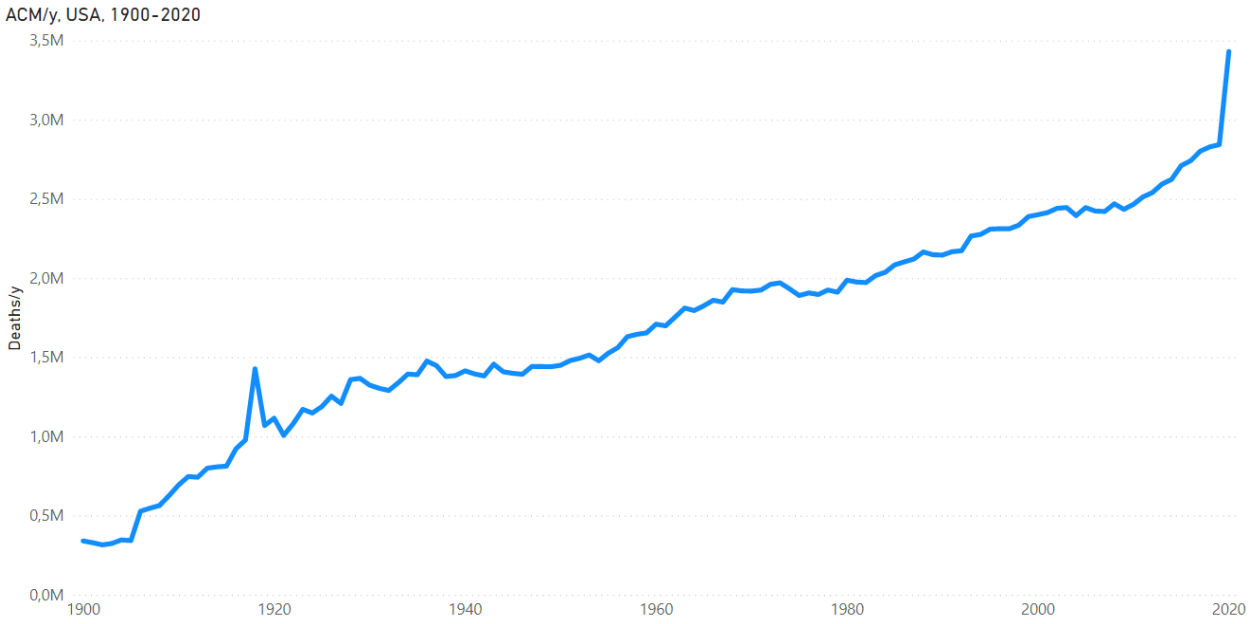


Figure 1. All-cause mortality by calendar-year in the USA from 1900 to 2020. Data were retrieved as described in Table 1.

The ACM/y 1900-2020 has the following main features. First, it has a generally increasing trend over the entire period, with a slope of approximately 16K deaths per year per year (16K/y/y) in the region 1920-2010. The overall increasing trend is due to population growth. One needs to normalize by population to remove this dominant effect (see below). Second, there is a large increase in 1918, which corresponds to the so-

called “1918 Flu Pandemic”. Third, there is a large increase in 2020, which corresponds to the first year of the COVID-era. Fourth, there are notable increases in the late-1920s and mid-1930s, which correspond to the hardships associated with The Great Depression and the accompanying decade-long Dust Bowl droughts of the Midwest. Fifth (by omission), there are no detected increases that would correspond to any of the major 20th-21st century influenza pandemics that are described to have occurred in 1957-58, 1968, and 2009 (Doshi, 2008) (Doshi, 2011).

These main features in ACM/y are clarified and enhanced on examining ACM/y by age group (available for 1900-2016). This is shown for all the ages, excluding <1 year, divided into 10 age groups in Figure 2.

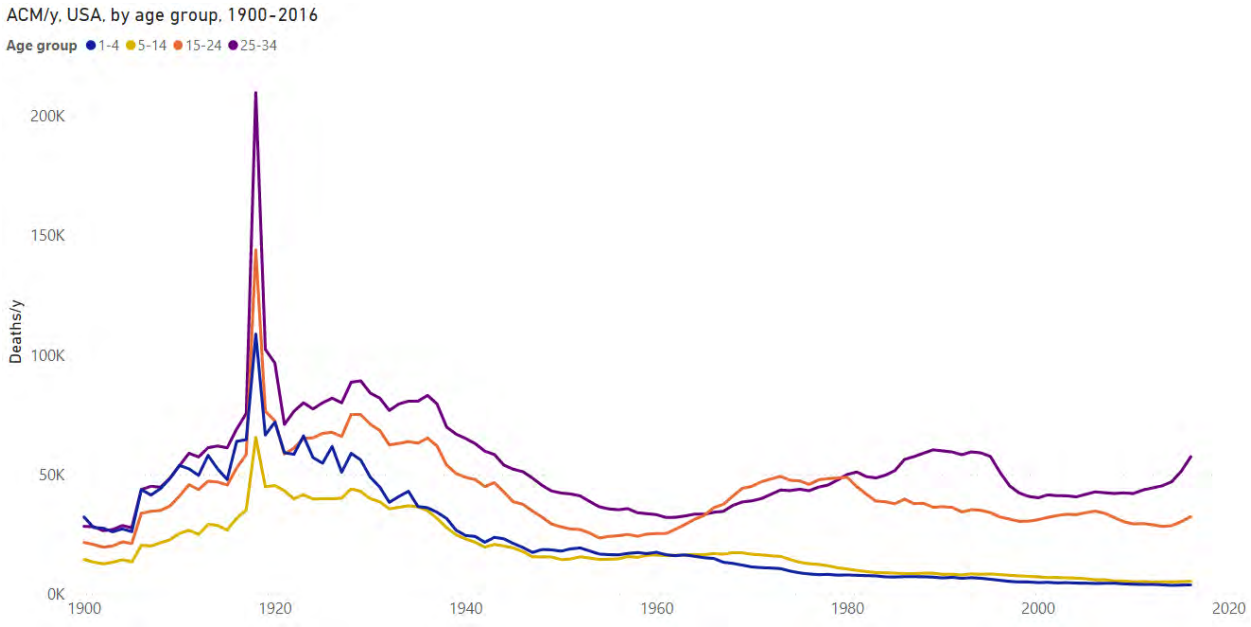


Figure 2a. All-cause mortality by year in the USA for the 1-4, 5-14, 15-24 and 25-34 years age groups, from 1900 to 2016. Data are displayed per calendar-year. Data were retrieved as described in Table 1.

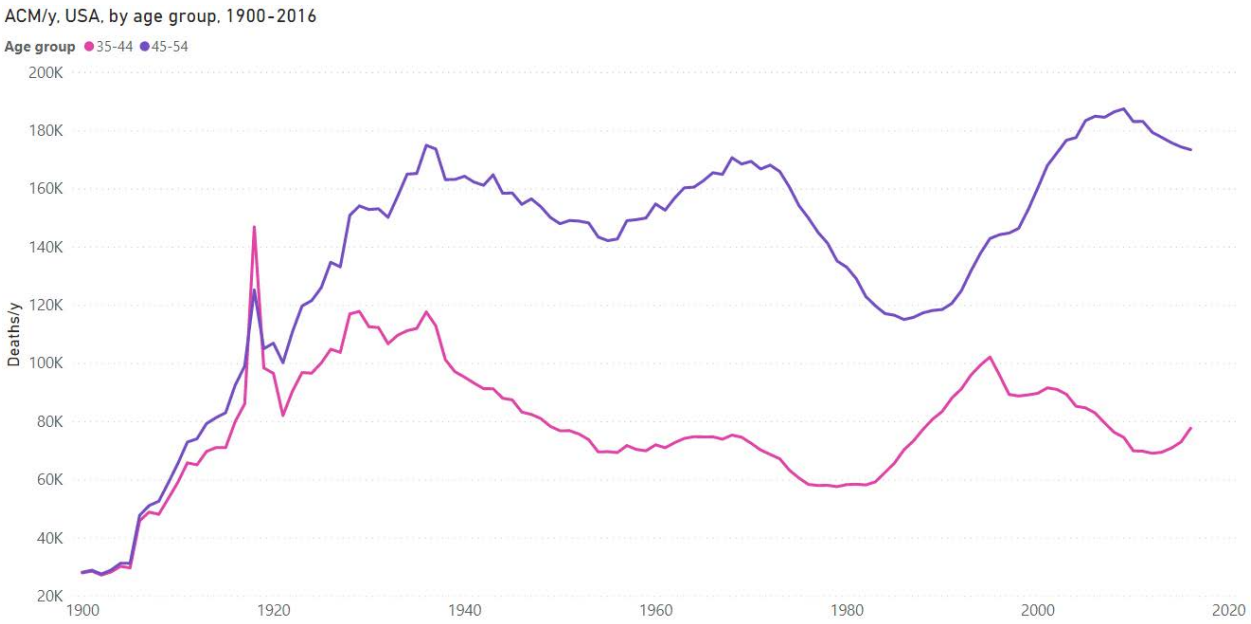


Figure 2b. All-cause mortality by year in the USA for the 35-44 and 45-54 years age groups, from 1900 to 2016. Data are displayed per calendar-year. Data were retrieved as described in Table 1.

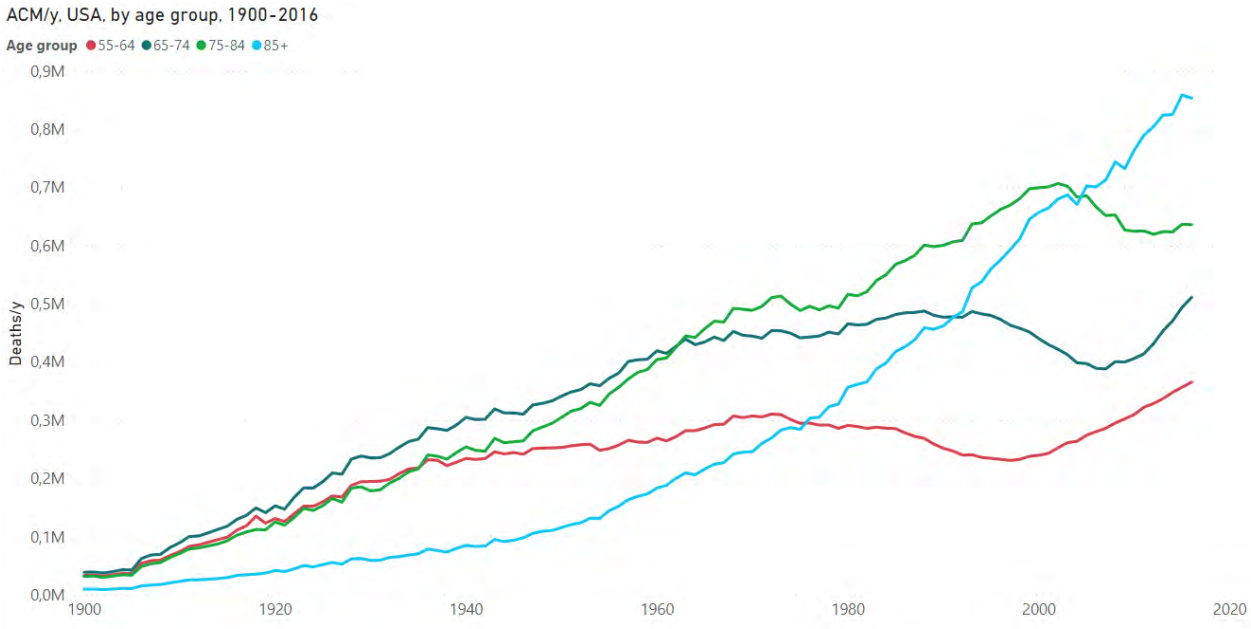


Figure 2c. All-cause mortality by year in the USA for the 55-64, 65-74, 75-84 and 85+ years age groups, from 1900 to 2016. Data are displayed per calendar-year. Data were retrieved as described in Table 1.

The ACM/y 1900-2016 by age-group data allows the following observations to be made.

Regarding 1918, the event was devastating for the age groups 15-24 years and 25-34 years, much less so for the age groups 35-44 years and 45-54 years, and virtually undetected for those 55 years and older, which would be very surprising for influenza. In fact, we know that most of the deaths were associated with massive bacterial lung infections (Morens et al., 2008) (Chien et al., 2009) (Sheng et al., 2011), in an era predating antibiotics, in a period massively perturbed by a world war, and that the event was concomitant with typhoid epidemics in Europe and Russia.

Regarding The Great Depression and the Dust Bowl devastation, the late-1920s and mid-1930s increases in ACM/y are prominent for the 15-24, 25-34, 35-44 and 45-54 years age groups, but are not detected for 55 year olds and older.

Regarding 20th-21st century purported influenza pandemics, there is no trace of increased mortality for 1957-58, 1968, and 2009, in any age group, including the older age groups of 55-64, 65-74, 75-84, and 85+ years. Clearly, these 20th century declared pandemics had negligible impacts on all-cause mortality; not comparable to the large impacts of the events of 1918, late-1920s-mid-1930s, <1945, and 2020, which are associated with major socio-economic upheavals (the First World War, The Great Depression and Dust Bowl, the Second World War, and the medical and government response to the declared COVID-19 pandemic, respectively).

The ACM/y by age group has long-period (decadal) variations with notable broad minima occurring at approximately:
~1975-1980: 35-44 years age group
~1985-1990: 45-54 years age group
~1995-2000: 55-64 years age group
~2005-2010: 65-74 years age group
~2010-2015: 75-84 years age group
These variations are due to the post Second World War baby boom effects on population.

The population of the USA varied from 1900 to 2020 as shown in Figure 3 (and from 1900 to 2016 for the age groups).

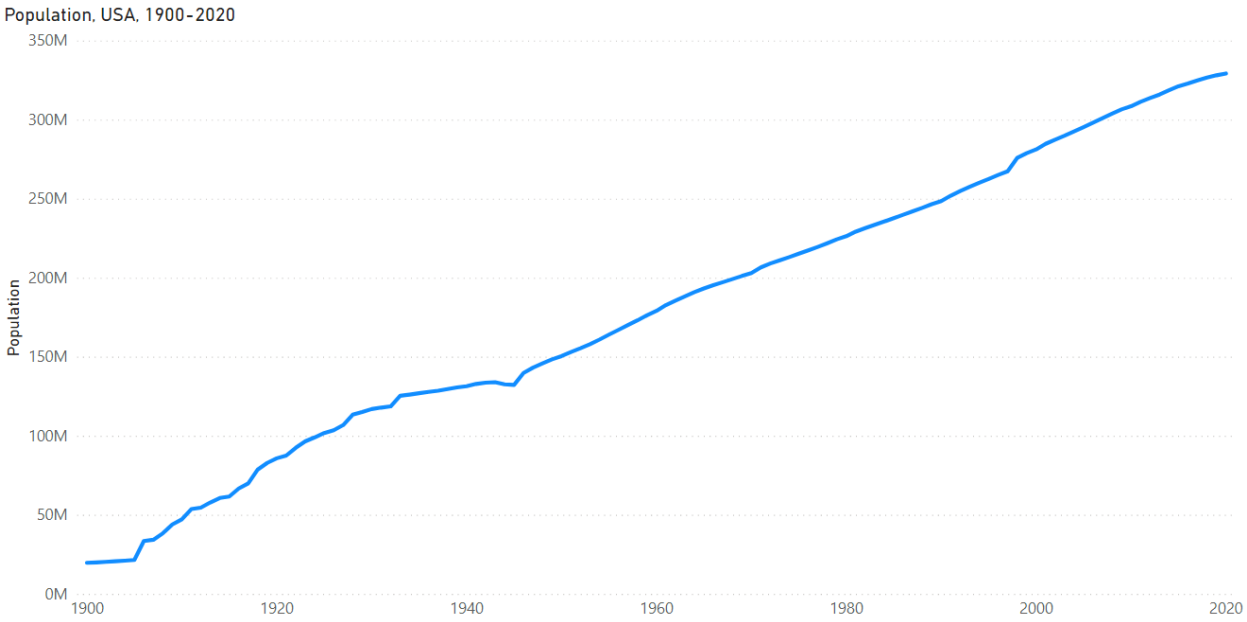


Figure 3a. Population of the USA from 1900 to 2020. Data are displayed per calendar-year. Data were retrieved as described in Table 1.

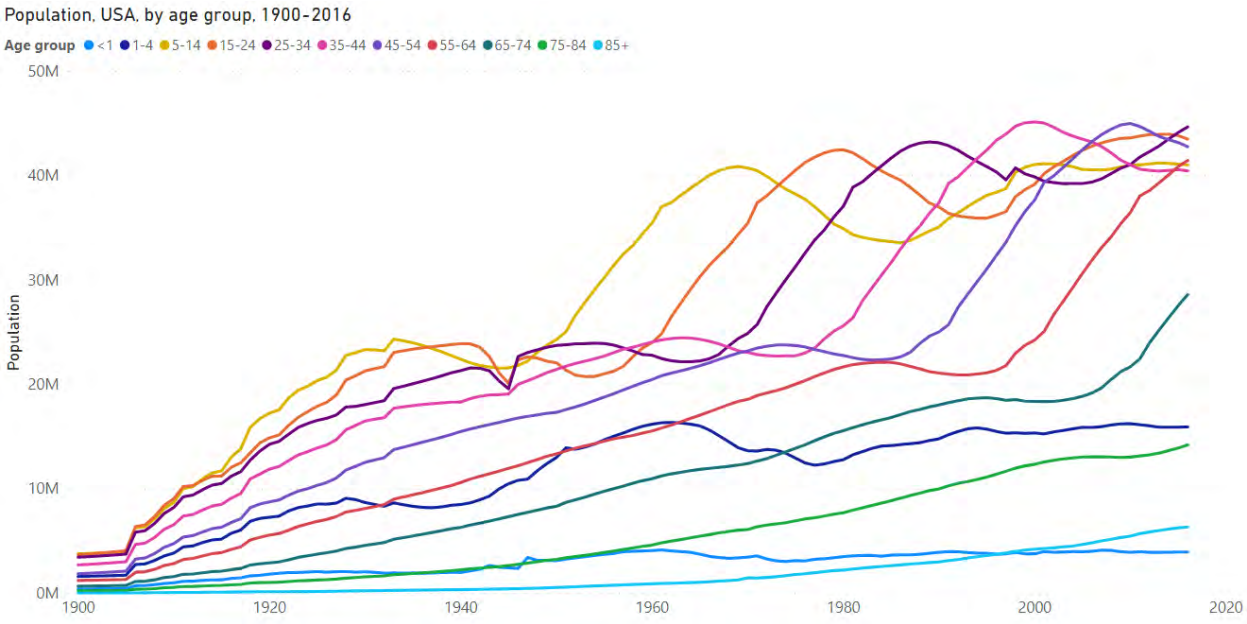


Figure 3b. Population of the USA by age group from 1900 to 2016. Data are displayed per calendar-year. Data were retrieved as described in Table 1.

Here (Figure 3a), we see a large dip in population at 1943-1945, related to the Second World War. The slope to population versus time also changes dramatically at 1943-1945, increasing after the war, in accordance with the known baby boom. The population by age group (Figure 3b) confirms that the dip at 1943-1945 is solely from the 15-24 and 25-34 years age groups, especially 15-24 years. This figure (Figure 3b) also shows the dramatic consequences of the baby boom, showing itself, age group after age group, as the baby boomers age. The monotonic increase in the 85+ years population (Figure 3b) is directly the cause of the monotonic increase in 85+ years deaths (Figure 2c).

Next, we normalize ACM/y (Figure 1) by population (Figure 3a), 1900-2020, to obtain ACM/y/pop shown in Figure 4a.

Figure 4a. All-cause mortality by year normalized by population for the USA from 1900 to 2020. Data are displayed per calendar-year. Data were retrieved as described in Table 1.

This allows us to see ACM/y expressed as a fraction of population. We again see the gigantic catastrophe that was the 1918 event (pneumonia/typhoid, wartime upheaval), peaks in the late-1920s and mid-1930s (Great Depression, Dust Bowl), a peak in the Second World War period (young men, 15-24 and 25-34 years age groups, as per

Figure 3b), relatively uneventful mortality after 1945 (no public health catastrophes detected), no sign of the announced pandemics of 1957-58, 1968, and 2009, and the COVID-era increase of 2020 (a subject of this article).

The mortality events of the late 1920s, mid-1930s and <1945, and the >1945 uneventful period, are elucidated further by examining ACM/y/pop resolved by age group and by sex, as per the following.

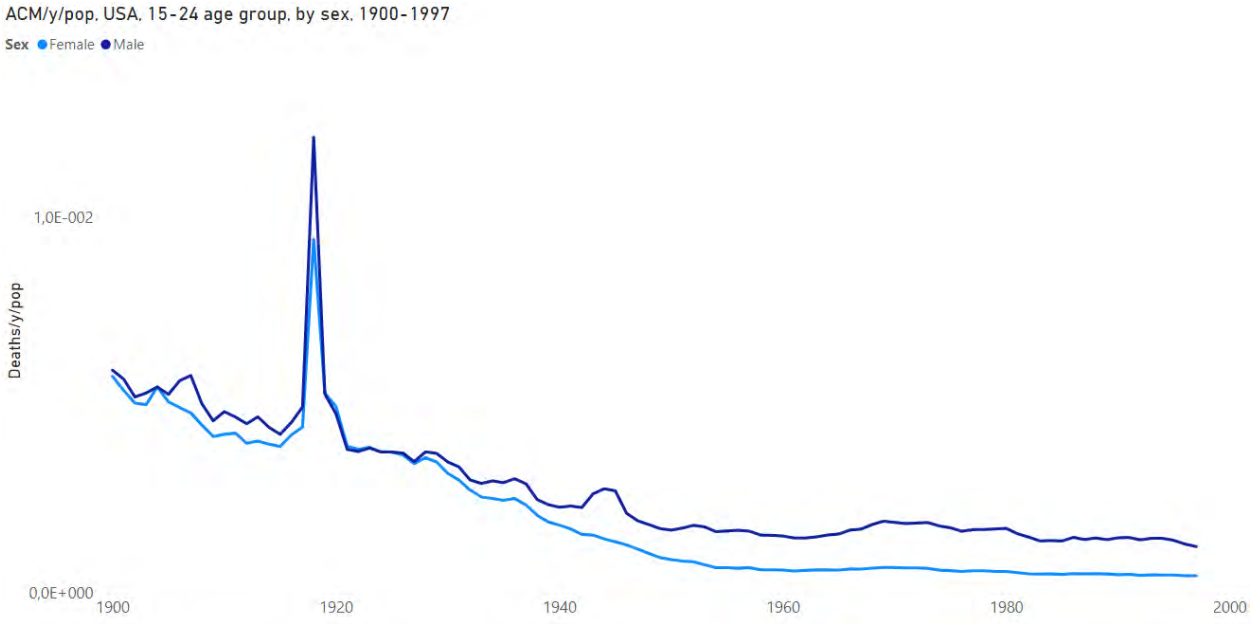


Figure 4b. All-cause mortality by year normalized by population for the USA for the 15-24 years age group, for each of both sexes, from 1900 to 1997. The population of the specific age group and sex is used for each normalization. Data are displayed per calendar-year. Data were retrieved as described in Table 1.

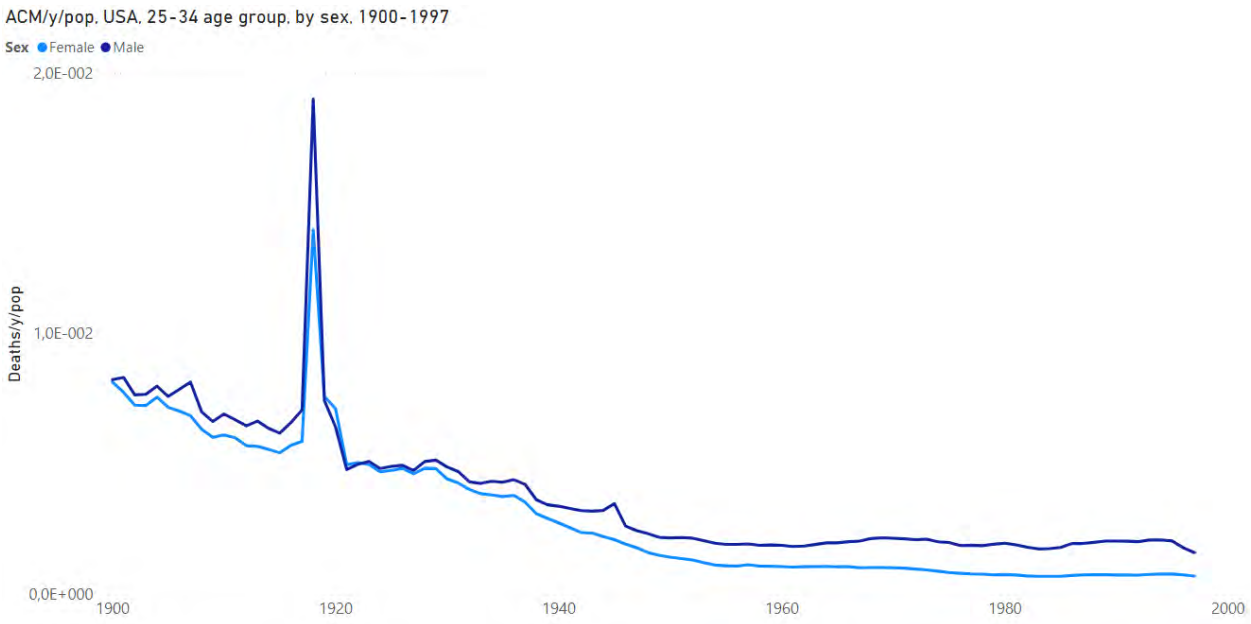


Figure 4c. All-cause mortality by year normalized by population for the USA for the 25-34 years age group, for each of both sexes, from 1900 to 1997. The population of the specific age group and sex is used for each normalization. Data are displayed per calendar-year. Data were retrieved as described in Table 1.

Figures 4b and 4c show that both young men and women were impacted by the hardships of the late-1920s and mid-1930s, but that only young men were impacted to death by the Second World War. Interestingly, 15-24 year old men had relatively high mortality between the mid-1960s and the early-1980s.

The 2020 value of ACM/y/pop brings us back to a mortality equal to the mortality by population that prevailed in 1945 (Figure 4a), which suggests that the socio-economic upheavals from COVID-19 response are comparable to the upheavals from the last major war period, with an albeit much older population presently, and possibly greater class disparity, since The New Deal had already been implemented in 1945, in response to the hardships of the 1930s.

3.2. ACM by week (ACM/w), USA, 2013-2021

The ACM/w for the USA from 2013 to 2021 is shown in Figure 5, with a straight-line trend for the bottoms of the summer troughs for 2013 through 2019 (of the pre-COVID-era). We call this trend-line the “summer baseline” (SB), and we use it to count above-SB deaths (“excess” deaths).

We are following our previous methodology in which we argued that mortality by time (day, week, month) is best analyzed using a SB, and winter burden deaths (WB) above the SB, over a (natural) cycle-year from summer to following summer, rather than use assumed underlying sinusoidal seasonal variations of any presumed component(s), since such sinusoidal theoretical curves fail to represent the data or any of its inferred principle components (e.g., Simonsen et al., 1997). It is a general feature with seasonal mortality data that SB trends are typically linear on the timescale of one decade or so, whereas above-SB features have significant randomness in their season to season variations, suggesting that summer baseline mortality is representative of “stable” mortality not influenced by the many different and seasonally variable winter-time life-threatening health challenges (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021).

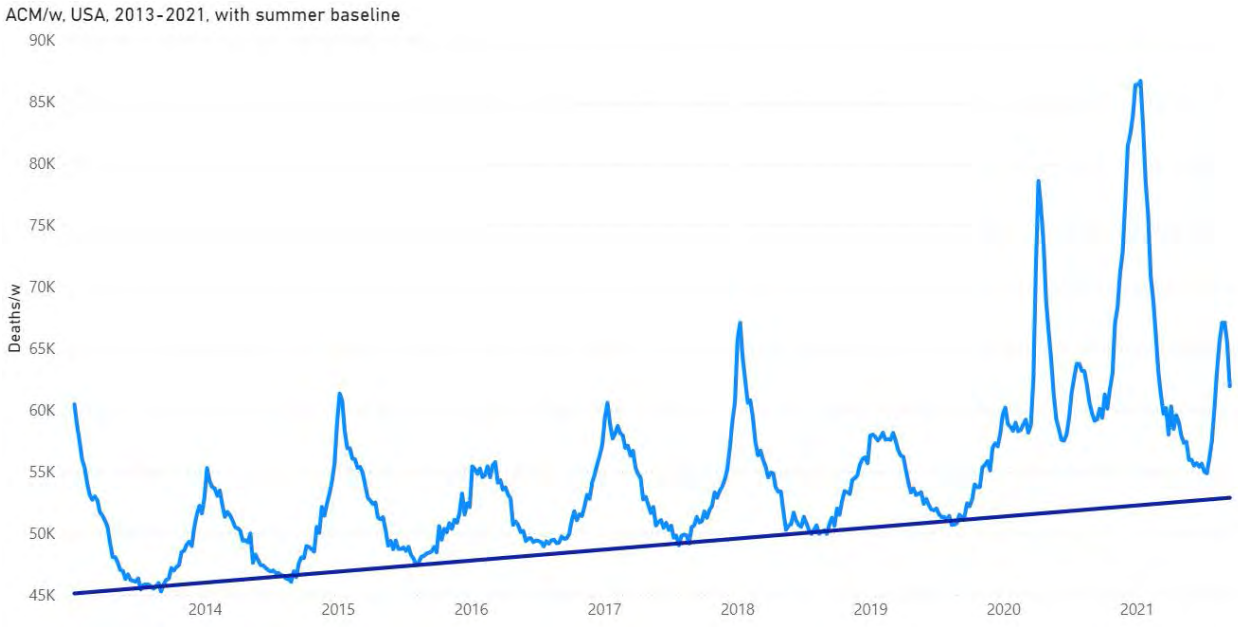


Figure 5. All-cause mortality by week in the USA from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The linear summer baseline (SB) is a least-squares fit to the summer troughs for summer-2013 through summer-2019, using the summer trough weeks 27 to 36, included, except for Alabama and Wisconsin for summer-2014 and summer-2015, respectively, and corrected by 1 % (see section 2). Data were retrieved from CDC (CDC, 2021a), as described in Table 1.

Next, for the sake of visualization, we can remove the SB from the ACM, week by week, to obtain ACM-SB/w. This is shown for the USA from 2013 to 2021, in Figure 6, where we have used different colours for the different cycle-years.

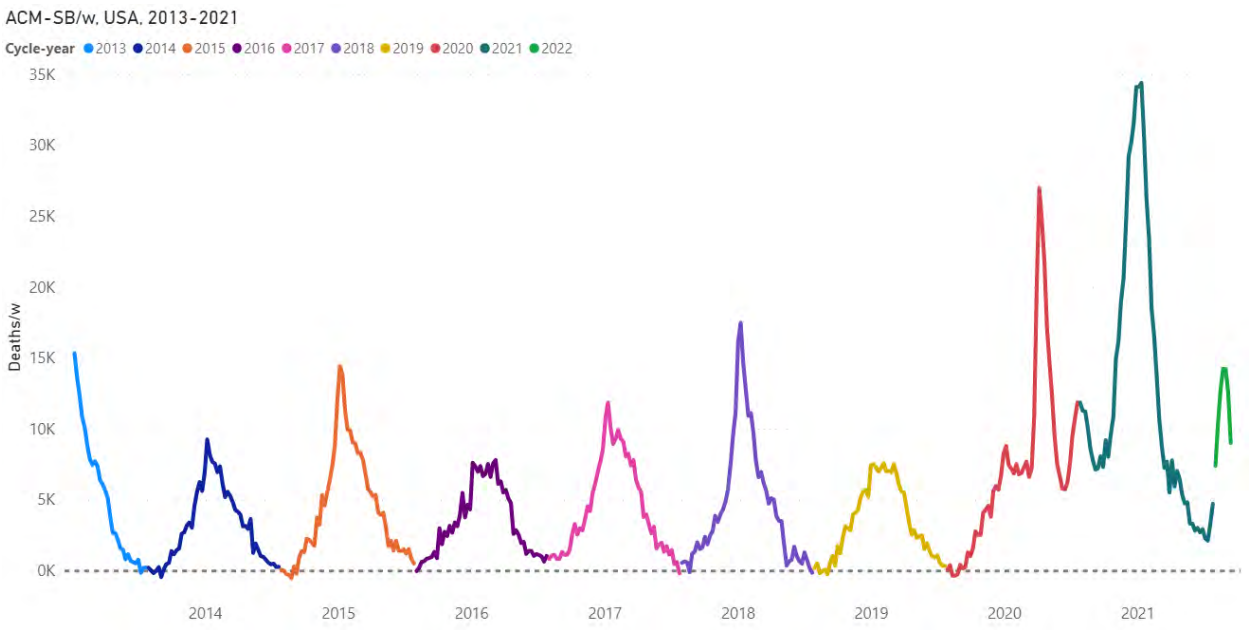


Figure 6. Difference between all-cause mortality and summer baseline mortality for the USA from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The different colours are for the different cycle-years. The cycle-year starts on week-31 of a calendar-year (beginning of August) and ends on week-30 of the next calendar-year (end of July). ACM data were retrieved from CDC (CDC, 2021a), as described in Table 1. SB was estimated as described in section 2.

Many striking features occur in ACM/w (or ACM-SB/w) in the COVID-era period for the USA (Figures 5 and 6):

- The WB (total above-SB deaths per cycle-year) is much greater in cycle-years 2020 (summer-2019 to summer-2020) and 2021 (summer-2020 to summer-2021) than in cycle years 2014 through 2019, which is consistent with ACM/y already discussed above (Figures 1 and 4).
- The 2020 cycle-year exhibits a sharp and intense feature spanning weeks 11 through 25 of 2020, starting when the pandemic was declared by the World Health Organization (WHO) on 11 March 2020, lasting three months, and which we have called “the COVID peak” and amply described in our previous articles (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021). In this article, we refer to this feature and its integrated intensity as “cvp1”.
- There is “no summer”, in terms of lower mortality, in the summer-2020. The ACM/w does not descend down to the SB. In fact, the summer of 2020 exhibits a

broad mid-summer peak in ACM/w, spanning weeks 26 through 39 of 2020 (approximately mid-June to mid-September), which is unprecedented in any ACM by time data that we have examined, for data since 1900 for dozens of countries and hundreds of jurisdictions. In this article, we refer to this feature and its integrated intensity as “smp1”.

- The 2021 cycle-year exhibits a massive peak, spanning from week-40 of 2020 through to week-11 of 2021 (approximately late-September 2020 to mid-March 2021). The peak extends to 35K deaths per week above SB. It is anticipated that the ACM/y for 2021 will be larger than for 2020, which in turn brought us back to mortality of the magnitude that was occurring just after the Second World War, on a per population basis (Figure 4a). In this article, we refer to this winter 2020-2021 feature and its integrated intensity as “cvp2”.
- Finally, there is a summer-2021 upsurge of mortality (ACM/w) in the last weeks of the usable data set, starting in mid-July 2021. This upsurge in ACM/w is particularly large for Florida, for example. We refer to this feature as “smp2”, which is interrupted by the end of the data set (week-37 of 2021 for consolidated data, as described in section 2).

To be clear, the three uninterrupted prominent features in the USA ACM/w for the COVID-era (cvp1, smp1, and cvp2) are shown, according to their operational definitions in Figure 7. For each feature, its quantification is achieved by summation of ACM-SB/w over the weeks spanned by the feature. The late-summer-2021 feature “smp2” is also indicated.

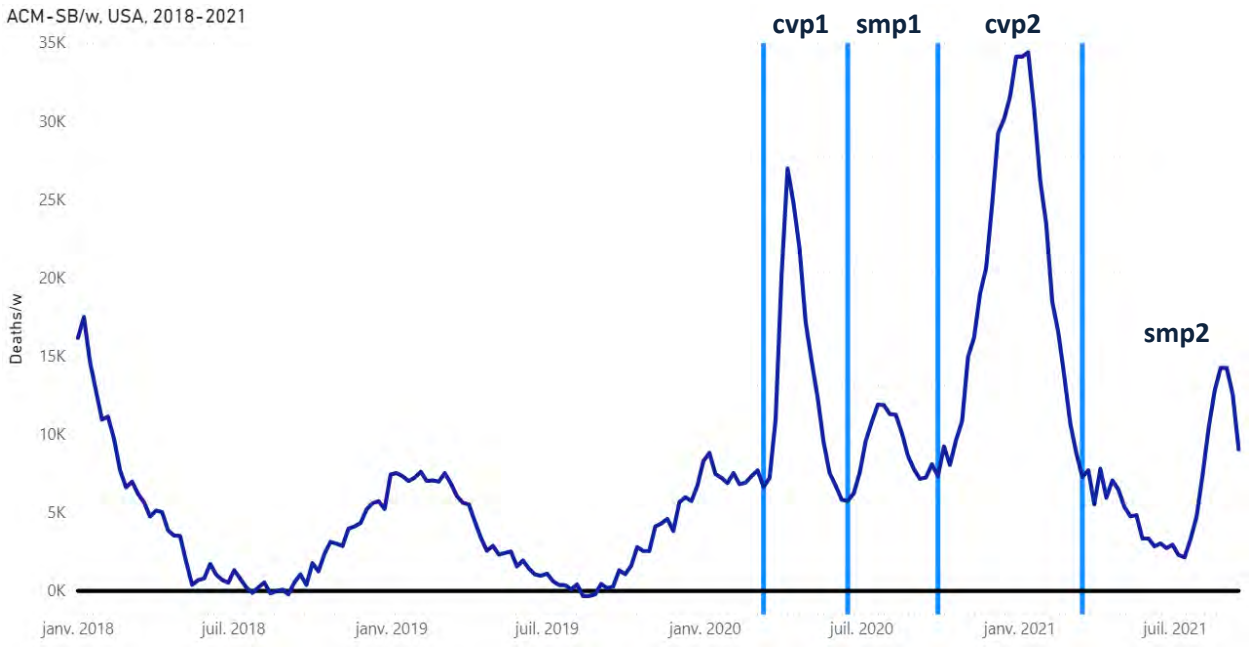


Figure 7. Difference between all-cause mortality and summer baseline mortality for the USA from 2018 to 2021. Data are displayed from week-1 of 2018 to week-37 of 2021. The cvp1, smp1, cvp2 and smp2 features discussed in the text are indicated. The light-blue vertical lines represent the weeks 11, 25, 40 of 2020 and 11 of 2021, emphasizing the delimiting weeks of the cvp1, smp1 and cvp2 features. The constant zero line is in black. ACM data were retrieved from CDC (CDC, 2021a), as described in Table 1. SB was estimated as described in section 2.

Although these features in USA ACM (cvp1, smp1, cvp2, smp2; highlighted in Figure 7) are unprecedented in recent decades and are shocking in themselves; an equally striking aspect is only seen on examining ACM/w (or ACM-SB/w) by state, for individual states. The later examination shows (below) that the said features in the COVID-era, unlike anything previously observed in epidemiology, are often dramatically different, in both relative and absolute magnitudes, and in shape and position, in going from state to state. The next section is devoted to illustrating this remarkable state-to-state variability in COVID-era ACM by time.

3.3. ACM by week (ACM/w), USA, 2013-2021, by state

Graphs of ACM/w, from 2013 to 2021, with colour-differentiated cycle-years, for all the individual states of continental USA (excluding Alaska and Hawaii) are shown in Appendix (attached below).

In these graphs (Appendix), note that the pre-COVID-era seasonal pattern (2013-2019) is essentially identical from state to state (more on this further below), whereas there are large state to state changes in the COVID-era patterns. This concurs with our previous findings that COVID-era behaviour in ACM by time is abnormally heterogeneous on a jurisdictional basis, which is the opposite of past seasonal epidemiological behaviour (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021). Woolf et al. (2021) also report large USA regional differences in all-cause excess mortality by time patterns during the COVID-era.

Some comparative and systematic features in these curves (Appendix) are as follows.

- **L0M / North-Easterly coastal states:** Several of the North-Easterly coastal states exhibit a pattern in cvp1-smp1-cvp2 (an “L0M” pattern) in which cvp1 is very large, smp1 is essentially zero (ACM/w comes down to the SB values) and cvp2 is of medium magnitude: New York, New Jersey, Connecticut, Massachusetts and Rhode Island, and Maryland and District of Columbia to some degree.
- **LSL / North-Central-Easterly non-coastal states:** A group of neighbouring North-Central-Easterly non-coastal states exhibit a pattern in cvp1-smp1-cvp2 (an “LSL” pattern) in which cvp1 is large, smp1 is small (near-zero) and cvp2 is large: Colorado, Delaware, Illinois, Indiana, Michigan, and Pennsylvania, although Michigan has a unique extra peak in ACM/w.
- **LSLx / Michigan:** Michigan has an LSL pattern and belongs to the latter group, however its LSL pattern is followed by a unique late peak occurring in March through May 2021, centered in mid-April. Therefore, we refer to Michigan’s pattern as “LSLx”.

- **00L / prairie states:** Seven of the ten prairie or Great Plains states, states that experienced the Dust Bowl drought of the 1930s, saw no anomalous mortality whatsoever until late into the COVID-era, until the fall of 2021. Here, cvp1 and smp1 are essentially zero or near-zero, and the only large feature is cvp2 ("00L" pattern). Easterly neighbouring states of Iowa, Missouri and Wisconsin also have this 00L pattern: Iowa, Kansas, Missouri, Montana, Nebraska, North Dakota, Oklahoma, South Dakota, and Wisconsin. The prairie states of New Mexico and Wyoming have a similar pattern, 0SL; whereas Texas has 0LL, and Colorado has LSL.
- **0SL / Central-Westerly and Central-Easterly states:** The cluster of adjacent states of Arkansas, Idaho, Kentucky, North Carolina, Tennessee, West Virginia, Wyoming, Nevada and Utah, and the prairie state of New Mexico, exhibit a "0SL" pattern. The 00L and 0SL patterns are similar: in 00L we characterize smp1 as "near-zero", whereas in 0SL we characterize smp1 as "small".
- **0SL / North-Westerly coastal states:** The North-Westerly coastal states of Oregon and Washington also have the 0SL pattern; and a sharp (one-week) heatwave signal discussed below (section 3.4).
- **SBL / North-Easterly states:** Minnesota, New Hampshire, Ohio, and Virginia exhibit an "SBL" pattern, intermediate between SSL and S0L.
- **SSL / California and Georgia:** California and Georgia exhibit similar patterns to each other, in which both cvp1 and smp1 are distinct but small or medium, and cvp2 is very large. We refer to this as an "SSL" pattern. The SSL pattern occurs in populous states but is otherwise similar to the 00L and 0SL patterns, in that relatively small or near-zero excess mortality occurs until late into the COVID-era, until the fall of 2021 when cvp2 starts and becomes a large feature in ACM/w.
- **0LL / Southern states:** Both Florida and Texas exhibit a "0LL" pattern in cvp1-smp1-cvp2 in which cvp1 is essentially zero, whereas smp1 and cvp2 are both large. Most of the most southerly states exhibit this pattern: Alabama, Arizona, Florida, Mississippi, South Carolina, and Texas; whereas Louisiana exhibits a pattern in which all three features are large, an "LLL" pattern. Thus, the Southern

states are generally characterized and distinguished by large mortalities in the summer of 2020, which is exceptional for these states, followed by large mortalities in the fall and winter of 2020-2021.

- **LLL / Louisiana:** Louisiana is the only state that has all three main features in ACM/w (cvp1, smp1, cvp2) being comparable and large. It is the only Southern state that experienced a large cvp1 mortality at the start of the COVID-era.
- The remaining states, Vermont and Maine, have borderline patterns to those described above, which could be characterized as 00S and 0SS, respectively.
- The summer-2021 feature “smp2” occurs in virtually all the states (see Appendix).

This distribution of cvp1-smp1-cvp2 pattern type is shown, colour coded, on a map of the USA, in Figure 8.

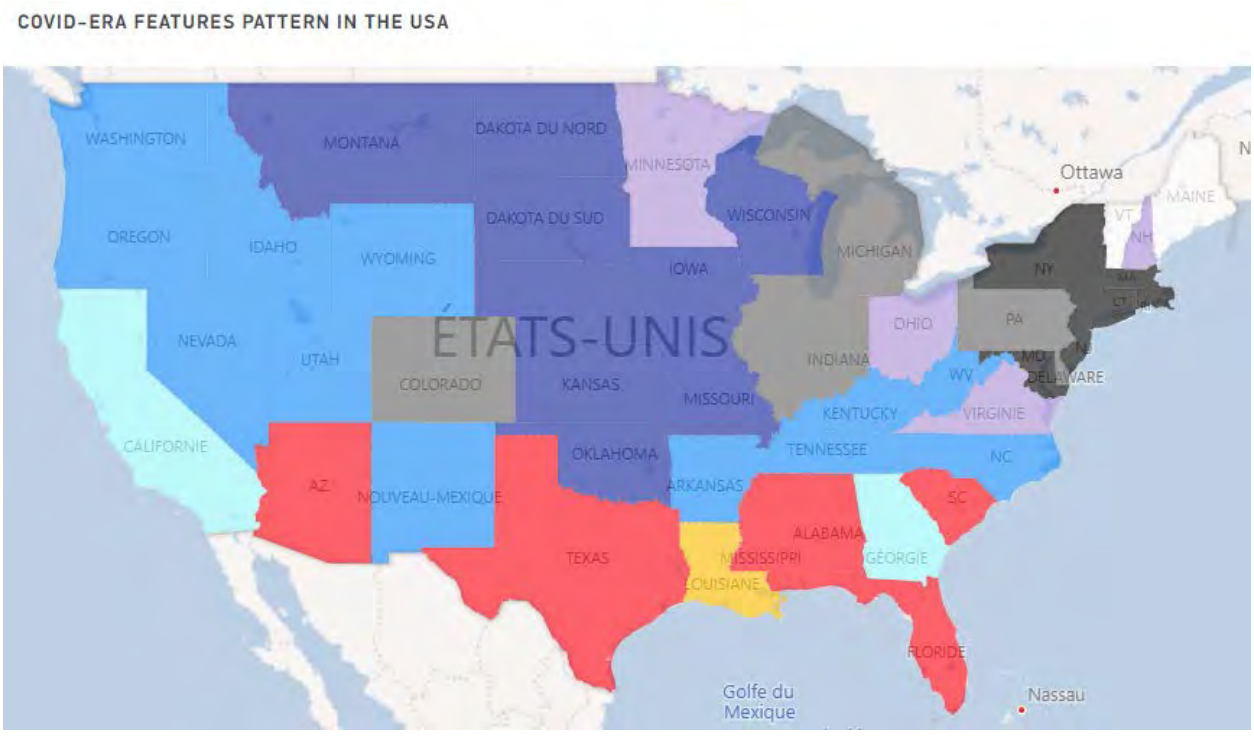


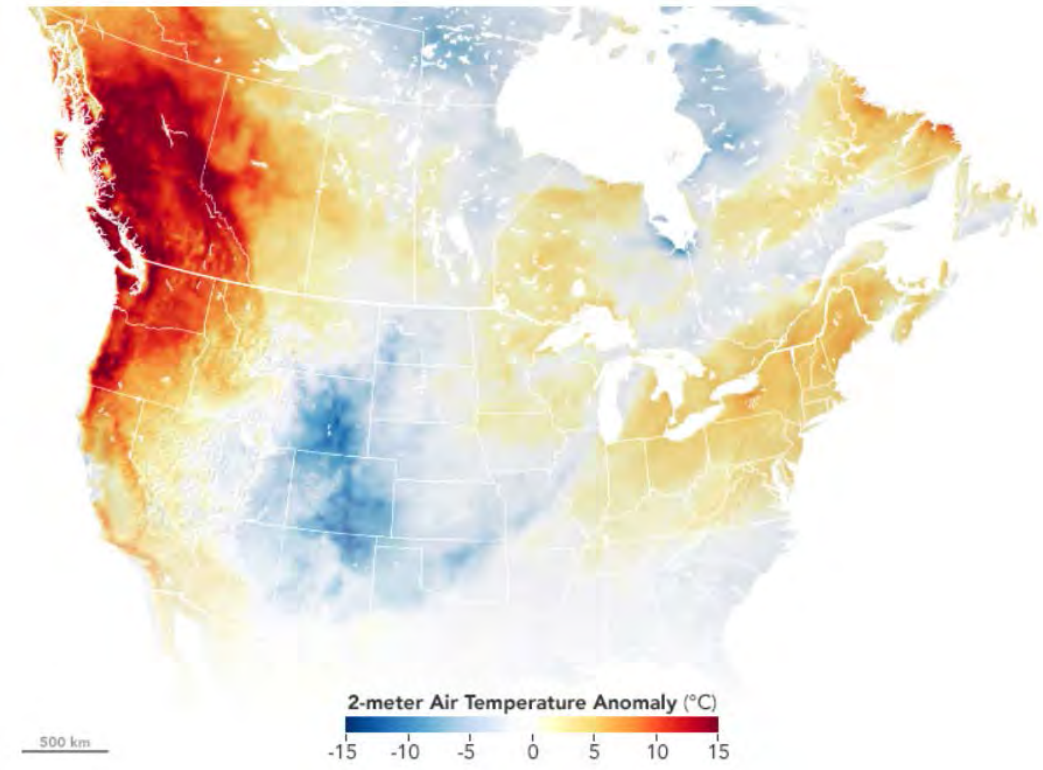
Figure 8. Map of COVID-era features pattern in the USA. The different colours represent the different pattern groups discussed in the text: black = L0M, gray = LSL, dark blue = 00L, blue = 0SL, light blue = SSL, purple = SBL, red = 0LL, yellow = LLL, white = 00S and 0SS. The first character of the pattern characterizes the cvp1 feature, the second the smp1 feature and the last the cvp2 feature. L stands for large, M for medium, S for small, B for borderline and 0 for zero / near-zero.

3.4. Late-June 2021 heatwave event in ACM/w for Oregon and Washington

There are sharp peaks (a single week or so) in the ACM/w data for Oregon and Washington, occurring at week-26 of 2021, which is the week of 28 June 2021 (Appendix).

The increased deaths coincide with an extraordinary weather event: The two states and British Columbia (Canada) experienced a short but record-breaking summer heatwave. NASA Earth Observatory (2021) described the heatwave as follows:

> The second map shows air temperature anomalies across the continental United States and Canada on June 27, 2021, when the heat intensified and records started to fall. The map is derived from the Goddard Earth Observing System (GEOS) model and depicts air temperatures at 2 meters (about 6.5 feet) above the ground. Red areas are where air temperatures climbed more than 27°F (15°C) higher than the 2014-2020 average for the same day.



Taking peak-to-local-baseline values, we estimate excess deaths from the heatwave to have been 246 and 475 deaths, respectively for Oregon and Washington.

This is a reminder of the deadliness of stress from atmospheric heat, which is relevant to our discussion about the COVID-era anomalies in the USA (below). We previously quantified such a heat-wave mortality event that occurred in France in 2003 (Rancourt et al., 2020).

3.5. ACM-SB/w normalized by population (ACM-SB/w/pop), by state

The different state-wise patterns of mortality in the USA during the COVID-era are best examined using ACM-SB/w normalized by population, ACM-SB/w/pop, and by reference to the cvp1-smp1-cvp2 patterns identified above. Normalization by population allows direct comparisons of the data for states with different populations.

In the following figures, normalization was done as follows:

Normalization of a cycle-year N was done with the population estimated just before the start of the cycle-year. Population estimates are each year on July 1st. The cycle-year starts on week-31 of a calendar-year (beginning of August). At the date of access, population estimates were from 2010 to 2020, so the cycle-year 2022 (last weeks of the data set) was normalized by the last available population estimate, the one for 2020.

When at the state level, the population used for normalization is the population of the specific state.

ACM-SB/w/pop curves are shown by groups of similar behaviours in Figure 9, as:

(a) L0M / North-Easterly coastal states: Connecticut, Maryland, Massachusetts, New Jersey, and New York.
(b) LSL / North-Central-Easterly non-coastal states: Colorado, Illinois, Indiana, Michigan (LSLx), and Pennsylvania.

(c) 00L / prairie states: Iowa, Kansas, Missouri, Montana, Nebraska, North Dakota, Oklahoma, and South Dakota. (Wisconsin is excluded because of bad data points for 2015, see Appendix.)

(d) 0SL / Central-Westerly non-coastal states: Idaho, Nevada, New Mexico, Utah, Wyoming.

(e) 0SL / North-Westerly coastal states: Oregon and Washington. (With June-2021 heatwave peak.)

(f) SSL / California and Georgia: California and Georgia.

(g) 0LL / Southern states: Arizona, Florida, Mississippi, South Carolina, and Texas (Alabama is excluded because of bad data points for 2014, see Appendix).

(h) LLL / Louisiana: Louisiana, shown with Michigan.

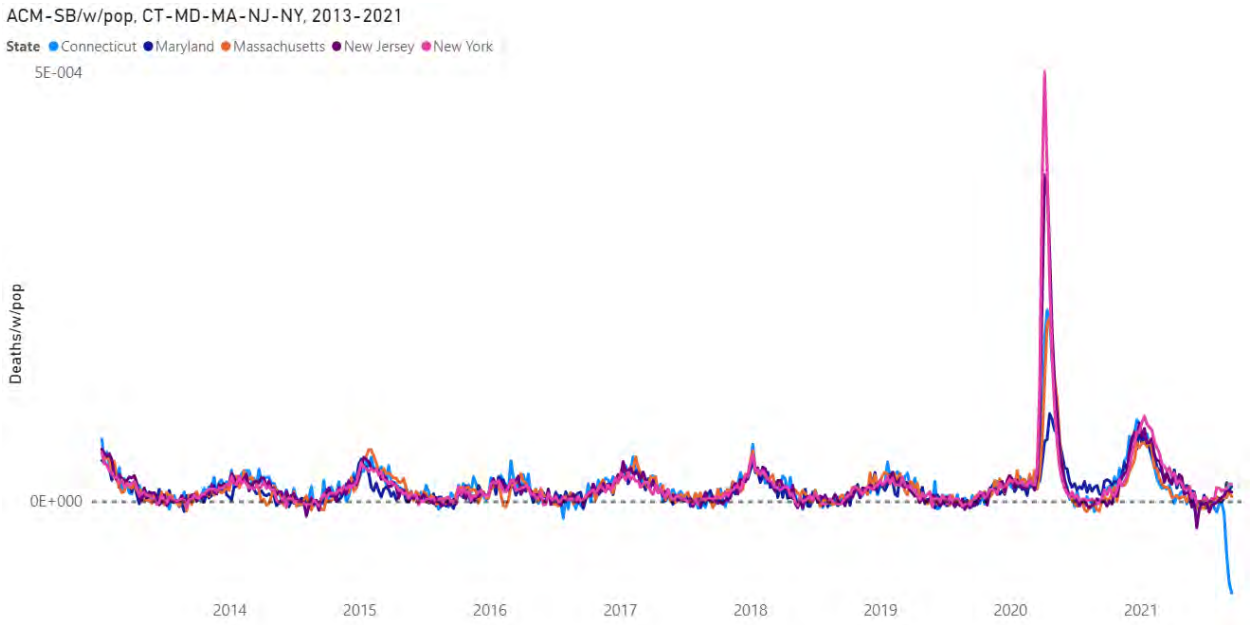


Figure 9a. Difference between all-cause mortality and summer baseline mortality by week normalized by population for Connecticut, Maryland, Massachusetts, New Jersey and New York from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

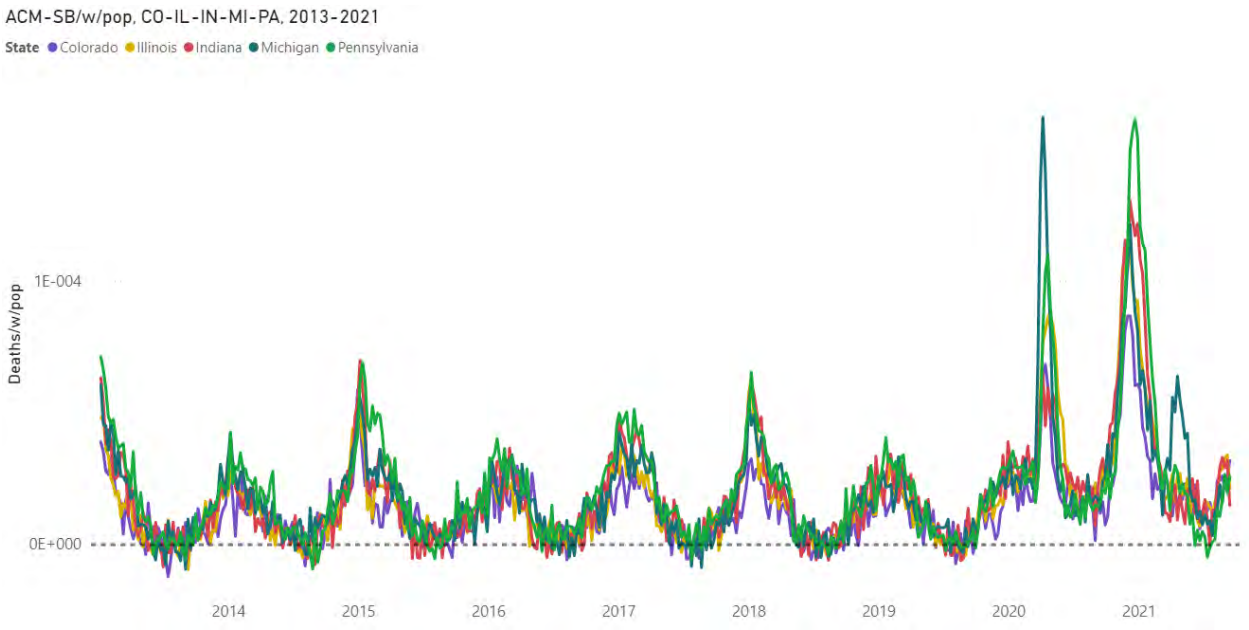


Figure 9b(i). Difference between all-cause mortality and summer baseline mortality by week normalized by population for Colorado, Illinois, Indiana, Michigan and Pennsylvania from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

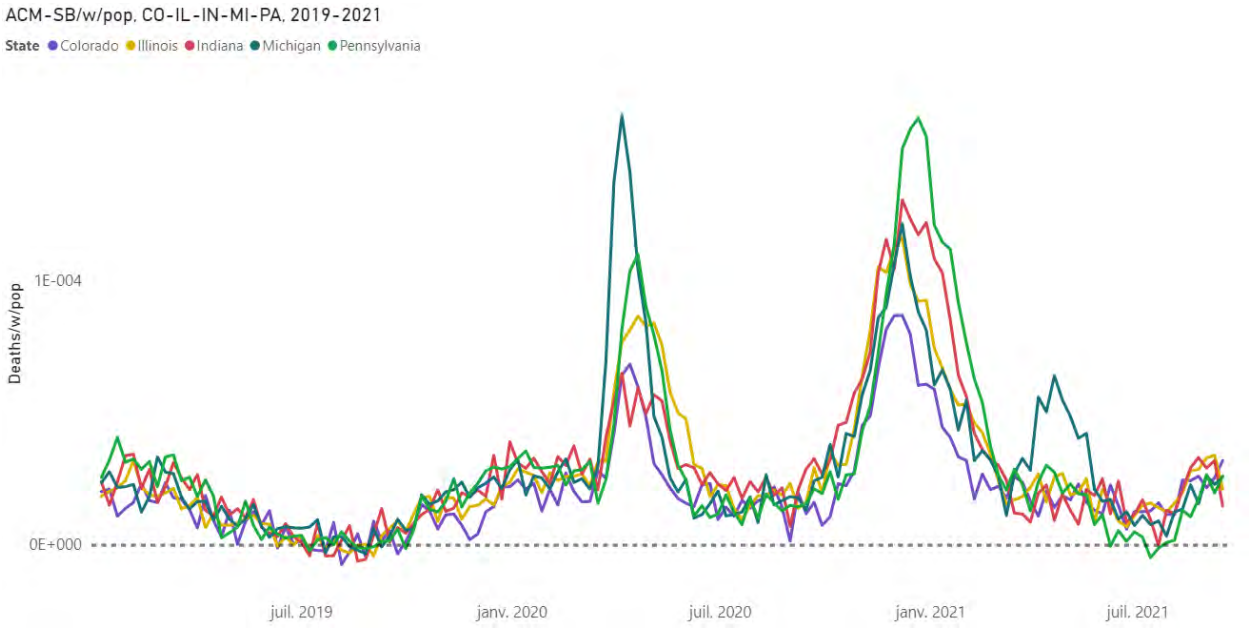


Figure 9b(ii). Difference between all-cause mortality and summer baseline mortality by week normalized by population for Colorado, Illinois, Indiana, Michigan and Pennsylvania from 2019 to 2021. Data are displayed from week-1 of 2019 to week-37 of 2021. The dashed

line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

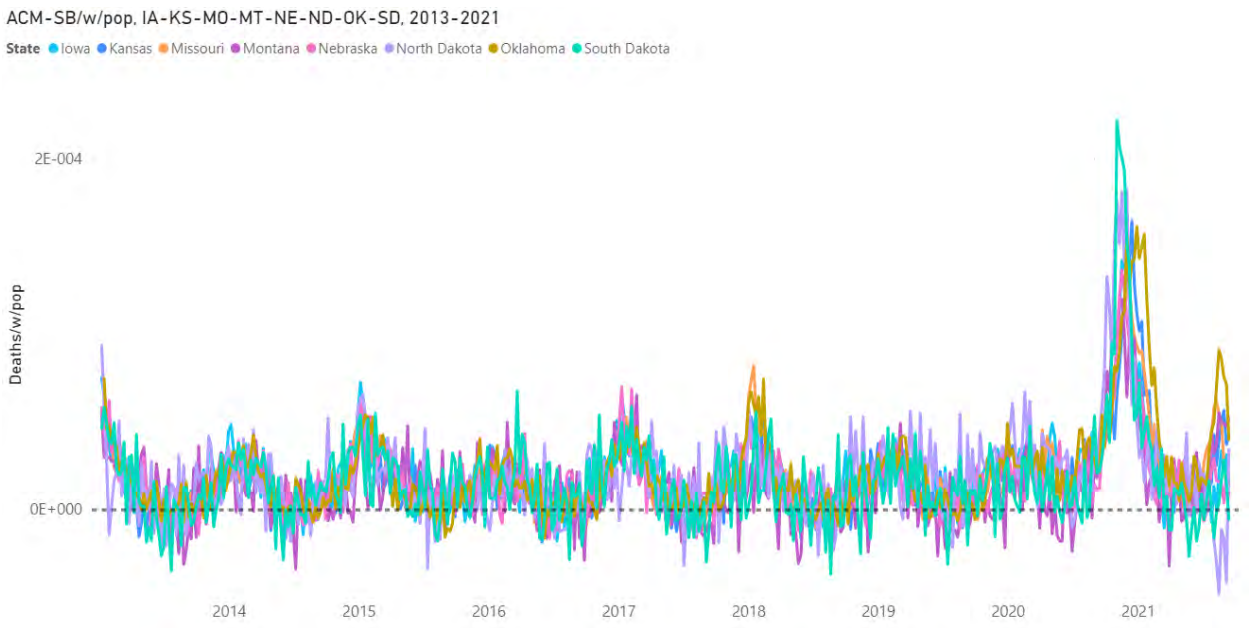


Figure 9c. Difference between all-cause mortality and summer baseline mortality by week normalized by population for Iowa, Kansas, Missouri, Montana, Nebraska, North Dakota, Oklahoma and South Dakota from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

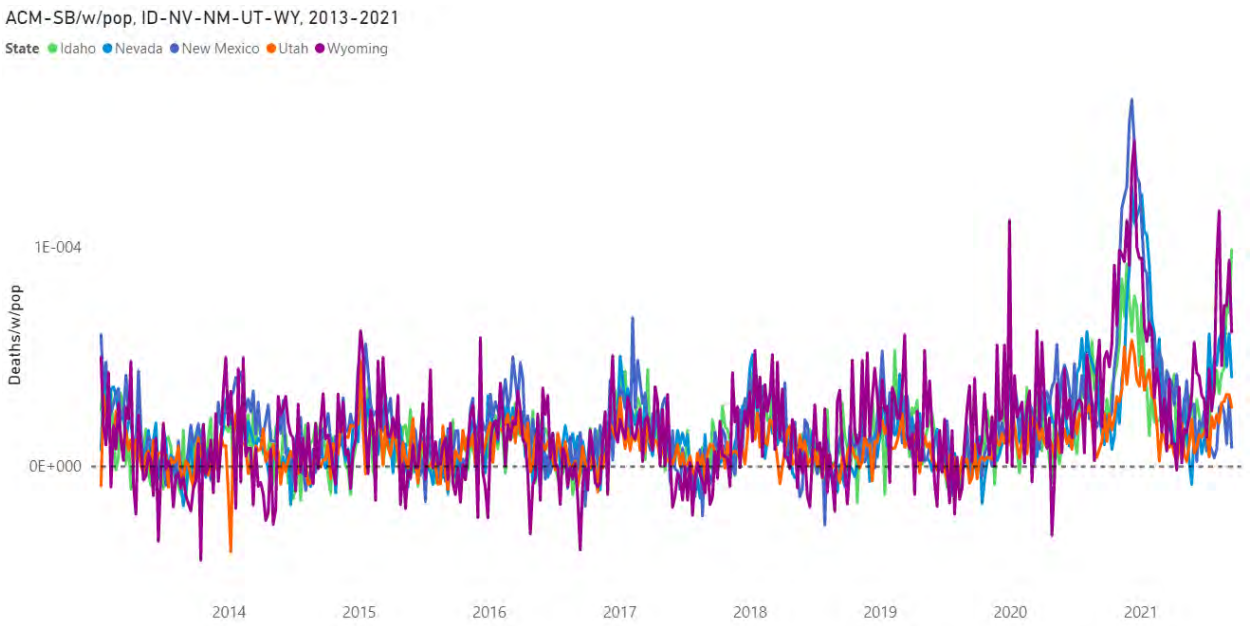


Figure 9d. Difference between all-cause mortality and summer baseline mortality by week normalized by population for Idaho, Nevada, New Mexico, Utah and Wyoming from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

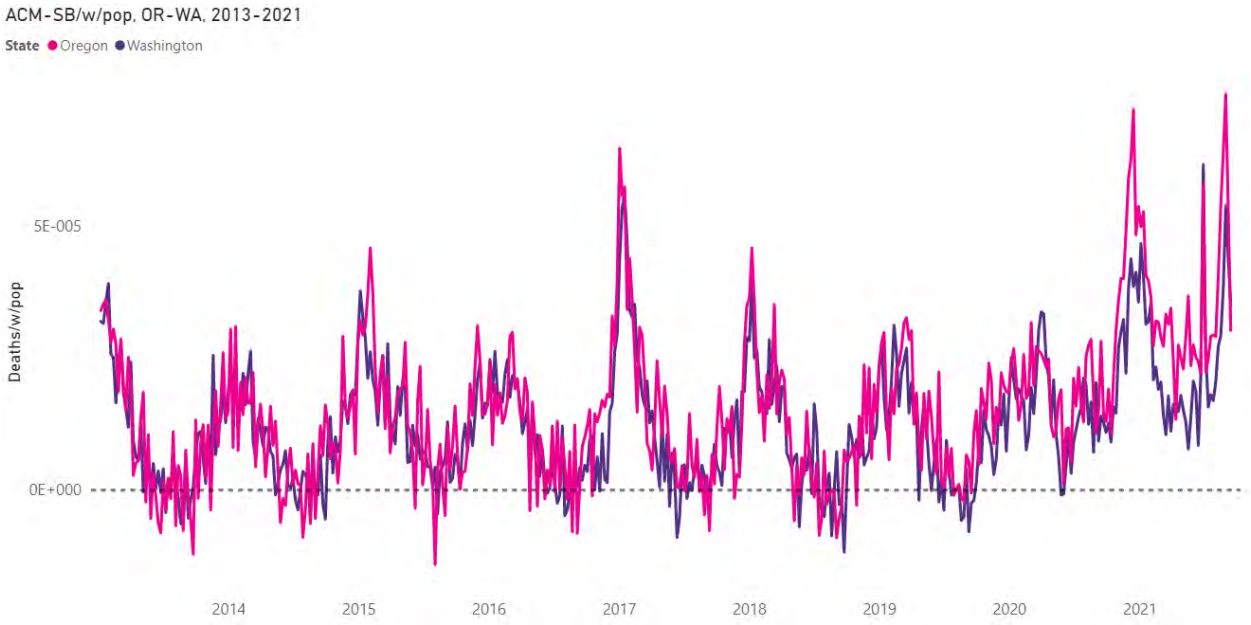


Figure 9e. Difference between all-cause mortality and summer baseline mortality by week normalized by population for Oregon and Washington from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The dashed line emphasizes the zero. ACM

data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

Figure 9f. Difference between all-cause mortality and summer baseline mortality by week normalized by population for California and Georgia from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

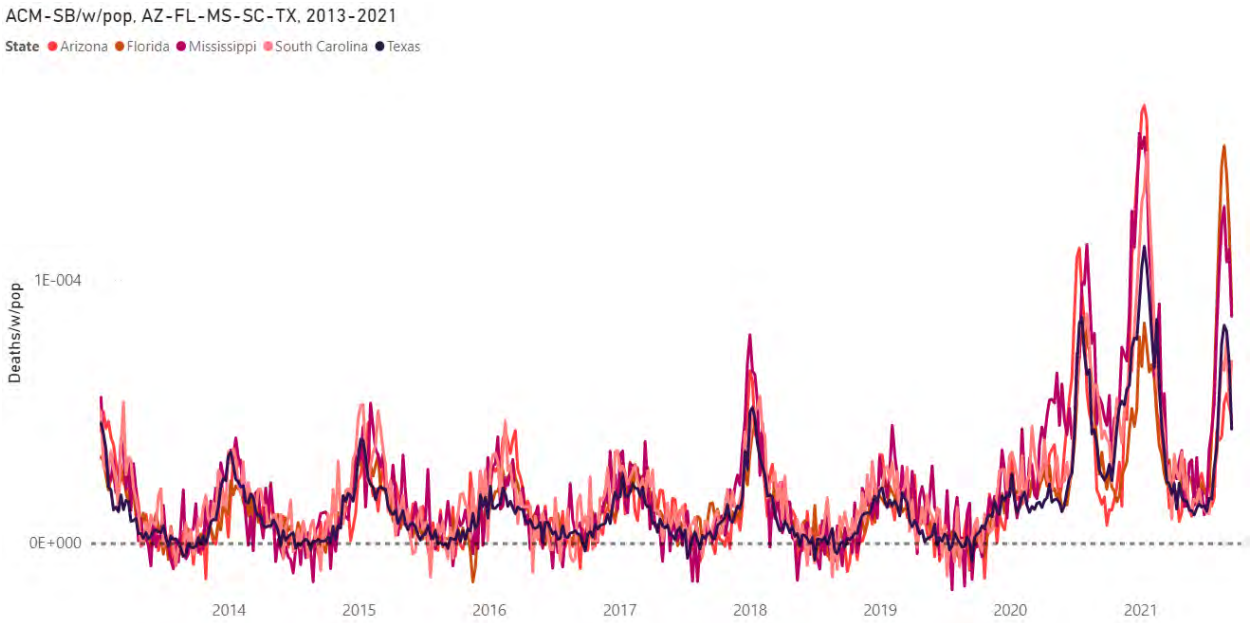


Figure 9g. Difference between all-cause mortality and summer baseline mortality by week normalized by population for Arizona, Florida, Mississippi, South Carolina and Texas from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

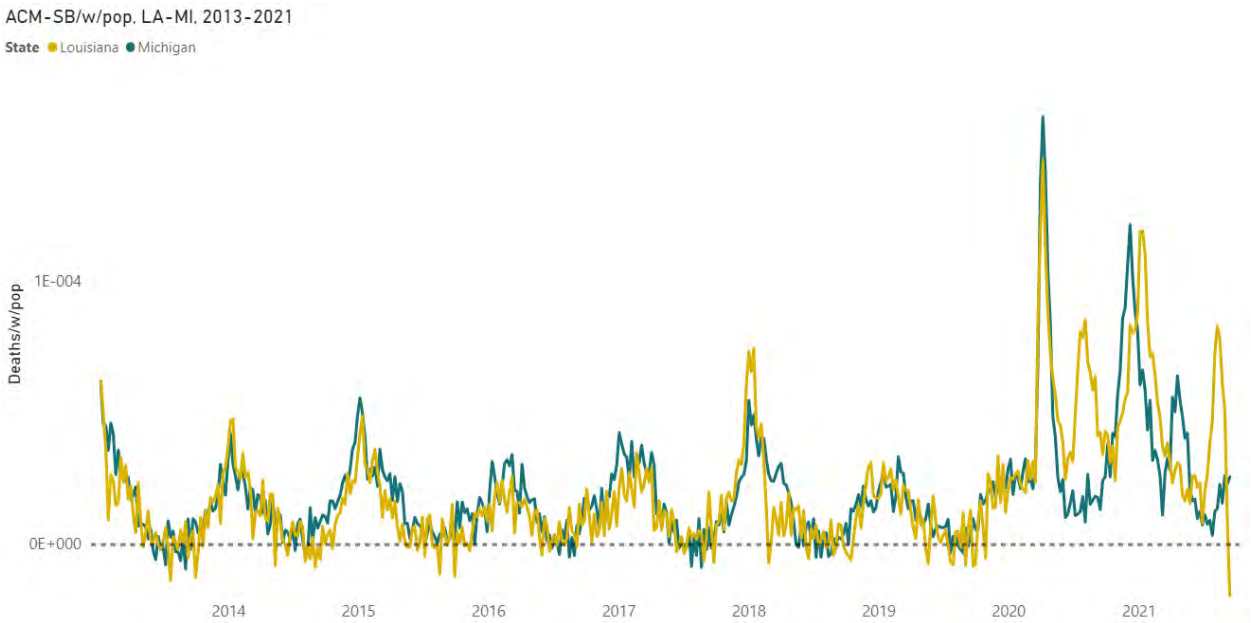


Figure 9h(i). Difference between all-cause mortality and summer baseline mortality by week normalized by population for Louisiana and Michigan from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The dashed line emphasizes the zero. ACM

data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

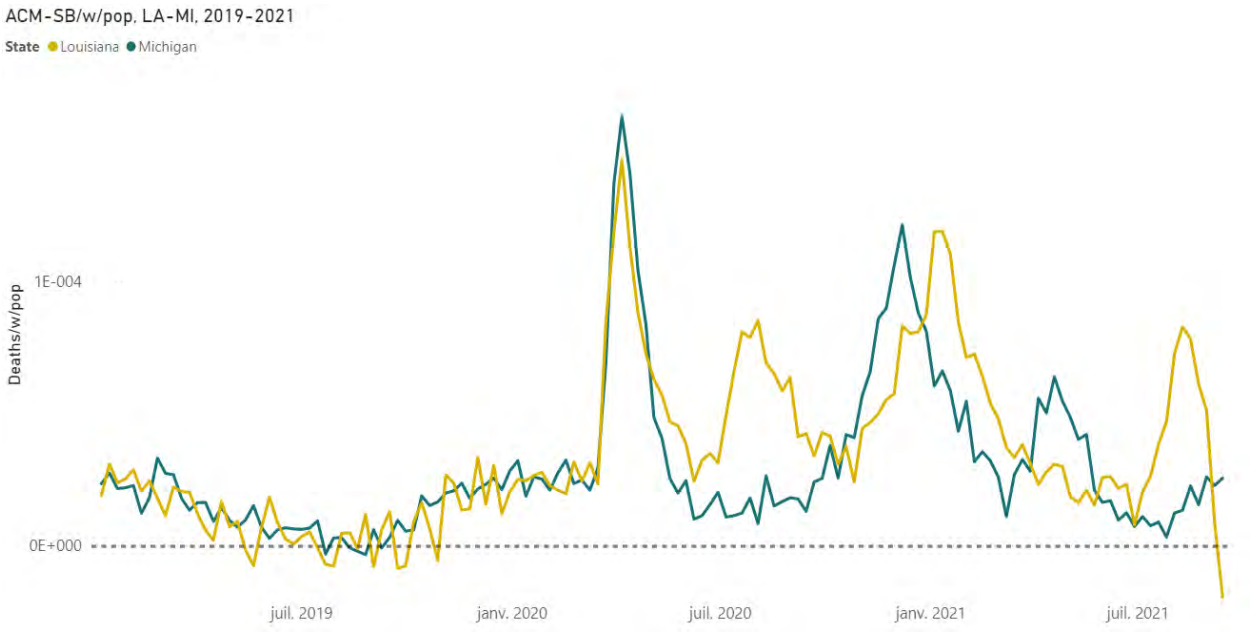


Figure 9h(ii). Difference between all-cause mortality and summer baseline mortality by week normalized by population for Louisiana and Michigan from 2019 to 2021. Data are displayed from week-1 of 2019 to week-37 of 2021. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

Figures 8 and 9 show that there are large state-to-state differences in COVID-era mortality by time, and that these differences approximately group into four (4) types, by geographical region, as:

- L0M : North-East coastal states
- LSL : North-East non-coastal states
- 00L / 0SL / SSL / SBL : Central and Western-Eastern states
- 0LL : Southern states

Louisiana is unique, with an LLL pattern, and large mortality in all three periods (cvp1, smp1, cvp2). Michigan (LSLx) has a unique late peak, occurring in March through May

2021, centered on mid-April 2021. Oregon and Washington have unique June-2021 single-week heatwave peaks.

This description is “coarse grain” and is simplified. For example, California has a distinct cvp1 feature even though it is much smaller than that occurring in the North-East states. Also, what happened in New York City is literally off-the-charts regarding cvp1 (Rancourt, 2020).

A most striking aspect of mortality during the COVID-era is precisely the state-wise heterogeneity in ACM by time, which we have described and illustrated above, and in the Appendix. This is striking because the seasonal cycle of all-cause deaths is usually remarkably uniform from state to state, from country to country, from province to province, from county to county… through all the inferred and declared epidemics and pandemics of viral respiratory diseases. Although the shapes of ACM by time change from season to season, the shapes for a given year are nonetheless synchronous and essentially the same across regions, over a global hemisphere, since good data has been available, since the end of the Second World War in most Western countries (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021).

Indeed, as an aside, we consider that this empirical fact (geographic homogeneity of synchronous mortality by time curves) represents a hard challenge against the theory that viral respiratory diseases spread person-to-person by proximity or “contact” and that such spread drives epidemics and pandemics, at the population level.

We quantify the said geographical heterogeneity of the COVID-era mortality by time below, but first we illustrate it further with direct comparisons of the ACM-SB/w/pop curves for states in different regions, with different cvp1-smp1-cvp2 patterns.

Figure 10 shows ACM-SB/w/pop for one state from each of the following cvp1-smp1-cvp2 patterns: California (SSL), Florida (0LL), Michigan (LSLx), Nevada (0SL), New York (L0M), South Dakoda (00L).

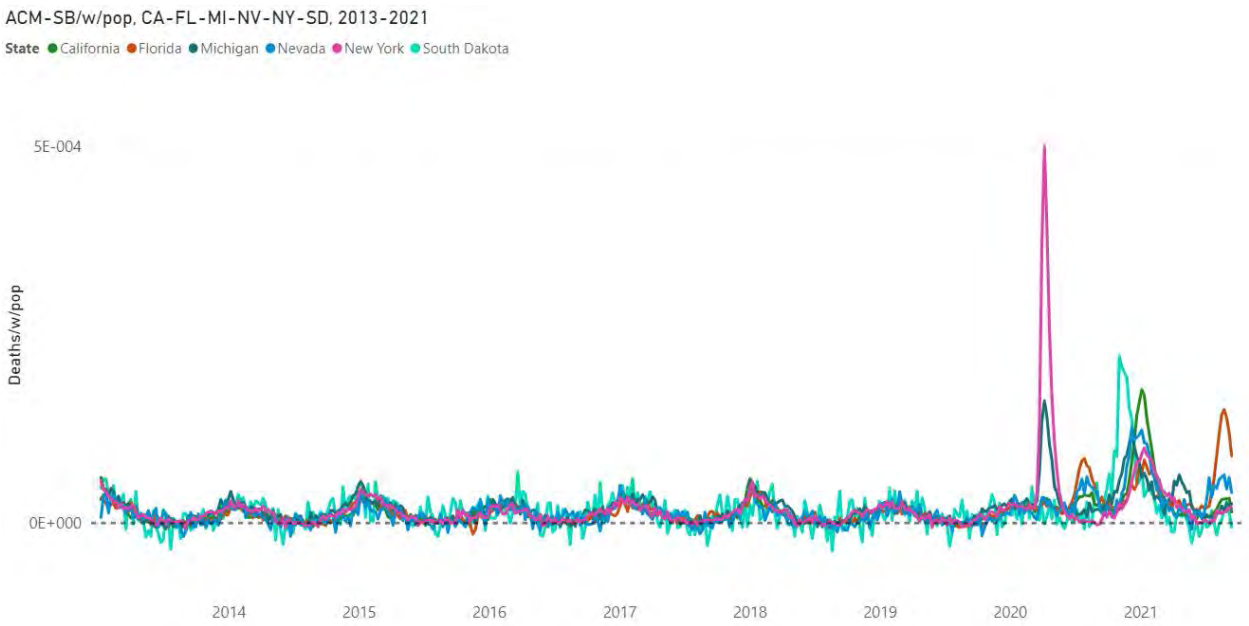


Figure 10a. Difference between all-cause mortality and summer baseline mortality by week normalized by population for California, Florida, Michigan, Nevada, New York and South Dakota from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

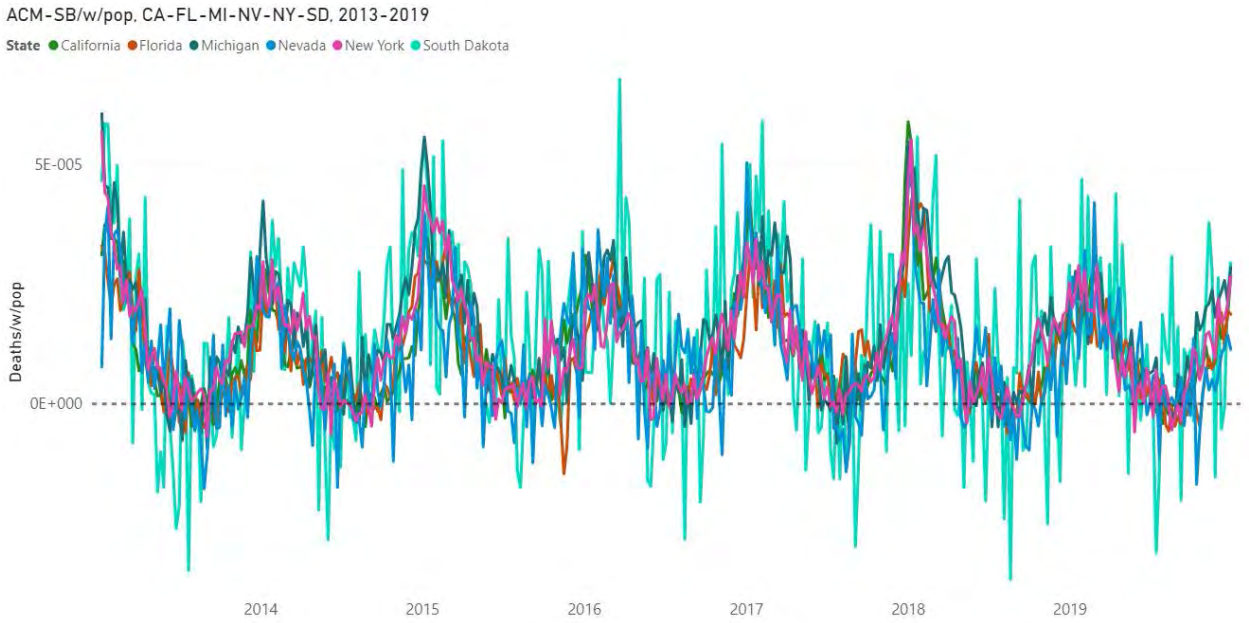


Figure 10b. Difference between all-cause mortality and summer baseline mortality by week normalized by population for California, Florida, Michigan, Nevada, New York and South Dakota from 2013 to 2019. Data are displayed from week-1 of 2013 to week-52 of 2019.

The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

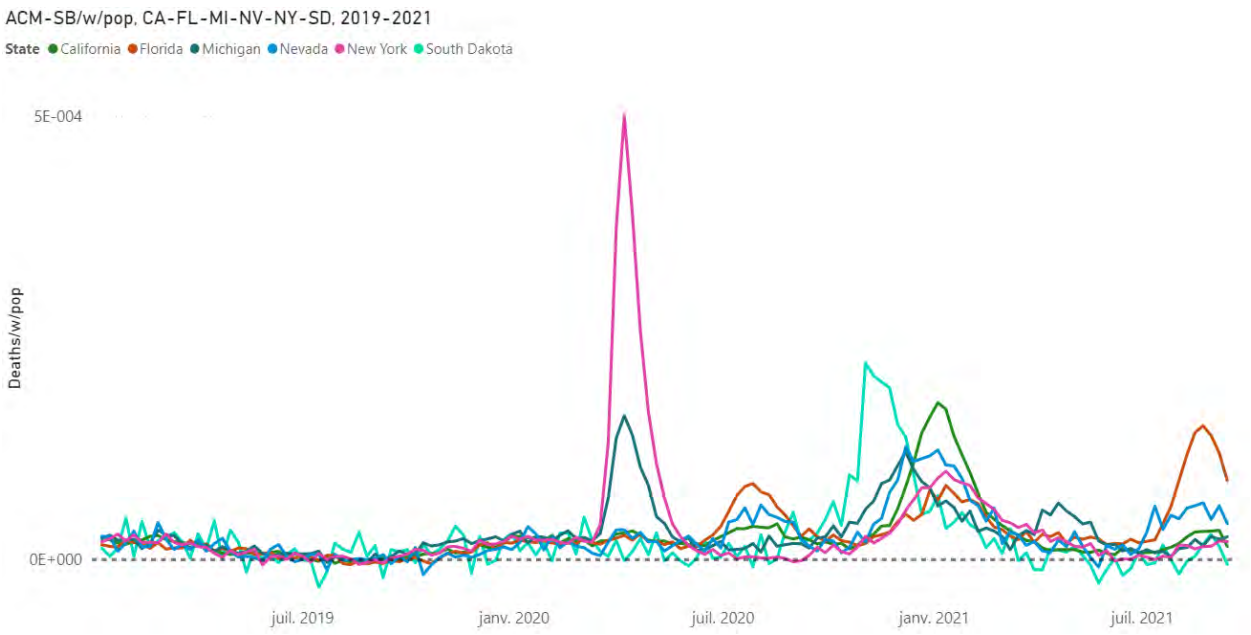


Figure 10c. Difference between all-cause mortality and summer baseline mortality by week normalized by population for California, Florida, Michigan, Nevada, New York and South Dakota from 2019 to 2021. Data are displayed from week-1 of 2019 to week-37 of 2021. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

Figure 11 makes the same kind of comparison for states that have large cvp1 features: Colorado (LSL), Connecticut (L0M), Illinois (LSL), Louisiana (LLL), New Jersey (L0M), New York (L0M).

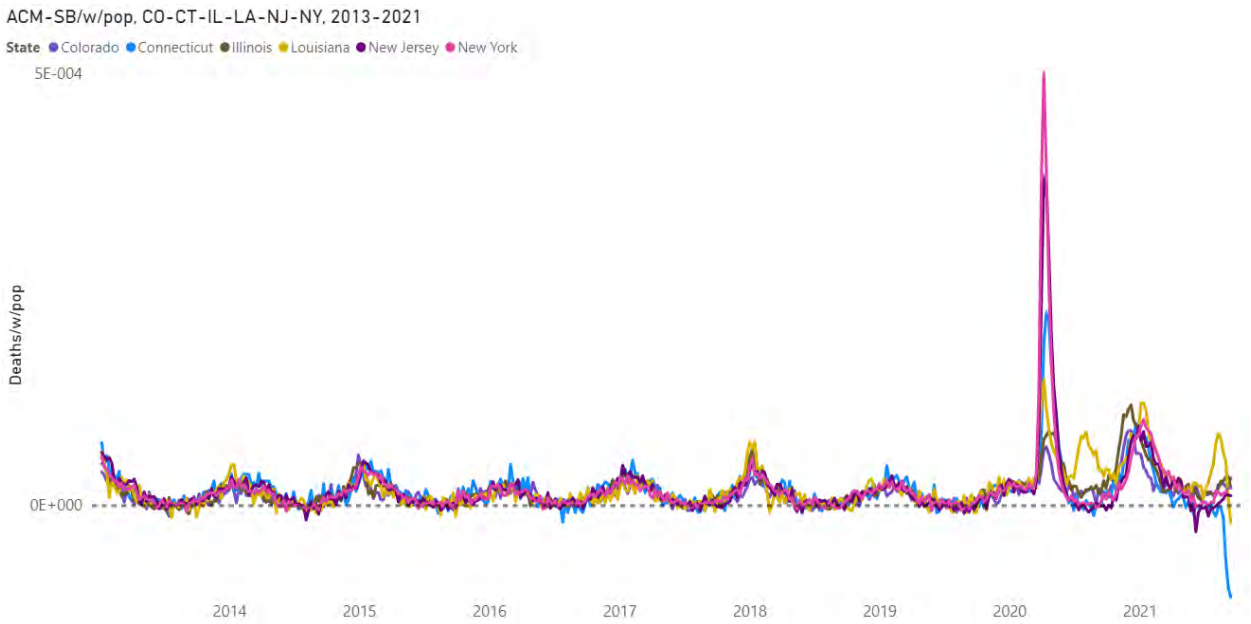


Figure 11a. Difference between all-cause mortality and summer baseline mortality by week normalized by population for Colorado, Connecticut, Illinois, Louisiana, New Jersey and New York from 2013 to 2021. Data are displayed from week-1 of 2013 to week-37 of 2021. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

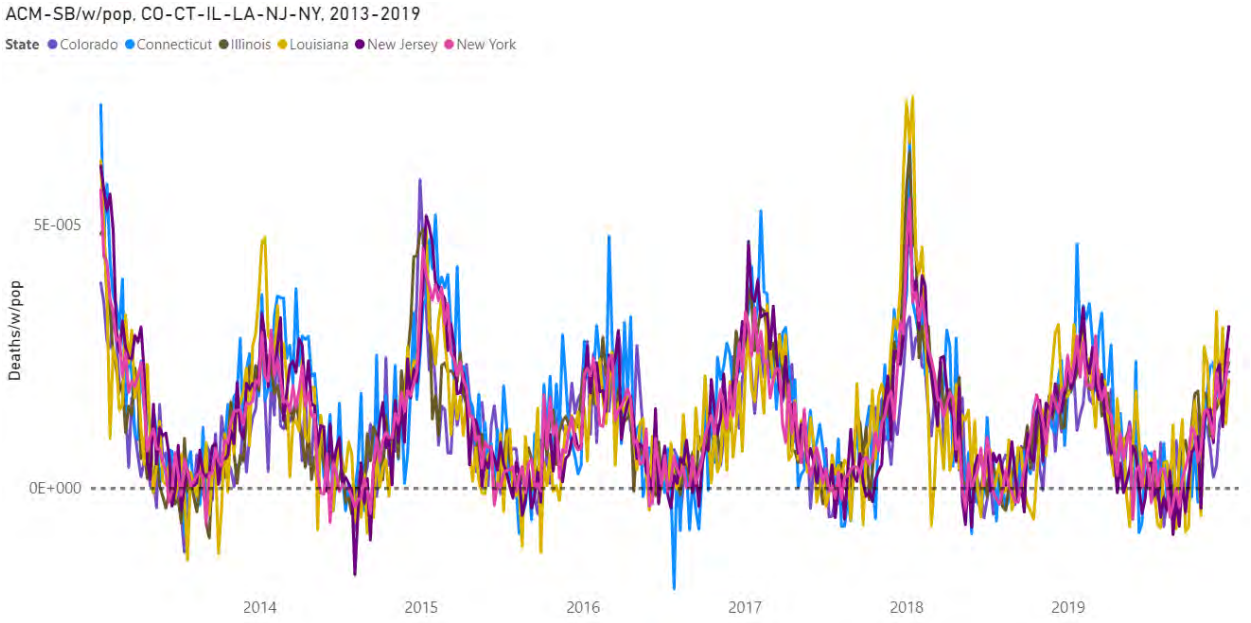


Figure 11b. Difference between all-cause mortality and summer baseline mortality by week normalized by population for Colorado, Connecticut, Illinois, Louisiana, New Jersey and New York from 2013 to 2019. Data are displayed from week-1 of 2013 to week-52 of

2019. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

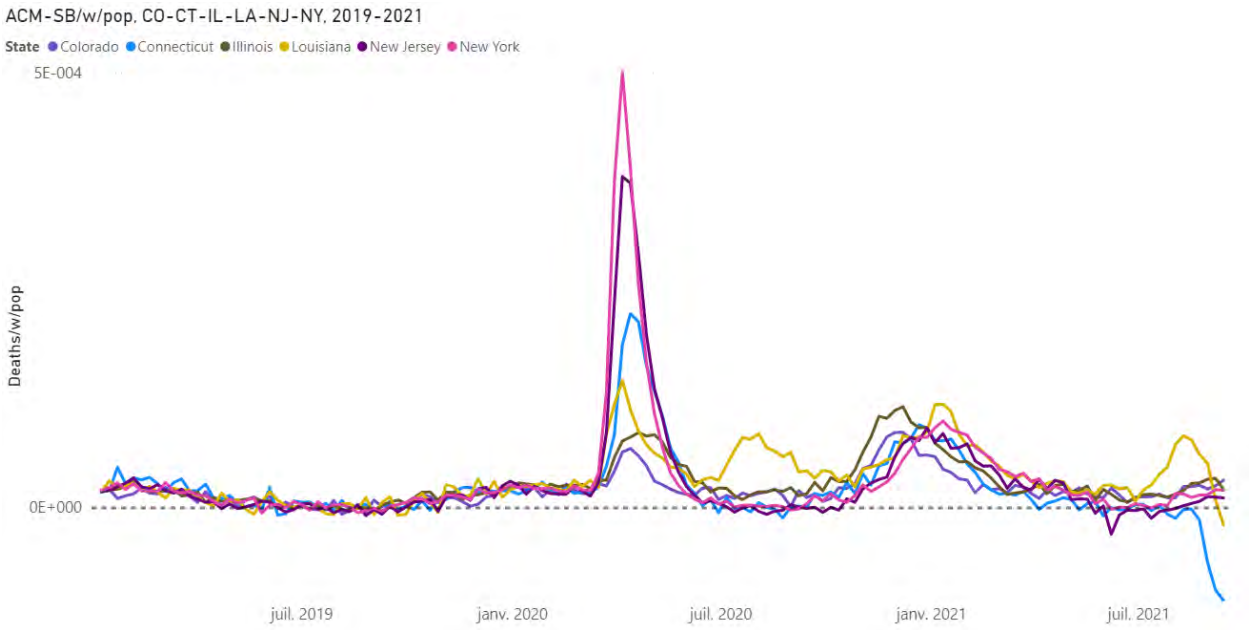


Figure 11c. Difference between all-cause mortality and summer baseline mortality by week normalized by population for Colorado, Connecticut, Illinois, Louisiana, New Jersey and New York from 2019 to 2021. Data are displayed from week-1 of 2019 to week-37 of 2021. The dashed line emphasizes the zero. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

3.6. ACM-SB by cycle-year (winter burden, WB) by population (WB/pop), USA and state-to-state variations

Next, we analyse ACM-SB/w in terms of integrated intensities over cycle-years. By definition, the said integrated intensity is the “winter burden”, WB, for the given cycle-year. WB is the excess (above-SB) mortality per cycle-year. We normalize WB by population, WB/pop, in order to make state-to-state and state-to-nation comparisons.

Figure 12a shows the WB/pop, for cycle-years 2014 to 2021 (cycle-year 2021 contains and is approximately centered on January 2021, and so on), for the entire continental

USA (49 states). We see the seasonal (year to year) variations 2014-2019, followed by the large COVID-era increase 2020-2021, which echoes the large 2020 calendar-year increase shown in Figures 1 and 4.

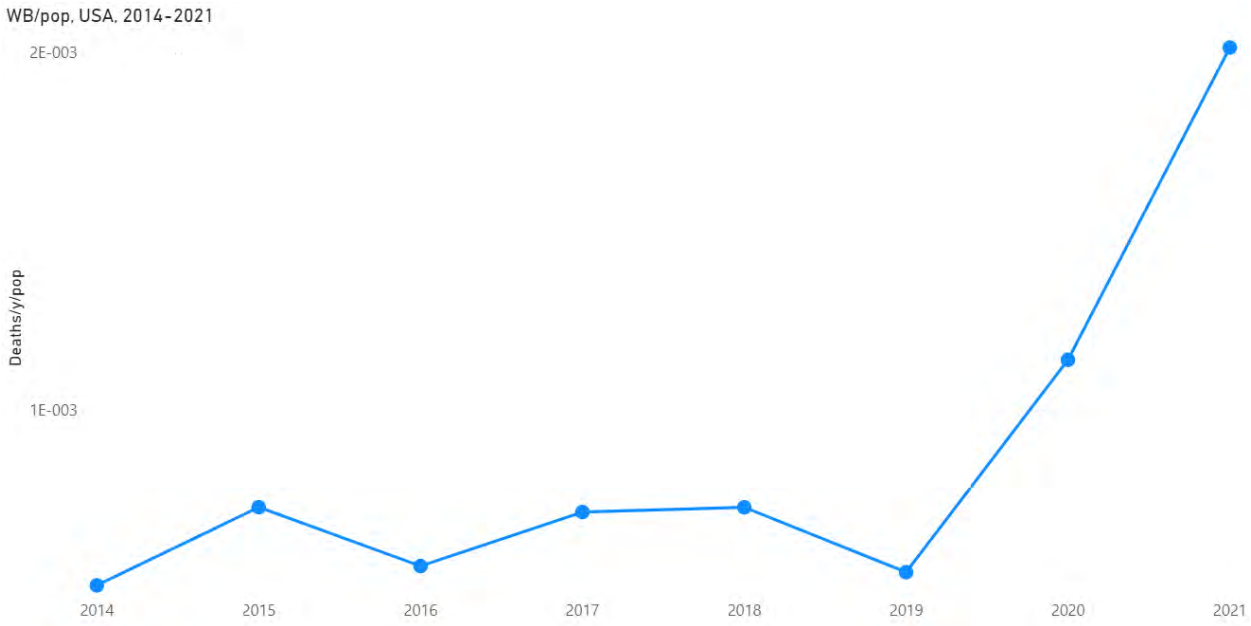


Figure 12a. Winter burden normalized by population in the USA for cycle-years 2014 to 2021. The cycle-year starts on week-31 of a calendar-year (beginning of August) and ends on week-30 of the next calendar-year (end of July). ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated and WB calculated as described in section 2.

Figure 12b shows WB/pop versus cycle-year (2014-2021), for all the continental USA states on the same graph.

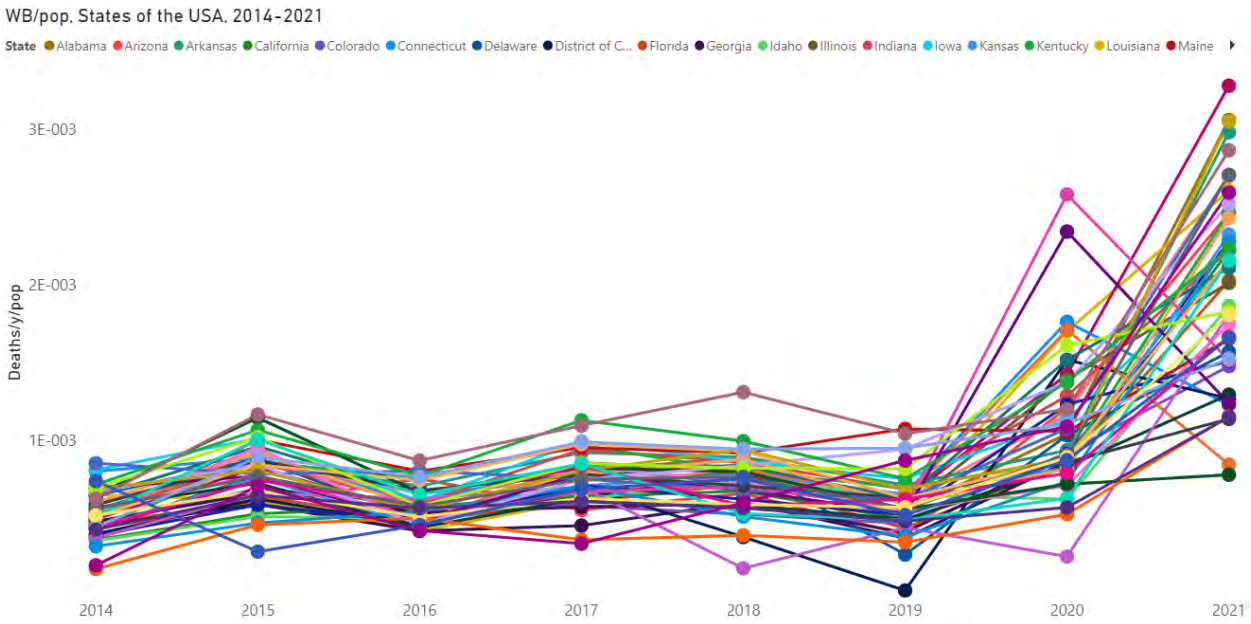


Figure 12b. Winter burden normalized by population for each of the continental states of the USA for cycle-years 2014 to 2021. The cycle-year starts on week-31 of a calendar-year (beginning of August) and ends on week-30 of the next calendar-year (end of July). The 49 continental states include the District of Columbia and exclude Alaska and Hawaii. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated and WB calculated as described in section 2.

Figure 12c shows WB/pop versus cycle-year (2014-2021) for the “0LL” group of Southern states (having a cvp1-smp1-cvp2 0LL pattern), and for Louisiana, which has the cvp1-smp1-cvp2 “LLL” pattern, on the same graph. We note a larger 2020 WB/pop value for Louisiana, than would be expected for a Southern state, because its large LLL-pattern cvp1 feature increases its 2020 WB/pop value.

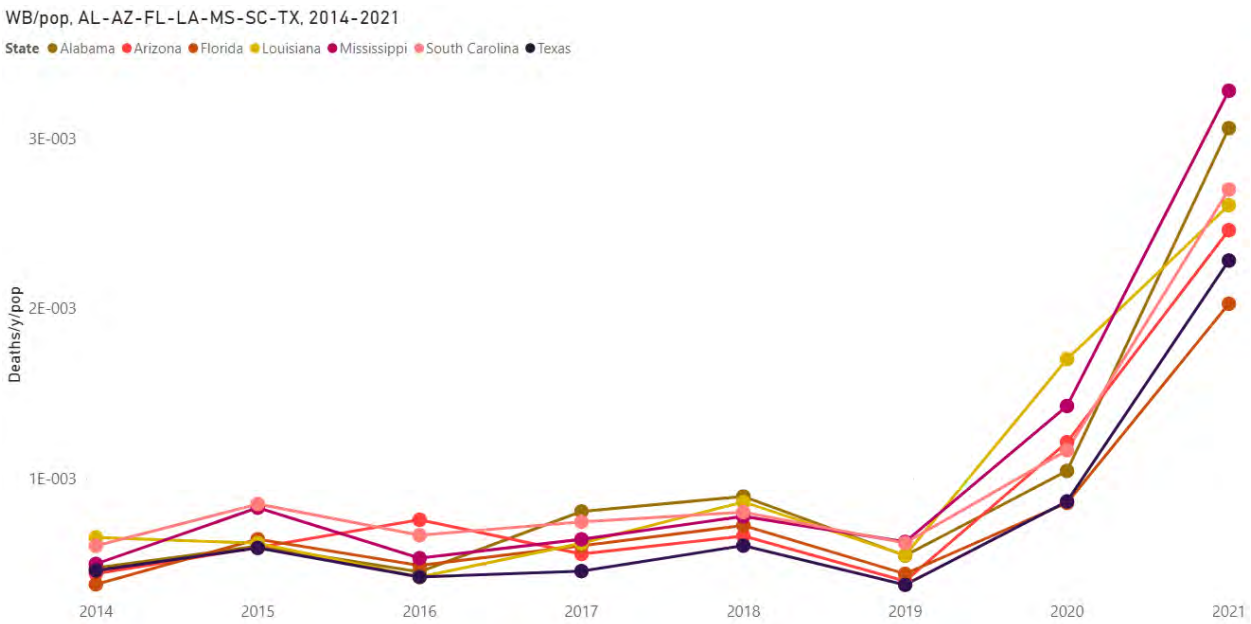


Figure 12c. Winter burden normalized by population in Alabama, Arizona, Florida, Louisiana, Mississippi, South Carolina and Texas for cycle-years 2014 to 2021. The cycle-year starts on week-31 of a calendar-year (beginning of August) and ends on week-30 of the next calendar-year (end of July). ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated and WB calculated as described in section 2.

Figure 12d shows WB/pop versus cycle-year (2014-2021) for the “L0M” group of North-East coastal states (having a cvp1-smp1-cvp2 L0M pattern), including Maryland, which has a limit behaviour to be included in this group. Since this group has exceptionally large cvp1 features, we see that generally the WB-2020 is larger than the WB-2021.

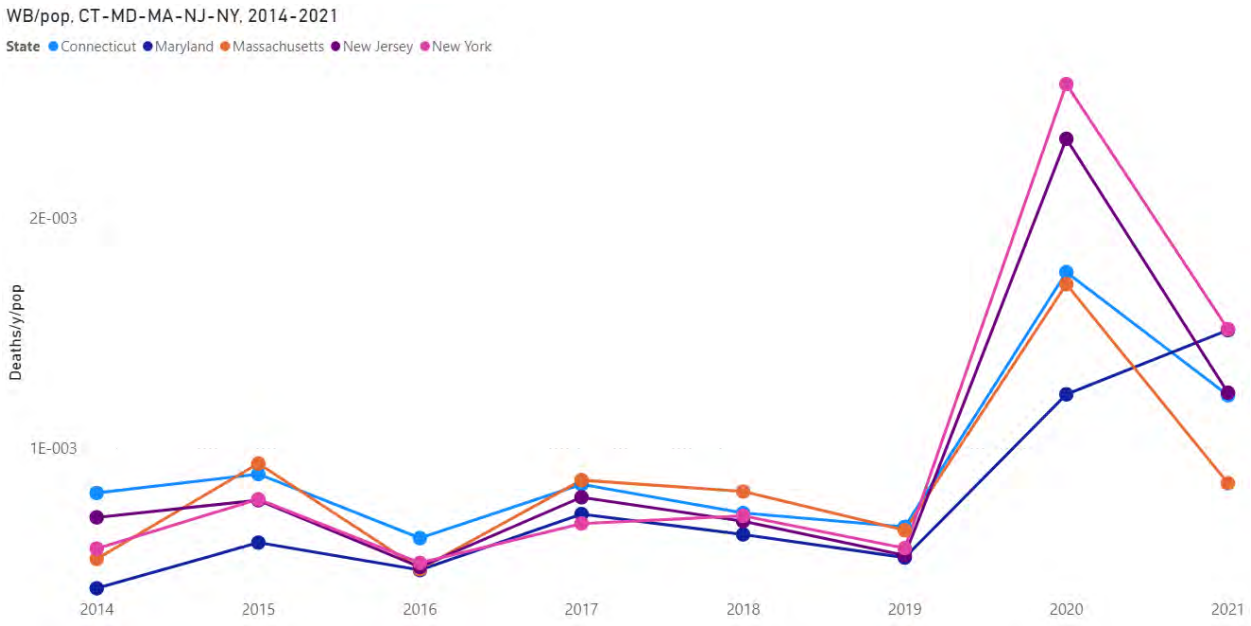


Figure 12d. Winter burden normalized by population in Connecticut, Maryland, Massachusetts, New Jersey and New York for cycle-years 2014 to 2021. The cycle-year starts on week-31 of a calendar-year (beginning of August) and ends on week-30 of the next calendar-year (end of July). ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated and WB calculated as described in section 2.

Figure 12b shows that, like the ACM-SB/w/pop curves themselves would suggest (Figures 10 and 11), the state-to-state spread in WB/pop values is much larger in the COVID-era than in the previous decade or so. We can illustrate this pre-COVID/COVID-era difference by plotting the frequency distribution of state-to-state values of WB/pop for each cycle-year. These distributions are shown together in Figure 13.

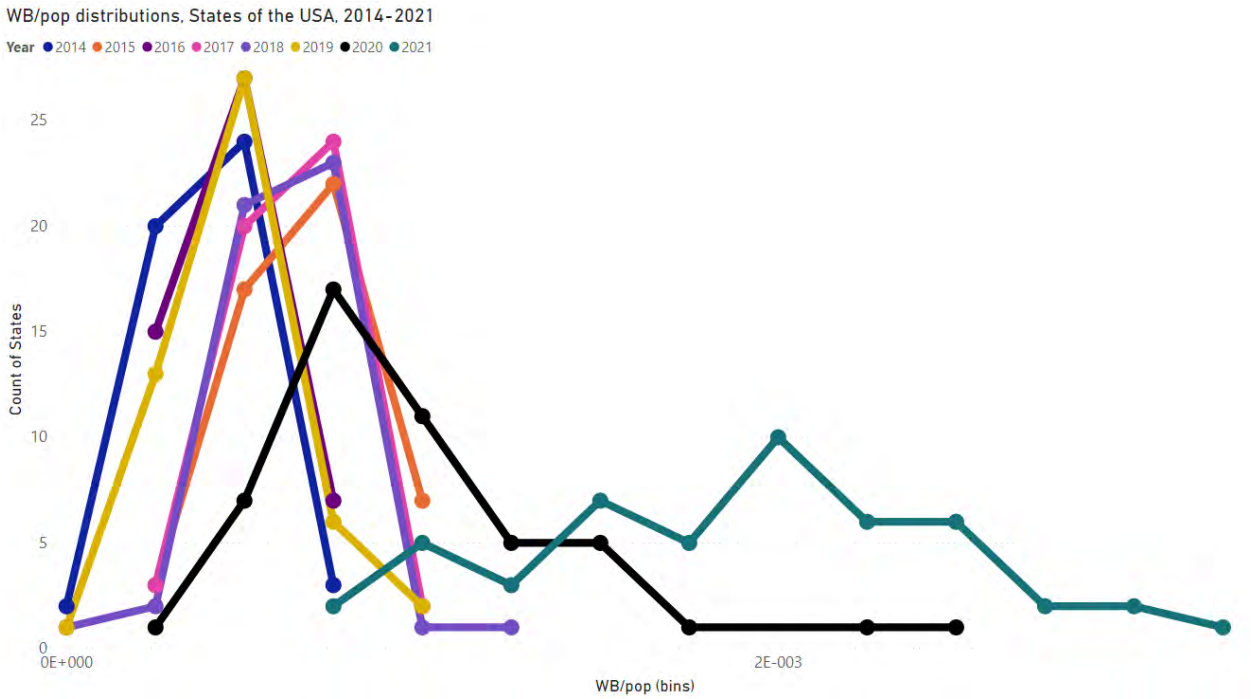


Figure 13. Frequency distributions of state-to-state values of WB/pop for each cycle-year, 2014-2021, as indicated by the colour scheme. Each distribution is normalized to 49, the number of continental USA states (including District of Columbia, excluding Alaska and Hawaii). A bin-width of 2.5E−4 deaths/pop was used. The cycle-year starts on week-31 of a calendar-year (beginning of August) and ends on week-30 of the next calendar-year (end of July). ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated and WB calculated as described in section 2.

Here (Figure 13), it is interesting to note that the six pre-COVID-era cycle-years (2014-2019) fall into two distinct distribution types, with the same widths but positions differing by a set amount, corresponding to “light” (2014, 2016, 2019; less deadly winter) and “heavy” (2015, 2017, 2018; deadlier winter) years that are also recognized in the ACM/w or ACM-SB/w patterns themselves (e.g., Figures 5 and 6).

By comparison, the distribution for cycle-year 2020 has larger WB/pop values and a tail that extends far towards even larger values. The distribution for cycle-year 2021 is exceedingly wide and extends to extremely large values.

Properties of the frequency distributions (Figure 13) can be quantified as follows. For each distribution (for a given cycle-year) we calculate: the average (“av”), the median (“med”), the standard deviation (“sd”), and the difference “av-med”. The latter difference av-med is related to the magnitude of the asymmetry of the distribution, and its sign indicates whether any extended tail extends toward small (negative) or large (positive) WB/pop values. These four parameters (av, med, sd, av-med) are shown versus cycle-year in Figure 14.

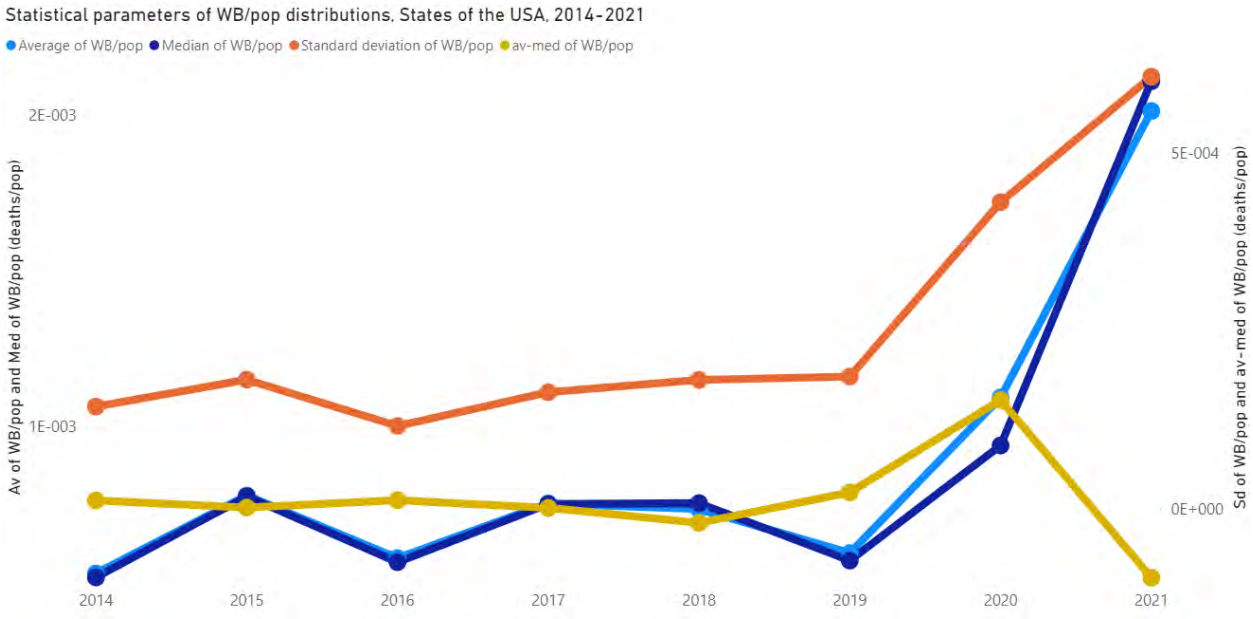


Figure 14. Statistical parameters of the WB/pop distributions of the 49 continental states of the USA for cycle-years 2014 to 2021. The 49 continental states include the District of Columbia and exclude Alaska and Hawaii. The cycle-year starts on week-31 of a calendar-year (beginning of August) and ends on week-30 of the next calendar-year (end of July). ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated and WB calculated as described in section 2.

Here (Figure 14), the variations of “av” and “med” are generally those expected, given the behaviour of WB/pop versus cycle-year for the entire continental USA (Figure 12a).

The “sd” (Figure 14) has a remarkably constant pre-COVID-era (prior to 2020) value of approximately 1.6(1.2—1.9 range)E−4 deaths/pop, and then shoots up to 4.3E−4

(2020) and 6.1E−4 (2021) deaths/pop. In other words, the COVID-era is characterized by an anomalously large state-to-state heterogeneity in WB/pop values, an approximately 4-fold increase in absolute magnitude.

In fact, using WB/pop masks the actual state-wise heterogeneity, since the COVID-era features cvp1 and smp1 have a much larger intrinsic (relative) heterogeneity than WB. The said large heterogeneity is evident in the ACM-SB/w/pop data itself (Figures 10 and 11), but let us quantify it, and let us examine “asymmetry” (presence of tails) as well. We use the dimensionless parameters sd/av and (av-med)/av, which are as follows.

Breadth and asymmetry of state-wise distributions of integrated deaths		
feature	**sd/av**	**(av-med)/av**
pre-COVID-era WB/pop 2014-2019	0.20—0.31	-0.03—+0.04
2020 WB/pop	0.39	+0.14
cvp1/pop	0.79	+0.27
smp1/pop	0.67	+0.17
cvp2/pop	0.28	0.00
2021 WB/pop	0.30	-0.05

Table 2. Breadth and asymmetry of state-wise distributions of integrated deaths for the pre-COVID-era WB/pop, and for features in the COVID-era. Features in the COVID-era include 2020 WB/pop, cvp1/pop, smp1/pop, cvp2/pop and 2021 WB/pop.

The state-wise heterogeneity of cvp1 is massive (sd/av: 0.79 compared to ~0.25) ((av-med)/av: +0.27 compared to ~+0.01), since cvp1 consists of essentially one extreme region in the North-East coastal states. The state-wise heterogeneity of smp1 is large (sd/av: 0.67 compared to ~0.25) ((av-med)/av: +0.17 compared to ~+0.01), since smp1 consists of essentially an extreme region in the Southern states.

We have observed such COVID-era jurisdictional heterogeneity in many countries, and country-wise in Europe, and we have argued that it is contrary to pandemic behaviour, and contrary to any (1945-2021) season of viral respiratory disease burden in the Northern hemisphere, and arises mainly from jurisdictional differences in applied medical and government responses to the pronouncement of a pandemic (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021).

In contrast, cvp2, which is entirely within the 2021 cycle-year and is the cycle-year's main (winter) feature, has normal pre-COVID-era state-wise homogeneity (sd/av: 0.28 compared to 0.20—0.31) ((av-med)/av: 0.00 compared to -0.03—+0.04). This suggests that cvp2 is not affected by any widely different state-to-state applied responses, but rather is the result of a broad, sustained, and state-wise homogenous stress on the USA population.

3.7. Geographical distribution and correlations between COVID-era above-SB seasonal deaths: cvp1 (spring-2020), smp1 (summer-2020) and cvp2 (fall-winter-2020-2021)

Recall that Figure 7 shows how we integrate to obtain the total above-SB deaths in each of the operationally defined features cvp1, smp1 and cvp2. Since the peak positions are operationally the same for all states (barring the extra peak for Michigan), we use the same delimiting weeks throughout, those shown in Figure 7. We normalize the state-wise deaths by state-wise population, in order to allow state-to-state comparisons.

Figure 15 shows a map of cvp1/pop for the continental states of the USA.

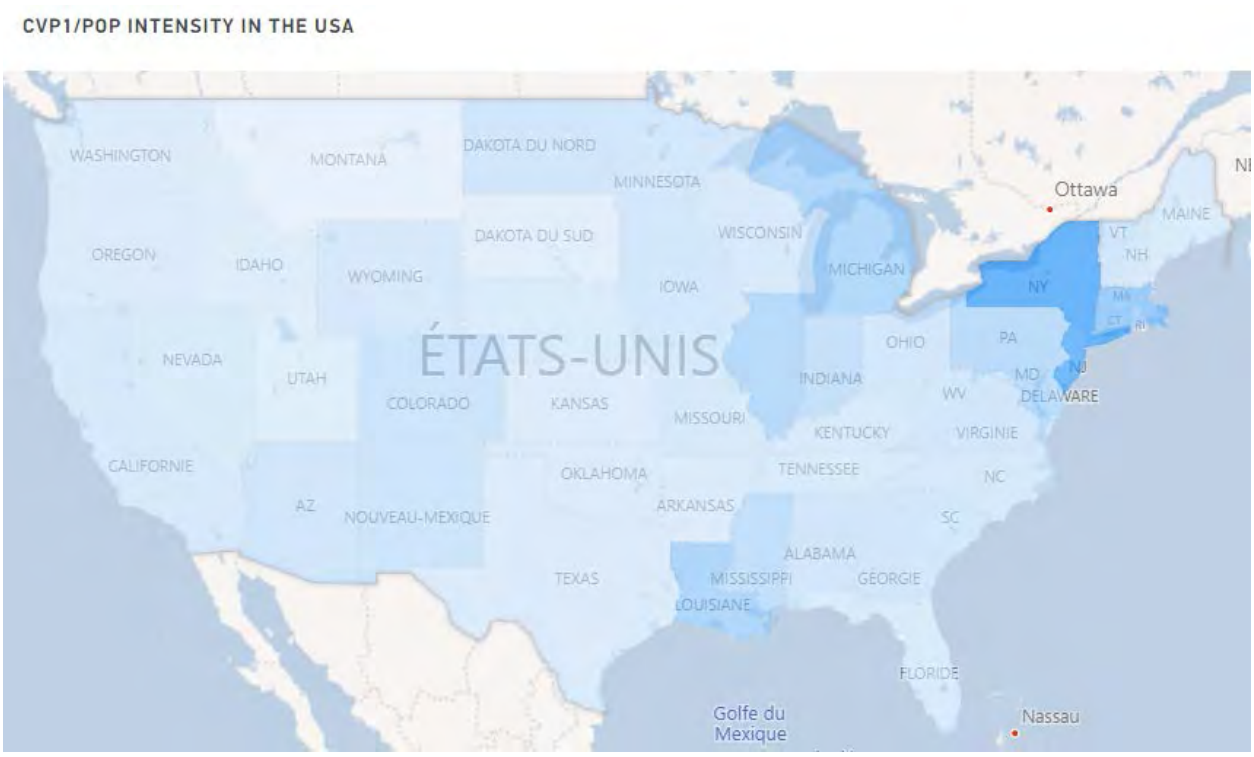


Figure 15. Map of the intensity of the cvp1 mortality normalized by population for the continental USA. Continental USA includes the District of Columbia and excludes Alaska and Hawaii. The cvp1 feature is the integrated deaths of ACM-SB between week-11 of 2020 and week-25 of 2020, inclusively. The darker the blue, the more intense the cvp1/pop. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

Here, we see that a cluster of North-East coastal states were essentially the only intense hot spot; and notable other states, including Louisiana, Illinois and Michigan, to a lesser degree. In fact, some 34 of the USA states do not have a resolved or detectable or significant cvp1 feature. We have described this previously (Rancourt, 2020) (Rancourt et al., 2020). We have argued that the cvp1 feature (the “covid peak”) is highly jurisdictionally heterogeneous, has a start synchronous with the 11 March 2020 WHO declaration of a pandemic, and is present throughout the mid-latitude Northern hemisphere, because it is caused by the medical and government responses to the declaration of a pandemic, especially in hospitals and care homes (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021). One can say with certainty that there

was no detectable or significant “first wave” in most of the USA, a phenomenon which is contrary to the very concept of a pandemic (Rancourt et al., 2021).

Figure 16 shows a map of smp1/pop for the continental states of the USA.

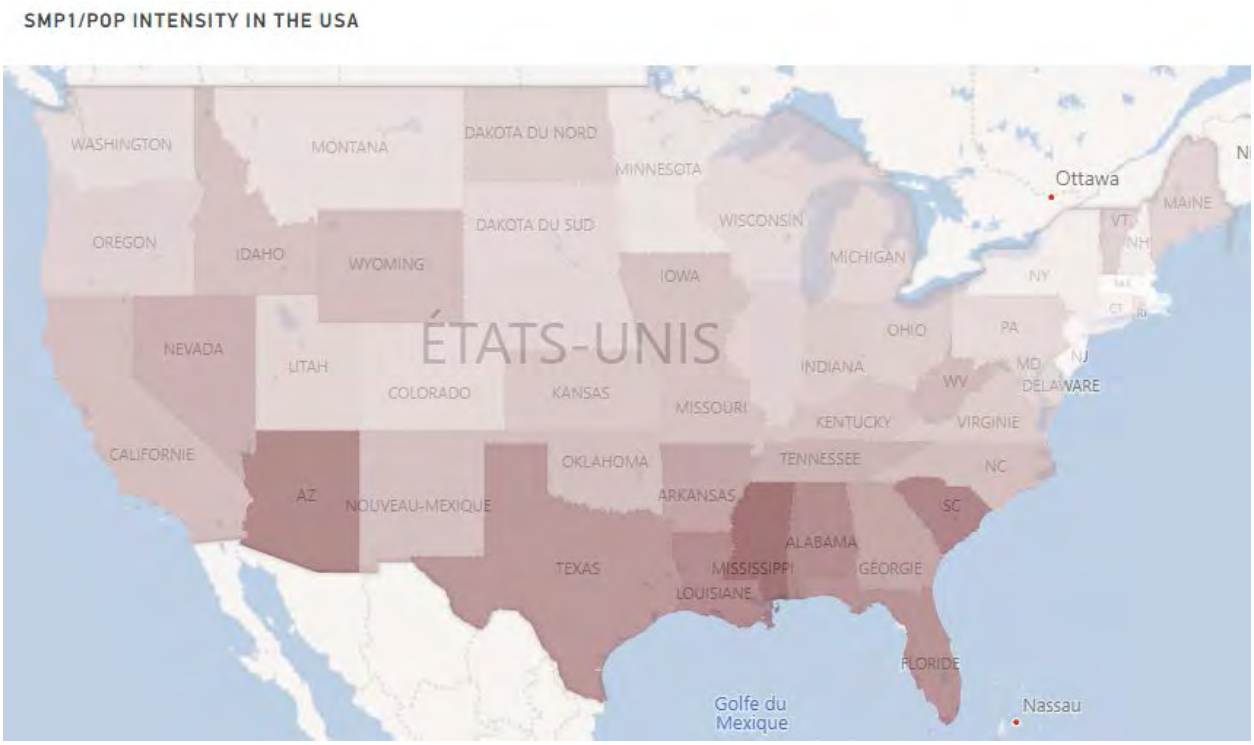


Figure 16. Map of the intensity of the smp1 mortality normalized by population for the continental USA. Continental USA includes the District of Columbia and excludes Alaska and Hawaii. The smp1 feature is the integrated deaths of ACM-SB between week-26 of 2020 and week-39 of 2020, inclusively. The darker the red, the more intense the smp1/pop. ACM data were retrieved from the CDC (CDC, 2021a) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021a), as described in Table 1. SB was estimated as described in section 2.

This is a remarkable map, which shows that the above-SB deaths in the summer of 2020 were concentrated in the Southern states of Arizona, Texas, Louisiana, Mississippi, Alabama, Florida and South Carolina. These results can be understood in terms of climatic, socio-economic and population health effects, as shown below. The results (Figure 16) are inconsistent with the theoretical concept of a viral respiratory disease pandemic. Furthermore, no previous large anomalous burden of all-cause

mortality has ever been concentrated in the Southern states, in one season, in the modern history of epidemiology for the USA.

There is no point showing a map of cvp2/pop for the continental states of the USA, because we showed above that the state-wise distribution of cvp2/pop is essentially homogeneous (Table 2). A map of cvp2/pop does not show any recognizable pattern.

Next, we examine whether there are any correlations or anti-correlations between the outcomes cvp1, smp1 and cvp2; and also smp2. Plots of one versus the other are as follows, in Figure 17.

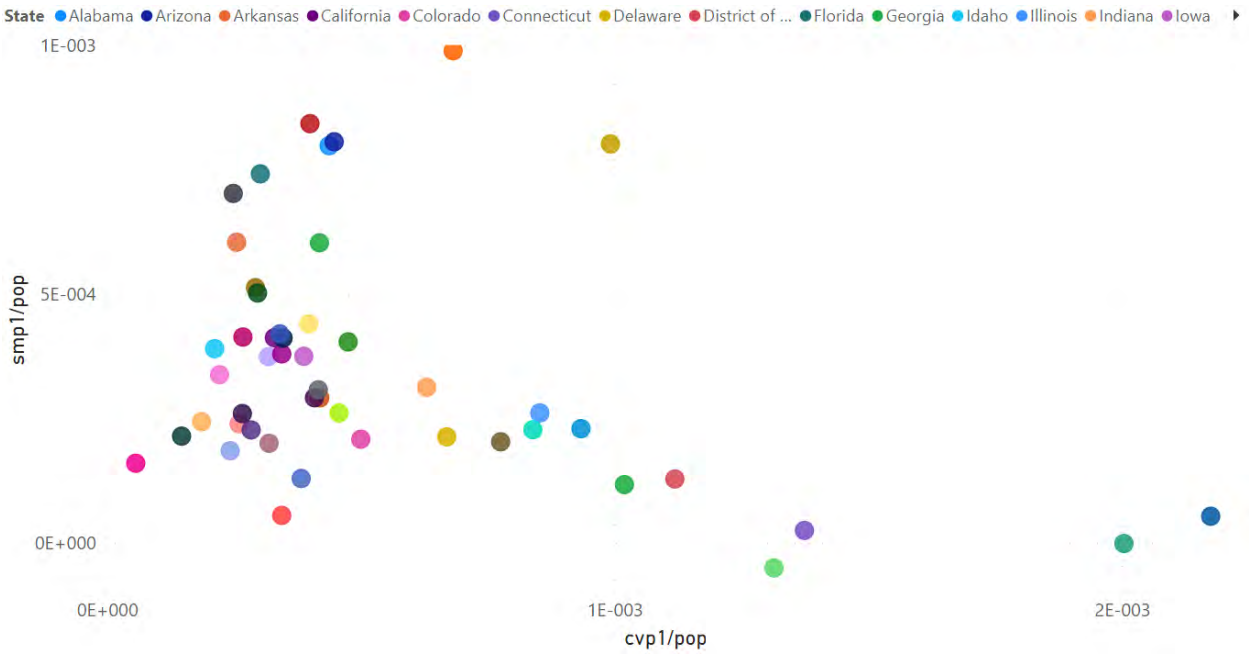


Figure 17a. smp1/pop versus cvp1/pop. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

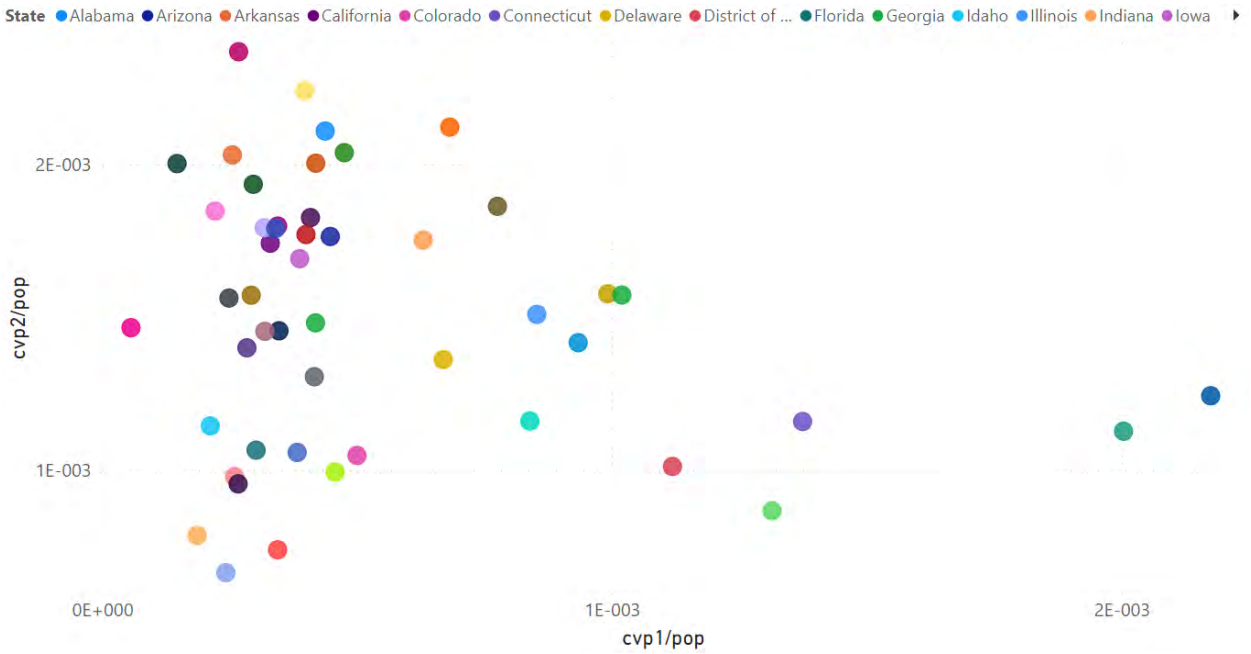


Figure 17b. cvp2/pop versus cvp1/pop. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

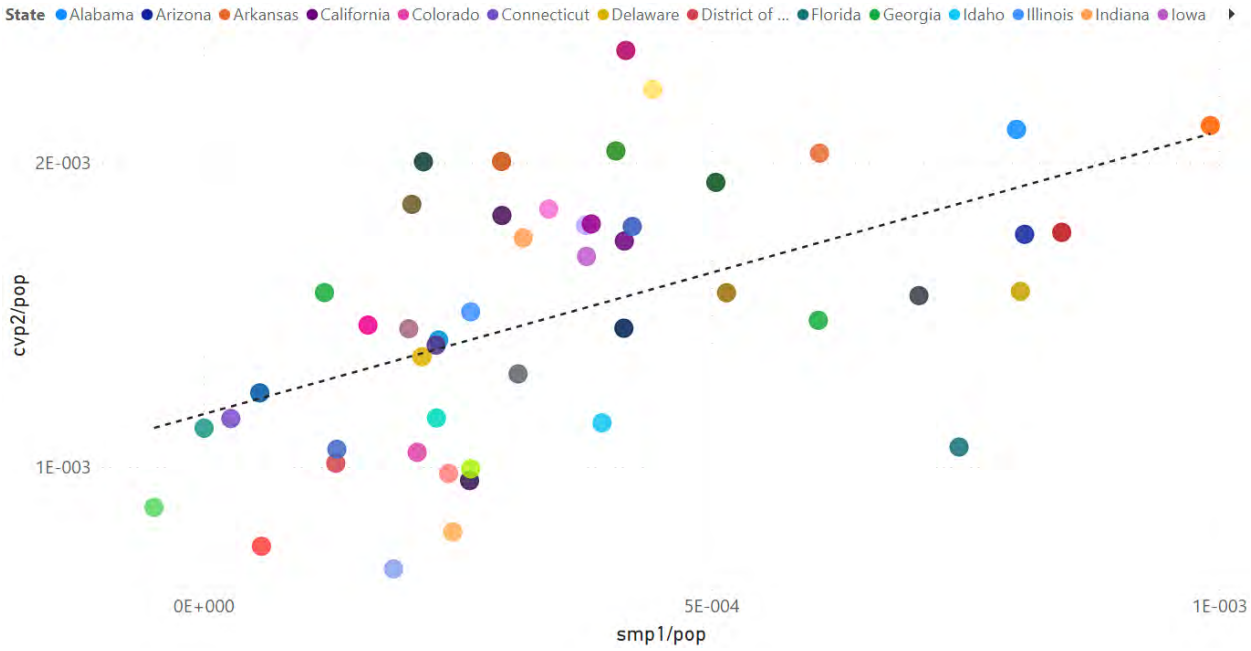


Figure 17c. cvp2/pop versus smp1/pop. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

Figure 17a shows that near-zero values of smp1/pop occur for the largest values of cvp1/pop, and that most large values of smp1/pop occur for small values of cvp1/pop. Similarly, Figure 17b shows that near-zero values of cvp2/pop occur for the largest values of cvp1/pop, and that most large values of cvp2/pop occur for small values of cvp1/pop.

This shows that the states with extremely large values of cvp1/pop (New York, New Jersey, Connecticut, Massachusetts… mainly the L0M pattern) had small (cvp2) or near-zero (smp1) values of mortality in the seasons that followed (summer-2020, fall-winter-2020-2021). Possible explanations include: the so-called “dry tinder” effect, in which those likely to die would have already died in the first “wave”, or socio-geo-economic and climatic factors that give large smp1 and cvp2 are absent in those states that have the largest cvp1 peaks. Our analysis shows that the latter explanation is more likely. Indeed, different age groups, social classes (poverty, obesity) and state jurisdictions predominantly contribute to cvp1 versus smp1 and cvp2. A dry tinder effect interpretation for cvp1/smp1-cvp2 is not compatible with the many observed correlations.

A notable exception (outlier) in the smp1-cvp1 relation (Figure 17a) is Louisiana, which has both large cvp1 and large smp1. We have interpreted large values of cvp1 (“covid peak”), occurring heterogeneously and synchronously around the world, as being due to local-jurisdictional aggressive immediate medical and government responses to the 11 March 2020 WHO pronouncement of a pandemic (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021). New York City and New York state directives are the defining examples of such aggression. There is circumstantial evidence that Louisiana has a medico-government culture approaching that of New York: “Louisiana's largest hospital system will impose fee on employees if their spouse is unvaccinated”, *Blaze media*, 01 October 2021, https://archive.ph/sDfL2.

Figure 17c shows that there is a correlation between cvp2/pop and smp1/pop. Such a correlation, as opposed to an anti-correlation, is contrary to a “dry tinder” effect

occurring between summer-2020 and fall-winter-2020-2021. Rather, it suggests that some or all of the same socio-geo-economic and climatic effects impact the mortality in both seasons.

The summer-2021 feature smp2 behaves similarly to smp1 (summer-2020) in many regards, although it starts later in the summer, and smp2/pop is correlated to smp1/pop, as shown in Figure 17d.

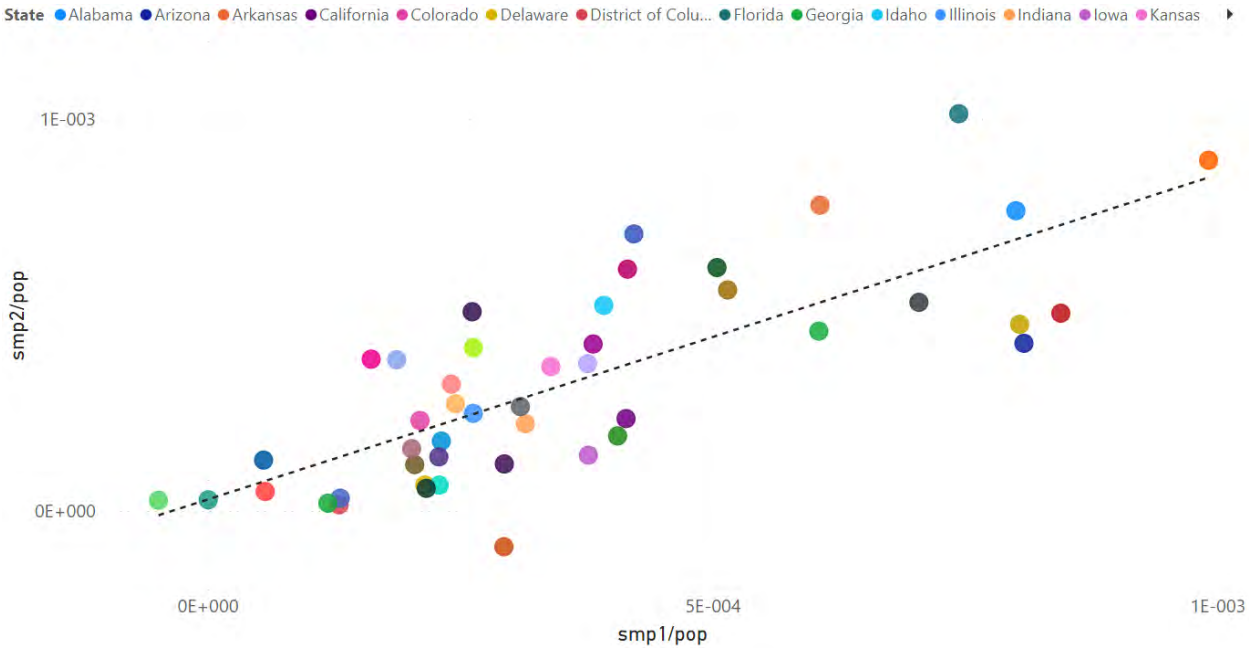


Figure 17d. smp2/pop versus smp1/pop. Each point is for one continental USA state. Connecticut, North Carolina and West Virginia are removed from the graph as there are not enough consolidated data points in ACM/w for smp2 for those states (see Appendix). The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

Figure 18 shows the same data as in Figure 17c, but with added circle-symbol-size (radius) determined by cvp1/pop.

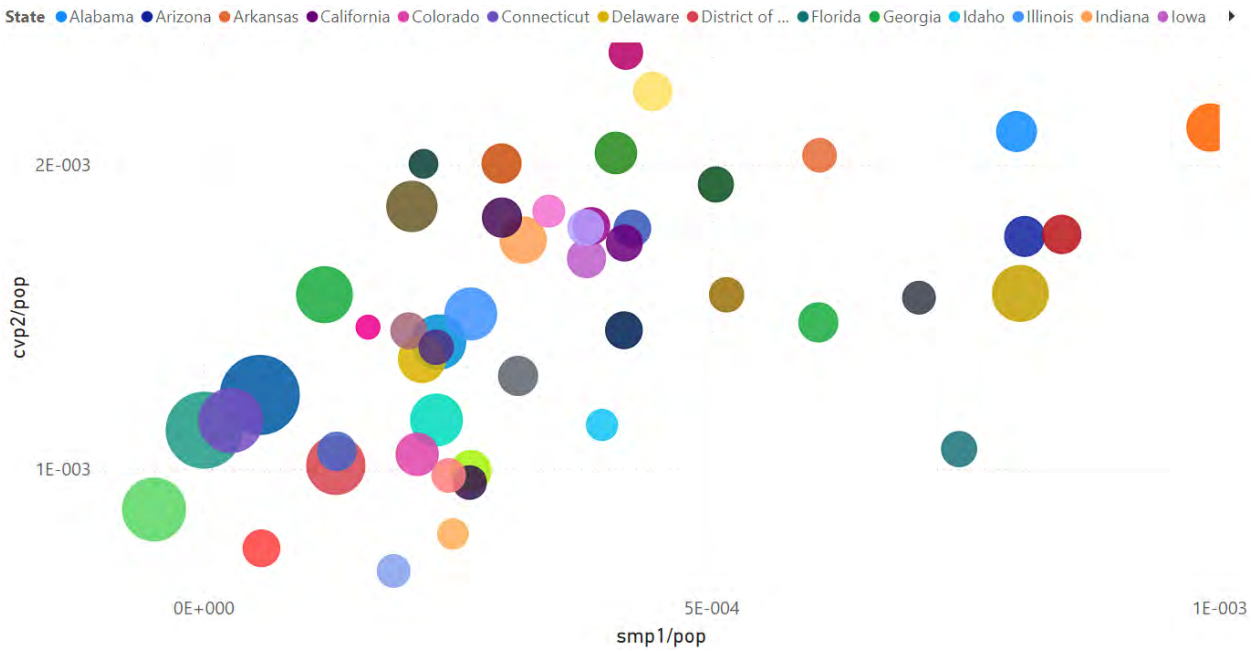


Figure 18. cvp2/pop versus smp1/pop, with the radius size determined by cvp1/pop. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

We note that the largest values of cvp1/pop (by state) are clustered at small values of both smp1/pop and cvp2/pop, with Louisiana as the main exception, followed by Mississippi.

3.8. Associations of COVID-era mortality outcomes with socio-geo-economic and climatic variables

The data, in which quantitative mortality outcomes (cvp1, smp1, cvp2, WB) are known by state, can be compared with state-wise or state-specific socio-geo-economic and climatic variables, in a search for correlations or relations, since all 49 diverse continental USA states can be used. This is a unique opportunity to identify factors which may cause or contribute to the excess (above-SB) USA mortality during the COVID-era.

We found three variables that appear to be determinative of COVID-era summer-2020 (smp1) and fall-winter-2020-2021 (cvp2) excess (above-SB) mortality in the USA. These are:

1. Climatic temperature (summer-period heatwave effect) (smp1)
2. Poverty (smp1 and cvp2)
3. Obesity (smp1 and cvp2)

The variables are somewhat correlated to each other, but have a significant degree of independence (one can be obese and rich, etc.). We found that using the product "OB.PV" of obesity (OB) and poverty (PV) gives a stronger correlation than either variable alone (being both obese and poor is deadlier than being either obese or poor).

We found that climatic temperature — evaluated using either maximum temperature (Tmax) or average temperature (Tav), either averaged in July-August-2020 or averaged over a calendar-year — is highly predictive of the geographical location of smp1 mortality (the hottest states were the most deadly in summer-2020, and dramatically so).

None of the variables (OB, PV, Tmax) that correlate with smp1 and cvp2 correlate with cvp1, which shows distinctly different death-causing phenomena in the two periods (cvp1 versus smp1-cvp2) in the COVID-era. We interpret cvp1 as being due to the immediate aggressive medical and government measures, whereas later deaths are apparently due to accumulated social and psychological chronic stress, combined with climatic stress, and affect younger individuals in broader age groups.

The latter age-dependence was shown by examining correlations between mortality outcomes and population age structure, by state. The smp1 feature (above-SB deaths in summer-2020) is uniquely anti-correlated with age of the state-wise population, which is contrary to WB mortality behaviour in all studied pre-COVID-era cycle-years, 2014-2019, and contrary to viral respiratory disease epidemiology.

Throughout this study, we compare our COVID-era results with a similar search for correlations in WB/pop mortality outcome in given cycle-years occurring prior to the COVID-era. Contrary to deaths in the COVID-era, normal epidemiology of the unperturbed society shows no state-to-state correlations of winter burdens with obesity, poverty or climatic temperature, whatsoever, in any of the six specific cycle-years 2014-2019. The only “normal era” correlation we find is with age structure, and it is persistent from year to year. The same is true for many more cycle-years for France, and so on. It seems clear to us that the variables obesity, poverty and climatic temperature become determinative, and have a disproportionate and immediate deadly impact, only in the significantly socio-economically perturbed and stressed population of the COVID-era measures.

Here are the details, as follows.

Obesity

Figure 19 shows the scatter plots for obesity (OB), defined as the prevalence of self-reported obesity among U.S. adults (CDC, 2021e).

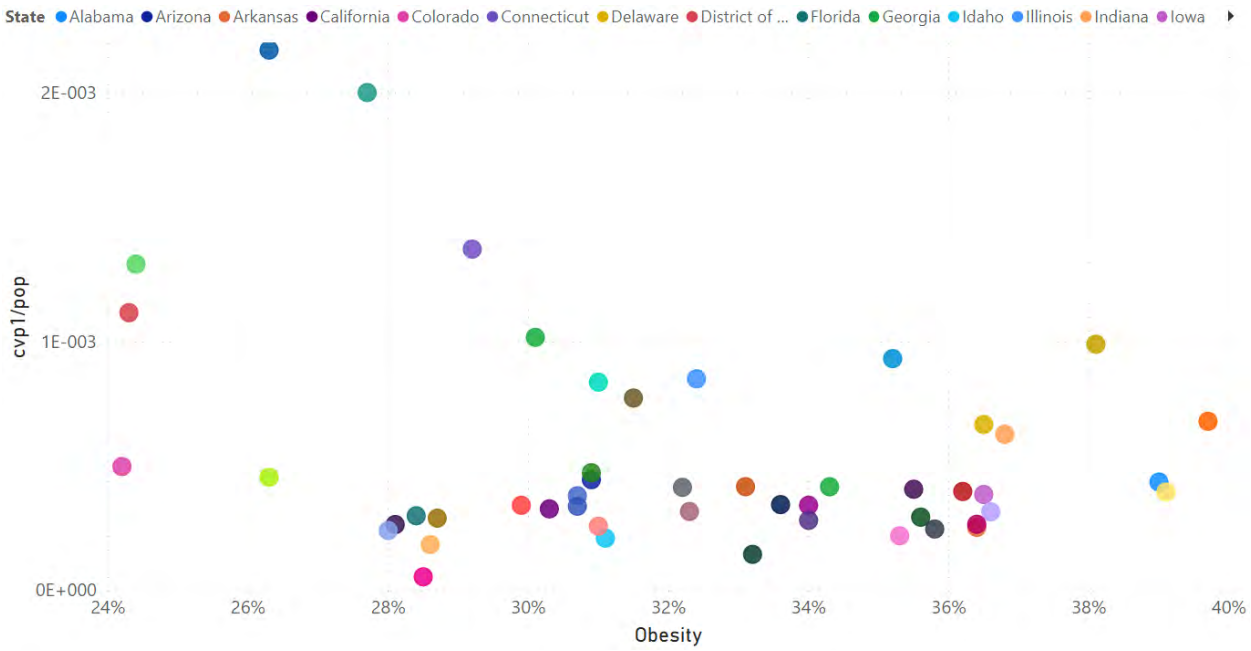


Figure 19a. cvp1/pop versus obesity. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

There is no discernable trend between cvp1/pop and OB.

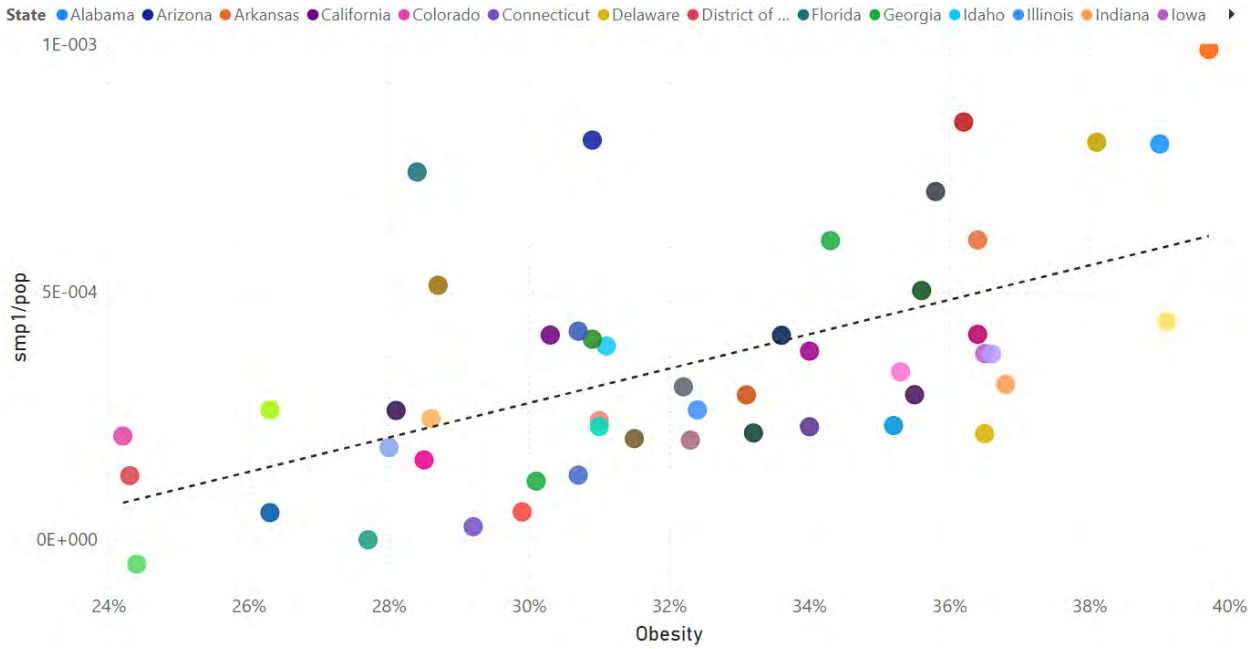


Figure 19b. smp1/pop versus obesity. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual

least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

There is a positive trend between smp1/pop and OB.

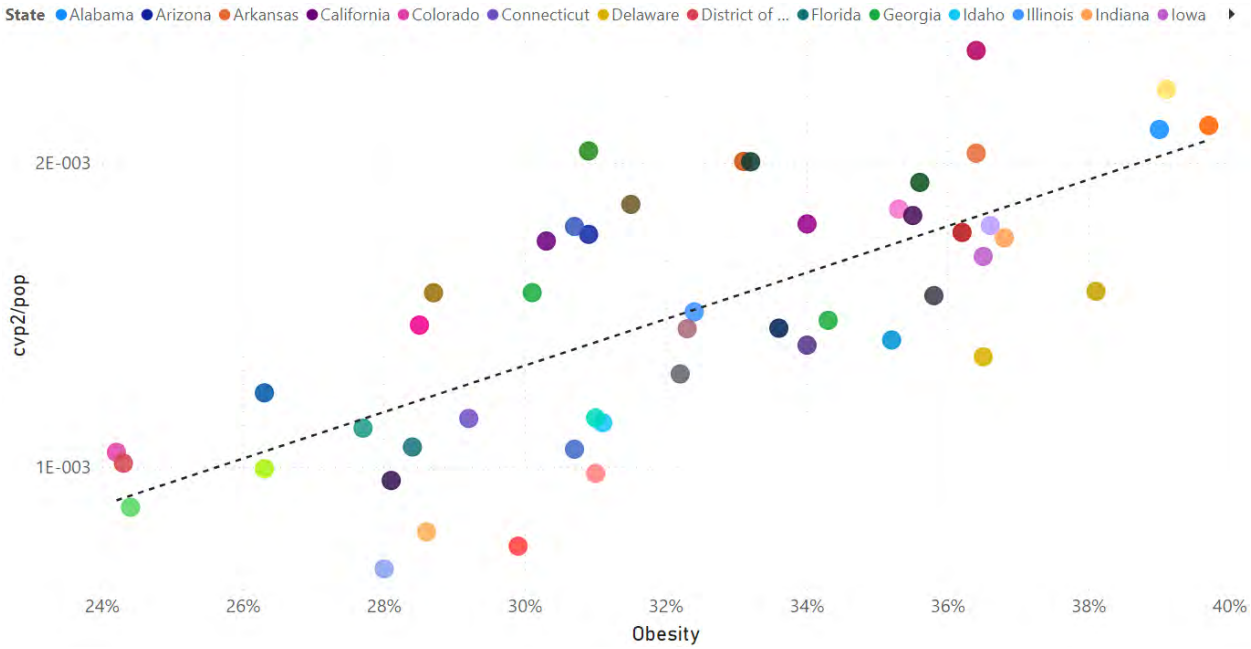


Figure 19c. cvp2/pop versus obesity. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

There is a positive trend between cvp2/pop and OB.

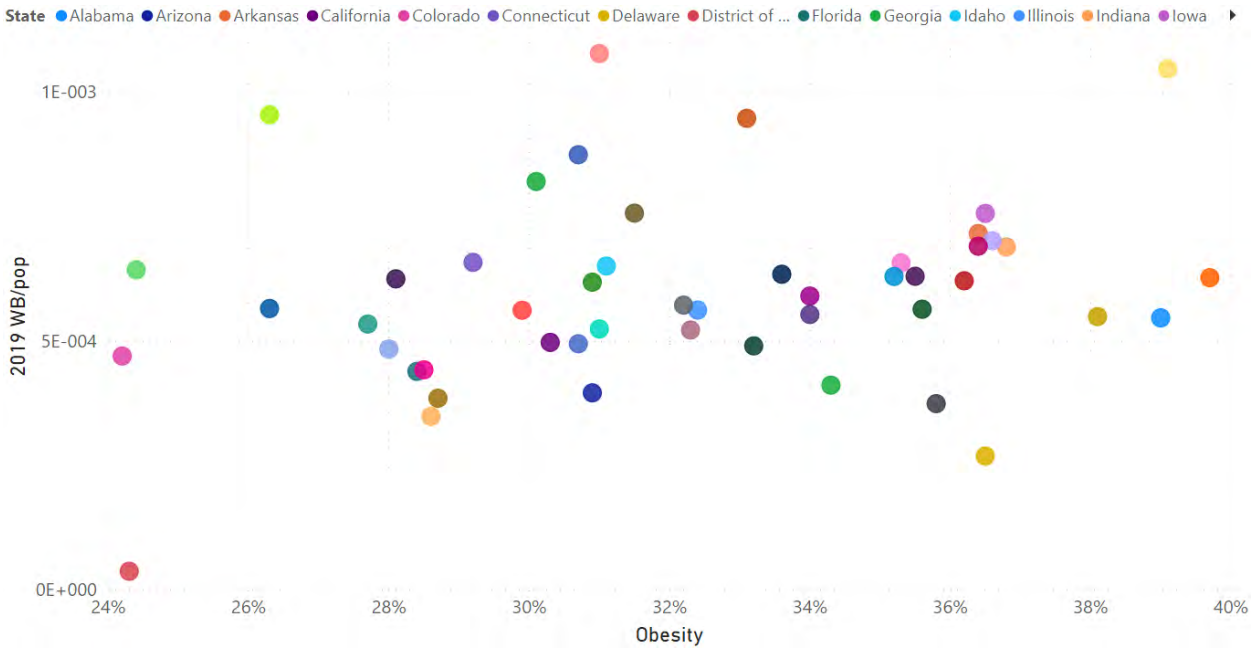


Figure 19d. WB/pop for cycle-year 2019 versus obesity. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

There is no correlation whatsoever. This is true for all pre-COVID-era cycle-years, 2014-2019 (data not shown). “Normal-era” winter burden deaths above-SB have no relation to obesity, on a state-wise basis.

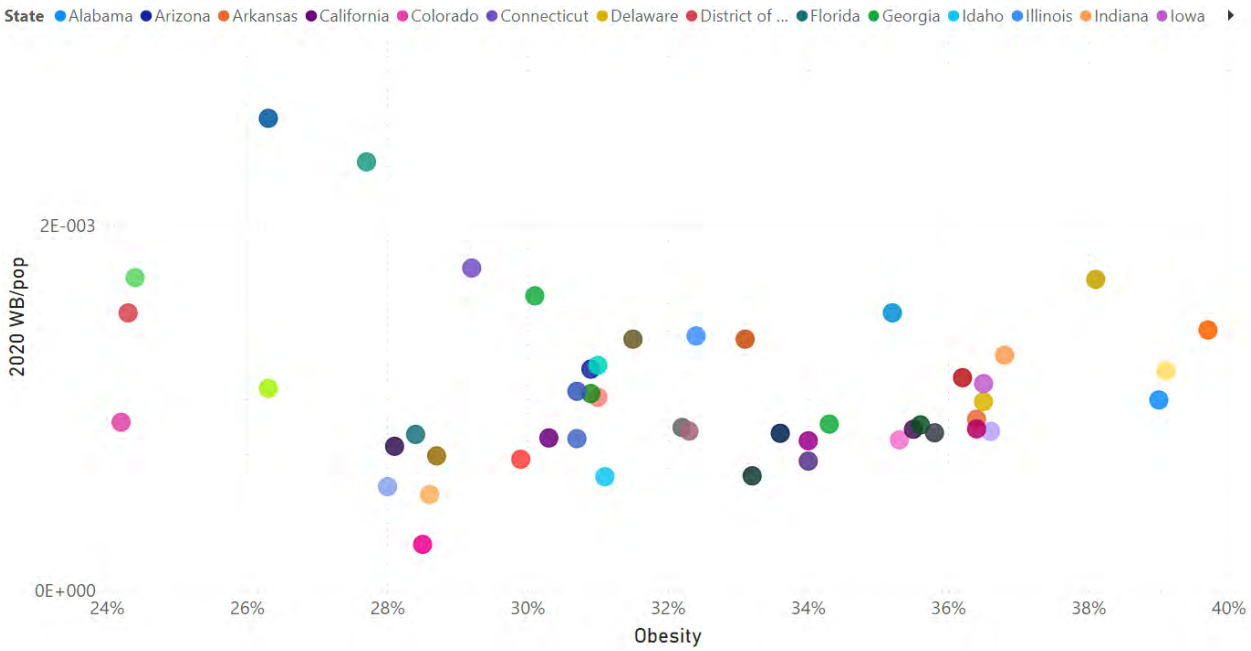


Figure 19e. WB/pop for COVID-era cycle-year 2020 versus obesity. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

Excluding the six states with highest 2020 WB/pop values and OB < 31 % (Connecticut, District of Columbia, Massachusetts, New Jersey, New York, Rhode Island), there is a positive trend for the remaining states. This is consistent with the fact that 2020 cycle-year includes both cvp1 and approximately half of smp1, and that the excluded states have extremely large cvp1/pop values in mostly wealthy states.

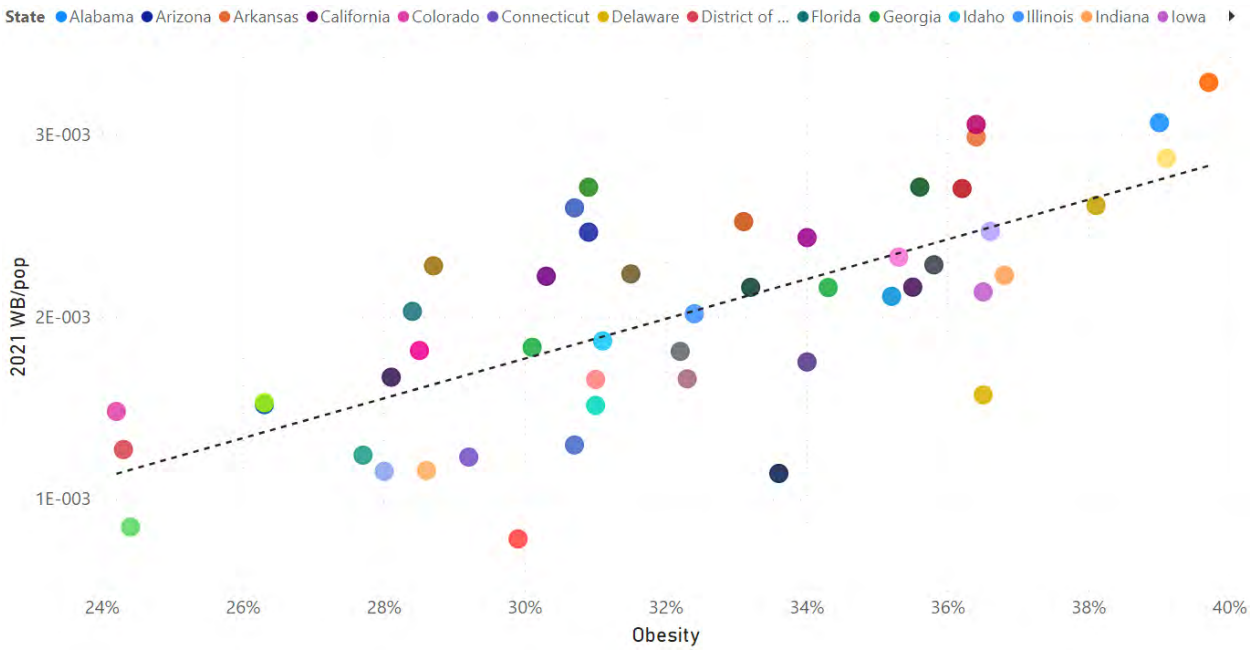


Figure 19f. WB/pop for COVID-era cycle-year 2021 versus obesity. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

There is a positive trend between WB/pop for COVID-era cycle-year 2021 and OB.

Poverty

Figure 20 shows the scatter plots for poverty (PV), defined as the estimated percent of people of all ages in poverty (US Census Bureau, 2021d).

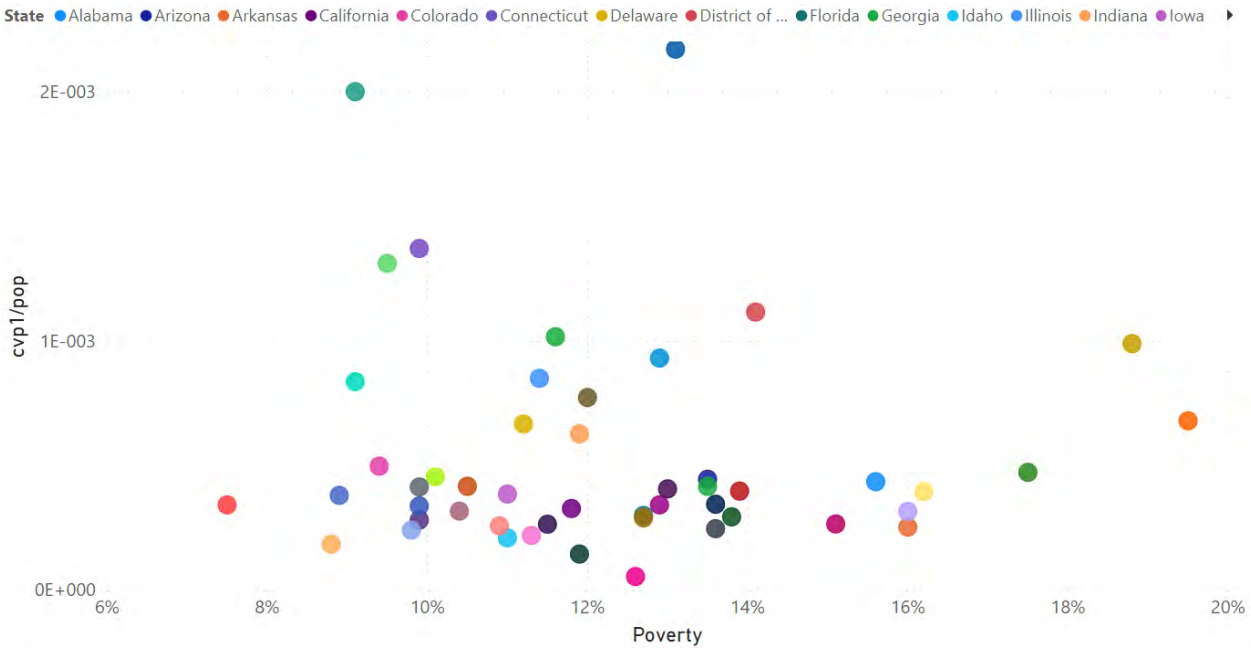


Figure 20a. cvp1/pop versus poverty. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

There is no discernable trend between cvp1/pop and PV.

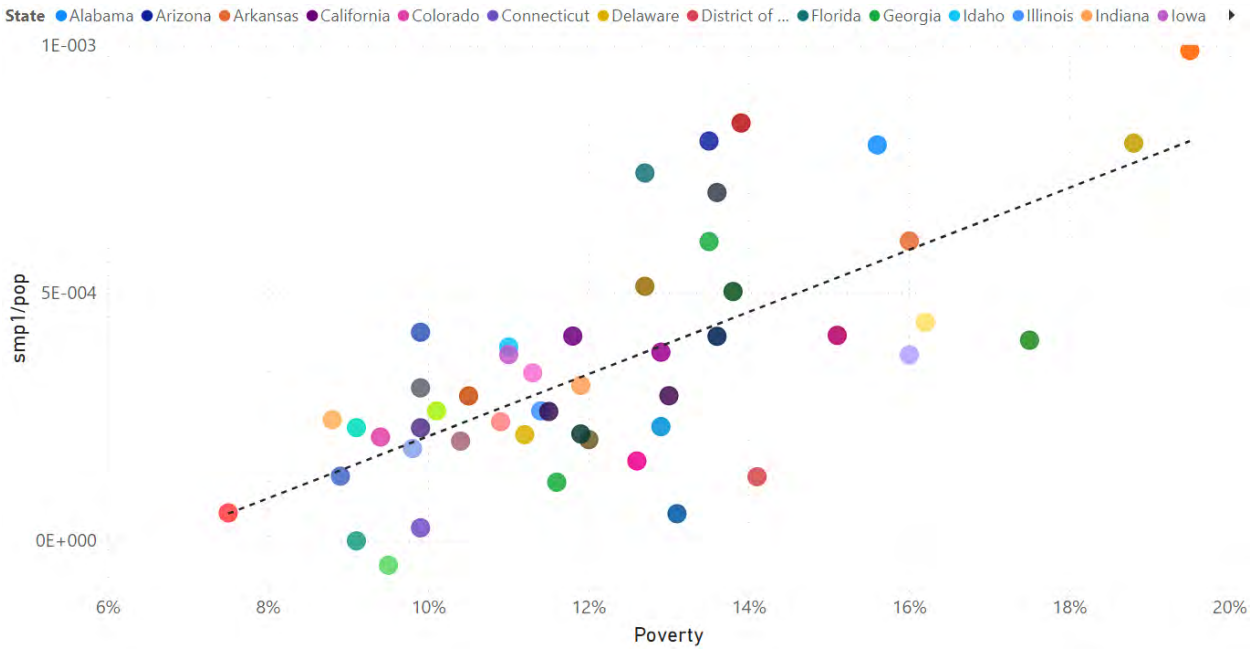


Figure 20b. smp1/pop versus poverty. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual

least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

There is a positive trend between smp1/pop and PV.

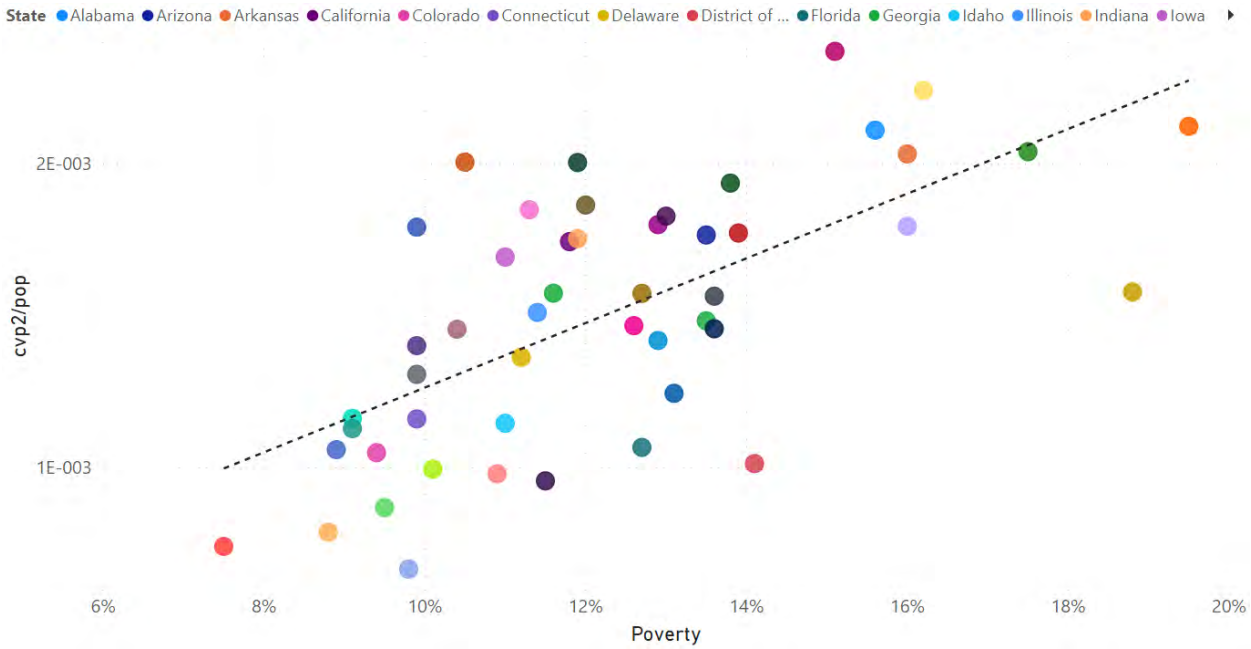


Figure 20c. cvp2/pop versus poverty. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

There is a positive trend between cvp2/pop and PV.

Figure 20d. WB/pop for cycle-year 2019 versus poverty. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

There is no correlation whatsoever. This is true for all pre-COVID-era cycle-years, 2014-2019 (data not shown). “Normal-era” winter burden deaths above-SB have no relation to poverty, on a state-wise basis.

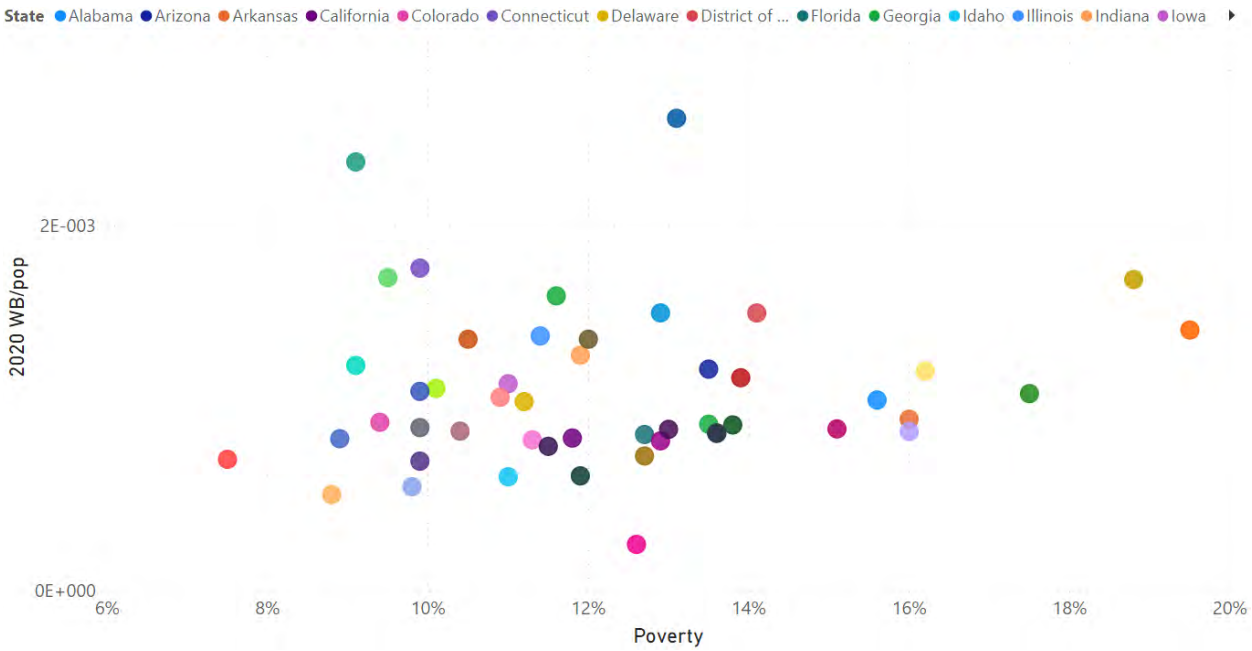


Figure 20e. WB/pop for COVID-era cycle-year 2020 versus poverty. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

Excluding the four states with highest 2020 WB/pop values (Connecticut, Massachusetts, New Jersey, New York), there is a positive trend for the remaining states. This is consistent with the fact that 2020 cycle-year includes both cvp1 and approximately half of smp1, and that the excluded states have extremely large cvp1/pop values in mostly wealthy states.

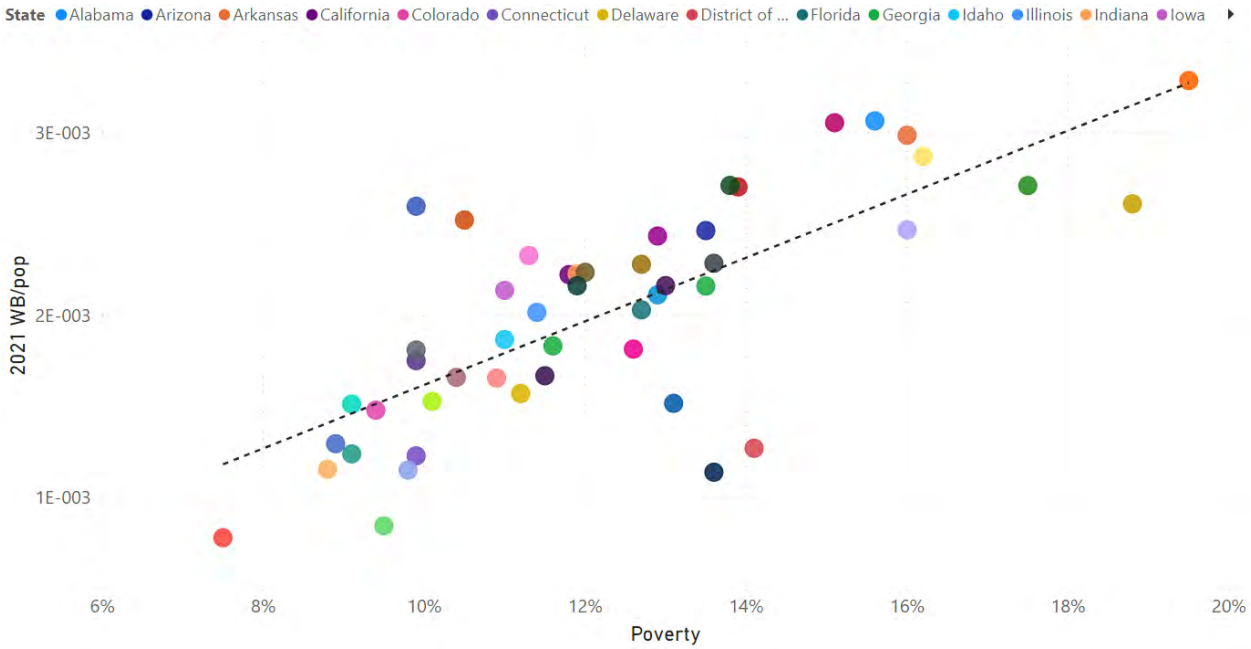


Figure 20f. WB/pop for COVID-era cycle-year 2021 versus poverty. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

There is a positive trend between WB/pop for COVID-era cycle-year 2021 and PV. The outlier at 13.6 % poverty is North Carolina, which is an artifact of incomplete data for the final weeks for this state (see Appendix).

Climatic temperature

One of the most striking results of our study is that the summer-2020 excess (above-SB) mortality is concentrated in Southern states (Figure 16). Excess summer mortality is striking in itself because viral respiratory diseases barely transmit in humid summer climates (aerosol particles are not stable in high absolute humidity: Harper, 1961; Shaman et al., 2010), and summers “always” exhibit seasonal lows of mortality in mid-latitude regions, seasonally inverted in the Southern hemisphere. Yet, here in the USA, there was an actual peaked maximum in ACM/w in the summer-2020 (Figures 5, 6, 7, 9, 10, and Appendix).

The geographical pattern of summer-2020 excess (above-SB) mortality, on a map of the USA (Figure 16), is remarkably well predicted by climatic temperature, shown in Figure 21.

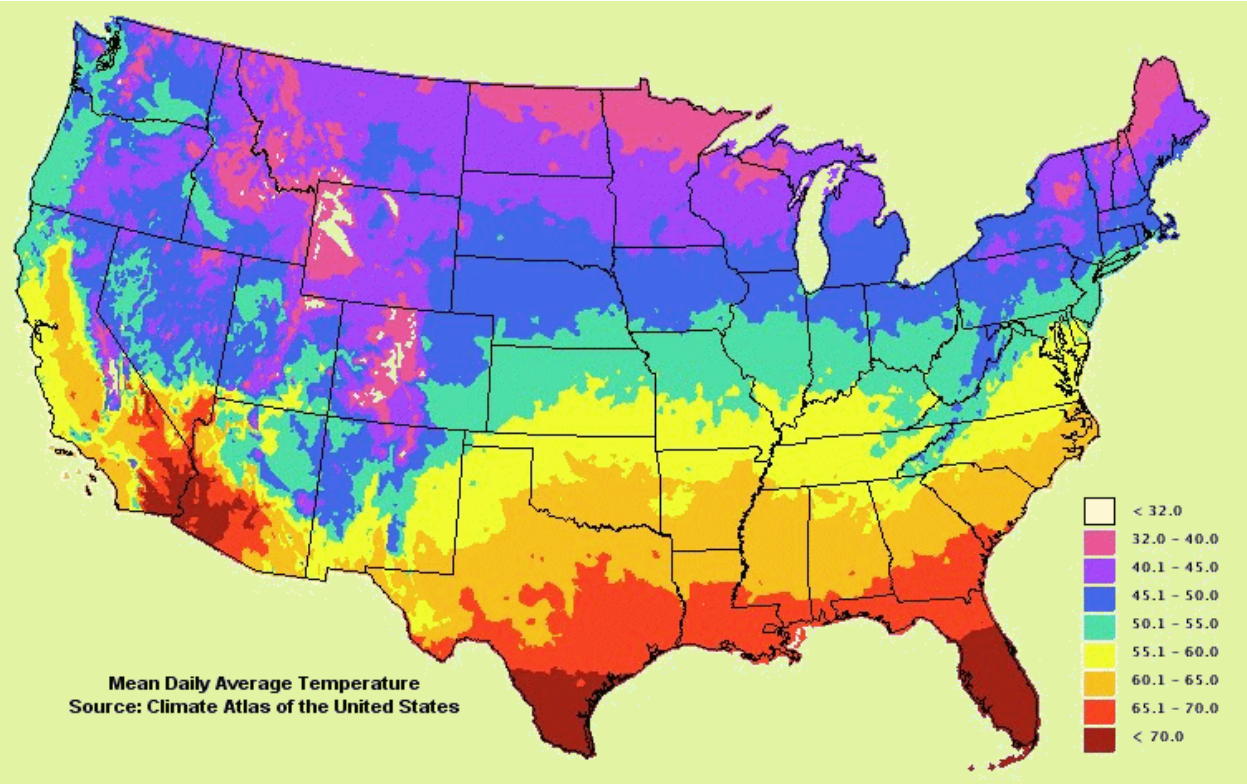


Figure 21. Mean daily average temperature: Mean of daily minimum and maximum, averaged over the year, and for three decades (1970-2000). This represents "climatic mean temperature" for the continental USA (spatial average is achieved using weighted cells, with the available surface air weather stations). Source: Climate Atlas of the United States, developed by NOAA's National Climatic Data Center in Asheville, NC., Version 2.0, CD-ROM, released September 2002. Figure accessed at http://www.virginiaplaces.org/climate/ on 26 September 2021. (Typo: "< 70.0" should be "> 70.0").

We illustrate this on a state-by-state basis, using the state-wise average August-2020 temperature, shown in Figure 22.

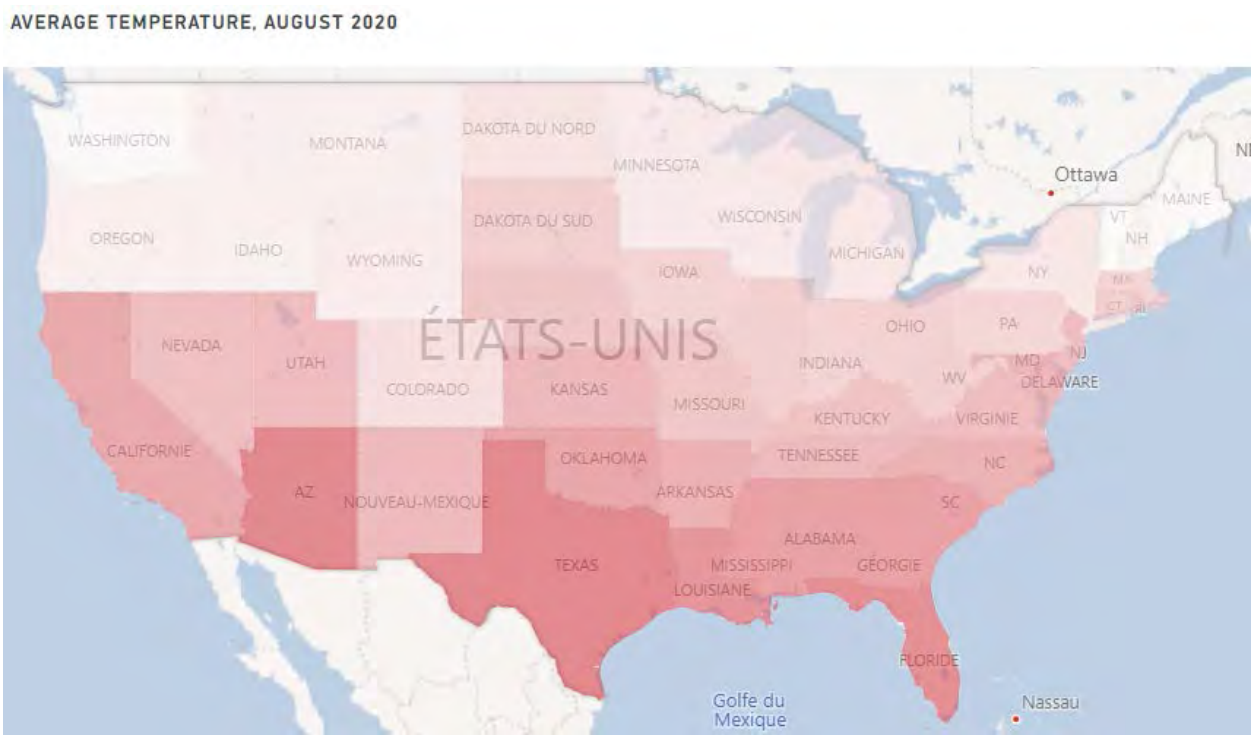


Figure 22. Average temperature, per state of the continental USA, for August 2020. Continental USA excludes Alaska and Hawaii. The darker the red, the higher the average temperature. Climatic temperature data were retrieved from the NOAA (NOAA, 2021), as described in Table 1. (The reader is asked to compare this map with the map shown in Figure 16.)

Essentially the same pattern occurs for July 2020, or for any month, or for yearly averages, or using daily maximum temperatures rather than daily average temperatures. Basically, all the average temperatures (averages of daily averages, or averages of daily maxima; on July or August, or on July and August, or on any calendar-year or cycle-year) chosen to represent climatic temperature are highly correlated to each other. For our purpose, these different averages are interchangeable.

The correlation between climatic temperature and summer-2020 excess (above-SB) mortality (smp1/pop, by state) is illustrated in Figure 23, using the July-August 2020 average daily maximum temperature (averaged by state and over the two-month period).

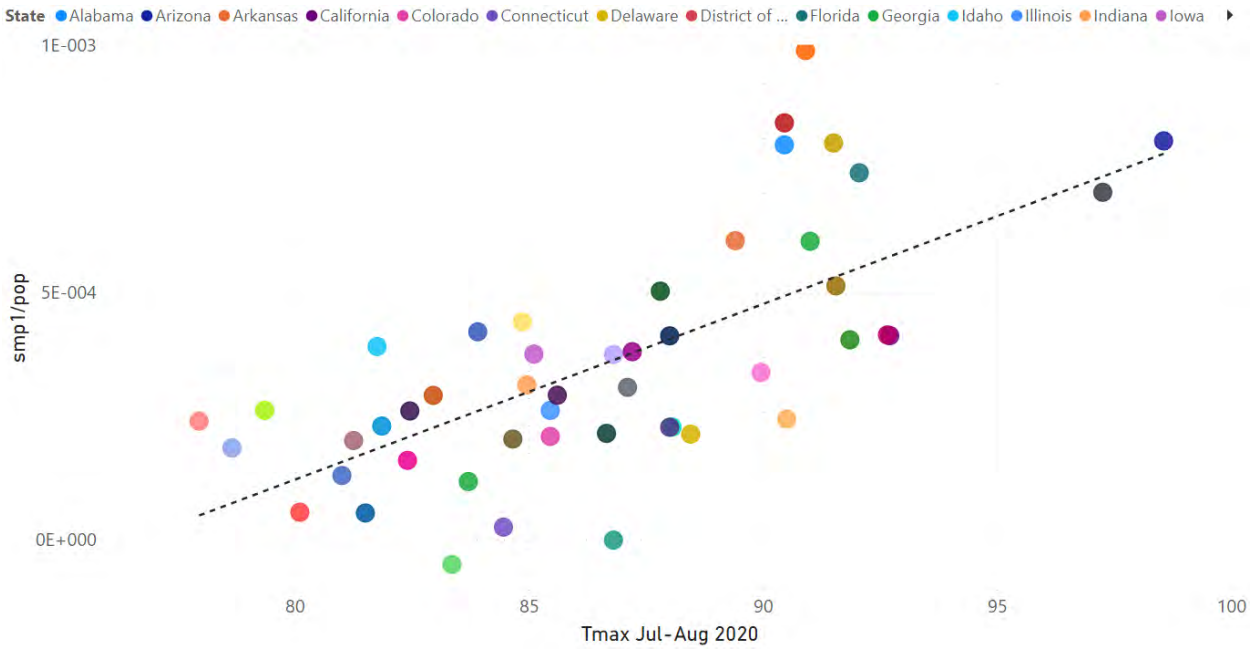


Figure 23. smp1/pop versus average daily maximum temperature over July and August 2020, Tmax Jul-Aug 2020. Each point is for one continental USA state, excluding District of Columbia, for which no temperature data were available (NOAA, 2021). The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

There is a clear positive trend. Here (Figure 23), the four main high-smp1/pop-value outliers are Mississippi, South Carolina, Alabama and Louisiana; whereas the three main low-smp1/pop-value outliers are Massachusetts, Connecticut and New Jersey.

Such a trend between an excess (above-SB) mortality and mean temperature, per state, does not exist, whatsoever, in the winter burden mortality (WB/pop) for any of the pre-COVID-era cycle-years, 2014-2019 (data not shown).

Obesity, poverty, and climatic temperature

Next, we examine the above correlations further. Figure 24 shows that obesity (OB) and poverty (PV) are somewhat correlated to each other.

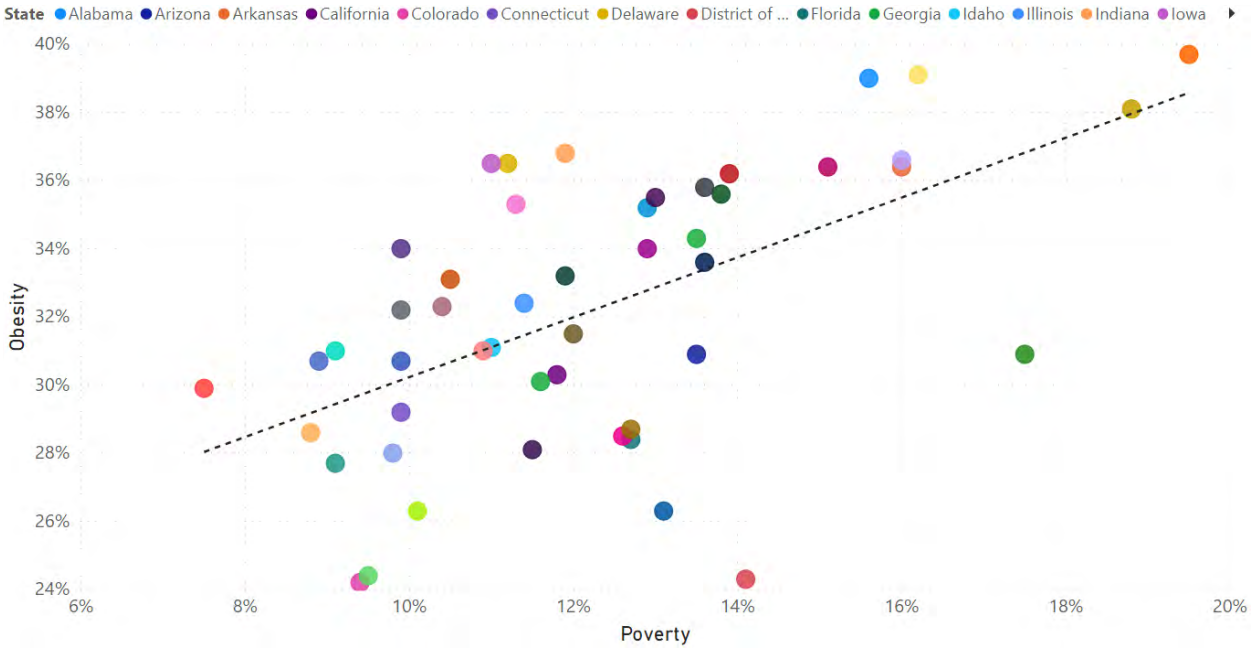


Figure 24. Obesity versus poverty. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved as described in section 2.

Given the above, we decided to try using the product of obesity and poverty (OB.PV) as a variable. Figure 25 shows smp1/pop versus OB.PV, with added circle-symbol-size (radius) determined by the July-August 2020 average daily maximum temperature (averaged by state and over the two-month period).

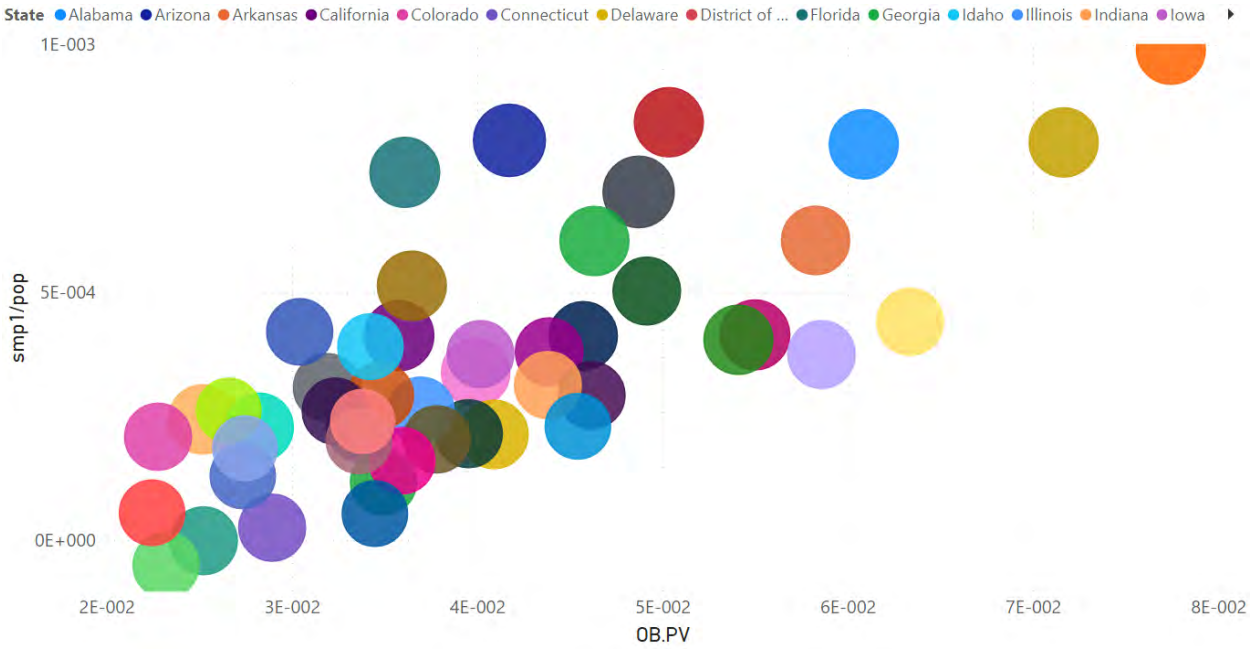


Figure 25. smp1/pop versus the product of obesity and poverty (OB.PV), with the radius size determined by Tmax Jul-Aug 2020. Each point is for one continental USA state, excluding District of Columbia, for which no temperature data were available (NOAA, 2021). The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

The correlation is excellent. Climatic temperature (circle size) also appears to be correlated to OB.PV (Figure 25). Figure 26 shows the average of daily average temperatures over the calendar-year 2020 (Tav 2020) versus OB.PV, with added circle-symbol-size (radius) determined by the outcome smp1/pop.

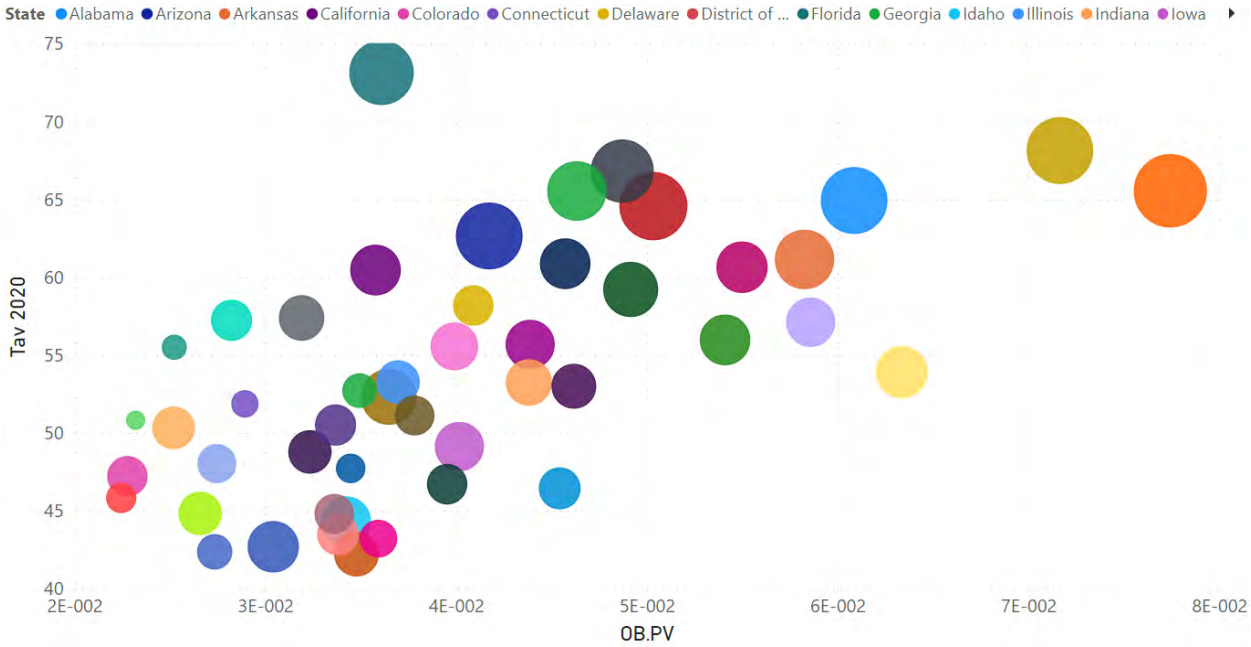


Figure 26. Tav 2020 versus the product of obesity and poverty (OB.PV), with the radius size determined by smp1/pop. Each point is for one continental USA state, excluding District of Columbia, for which no temperature data were available (NOAA, 2021). The colour-code of the other 48 continental states is shown in section 2. Data were retrieved as described in section 2.

Figure 26 shows two things.

First, climatic temperature is correlated to the product OB.PV.

Second, a diagram of climatic temperature versus OB.PV provides a strong predictor of whether there will be large summer mortality following an extended period of chronic psychological stress applied to the population.

Age structure of the population

More than 60 % of COVID-assigned deaths in the USA occur in the 85+ years age group (Kostoff et al., 2021; their Figure 1). The same is generally true of all viral respiratory diseases in Western nations.

Figure 27 shows WB/pop versus percent of population consisting of 85+ year olds (“85+/pop”), for each pre-COVID-era cycle-year, 2014-2019. The latter percentage more than doubles across all states, from approximately 1.2 % to approximately 2.6 %. Whereas the illustrated correlation is weak, it is persistently positive, having similar slope magnitudes, across all cycle-years, except for cycle-year 2016 (Figure 27c) where the nominally positive correlation (not shown) is not statistically meaningful.

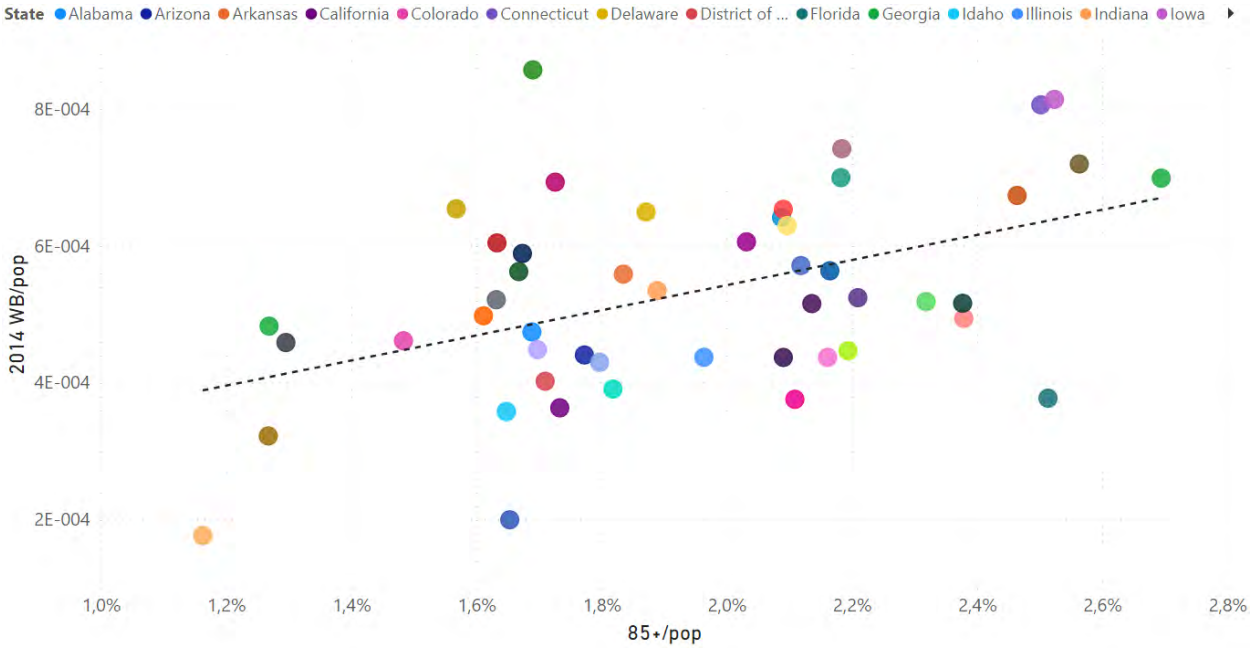


Figure 27a. WB/pop versus 85+/pop for cycle-year 2014. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2. Outliers: Utah (bad data point in 2014), Wyoming (less populous state, poor statistics, underestimation of SB).

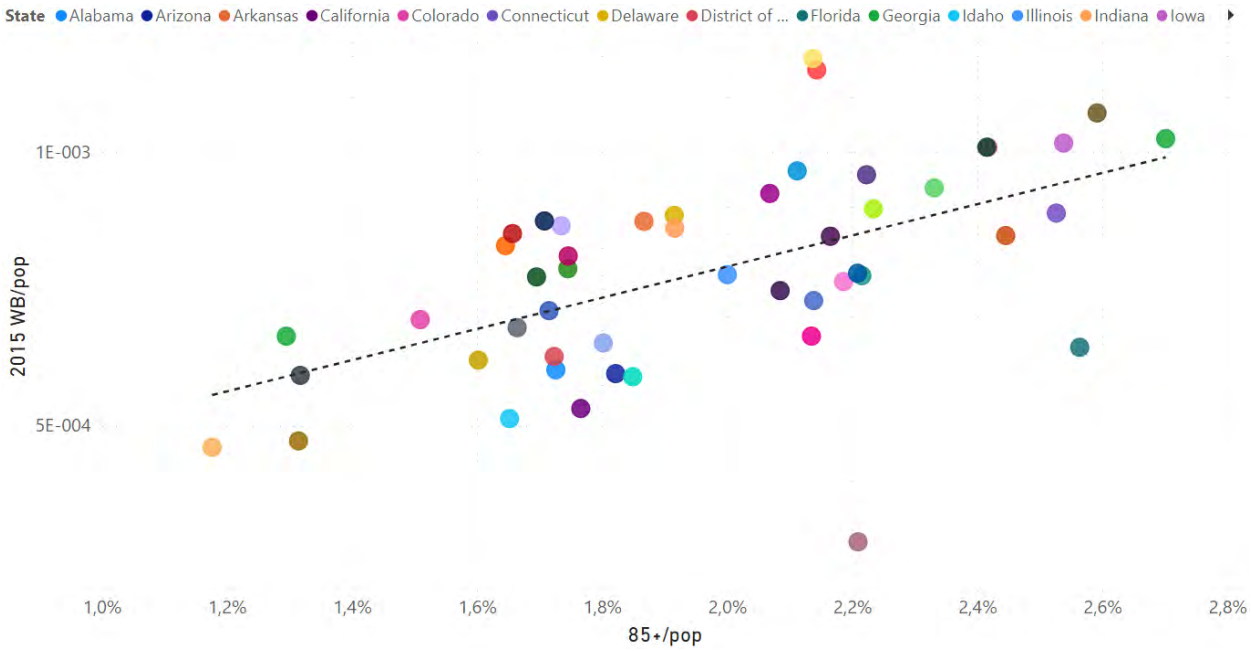


Figure 27b. WB/pop versus 85+/pop for cycle-year 2015. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2. The outlier Wisconsin is due to bad data points in 2015 for this state (see Appendix).

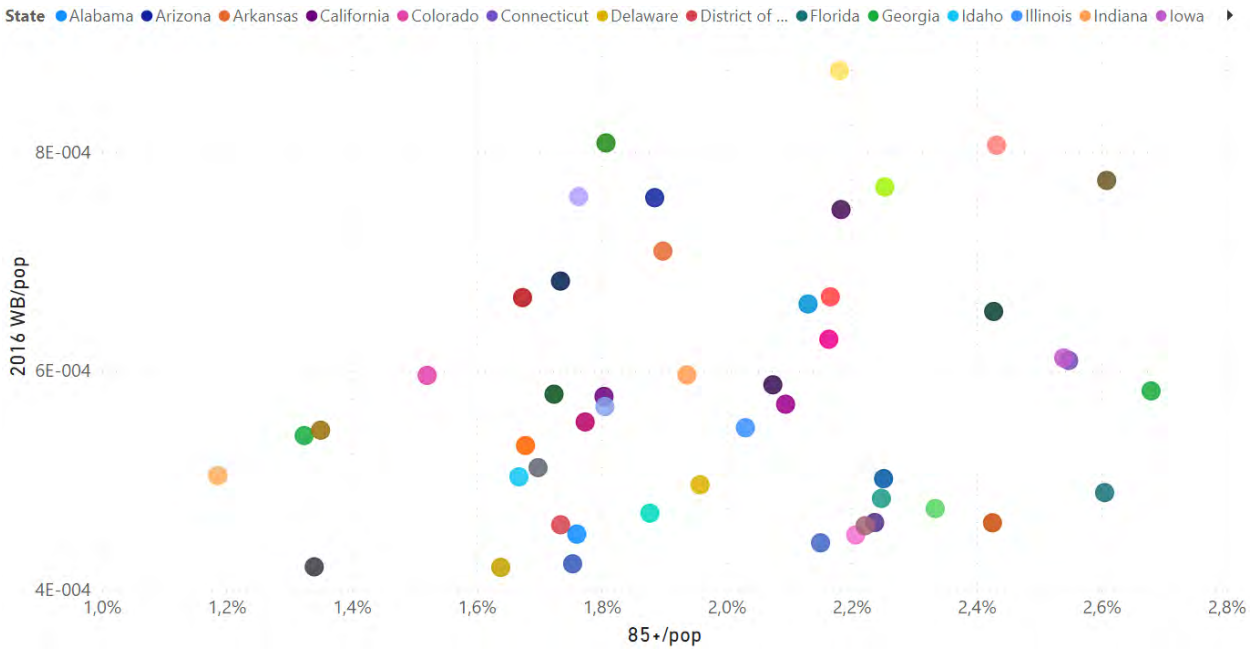


Figure 27c. WB/pop versus 85+/pop for cycle-year 2016. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

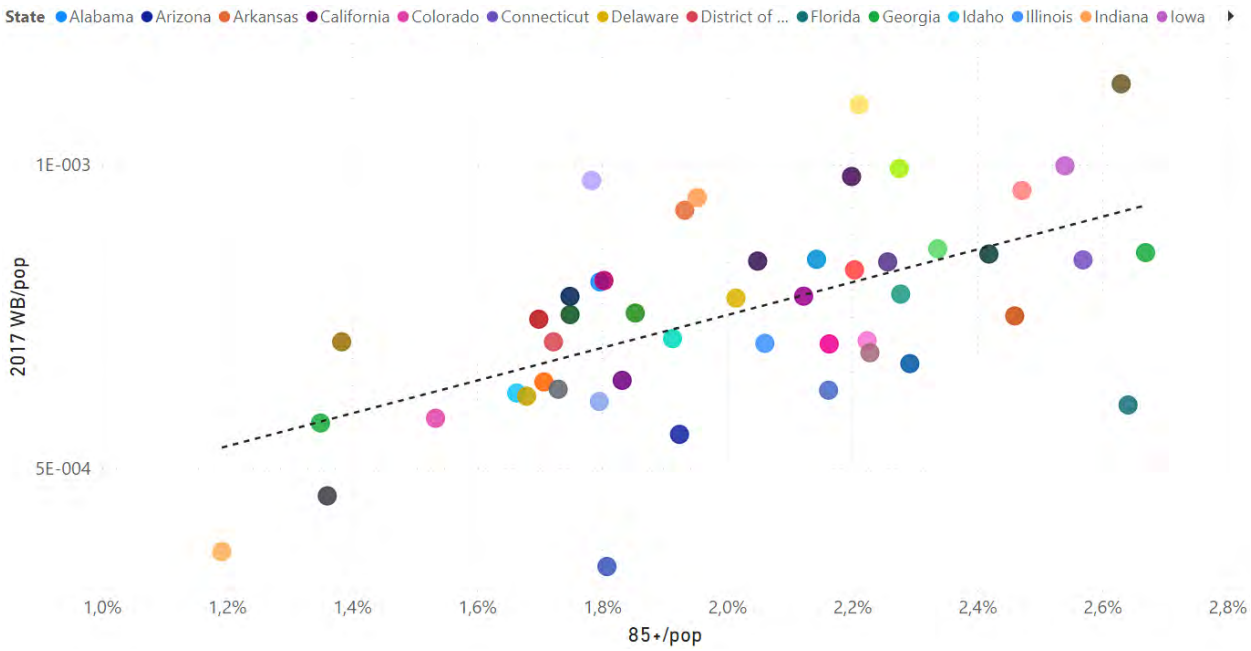


Figure 27d. WB/pop versus 85+/pop for cycle-year 2017. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2. Outlier: Wyoming (less populous state, poor statistics).

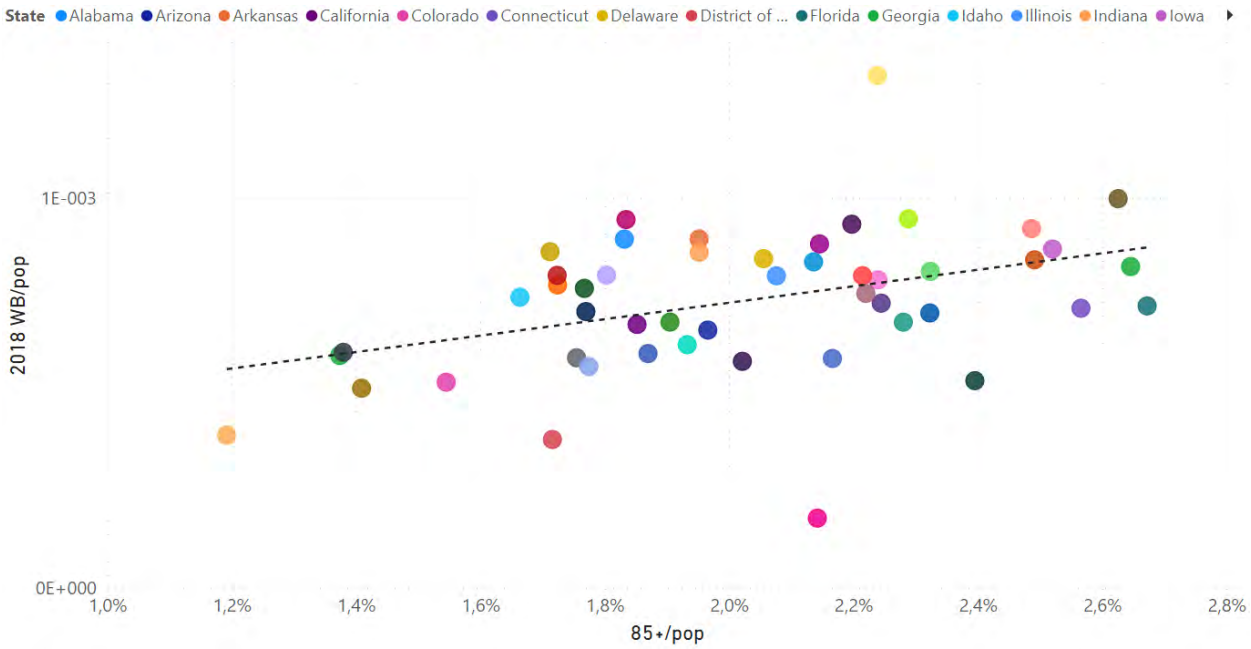


Figure 27e. WB/pop versus 85+/pop for cycle-year 2018. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2. Outliers: West Virginia (underestimation of SB, overestimation of WB), Montana (reverse).

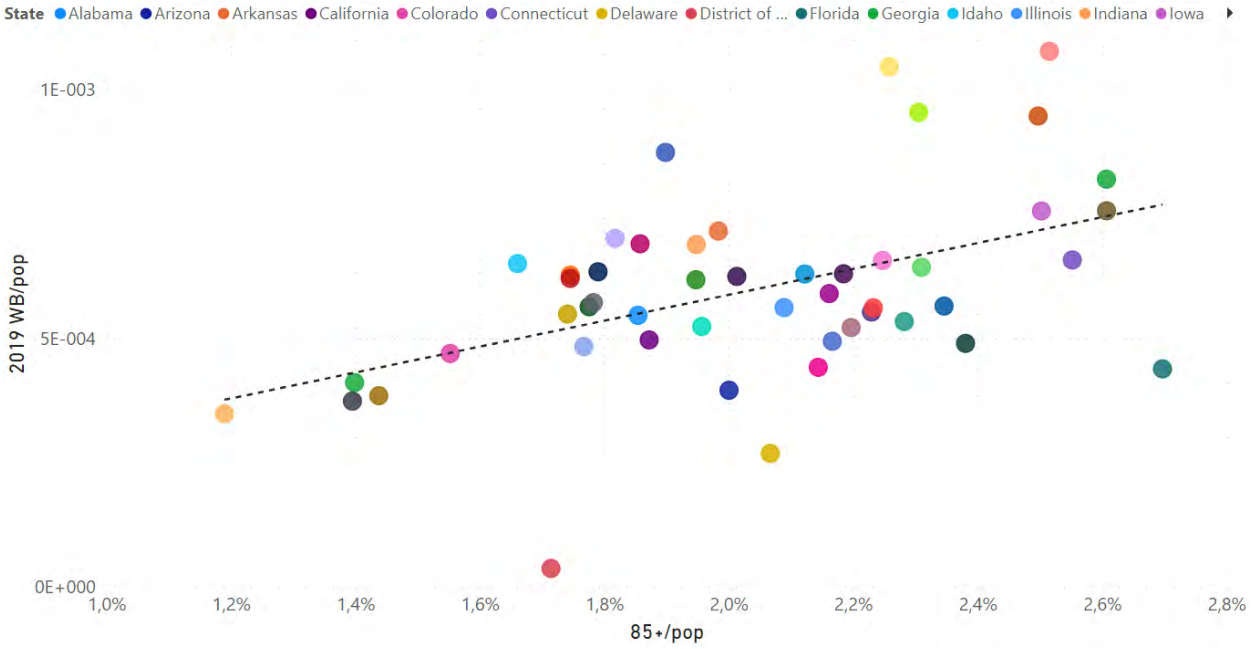


Figure 27f. WB/pop versus 85+/pop for cycle-year 2019. Each point is for one continental USA state. Outlier: District of Columbia (small state, poor statistics).

The same phenomenon (positive correlation of WB/pop with population fraction of the age group, in the pre-COVID-era cycle-years) occurs for all the older age groups: 45-54, 55-64, 65-74, 75-84, and 85+ ages. The correlation is then negative (anti-correlation) for 35-44 years, and not discernable for younger age groups (data not shown).

This age-dependence of winter burden mortality was expected, and is well known. Young people do not generally die of viral respiratory diseases that are prevalent in the winter.

In the COVID-era, cvp1/pop does not have a statistically meaningful correlation with 85+/pop, as shown in Figure 28a. It might best be described as no correlation whatsoever for states having essentially zero-magnitude cvp1/pop values, and several randomly placed outliers above the group having near-zero values of cvp1/pop. This is consistent with the idea that the cvp1 feature is predominantly due to the jurisdiction-specific response to the declaration of a pandemic.

Surprisingly, however, the summer-2020 excess (above-SB) mortality (smp1/pop) has an anti-correlation (“neg-cor”) with 85+/pop, again with significant outliers, as shown in Figure 28b; and the fall-winter-2020-2021 mortality (cvp2/pop) has no discernable correlation with 85+/pop, as shown in Figure 28c. Correspondingly, the WB/pop versus 85+/pop has a positive correlation for cycle-year 2020 (Figure 28d), and a uniquely strong negative (anti-)correlation for cycle-year 2021 (Figure 28e).

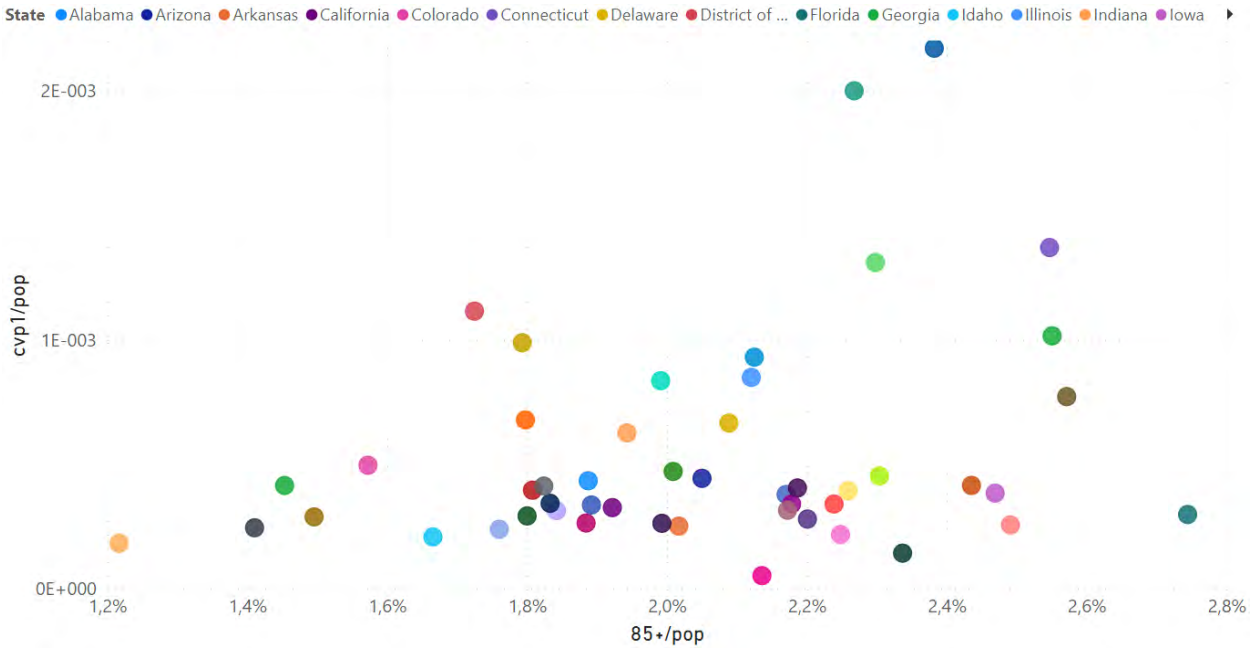


Figure 28a. cvp1/pop versus 85+/pop. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

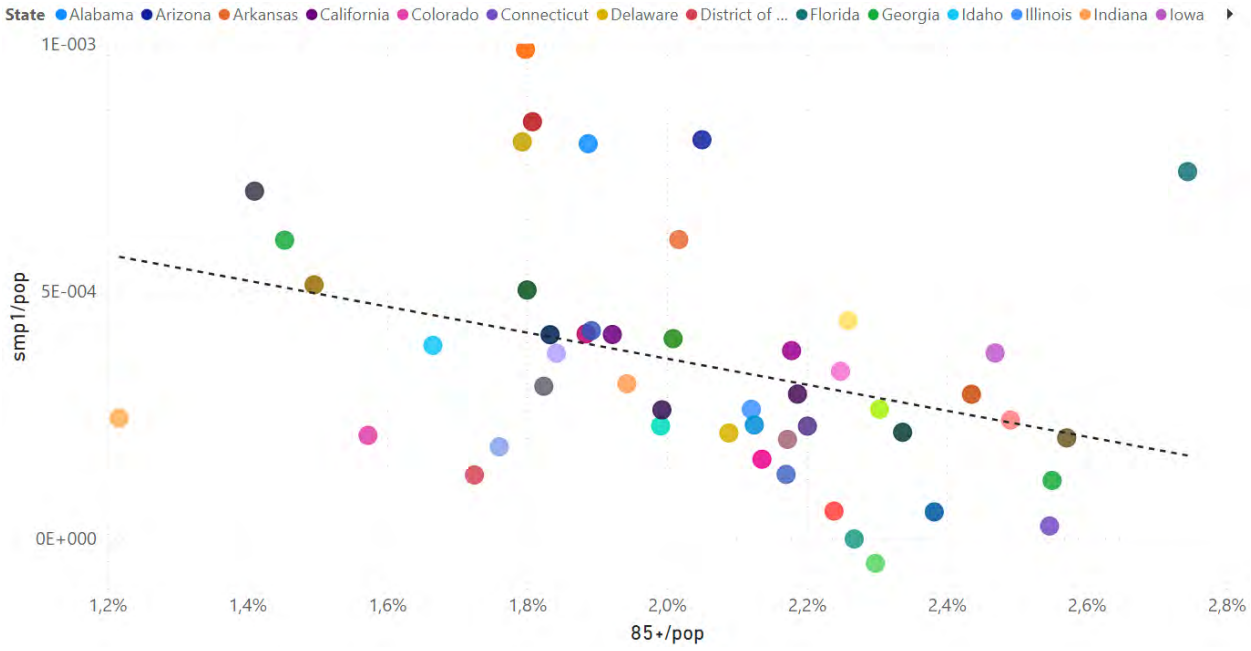


Figure 28b. smp1/pop versus 85+/pop. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

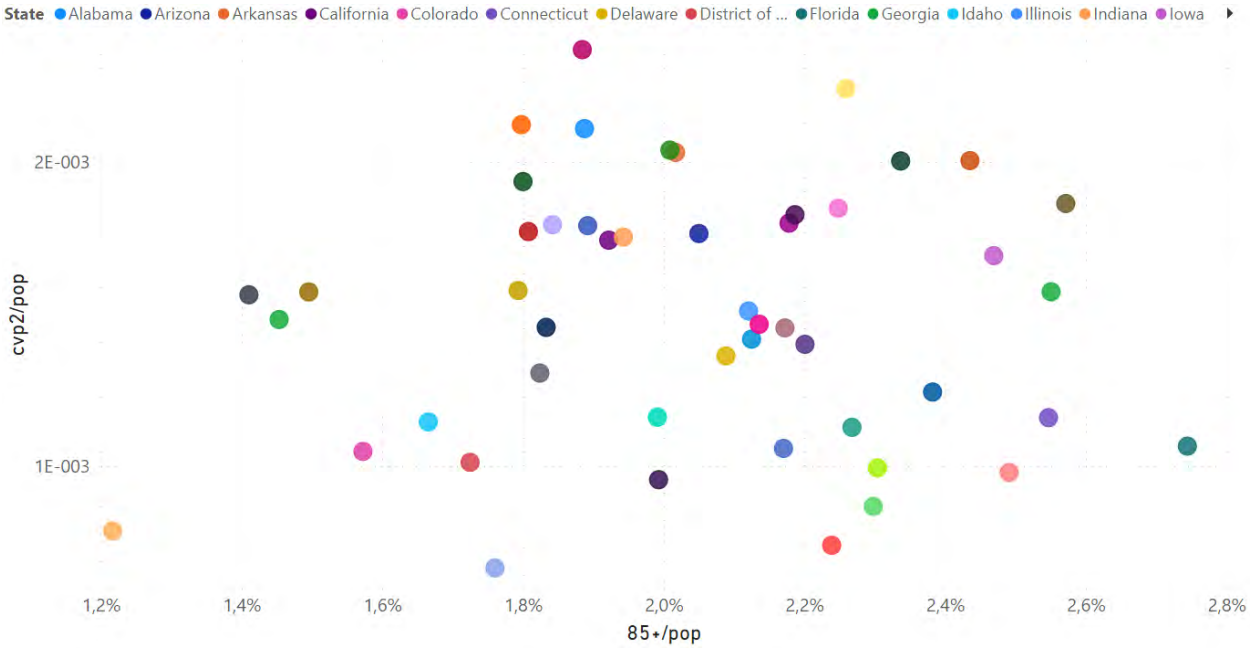


Figure 28c. cvp2/pop versus 85+/pop. Each point is for one continental USA state. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

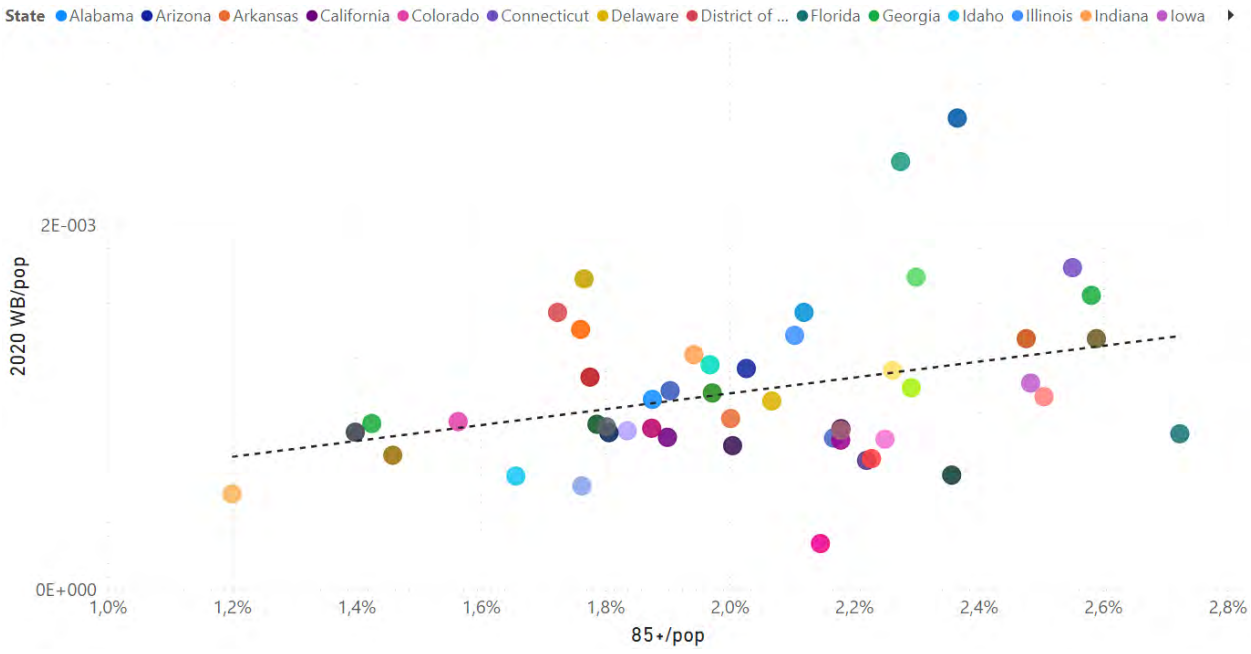


Figure 28d. WB/pop versus 85+/pop for cycle-year 2020. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

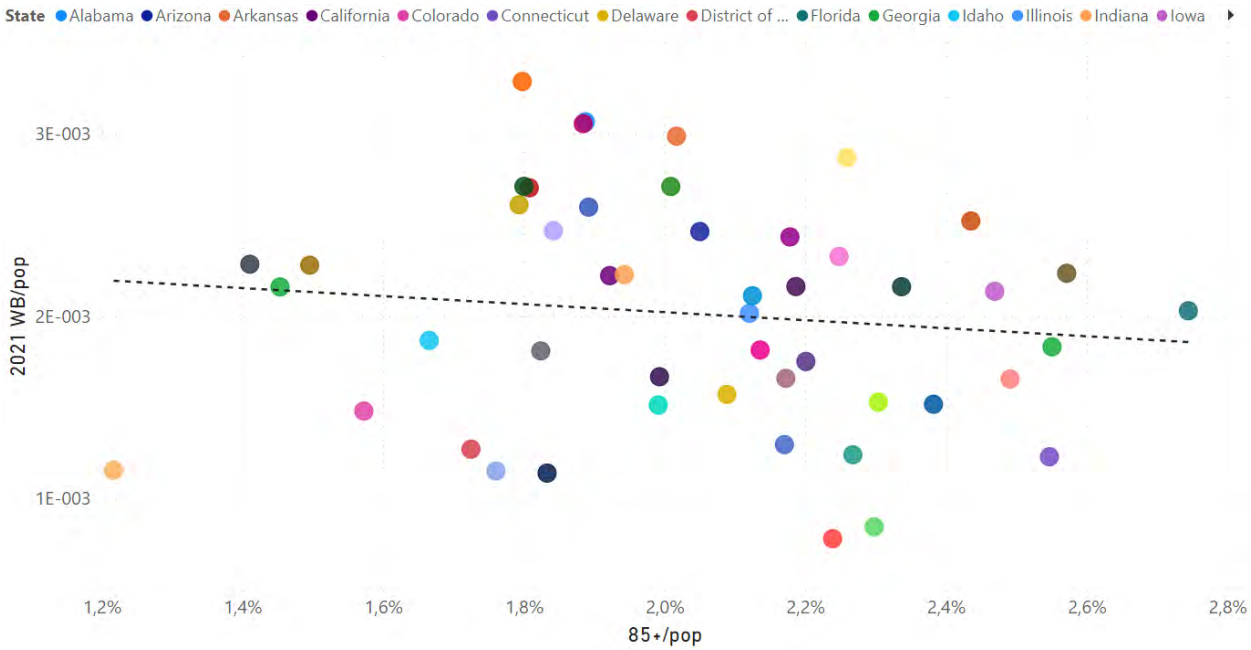


Figure 28e. WB/pop versus 85+/pop for cycle-year 2021. Each point is for one continental USA state. The trend line is meant merely to illustrate the correlation discussed in the text. It results from the usual least squares fit, using all the points in the graph. The colour-code of the 49 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

The same types of state-wise correlations for smp1 and cvp2 occur for other age groups also (data not shown). In summary, as follows.

- smp1/pop: pos-cor with -18/pop, neg-cor with 55-64/pop, neg-cor with 85+/pop
- cvp2/pop: pos-cor with -18/pop, neg-cor with 45-54/pop, neg-cor with 55-64/pop

Population density

The USA state-wise data offers a unique opportunity to examine the relation between population density (“popD”) (number of inhabitants per unit surface area) and excess (above-SB) mortality, since popD varies by more than two orders of magnitude, from Wyoming to New Jersey.

Figure 29 shows WB/pop versus popD, for each pre-COVID-era cycle-year, 2014-2019. Here (Figure 29), there is no detectable, statistically significant, correlation between winter burden mortality (WB/pop) and popD, in any of the years studied.

Given the synchronous mortality patterns, state-to-state (Figures 10 and 11, for the pre-COVID-era cycle-years), and given present theoretical understanding of contagious disease transmission (Hethcote, 2000) (McCallum et al., 2001), our results (Figure 29) impose constraints on models of the phenomenon of seasonal mortality, and strongly suggest that the seasonal preponderance of viral respiratory diseases is not the result of transmission and spread by person-to-person “contact”.

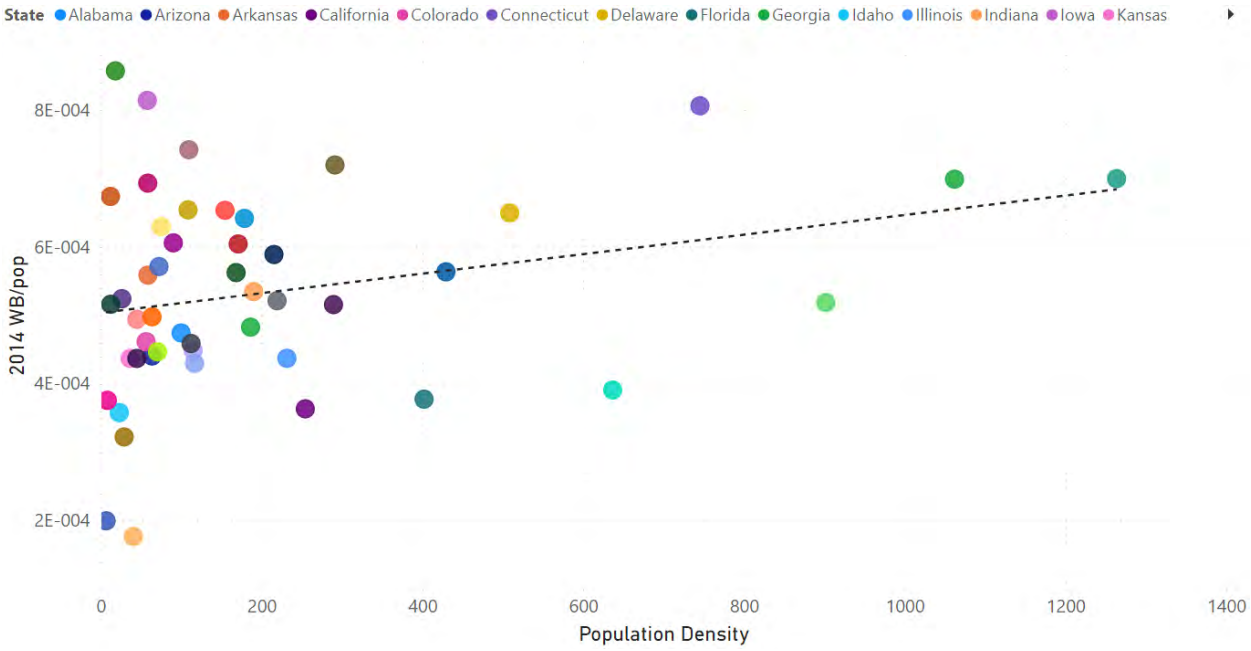


Figure 29a. WB/pop for cycle-year 2014 versus population density. Each point is for one continental USA state, excluding District of Columbia, which has an extreme density. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

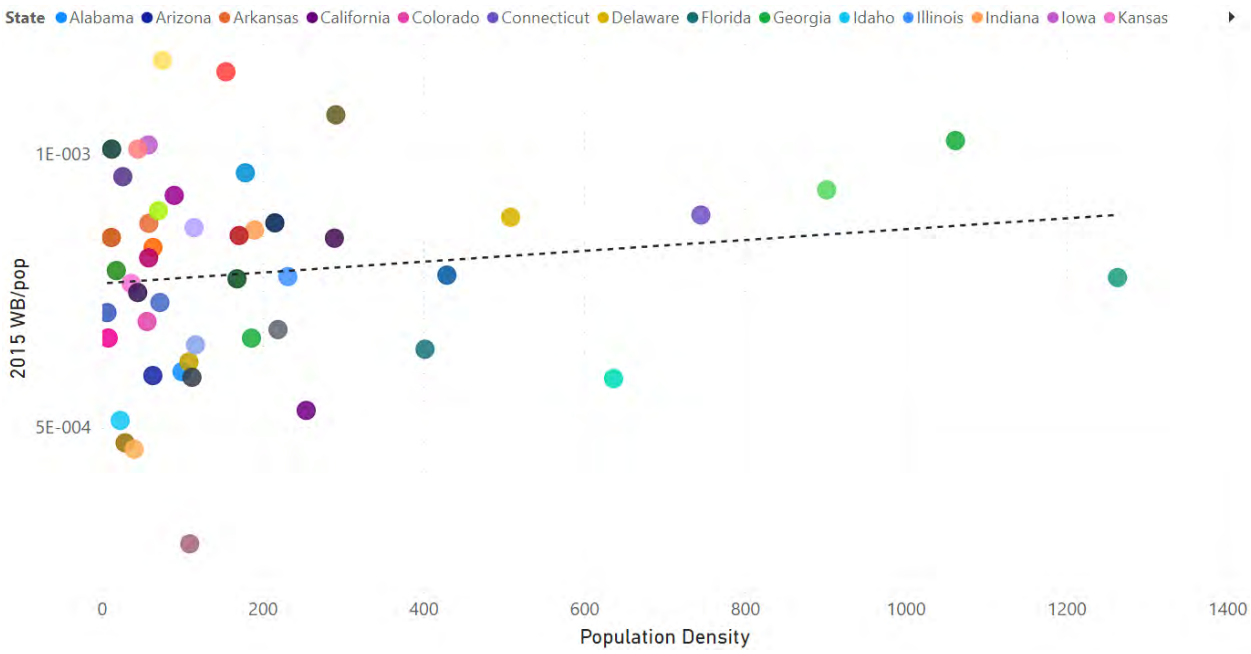


Figure 29b. WB/pop for cycle-year 2015 versus population density. Each point is for one continental USA state, excluding District of Columbia, which has an extreme density. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

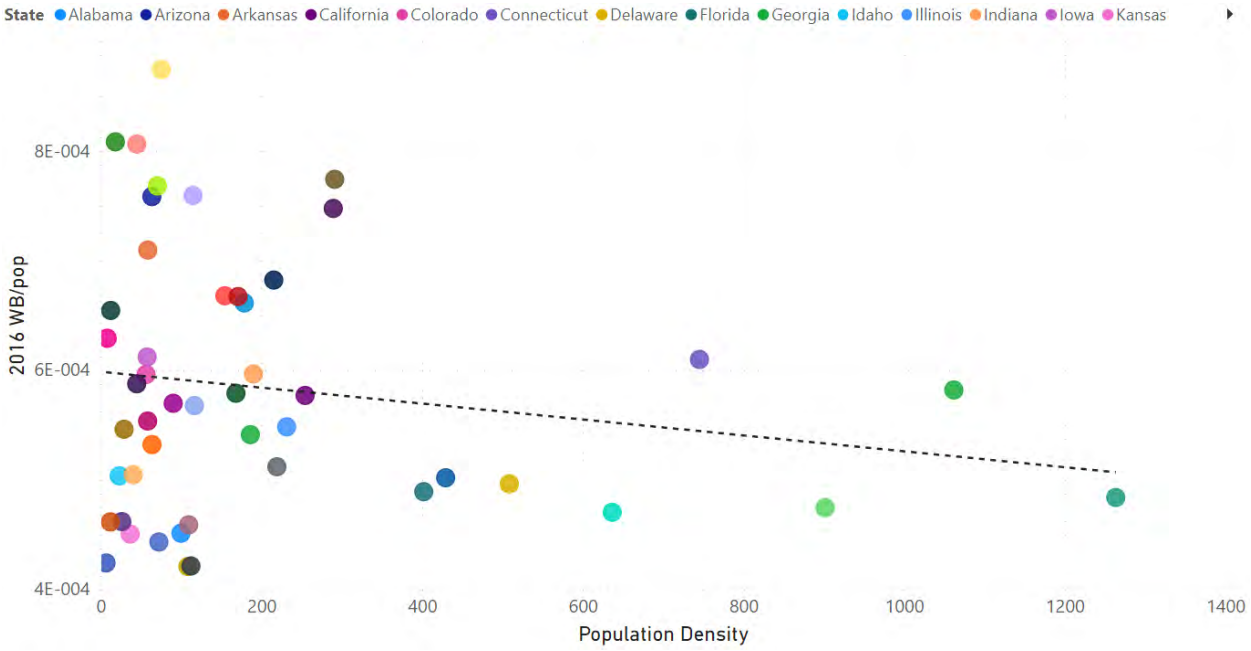


Figure 29c. WB/pop for cycle-year 2016 versus population density. Each point is for one continental USA state, excluding District of Columbia, which has an extreme density. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

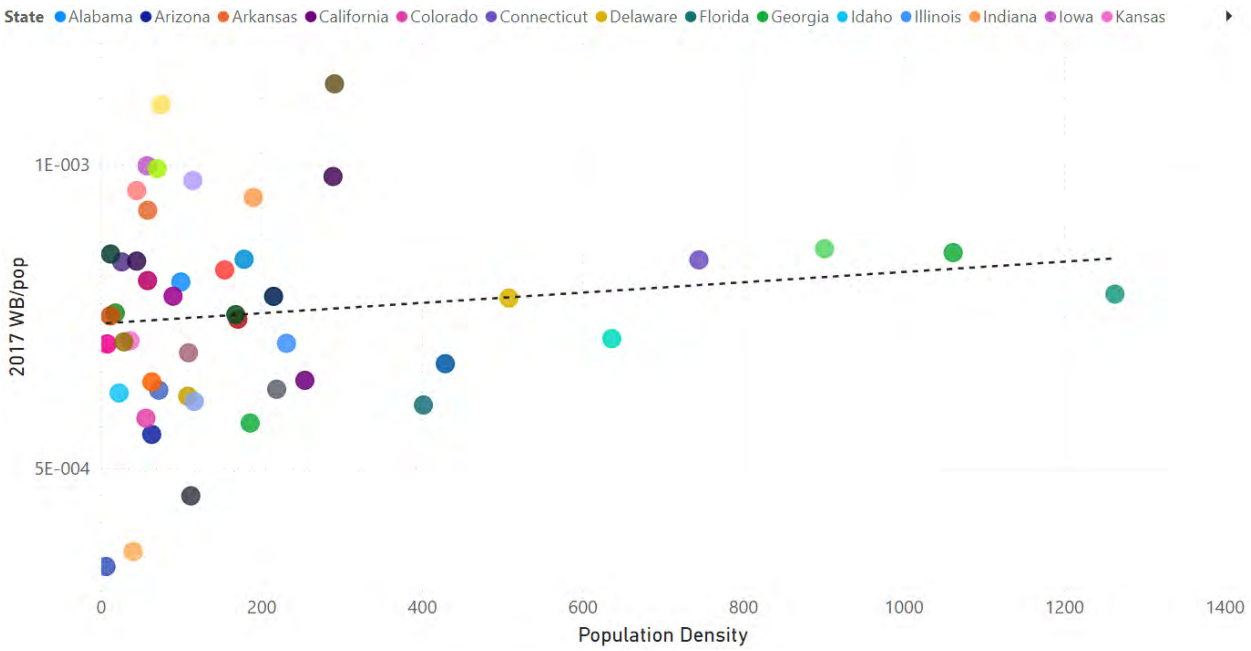


Figure 29d. WB/pop for cycle-year 2017 versus population density. Each point is for one continental USA state, excluding District of Columbia, which has an extreme density. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

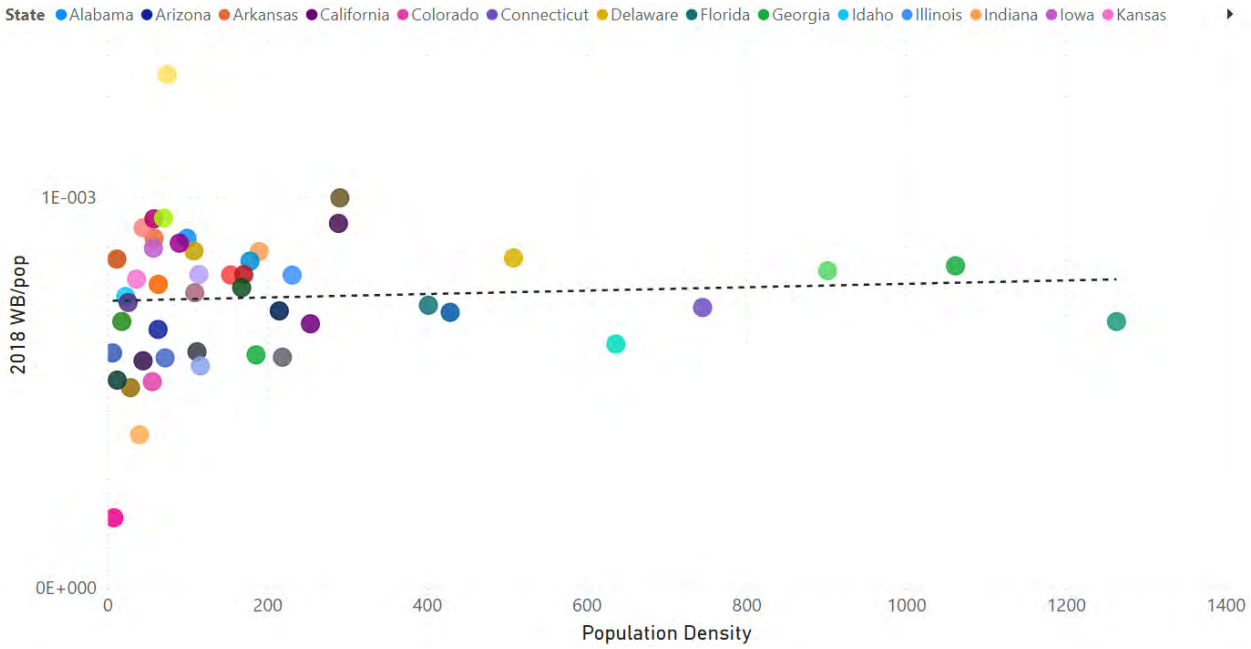


Figure 29e. WB/pop for cycle-year 2018 versus population density. Each point is for one continental USA state, excluding District of Columbia, which has an extreme density. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

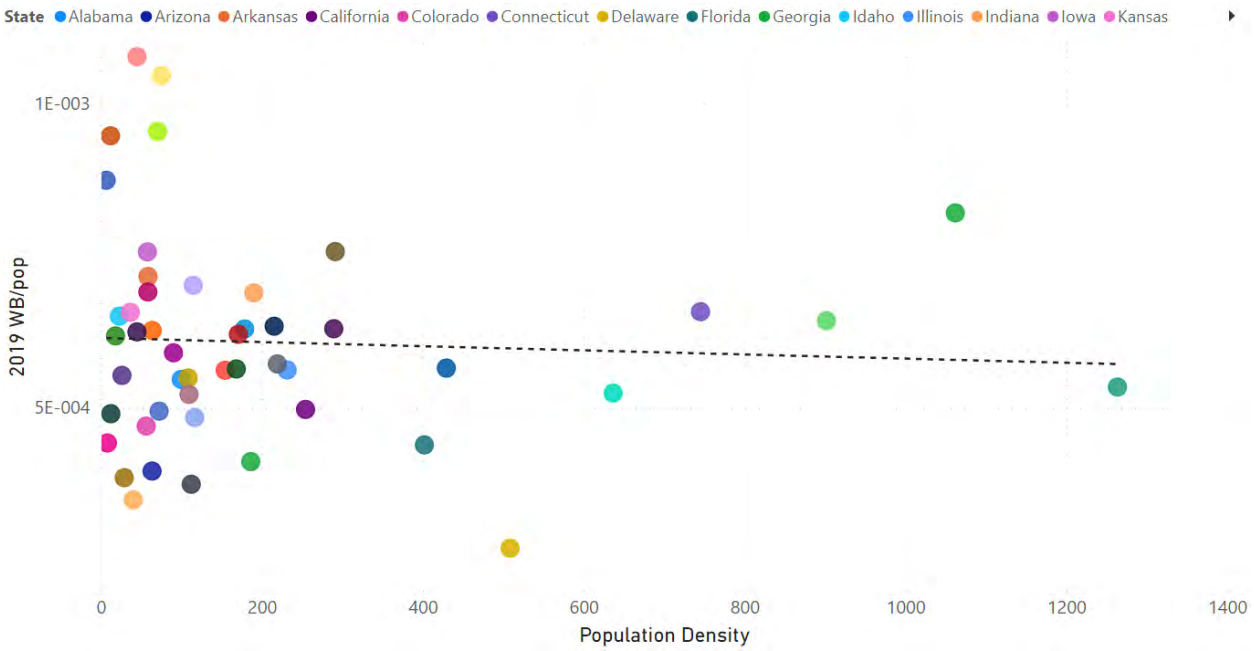


Figure 29f. WB/pop for cycle-year 2019 versus population density. Each point is for one continental USA state, excluding District of Columbia, which has an extreme density. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

This result (Figure 29) is in contrast to correlations observed for the COVID-era, where mortality has strong correlations and anti-correlations with popD. In the COVID-era, cvp1/pop has a large positive correlation with popD, although the New York outlier is significant, as shown in Figure 30a. While, on the other hand, both the summer-2020 excess (above-SB) mortality (smp1/pop) and the fall-winter-2020-2021 mortality (cvp2/pop) have anti-correlations with popD (Figures 30b and 30c, respectively). Correspondingly, the WB/pop versus popD has a large positive correlation for cycle-year 2020, with New York outlier (Figure 30d), and a strong negative (anti-)correlation for cycle-year 2021 (Figure 30e).

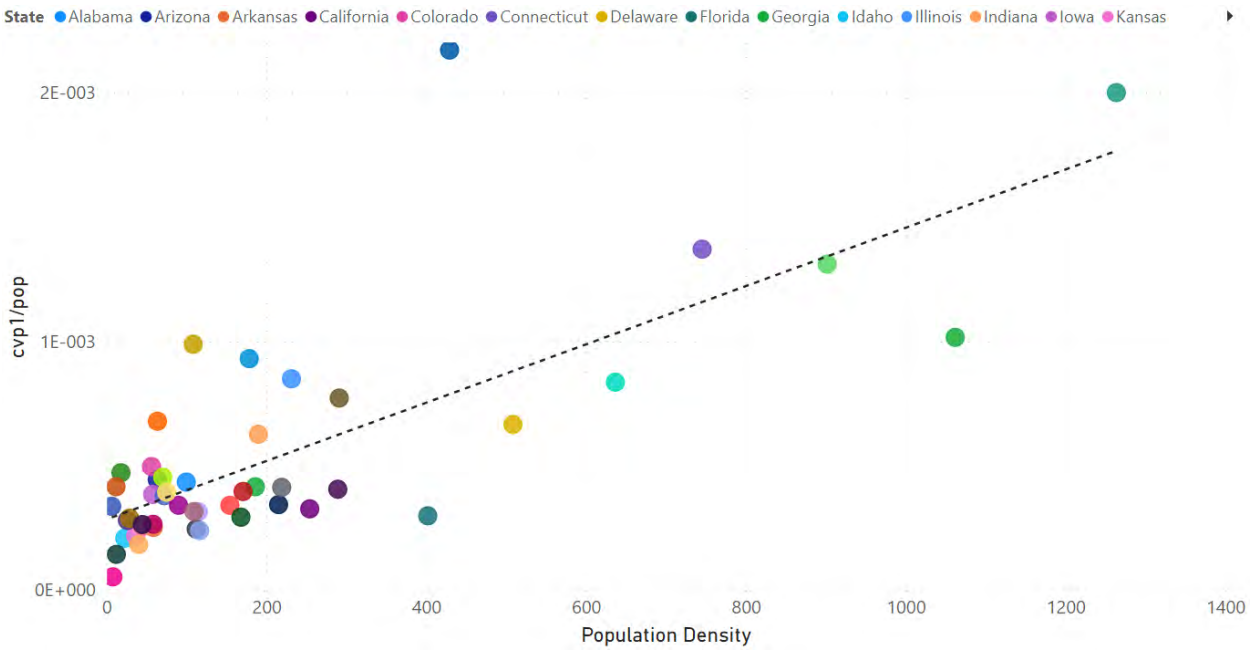


Figure 30a. cvp1/pop versus population density. Each point is for one continental USA state, excluding District of Columbia, which has an extreme density. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

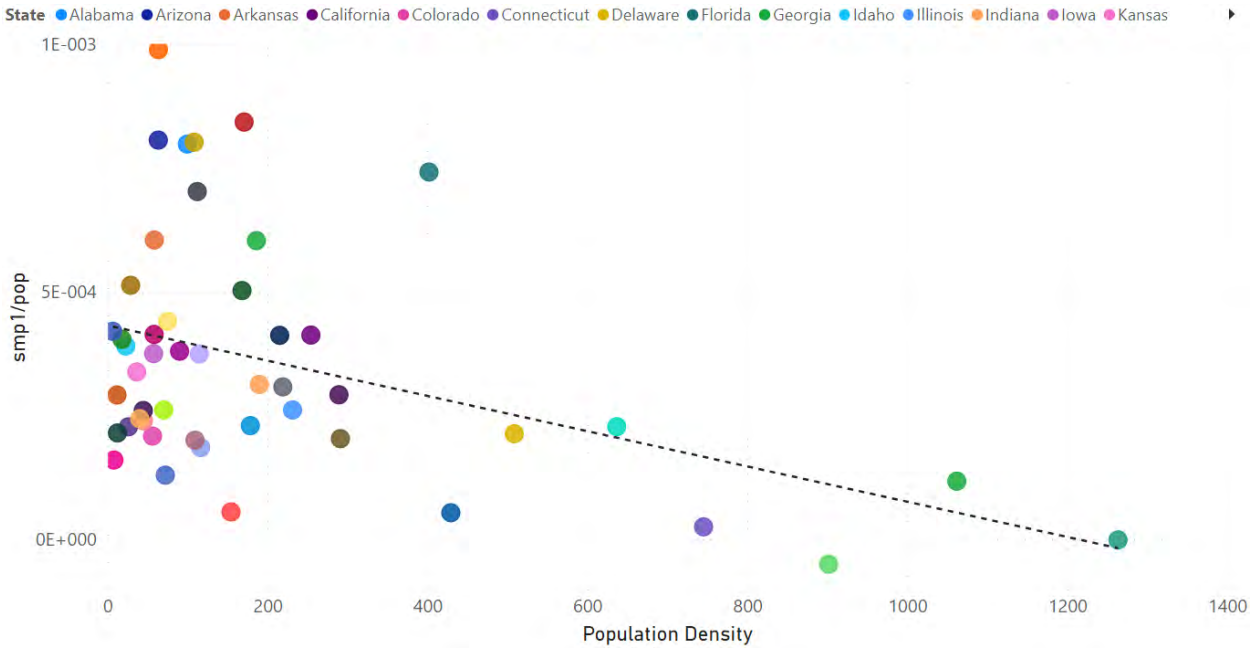


Figure 30b. smp1/pop versus population density. Each point is for one continental USA state, excluding District of Columbia, which has an extreme density. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

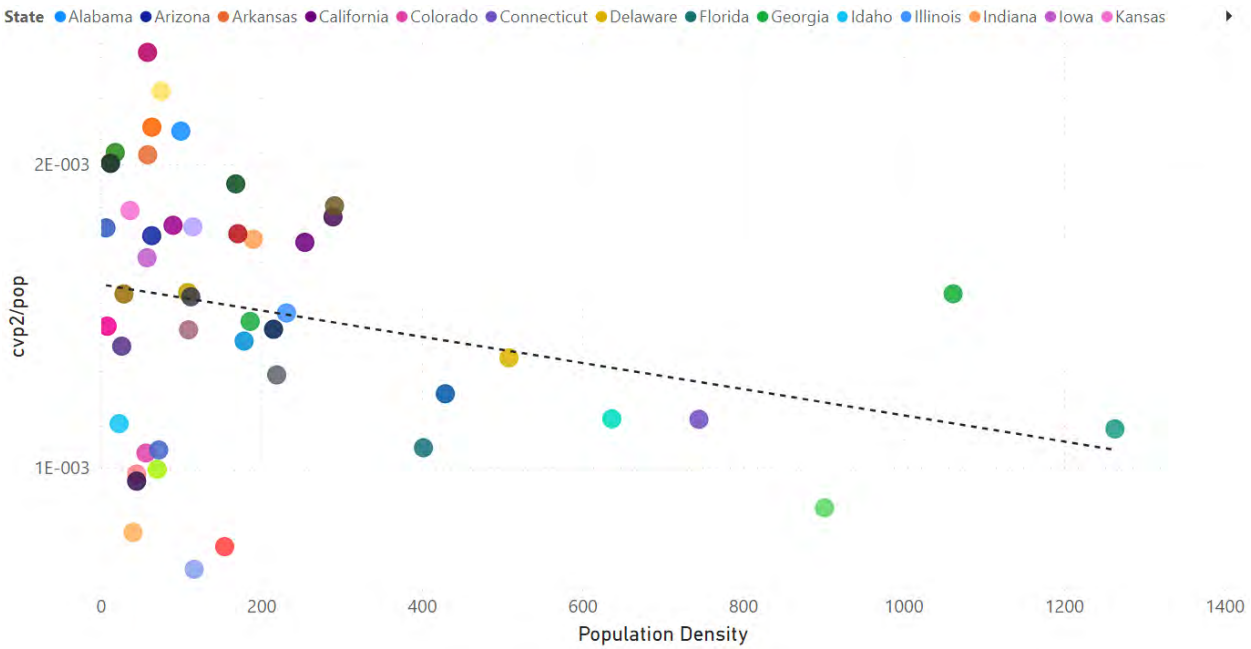


Figure 30c. cvp2/pop versus population density. Each point is for one continental USA state, excluding District of Columbia, which has an extreme density. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

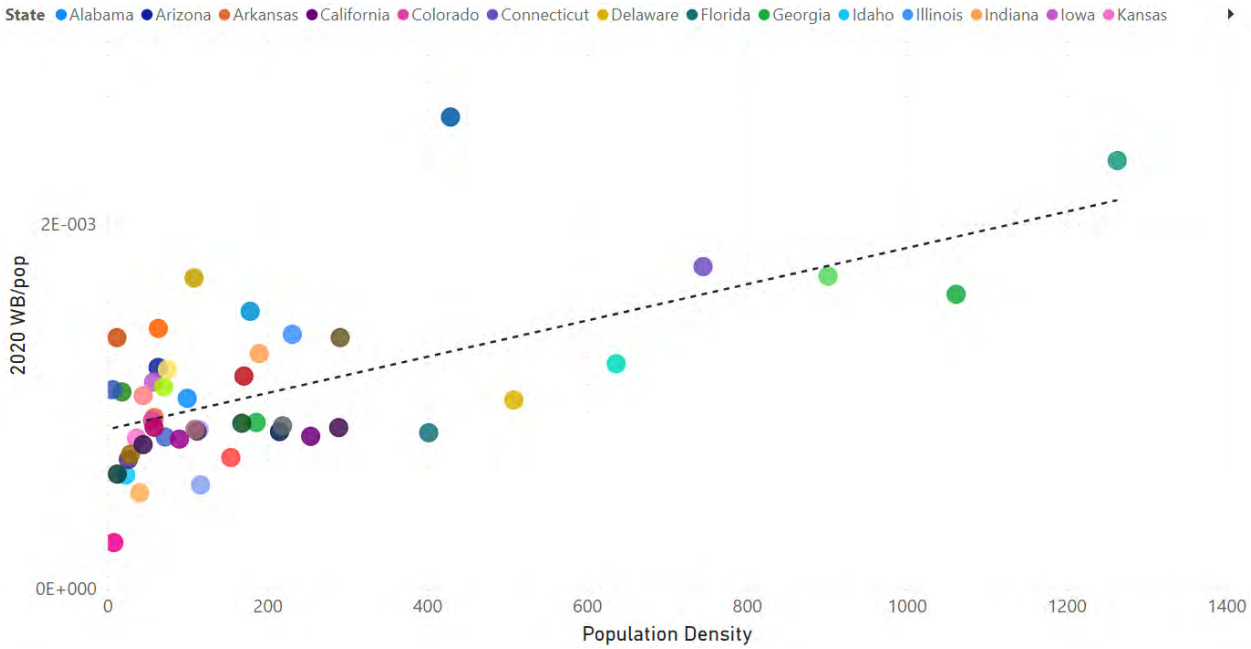


Figure 30d. WB/pop for cycle-year 2020 versus population density. Each point is for one continental USA state, excluding District of Columbia, which has an extreme density. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

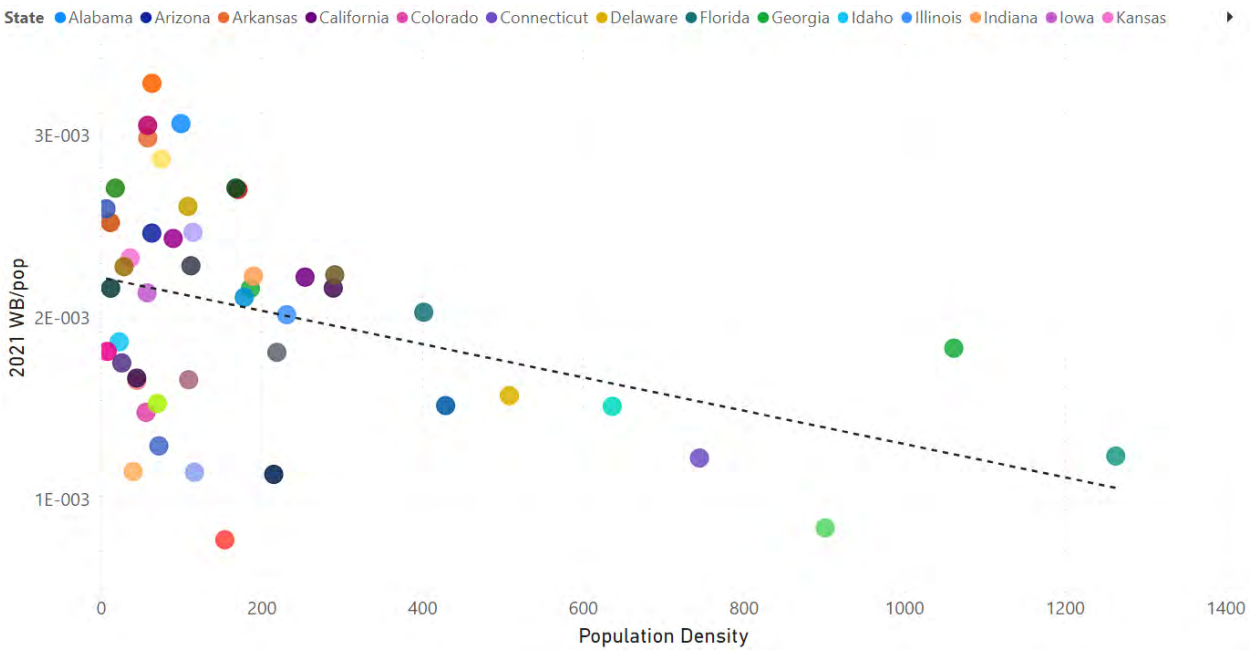


Figure 30e. WB/pop for cycle-year 2021 versus population density. Each point is for one continental USA state, excluding District of Columbia, which has an extreme density. The colour-code of the other 48 continental states is shown in section 2. Data were retrieved and calculations made as described in section 2.

We do not believe that a new virus causes the unprecedented correlations of mortality with popD, in the COVID-era. Rather, we interpret the results to mean that high-population-density states, with large urban centers would have had similar institutional structures and policy responses, generally different from those in low-population-density states. Also, the Southern states with large smp1 mortality due to climatic temperature, poverty and obesity are lower population-density states.

One pair of states, New York and Florida, strikingly demonstrates that population density in itself is not a controlling factor. Whereas these two states have essentially identical values of popD, they have diametrically opposed values of cvp1 mortality (Figure 30a), and, in the opposite order, of summer-2020 (smp1) mortality (Figure 30b).

Indeed, the correlations with popD in the COVID-era are an indication that the mortality is not the result of viral respiratory diseases, and rather that the mortality is tied to institutional, governmental, socio-economic and climatological differences.

All-cause mortality by week (ACM/w) by age group

The age dependencies of mortality in the pre-COVID and COVID-eras are shown more directly than only examining state-wise correlations, by examining ACM/w itself for the USA (no state-wise resolution is available) by age group, as follows.

We represent the ACM/w for the USA (Figure 5) by age group, for the two age groups 18-64 and 65+ ages, in Figure 32a. Here (Figure 32a), we have multiplied the ACM/w for the 18-64 years age group by a factor sufficient to make the ACM/w equal to that for the 65+ years age group, in the summer-2014 trough. This is equivalent to multiplying the population of the 18-64 years age group until the deaths per week are equal to the deaths per week in the 65+ years age group, in the summer-2014 trough. This is done to better visualize and compare the relative seasonal changes in mortality between the two age groups.

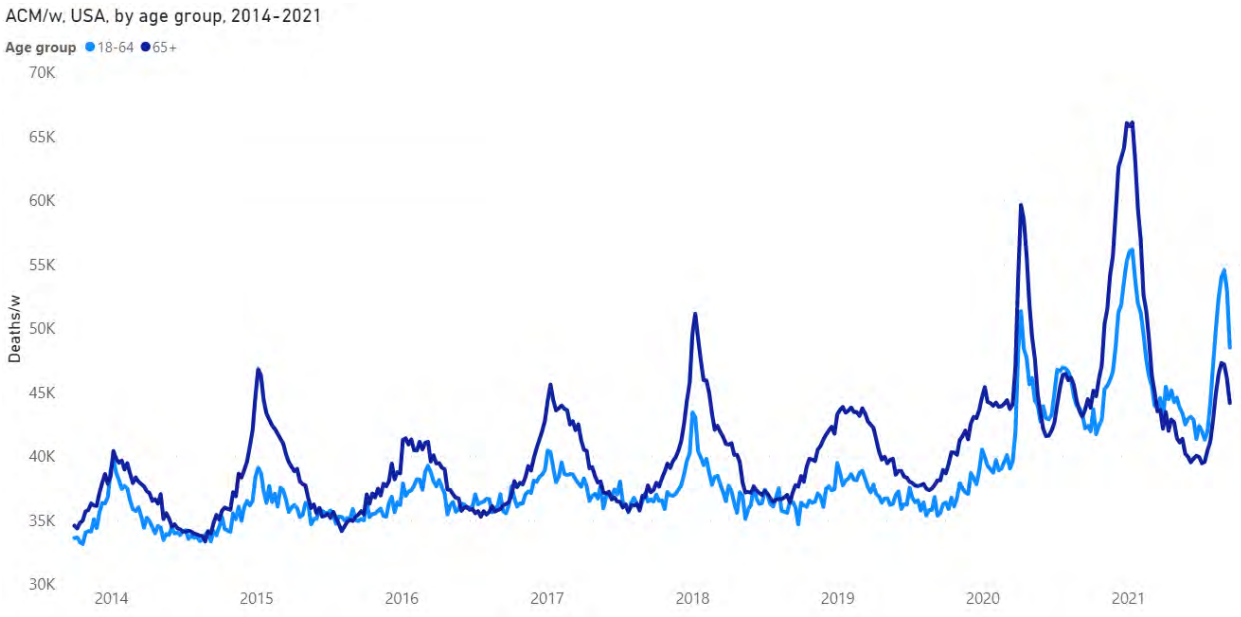


Figure 32a. All-cause mortality by week in the USA for the 18-64 and 65+ years age groups (light blue and dark blue lines, respectively), from 2014 to 2021. The ACM/w for the 18-64 years age group is rescaled (multiplied), as explained in the text, to make the number of deaths per week of both age groups equal in the summer-2014 trough, for comparison purposes. Data are displayed from week-40 of 2013 to week-37 of 2021 for the whole

continental USA, including Alaska and Hawaii. Data were retrieved from CDC (CDC, 2021a), as described in Table 1.

Figure 32a shows that, in the pre-COVID-era, the elderly group (65+ years) is always approximately 2-3 times more susceptible to the additional challenges and stress of winter than the younger group (18-64 years). This rule is not followed in the COVID-era. In the COVID-era, the relative summer-2020 and summer-2021 mortalities are greater for the younger age group than for the elderly group (Figure 32a), which is reversed compared to known age-dependent vulnerability to dying from viral respiratory diseases.

This reversal in the COVID-era is more explicitly illustrated in Figure 32b, which shows the difference by week of the two curves depicted in Figure 32a.

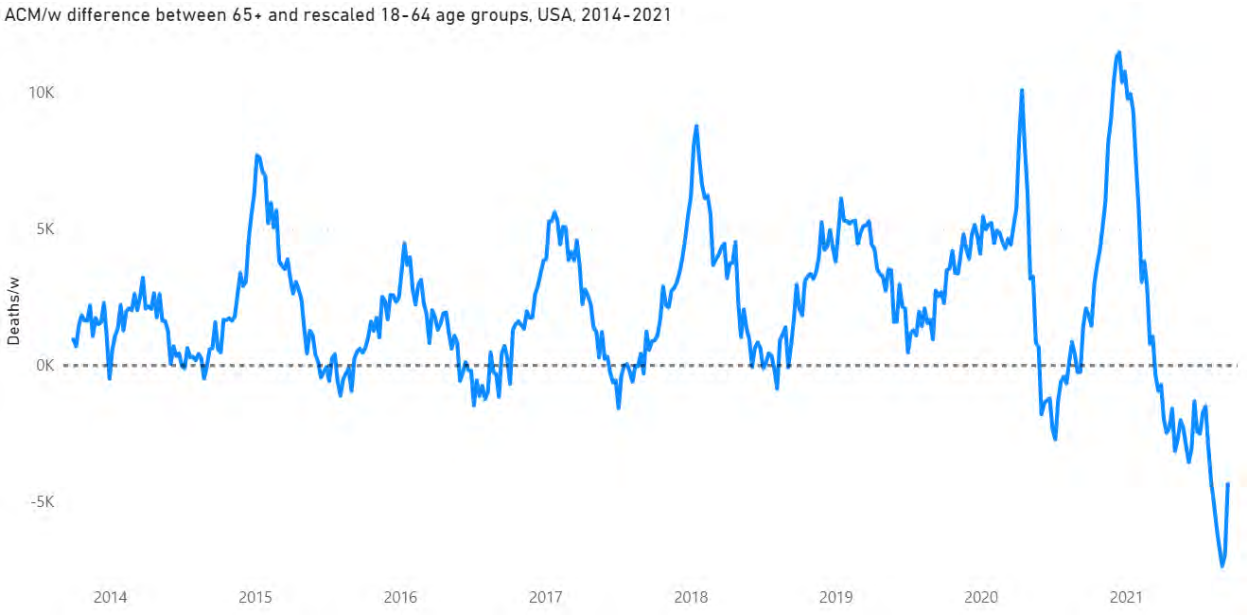


Figure 32b. Difference in all-cause mortality by week in the USA between the 65+ years and the rescaled 18-64 years age groups, from 2014 to 2021. The ACM/w for the 18-64 years age group was rescaled (multiplied), as explained in the text, to make the number of deaths per week of both age groups equal in the summer-2014 trough, for comparison purposes. Data are displayed from week-40 of 2013 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The dashed line emphasizes the zero. Data were retrieved from CDC (CDC, 2021a), as described in Table 1.

Here (Figure 32b), we see that the younger age group (18-64 years) has moderately more (rescaled) deaths in summer-2020, and significantly more (rescaled) deaths in summer-2021. Two possible interpretations come to mind: either the integrated cumulative long-term stress from the government measures takes longer to affect more tolerant younger individuals than older individuals, or the massive vaccination campaign administered between the two summers (Figure 31, below) has had a disproportionate negative impact on the younger age group.

A more detailed examination of the COVID-era is possible thanks to more age-group resolution being publicly available for that time period (CDC, 2021b), at the national level (not state-resolved), as follows. A selection of these data is shown in Figure 33.

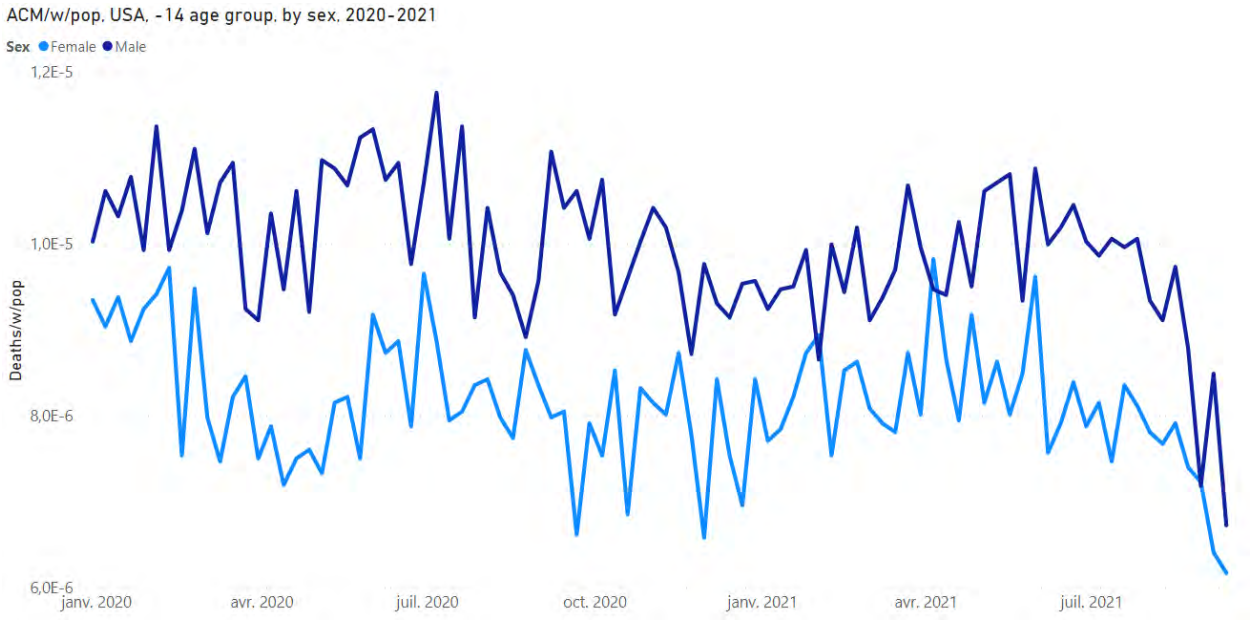


Figure 33a. All-cause mortality by week normalized by population for the USA for the 14 years and less ("-14 years") age group, for each of both sexes, from 2020 to 2021. Data are displayed from week-1 of 2020 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The population used for normalization is the population of the specific age group and sex. ACM data were retrieved from the CDC (CDC, 2021b) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021b), as described in Table 1.

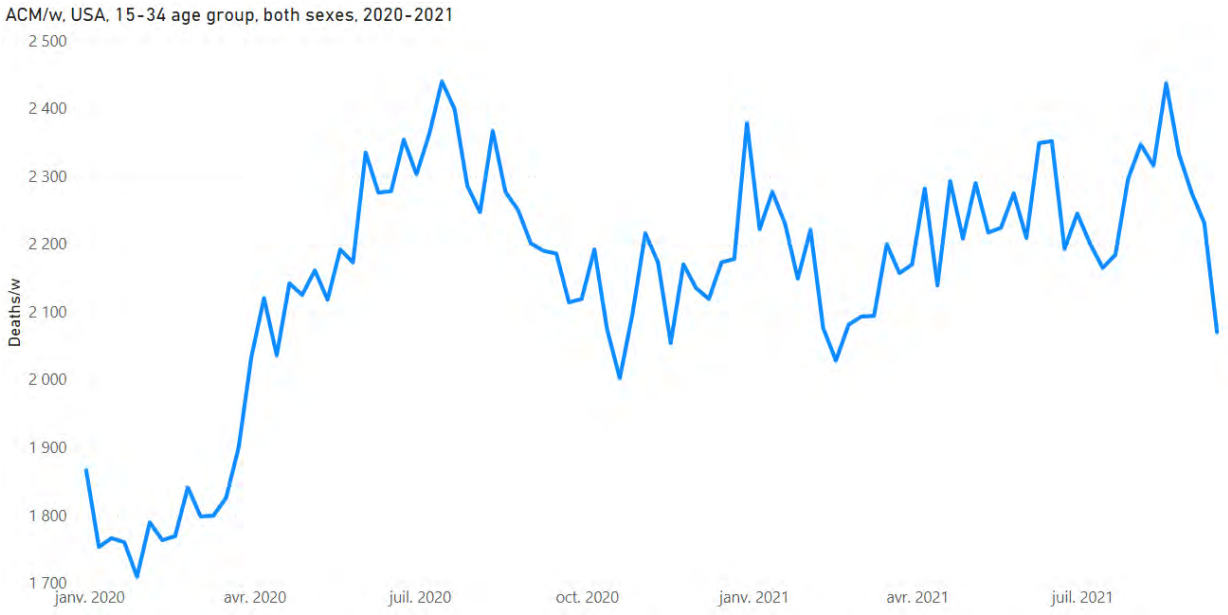


Figure 33b. All-cause mortality by week for the USA for the 15-34 years age group, both sexes, from 2020 to 2021. Data are displayed from week-1 of 2020 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The population used for normalization is the population of the specific age group. ACM data were retrieved from the CDC (CDC, 2021b) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021b), as described in Table 1.

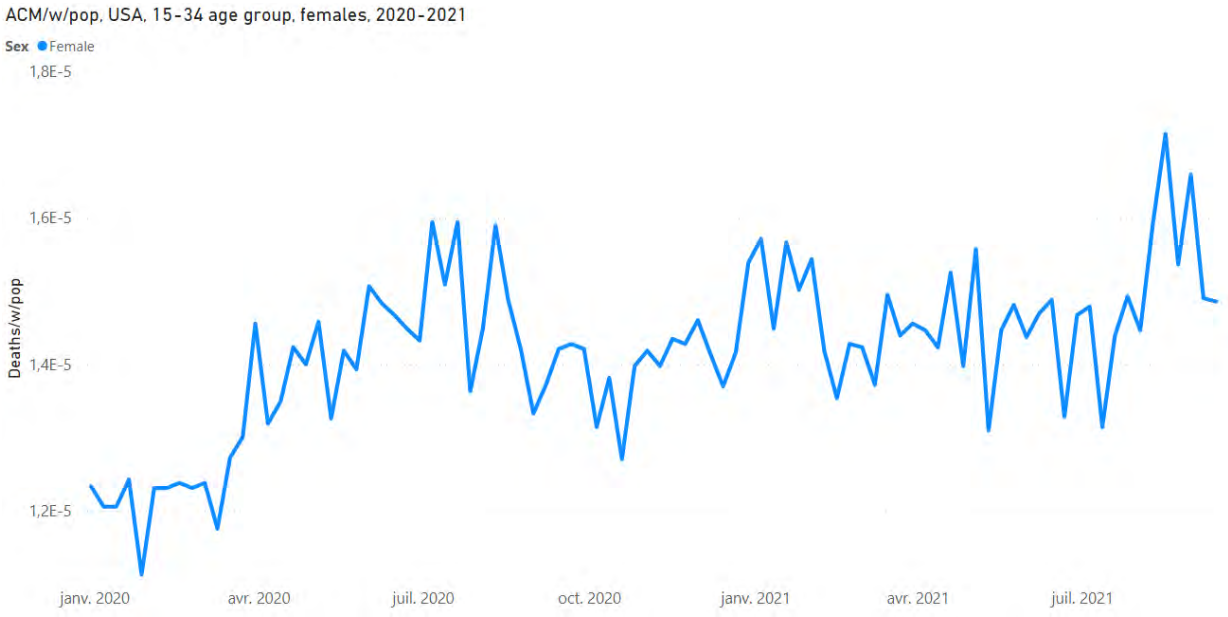


Figure 33c. All-cause mortality by week normalized by population for the USA for females of the 15-34 years age group, from 2020 to 2021. Data are displayed from week-1 of 2020 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The population

used for normalization is the population of the specific age group and sex. ACM data were retrieved from the CDC (CDC, 2021b) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021b), as described in Table 1.

Figure 33d. All-cause mortality by week for the USA for the 35-54 years age group, both sexes, from 2020 to 2021. Data are displayed from week-1 of 2020 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The population used for normalization is the population of the specific age group. ACM data were retrieved from the CDC (CDC, 2021b) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021b), as described in Table 1. The horizontal line at “5 500” is a visual aide of the plateau of mortality discussed in the text.

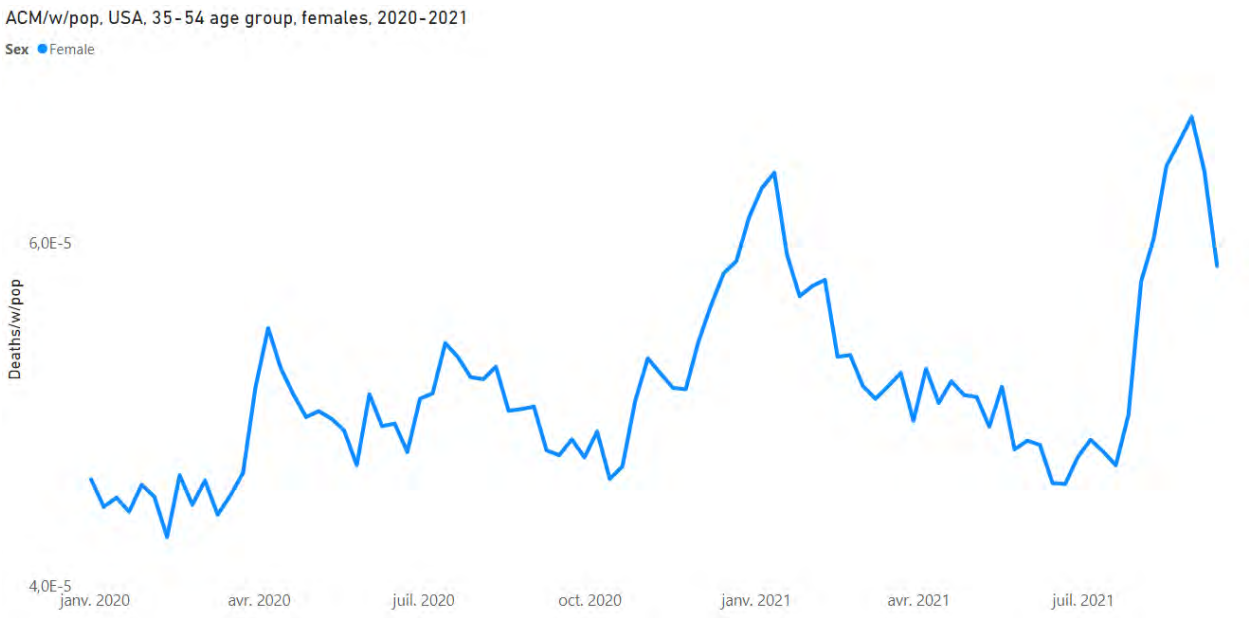


Figure 33e. All-cause mortality by week normalized by population for the USA for females of the 35-54 years age group, from 2020 to 2021. Data are displayed from week-1 of 2020 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The population used for normalization is the population of the specific age group and sex. ACM data were retrieved from the CDC (CDC, 2021b) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021b), as described in Table 1.

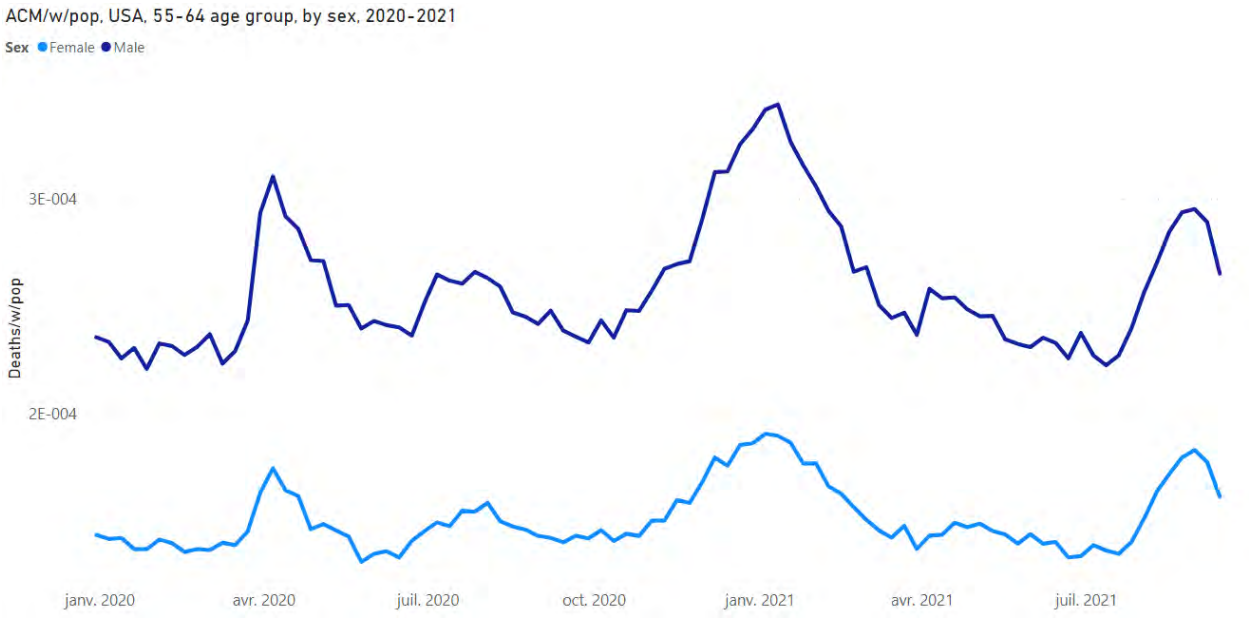


Figure 33f. All-cause mortality by week normalized by population for the USA for the 55-64 years age group, for each of both sexes, from 2020 to 2021. Data are displayed from week-1 of 2020 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii.

The population used for normalization is the population of the specific age group and sex. ACM data were retrieved from the CDC (CDC, 2021b) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021b), as described in Table 1.

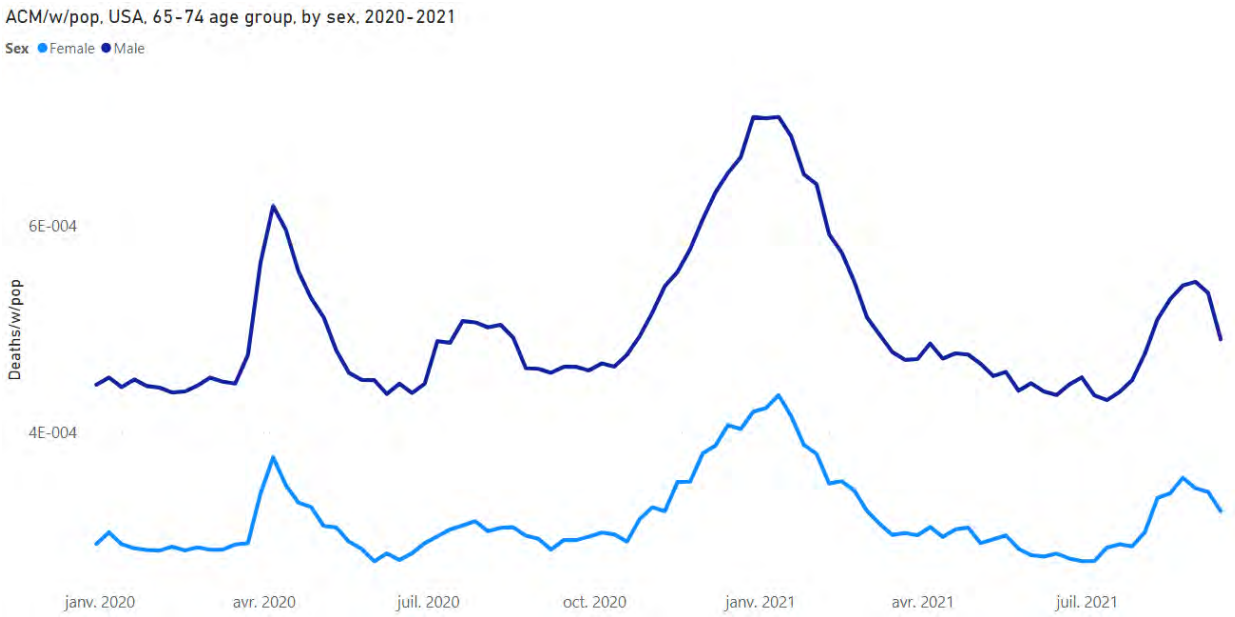


Figure 33g. All-cause mortality by week normalized by population for the USA for the 65-74 years age group, for each of both sexes, from 2020 to 2021. Data are displayed from week-1 of 2020 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The population used for normalization is the population of the specific age group and sex. ACM data were retrieved from the CDC (CDC, 2021b) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021b), as described in Table 1.

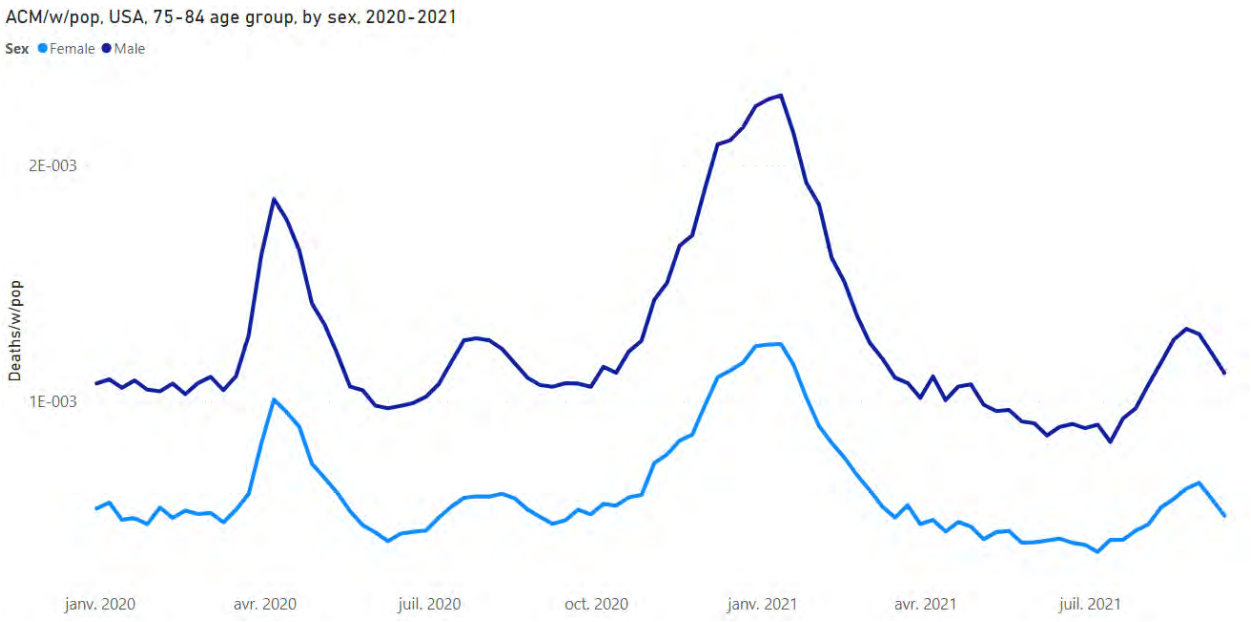


Figure 33h. All-cause mortality by week normalized by population for the USA for the 75-84 years age group, for each of both sexes, from 2020 to 2021. Data are displayed from week-1 of 2020 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The population used for normalization is the population of the specific age group and sex. ACM data were retrieved from the CDC (CDC, 2021b) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021b), as described in Table 1.

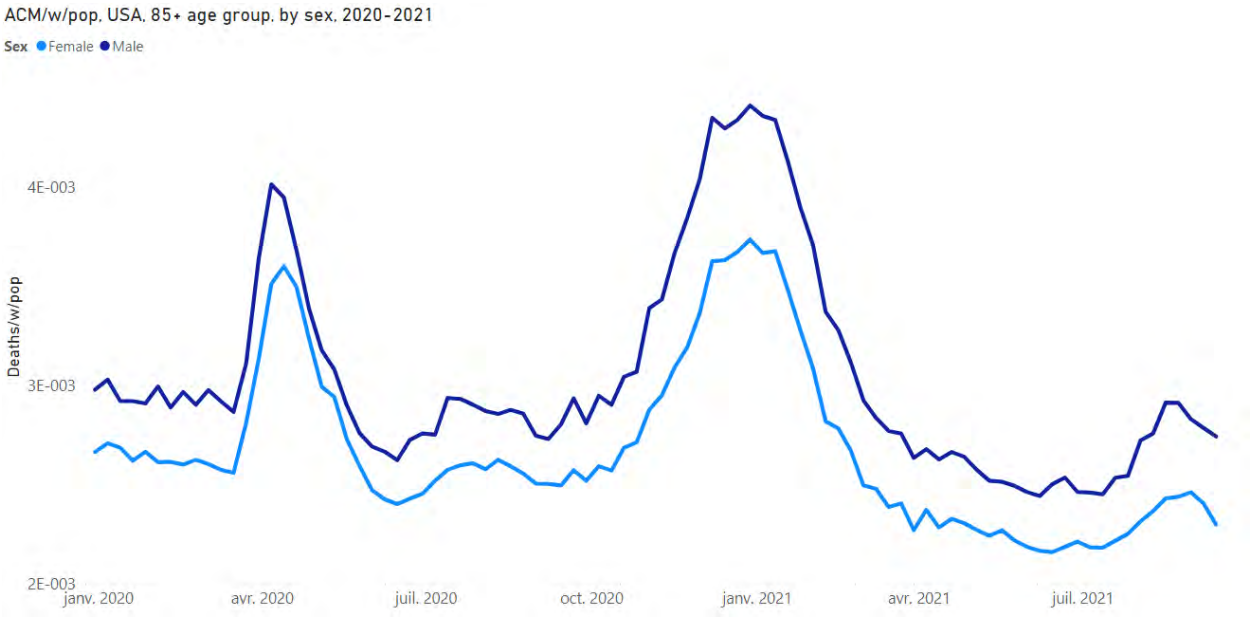


Figure 33i. All-cause mortality by week normalized by population for the USA for the age group 85 years and older ("85+ years"), for each of both sexes, from 2020 to 2021. Data are displayed from week-1 of 2020 to week-37 of 2021 for the whole continental USA, including

Alaska and Hawaii. The population used for normalization is the population of the specific age group and sex. ACM data were retrieved from the CDC (CDC, 2021b) and population data were retrieved from the US Census Bureau (US Census Bureau, 2021b), as described in Table 1.

Figure 33 shows the following:

- (Figure 33a) In the -14 years age group there is no evidence for any summer/winter seasonality, or any COVID-era anomalies. The ACM/w/pop is essentially flat over the time period. Young (-14 years) residents of the USA are essentially not killed by viral respiratory diseases or COVID-19 or any cause of death having a strong seasonal variation in its effect.
- (Figures 33b and 33c) Figure 33b shows that the onset of the COVID-era (March 2020) is associated with an increase in deaths of 15-34 year olds to a new plateau in ACM/w (approximately 400 more deaths per week), which does not return to normal over the period studied. The rise to a COVID-era plateau of increased mortality occurs for both males and females (Figure 33c).
- (Figures 33d and 33e) The 35-54 years age group, like the 15-34 years age group, also experiences a high essentially uniform baseline plateau of mortality, which does not return to normal values over the period studied, but the ACM/w for this age group (35-54 years) also shows distinct cvp1, smp1, cvp2 and smp2 features superposed on the said plateau. This age group (35-54 years) has a disproportionately large smp2 feature (summer-2021 mortality), compared to the other features, and using the smp1 and cvp2 features as references, which holds for both males and females (Figure 33e).
- (Figures 33f, 33g, 33h and 33i) The age groups 55-64, 65-74, 75-84 and 85+ years do not exhibit the COVID-era increased baseline plateau mortalities seen in the 15-34 and 35-54 years age groups. Summer mortality for both 2020 (smp1) and 2021 (smp2) monotonically decrease in relative magnitude, compared to the cvp1 and cvp2 features, as age increases in the sequence 55-64, 65-74, 75-84 and 85+ years.

The results regarding dependence of mortality on state-to-state age structure of the population (Figures 27 and 28) show that the summer-2020 excess (above-SB) deaths

were not predominantly due to viral respiratory diseases, and impacted younger people. Likewise, we deduce that the excess (above-SB) deaths in fall-winter-2020-2021 must predominantly be due to causes other than viral respiratory diseases, and impacted younger people. The inferred impacts on younger residents are corroborated by the age-group-specific mortalities at the national level (Figures 32 and 33).

Comparing all-cause excess mortality and COVID-assigned mortality

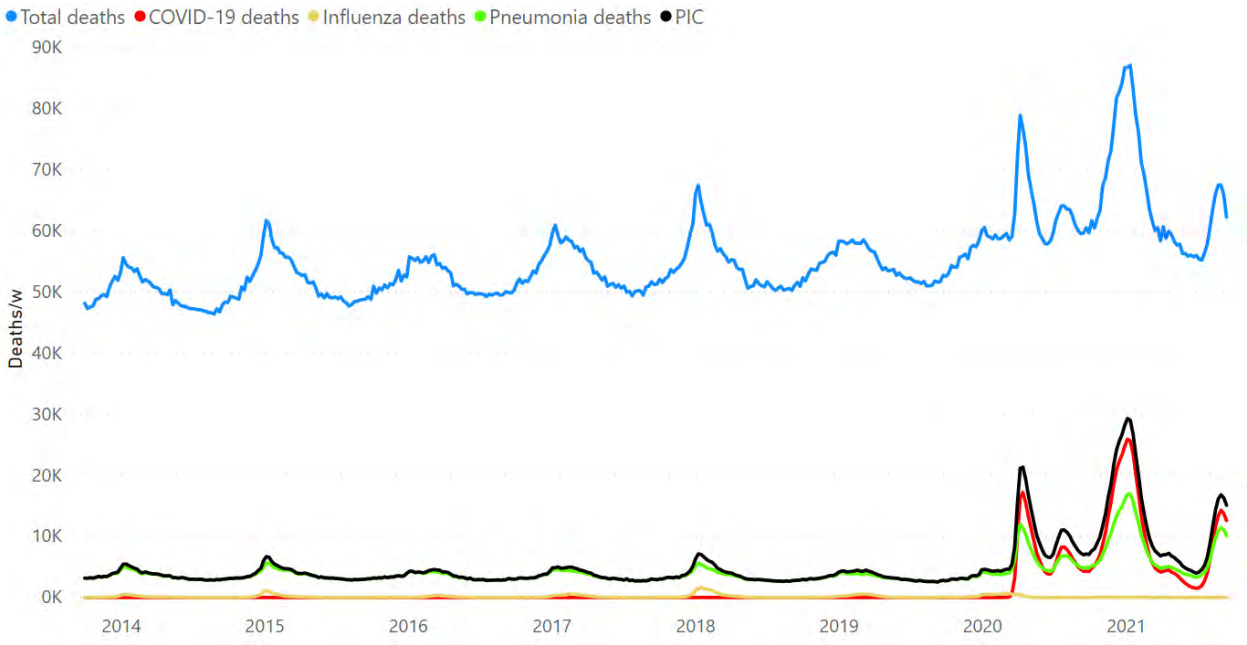
COVID-19-assigned deaths cannot be trusted to be deaths actually caused by COVID-19 (Borger et al., 2021). Furthermore, it is likely that the COVID-19 assignation of cause of death captures far too many deaths (Elsoukkary et al., 2021). Nonetheless, we can compare the total number of COVID-19-assigned deaths in the USA to excess (above-SB) all-cause mortality.

For the two cycle-years 2020 and 2021 (July 2019 to July 2021), the total WB is 1.071 M deaths, compared to total CDC-reported COVID-assigned deaths up to July 2021 (up to the last week of the 2021 cycle-year, week-30 of 2021, which is the week of 26 July 2021) equal to 613 K deaths (CDC, 2021a, as described in the Table 1). Both numbers include Alaska and Hawaii. This leaves some 458 K above-SB deaths, up to July 2021, which are not accounted for by COVID-19 according to the relevant CDC statistics.

The difference of 458 K deaths, if the COVID-19-assignations could be trusted (they cannot), would be consistent with a large number of deaths (458 K) of younger residents whose deaths are not assigned to COVID-19 (Kostoff et al., 2021; their Figure 1). In addition to our results, above, Jacobson and Jokela (2021) also found that large numbers of individuals, too young to have died from COVID-19, died in the COVID-era.

To examine this difference (458 K deaths) more closely, we compare the all-cause mortality by week to assigned-cause deaths by week for pneumonia (P), influenza (I)

and COVID-19 (C), reported by the CDC (2021a), in Figure 34; for 2014-2021 (Figure 34a) and on the expanded scale 2019-2021 (Figure 34b). PIC by week is also shown, which is the deaths assigned by the CDC as “pneumonia, influenza, and/or COVID-19”, which means that the death certificate includes pneumonia and/or influenza and/or COVID-19 listed as cause(s) of death.



Figures 34a. All-cause (blue), COVID-19 (red), influenza (yellow), pneumonia (green) and PIC (black) mortality by week for the USA from 2014 to 2021. Data are displayed from week-40 of 2013 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. PIC is the deaths assigned to pneumonia and/or influenza and/or COVID-19. ACM and cause-assigned deaths data were retrieved from CDC (CDC, 2021a) as described in Table 1.

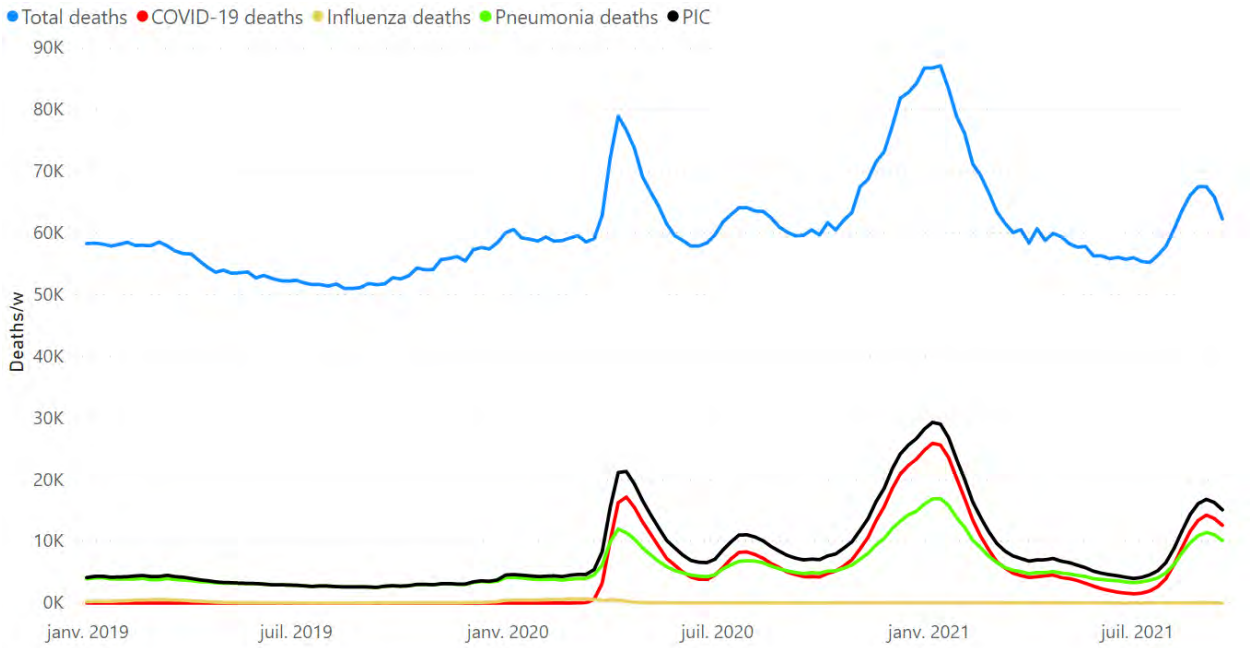


Figure 34b. All-cause (blue), COVID-19 (red), influenza (yellow), pneumonia (green) and PIC (black) mortality by week for the USA from 2019 to 2021. Data are displayed from week-1 of 2019 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. PIC is the deaths assigned to pneumonia and/or influenza and/or COVID-19. ACM and cause-assigned deaths data were retrieved from CDC (CDC, 2021a) as described in Table 1.

We interpret the similarity in patterns of temporal variation between CDC-reported weekly COVID-19-assigned or PIC deaths and the all-cause mortality (ACM/w) as arising because many or most of the COVID-19-assigned deaths are drawn from our above-SB deaths; that is, are drawn from deaths induced by the government measures, *via* the combined poverty, obesity and climatic factors, made potent by sustained chronic psychological stress, and from the deaths resulting from the direct assault against the elderly in March-June 2020 (cvp1) (Rancourt, 2020).

Let us examine these relations further. Figure 34c shows the P, I, C and PIC by week CDC data with our ACM-SB/w, 2014-2021, while Figure 34d shows the same data for the period 2019-2021.

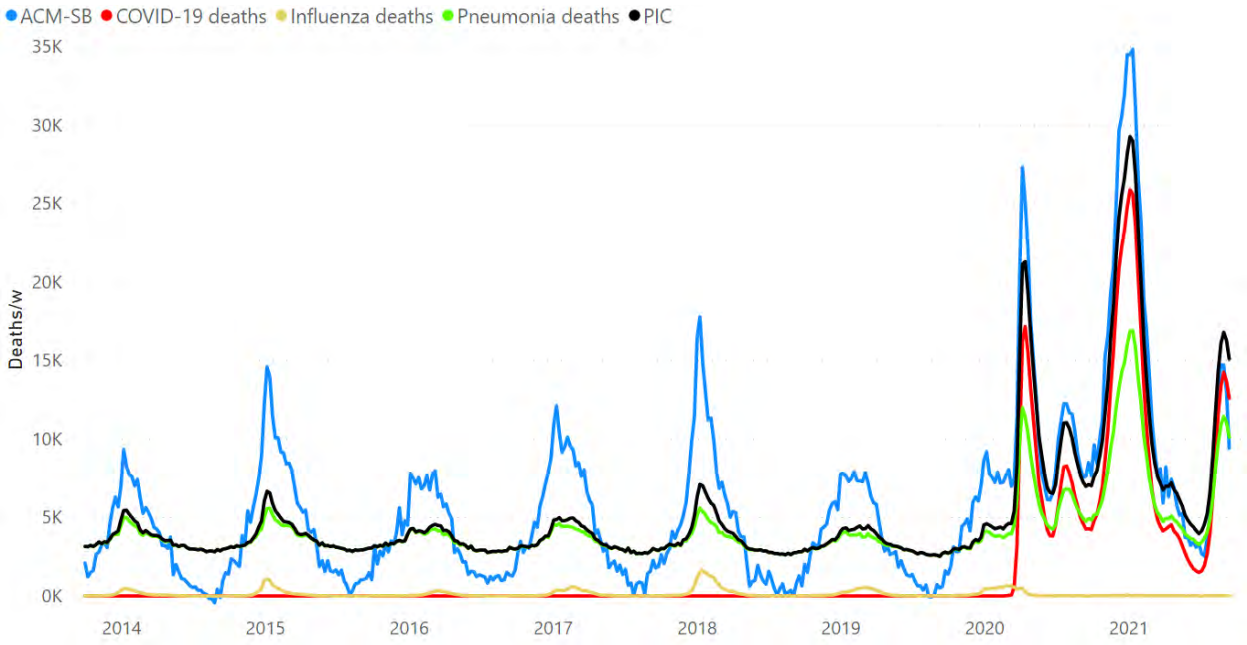


Figure 34c. All-cause above-SB (ACM-SB) (blue), COVID-19 (red), influenza (yellow), pneumonia (green) and PIC (black) mortality by week for the USA from 2014 to 2021. Data are displayed from week-40 of 2013 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. PIC is the deaths assigned to pneumonia and/or influenza and/or COVID-19. ACM and cause-assigned deaths data were retrieved from CDC (CDC, 2021a) as described in Table 1. SB was estimated as described in section 2.

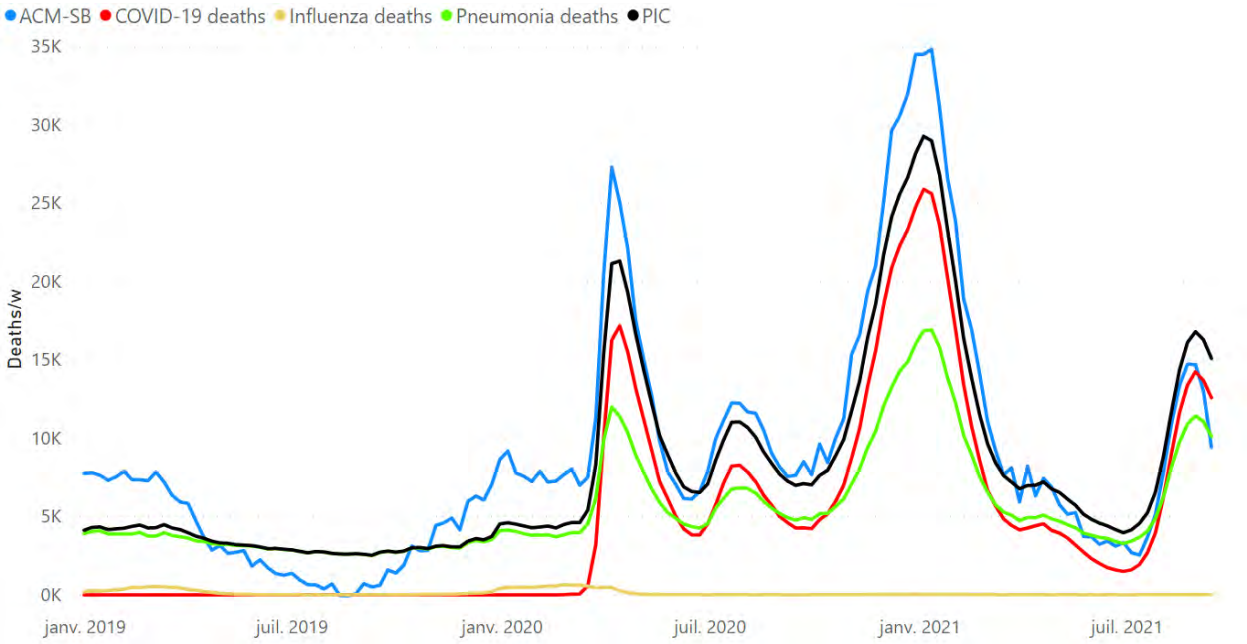


Figure 34d. All-cause above-SB (ACM-SB) (blue), COVID-19 (red), influenza (yellow), pneumonia (green) and PIC (black) mortality by week for the USA from 2019 to 2021. Data

are displayed from week-1 of 2019 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. PIC is the deaths assigned to pneumonia and/or influenza and/or COVID-19. ACM and cause-assigned deaths data were retrieved from CDC (CDC, 2021a) as described in Table 1. SB was estimated as described in section 2.

We note (Figures 34c and 34d) that pneumonia contributes significantly to summer deaths and that its summer-trough values are on a linear trend that is essentially horizontal for the years shown (approximately 2,680 pneumonia deaths per week, baseline). The same is true for PIC. Next, we therefore remove the "pneumonia-SB" ("pSB") from the pneumonia data, and from the PIC data, in order to visualize solely deaths above summer-normal mortality.

The result is shown in Figure 34e (2014-2021) and Figure 34f (2019-2021).

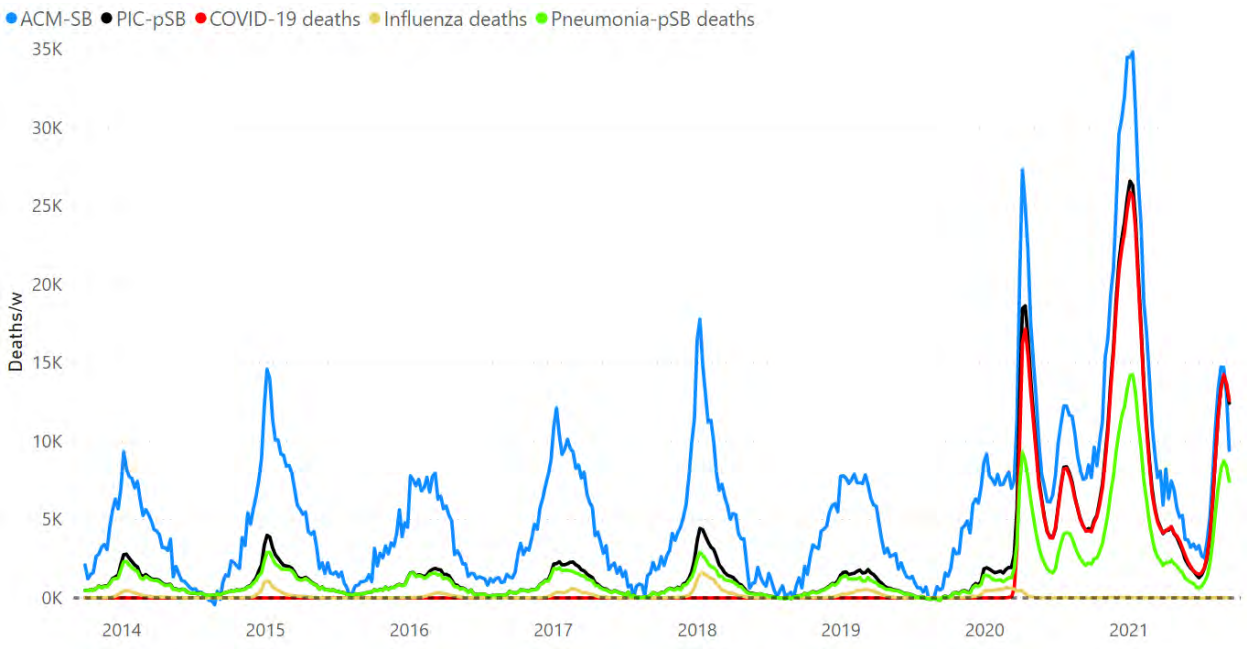


Figure 34e. All-cause above-SB (ACM-SB) (blue), COVID-19 (red), influenza (yellow), pneumonia-pSB (green) and PIC-pSB (black) mortality by week for the USA from 2014 to 2021. Data are displayed from week-40 of 2013 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The dashed line emphasizes the zero. pSB, the summer-trough pneumonia mortality, is removed from each week of pneumonia, and of PIC deaths. PIC is the deaths assigned to pneumonia and/or influenza and/or COVID-19. ACM and cause-assigned deaths data were retrieved from CDC (CDC, 2021a) as described in Table 1. SB was estimated as described in section 2.

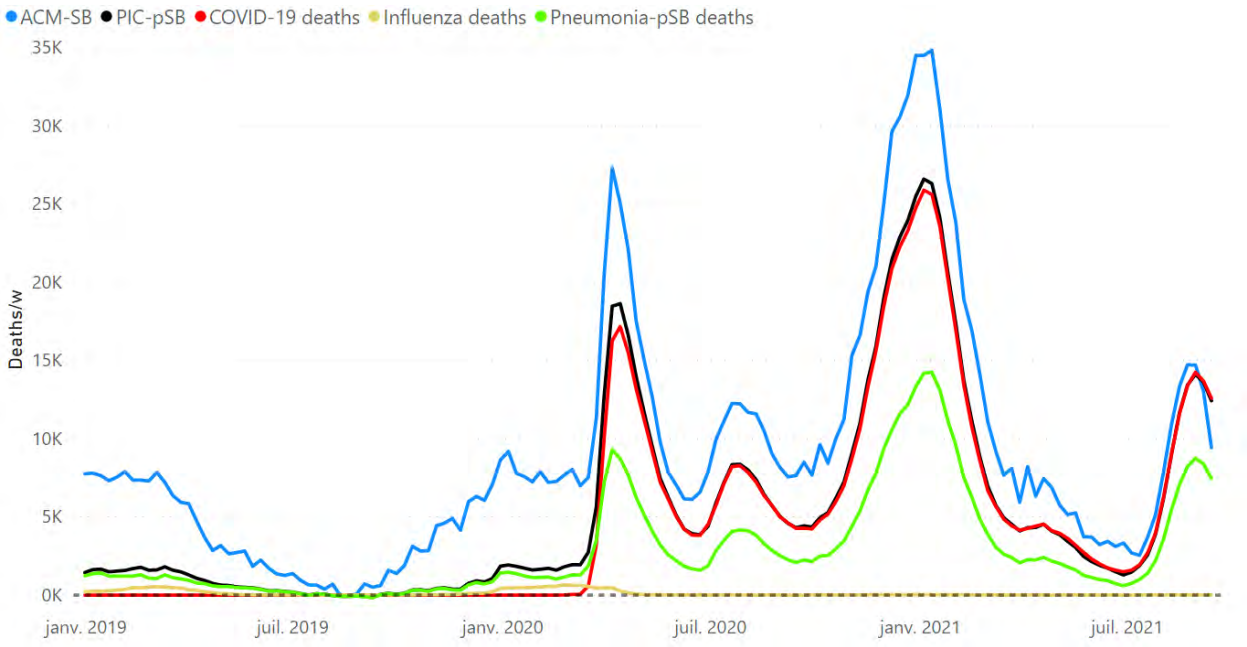


Figure 34f. All-cause above-SB (ACM-SB) (blue), COVID-19 (red), influenza (yellow), pneumonia-pSB (green) and PIC-pSB (black) mortality by week for the USA from 2019 to 2021. Data are displayed from week-1 of 2019 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The dashed line emphasizes the zero. pSB, the summer-trough pneumonia mortality, is removed from each week of pneumonia, and of PIC deaths. PIC is the deaths assigned to pneumonia and/or influenza and/or COVID-19. ACM and cause-assigned deaths data were retrieved from CDC (CDC, 2021a) as described in Table 1. SB was estimated as described in section 2.

Figures 34g and 34h show some of the same data as above but also the difference (residual) “ACM-SB” minus “PIC-pSB”, by week (black curve), for the USA. This difference (ACM-SB minus PIC-pSB) shows deaths that are not assigned to a respiratory disease (viral or any pneumonia) as a contributing cause of death.

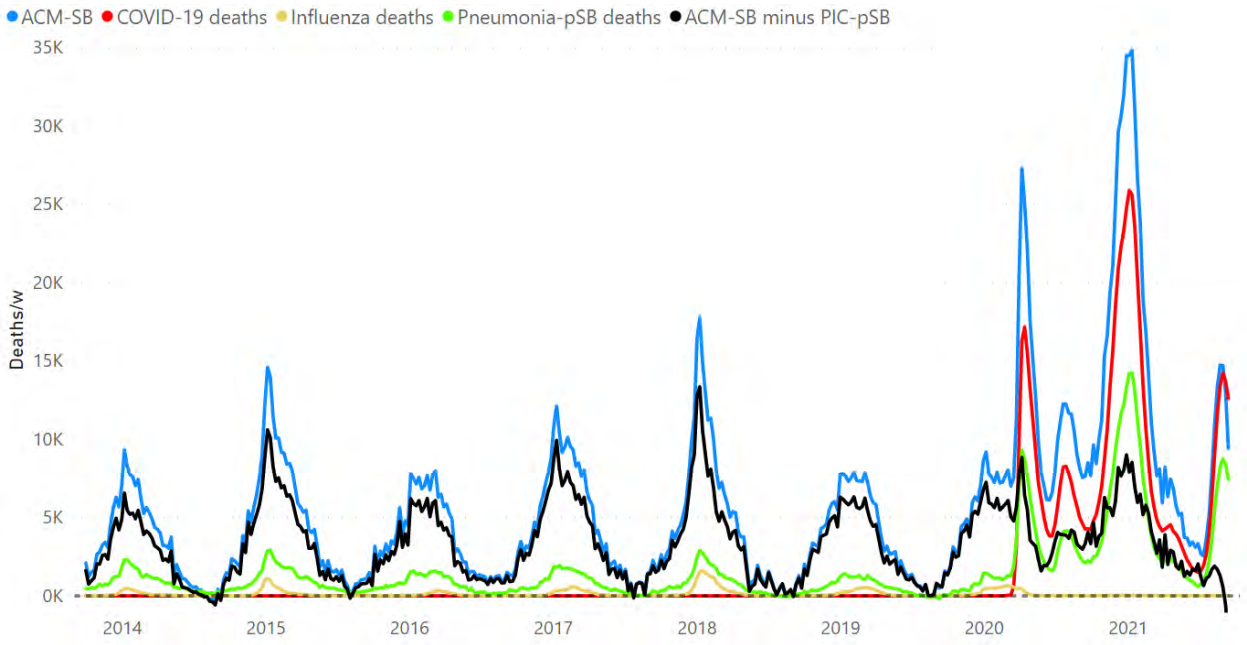


Figure 34g. All-cause above-SB (ACM-SB) (blue), COVID-19 (red), influenza (yellow), pneumonia-pSB (green) and ACM-SB minus PIC-pSB (black) mortality by week for the USA from 2014 to 2021. Data are displayed from week-40 of 2013 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The dashed line emphasizes the zero. pSB, the summer-trough pneumonia mortality, is removed from each week of pneumonia, and of PIC deaths. PIC is the deaths assigned to pneumonia and/or influenza and/or COVID-19. ACM and cause-assigned deaths data were retrieved from CDC (CDC, 2021a) as described in Table 1. SB was estimated as described in section 2.

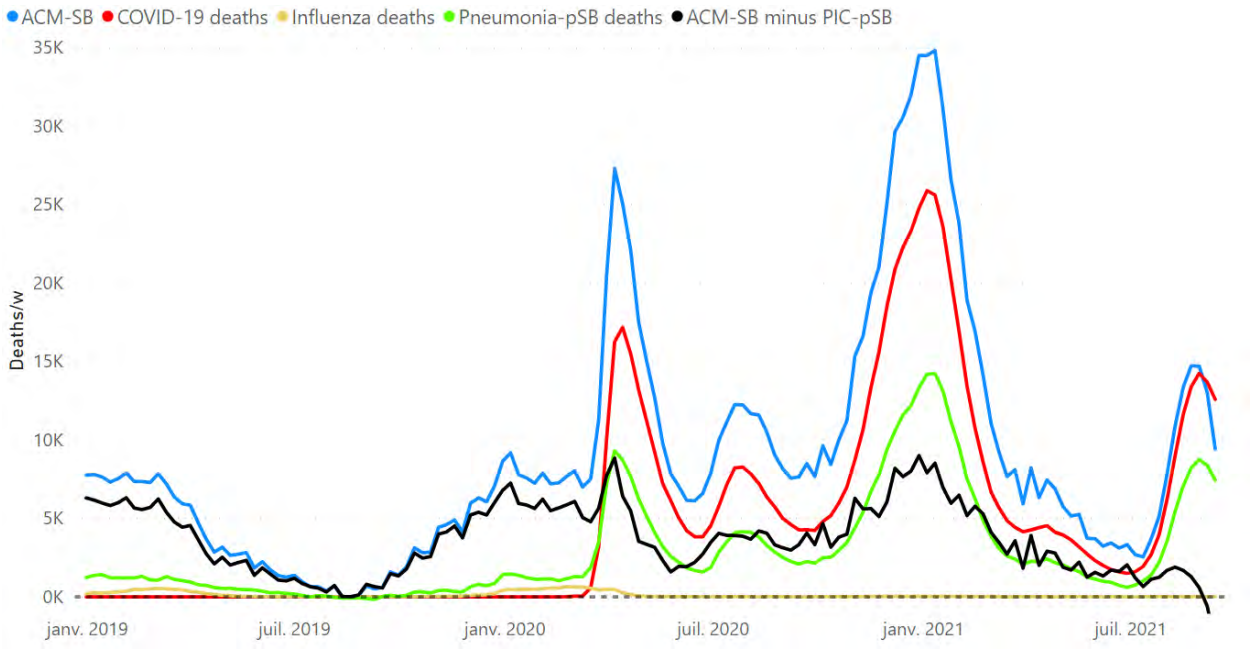


Figure 34h. All-cause above-SB (ACM-SB) (blue), COVID-19 (red), influenza (yellow), pneumonia-pSB (green) and ACM-SB minus PIC-pSB (black) mortality by week for the USA from 2019 to 2021. Data are displayed from week-1 of 2019 to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The dashed line emphasizes the zero. pSB, the summer-trough pneumonia mortality, is removed from each week of pneumonia, and of PIC deaths. PIC is the deaths assigned to pneumonia and/or influenza and/or COVID-19. ACM and cause-assigned deaths data were retrieved from CDC (CDC, 2021a) as described in Table 1. SB was estimated as described in section 2.

Figures 34a through 34h show that, in addition to COVID-19-associated deaths, there was a massive increase in pneumonia-associated deaths in the COVID-era in the USA, which had the same temporal pattern as both ACM and COVID-19-assigned deaths.

Figure 34i shows that COVID-19-assigned deaths were consistently associated with pneumonia as a contributing cause of death, some 40 to 60 % of the cases, throughout the COVID-era. Also, virtually all the above-pSB pneumonia assignations had COVID-19 co-assignations. That is, in number, all the excess pneumonia assignations in the COVID-era had COVID-19 co-assignations.

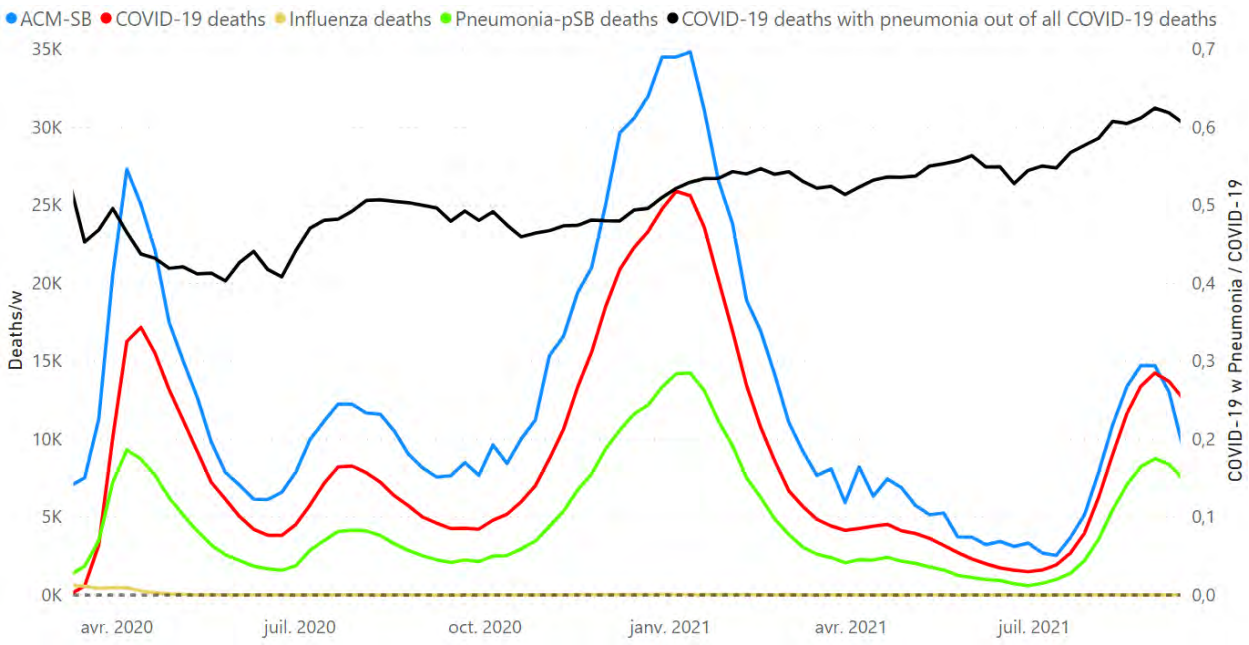


Figure 34i. All-cause above-SB (ACM-SB) (blue), COVID-19 (red), influenza (yellow) and pneumonia-pSB (green) mortality by week, and the ratio of COVID-19 deaths with pneumonia to all COVID-19 deaths (black, right Y-scale) by week, for the USA in the COVID-era (March-2020 into 2021). Data are displayed from week-11 of 2020 (week of March 11 2020, date of the WHO pronouncement of the pandemic) to week-37 of 2021 for the whole continental USA, including Alaska and Hawaii. The dashed line emphasizes the zero. pSB, the summer-trough pneumonia mortality, is removed from each week of pneumonia deaths. ACM and cause-assigned deaths data were retrieved from CDC (CDC, 2021a) as described in Table 1. SB was estimated as described in section 2.

The difference (ACM-SB minus PIC-pSB) shown in Figures 34g and 34h shows that excess (above-SB) deaths not assigned to a respiratory disease (viral or any pneumonia) as a contributing cause of death are approximately the same in number during the COVID-era as in previous years. Known causes of death for excess (above-SB, winter burden) deaths include heart disease, Alzheimer disease/dementia, and diabetes (Woolf et al., 2021). However, the difference (ACM-SB minus PIC-pSB) does show anomalies in the COVID-era: a sharp peak in March-May 2020, and a consistently large value in the summer-2020 period. A striking feature is that, unlike summer-2020, the rise in ACM-SB in summer-2021 is entirely assigned as PIC, virtually without any non-respiratory assignation.

The result that there were essentially no excess deaths (in number) assigned to non-respiratory causes in the COVID-era in the USA (Figure 34g) is surprising in that, for England and Wales, Kontopantelis et al. (2021) found, looking at excess deaths above historical trends, that in the first 30 weeks of the declared pandemic there were 62,321 excess deaths: 46,221 (74 %) attributable to respiratory causes, and 16,100 (26 %) to other causes.

Some authors have argued that COVID-19 deaths may be vastly underestimated by failing to correctly assign respiratory deaths to COVID-19 (Stokes et al., 2021) (IHME, 2021). We find this highly implausible for the USA. Acknowledging similar numbers of non-respiratory excess (above-SB) deaths in the COVID-era as in the pre-COVID-era (Figure 34g), leads one to conclude that virtually all other excess (above-SB) deaths (in number) in the COVID-era have been assigned as COVID-19, consistently including pneumonia as a jointly assigned cause of death in approximately 40-60 % of the thus COVID-19-assigned cases (Figure 34i). There is no room for more COVID-19 deaths in the USA accounting of mortality. Indeed, how could COVID-19-assignations be undercounted in the middle of the most mediatized, tested and medical-protocol regulated declared pandemic in memory, in a country that has some of the best medical statistics gathering in the world?

Respiratory causes appear to have been the main agent of death, regarding excess (above-SB) deaths in the USA in the COVID-era; however COVID-19 assignment remains suspect (Borger et al., 2021).

Shockingly, there was a massive epidemic or co-epidemic of pneumonia in the USA in the COVID-era, according to CDC data (CDC, 2021a) (Figure 34), which is never mentioned in the media and essentially not on the radar in the medical research literature. To the extent that there is COVID-19 over-assignation, it may represent up to 100 % of the COVID-era excess deaths from respiratory causes. It would not be the first time that the actual cause of a large epidemic is bacterial infection rather than the

presumed viral pathogen (Morens et al., 2008) (Chien et al., 2009) (Sheng et al., 2011). In the words of Ginsburg and Klugman (2020):

> Data regarding bacterial superinfections in COVID-19 pneumonia are still emerging, but an association has been made between the detection of bacterial products in blood with disease severity in COVID-19 patients.[ref] Diagnosing coinfections is complex in the best of circumstances and because there is a desire to avoid diagnostic procedures and minimise the exposure of COVID-19 to health-care workers, diagnosing potential bacterial superinfections during COVID-19 has been challenging.
> […] Although many serum biomarkers lack specificity, increased procalcitonin concentrations have been investigated as a specific bacterial differentiation from viral response to bacterial respiratory tract infection.[refs] From accumulating data and reports, there appears to be a clear association between elevated concentrations of procalcitonin and increasing COVID-19 disease severity, despite a variety of cutoffs chosen.[refs]
> Most bacterial pneumonias caught early enough can be safely and effectively treated with antibiotics […]

Vaccination

It is important to examine whether the large COVID vaccination campaign has had any influence on mortality and on the phenomena that we describe in this article. Figure 31 shows all-cause mortality by week (ACM/w), the number of total (all manufacturers) administered vaccines (doses/day) and the number of fully vaccinated individuals (vaccinated/day), on the same time axis, in the COVID-era (CDC, 2021a; CDC, 2021f).

An individual is considered fully vaccinated when second dose of a two-dose vaccine or one dose of a single-dose vaccine is completed (CDC, 2021f).

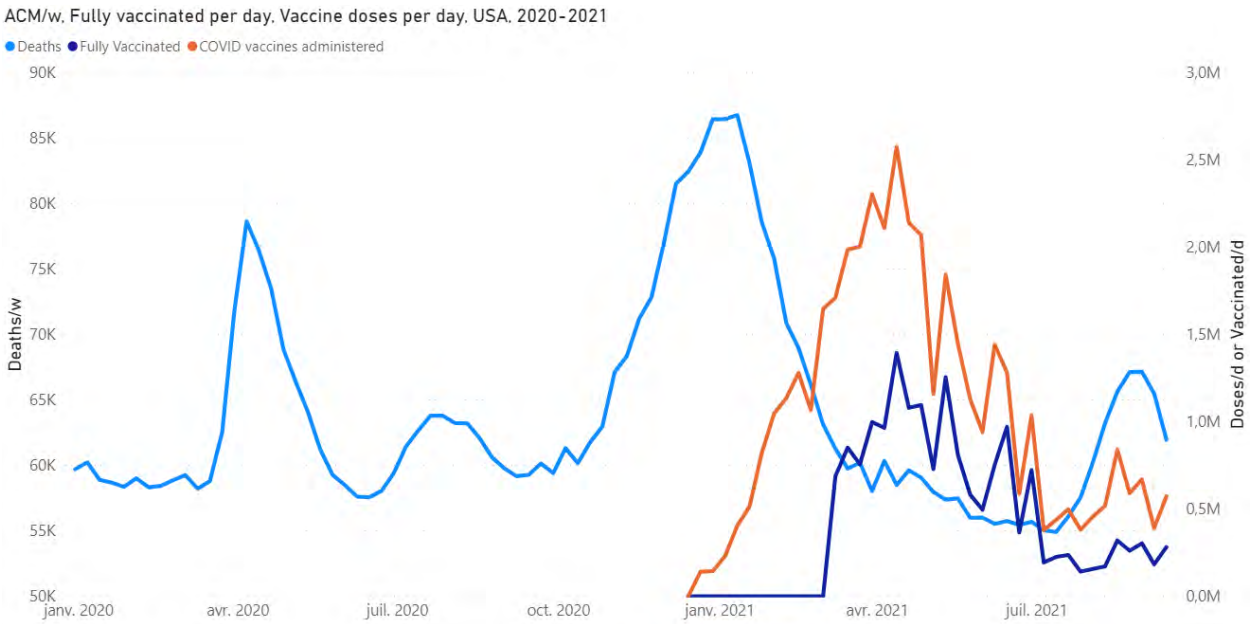


Figure 31. All-cause mortality by week (light blue), fully vaccinated individuals by day (dark blue) and COVID vaccine doses administered by day (orange), in the USA, from 2020 to 2021. Data are displayed from week-1 of 2020 to week-37 of 2021. For data by day, only one day a week is represented on the graph (Monday). An individual is considered fully vaccinated when second dose of a two-dose vaccine or one dose of a single-dose vaccine is completed. USA means 49 continental states, including the District of Columbia and excluding Alaska and Hawaii. Data were retrieved from CDC (CDC 2021a, CDC 2021f), as described in Table 1.

The total number of doses in the period illustrated is approximately 380 M and the total number of people being fully vaccinated is approximately 178 M. Therefore, the large hump in vaccinations per day constitutes the majority of the planned vaccination campaign (Figure 31).

Here (Figure 31), we note that our interpretations concerning cvp1 and smp1 mortality cannot be impacted whatsoever by vaccination because the vaccination injections and the fully vaccinated status started later, beyond the week of the inflection point on the rise of the cvp2 feature and towards the end of the cvp2 feature, respectively.

Readers who would be tempted to ascribe the downturn in the cvp2 peak to the vaccination campaign should note that the downturn coincides with the expected

seasonal downturn of every seasonal winter maximum that has ever been observed by epidemiologists in the last century or more.

More importantly, the largely completed vaccination campaign did not prevent a second surge of summer deaths (2021, “smp2”) (Figure 31). The mortality in the said second surge appears to be comparable to or more than the mortality for summer-2020. Furthermore, the COVID-19-assigned deaths (CDC, 2021a) are significantly greater in number in summer-2021 than in summer-2020 (Figure 34), and, unlike at any other time in the COVID-era, account for virtually all the excess (above-SB) deaths, in the summer-2021 feature (smp2) (Figure 34), following the vaccination campaign.

There is no sign in the ACM/w that the vaccination campaign has had any positive effect. However, given that the vaccination campaign starts well after the 2020 summer and essentially ends mid-summer-2021 prior to the start of the smp2 feature, given that the 2021 excess (above-SB) summer deaths (smp2) occur in significantly younger individuals than the excess summer-2020 deaths, and given that the smp2 feature is significantly larger than the smp1 feature for the said younger individuals (35-54 years, Figures 33d and 33e; and 55-64 years, Figure 33f, to a lesser degree), it is possible that vaccination made 35-54 year olds and others more vulnerable to death, especially summer death in disadvantaged individuals in hot-climate states (Montgomery et al., 2021) (Simone et al., 2021).

4. Comparison with Canada, and implications

One of the most striking aspects about mortality in the USA is that total yearly mortality in Canada is completely normal in the COVID-era: it lies precisely on the decadal trend established since 2010. We elaborated this fact about Canada in our recent article (Rancourt et al., 2021). At the time of publication, there was only enough weekly data to complete cycle-year 2020 for Canada. More data is now available, such that we can

now obtain cycle-year 2021, by implementing a short (10-week) reliable extrapolation to complete the needed summer-2021 trough section.

The latest Canadian data is shown in Figure 35.

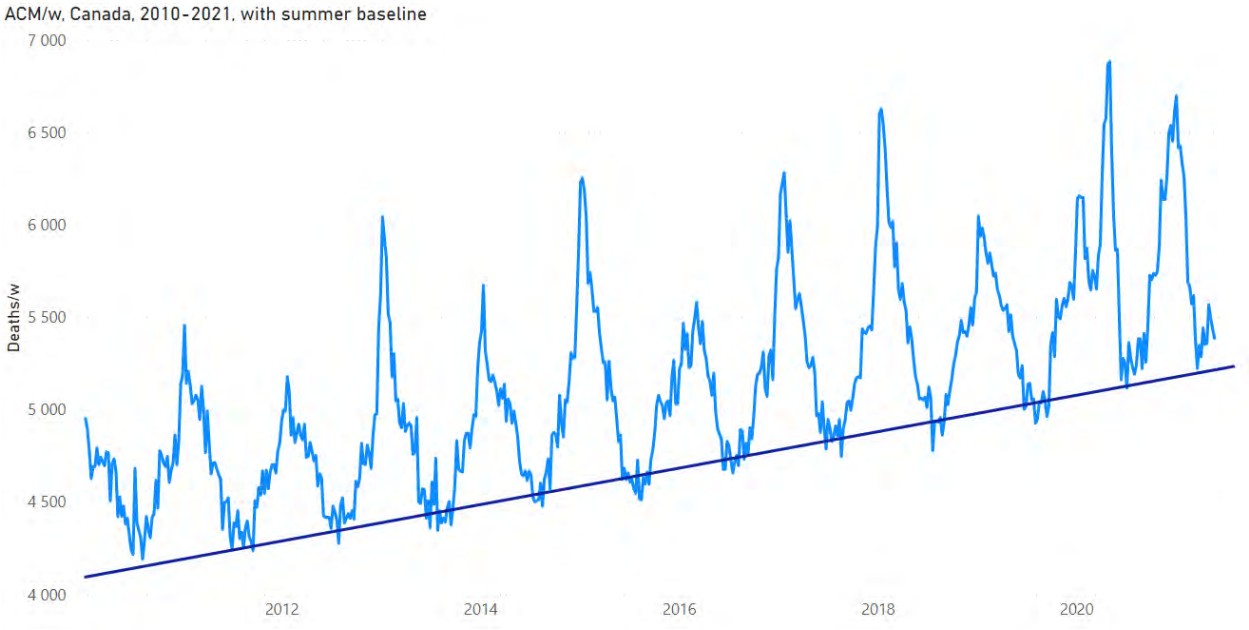


Figure 35. All-cause mortality by week in Canada from 2010 to 2021. The linear summer baseline (SB) is a least-squares fit to the summer troughs for summer-2013 through summer-2019, using the following summer trough weeks: 2013-weeks [24-37], 2014-weeks [28-33], 2015-weeks [27-37], 2016-weeks [24-34], 2017-weeks [25-34], 2018-weeks [28-35], 2019-weeks [26-38]. Data are displayed from week-1 of 2010 (week ending on January 9, 2010) to week-20 of 2021 (week ending on May 22, 2021) for the ACM and to week-30 of 2021 (week ending on July 31, 2021) for the SB. That way, the SB extends to the end of the 2021 cycle-year (week-30 of 2021), thereby showing the segment needing extrapolation discussed in the text. Data were retrieved from StatCan (StatCan, 2021), as described in Table 1.

The said extrapolation is performed as follows. We work with ACM-SB/w, average the values for 2021 weeks 10 through 20, which is a relatively flat region in ACM-SB/w, in the summer 2021 “trough” (week 20 is the last usable week in the data), and this average value is adopted for weeks 21 through 30 in ACM-SB/w (week 30 is the last week of the 2021 cycle-year). We then take this ACM-SB/w (including the thus extrapolated 10-week segment) and transform back to an ACM/w by adding the SB. The total mortalities per cycle-year are then calculated from sums on this ACM/w data,

which now is extended to complete the last (2021) cycle-year. The extrapolation is an accurate representation of the last 10 weeks in the 2021 cycle-year, unless something unexpected and significant occurs in those 10 weeks in mid-summer-2021, beyond the already higher summer-trough values occurring in the COVID-era for Canada (Figure 35).

The resulting ACM per cycle-year versus cycle-year for Canada is shown in Figure 36, with a best-line fit to illustrate the trend.

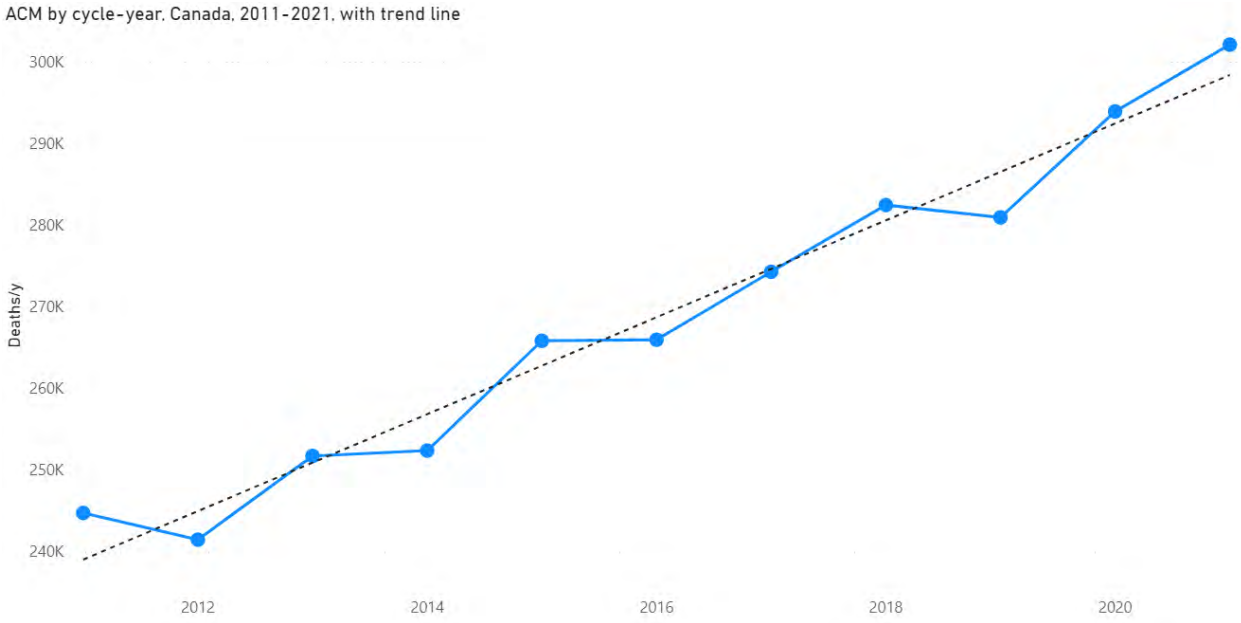


Figure 36a. All-cause mortality by cycle-year for Canada, cycle-years 2011 to 2021. The dashed line is a least-squares fitted straight line. The cycle-year starts on week-31 of a calendar-year (beginning of August) and ends on week-30 of the next calendar-year (end of July). The ACM over the weeks 21 to 30 of 2021 was extrapolated, as described in the text, in order to complete the 2021 cycle-year. Raw data were retrieved from StatCan (StatCan, 2021), as described in Table 1.

Figure 36a is the same as Figure 2 in our prior article (Rancourt et al., 2021), except for the addition of one more cycle-year (2021). This further confirms that “there was no pandemic in Canada” (Rancourt et al., 2021).

We also calculated the WB of deaths for cycle-years 2011 through 2021, which is shown in Figure 36b. A slight increase by year is expected because the population of those most vulnerable to winter-time deaths is increasing. Again, as with ACM itself, nothing in the values of WB deaths indicates any pandemic or any unusual additional cause of yearly mortality in cycle-years 2020 or 2021.

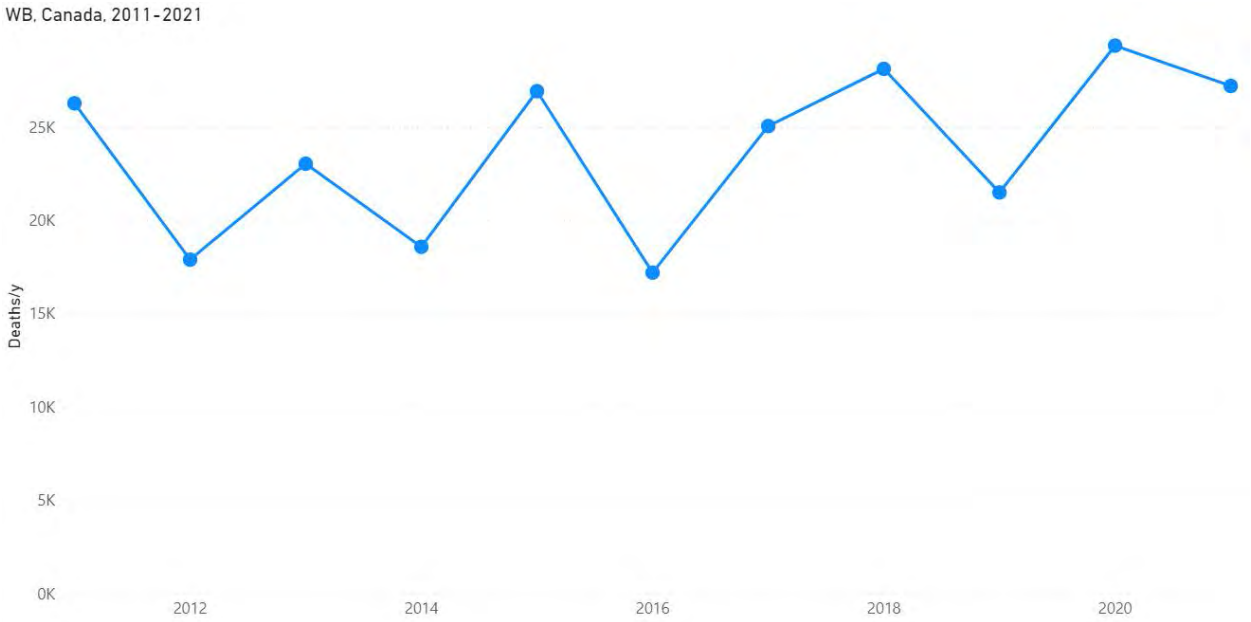


Figure 36b. Winter burden (WB) for Canada for cycle-years 2011 to 2021. The cycle-year starts on week-31 of a calendar-year (beginning of August) and ends on week-30 of the next calendar-year (end of July). The ACM-SB over the weeks 21 to 30 of 2021 was extrapolated, as described in the text, in order to complete the WB of the cycle-year 2021. Raw data were retrieved from StatCan (StatCan, 2021), as described in Table 1.

The ACM/w can also be used to calculate ACM by calendar-year, which is shown, compared to ACM by cycle-year, in Figure 37 for Canada.

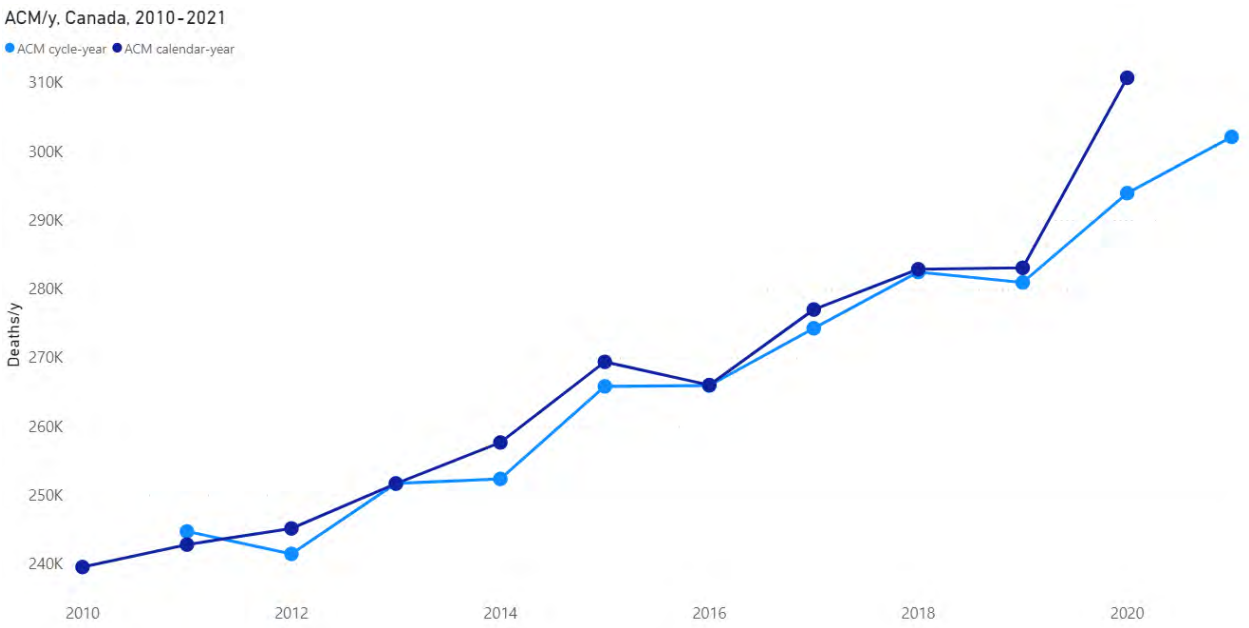


Figure 37. All-cause mortality by calendar-year (dark blue), calendar-years 2010 to 2020, shown with all-cause mortality by cycle-year (light blue), cycle-years 2011 to 2021, for Canada. Cycle-year N means the period from mid-summer of calendar-year N-1 to mid-summer of calendar-year N. The ACM over the weeks 21 to 30 of 2021 was extrapolated, as described in the text, in order to complete the 2021 cycle-year. Raw data were retrieved from StatCan (StatCan, 2021), as described in Table 1.

In Figure 37 the ACM by calendar-year for 2020 is higher than the visible trend because of an accident in the positions of ACM/w peaks: there is a large late peak in cycle-year 2020 (the March-June 2020 so-called “covid” peak, or “cvp1”) and a large early rise in the winter peak of cycle-year 2021. In this figure, recall that cycle-year N means the period from mid-summer of calendar-year N-1 to mid-summer of calendar-year N.

Clearly, there is no sign of a pandemic in Canada, or of a COVID-era anomaly, in terms purely of ACM by cycle-year and WB (Figure 36), which is at odds with the dramatic increase seen for the neighbouring USA: Figure 1, by calendar-year up to 2020; Figure 5, in the ACM/w data itself; Figure 12a, expressed as WB versus cycle-year.

If a new pathogen caused the havoc that we have described for the USA during the COVID-era, then how could such a virulent and contagious pathogen not have crossed the world's longest international land border (8,890 km) between two major trading

partners? Did Canada apply effective mitigation strategies, completely different from those applied in the major states of the USA, which reduced the mortality impact of the new pathogen to zero on the Canadian territory? The answers must be “that would be impossible” and “no”, respectively.

Viral respiratory diseases, in particular, are believed to be very contagious, and more so for presumed pandemic-causing new viruses for which there is no prior immunity in the world populations. Either the presumed new virus was not able to cross the USA-Canada border or Canadians of heterogeneous origins are genetically resilient to the new virus or the massive excess deaths in the USA during the COVID-era are not primarily due to any new respiratory virus. We think the latter must be concluded, and this is consistent with our findings of co-correlations with socio-geo-economic and climatic factors, which project to zero excess deaths for sufficiently small values of the correlated or co-correlated factors (e.g., Figure 25, for summer-2020 deaths).

5. Mechanistic causes for COVID-era deaths

To be clear, we have not shown that USA deaths are correlated to poverty, obesity and hot climatic regions, although that in itself is probably true to a significant degree, as can be inferred from a map of life expectancy at birth by state of the USA, such as the one shown in Figure 38a.

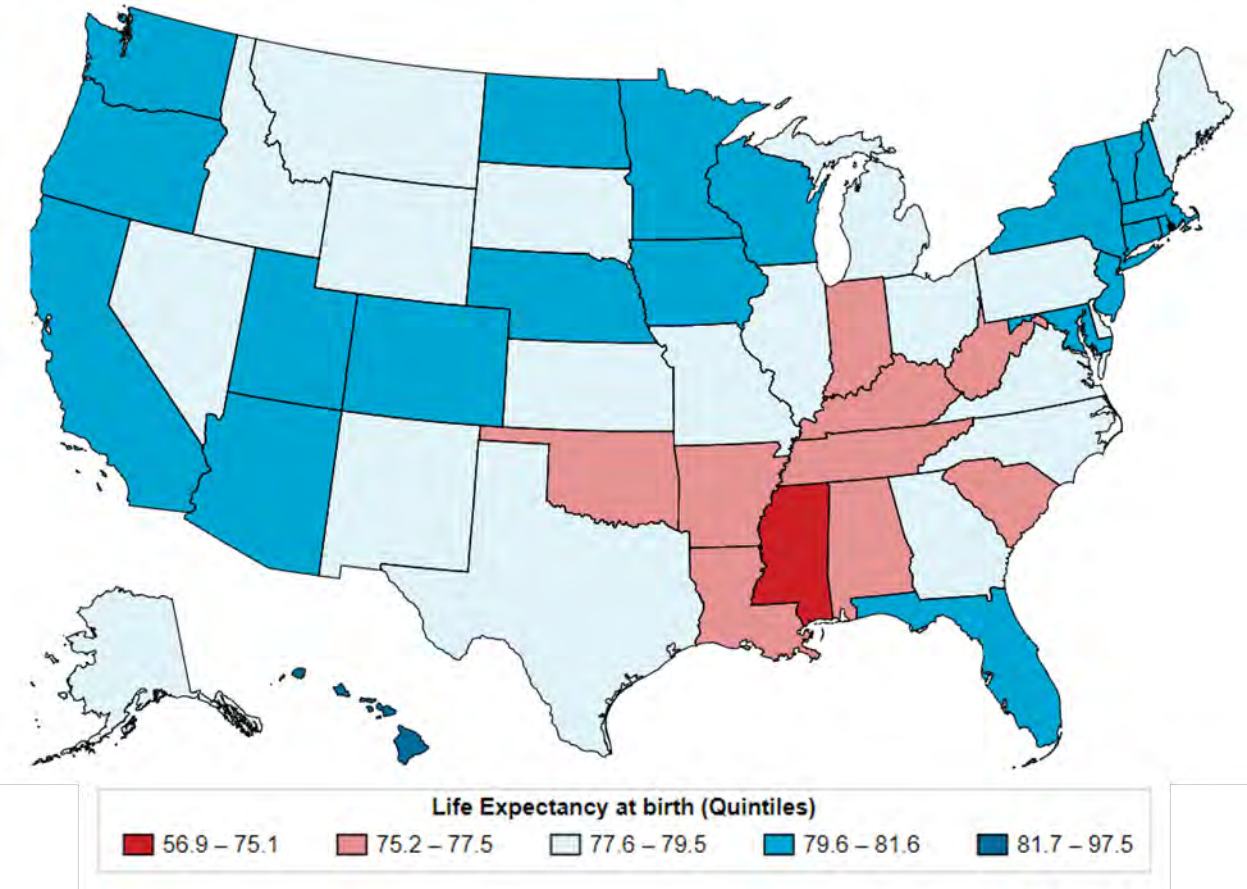


Figure 38a. Map of life expectancy at birth for USA states, from census tracts 2010-2015 (Tejada-Vera et al., 2020). Present interactive map location: https://www.cdc.gov/nchs/data-visualization/life-expectancy/index.html

This map of life expectancy at birth by state (Figure 38a) is in turn very similar to a map of antibiotic prescriptions by population by state, such as the one shown in Figure 38b.

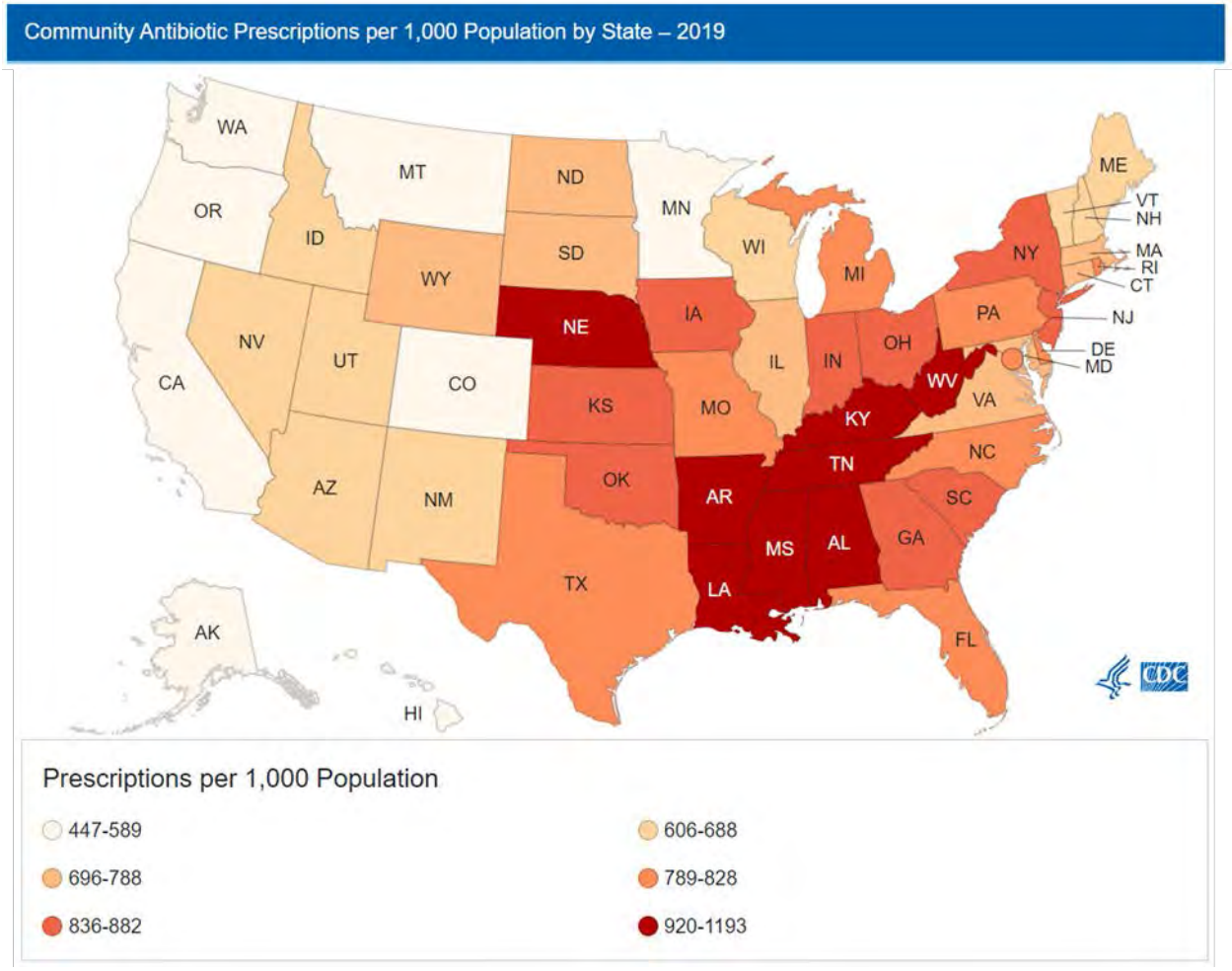


Figure 38b. Antibiotic prescriptions per 1,000 persons by state (sextiles) for all ages, United States, 2019. "Healthcare providers prescribed 251.1 million antibiotic prescriptions—equivalent to 765 antibiotic prescriptions per 1,000 persons", in 2019 (CDC, 2021g).

Given the similarity in state-wise distributions of life expectancy at birth (Figure 38a) and antibiotic prescriptions (Figure 38b), it is not unreasonable to conclude that a dominant cause of death limiting life expectancy, in the USA in the pre-COVID-era, is bacterial infection, the most common fatal such infection being bacterial pneumonia.

However, what we have shown is that, in the COVID-era, during summer-2020 (smp1), fall-winter-2020-2021 (cvp2) and summer-2021 (smp2), combined factors including poverty, obesity and hot climate became deadly associations for excess (above-SB)

deaths, beyond the deaths that would have occurred from the pre-COVID-era background of preexisting risk factors.

In addition, we have repeatedly concluded that the sharp peak in excess mortality occurring in March-June 2020 in some USA states (“covid” peak) (cvp1) must be a consequence of aggressive government and medical response to the WHO 11 March 2020 declaration of a pandemic, in those hot-spot jurisdictions, such as New York City in particular in the USA, and we have outlined likely mechanisms whereby this aggression would have caused a large surge of deaths in care homes and hospitals everywhere that it occurred (Rancourt, 2020) (Rancourt et al., 2020) (Rancourt et al., 2021).

The question now arises: By what mechanism(s) did the COVID-era government and medical disruptions induce excess deaths, at the population level, in the most vulnerable populations (elderly, and poverty + obesity + hot climate)? Alternatively (Figure 34), by what mechanism(s) did the COVID-era government and medical disruptions make respiratory diseases, including pneumonia, so much more fatal than usual, at the population level, in the most vulnerable populations (elderly, and poverty + obesity + hot climate)? What about the COVID-era so dramatically multiplied the deadliness of poverty + obesity + hot climate, in the USA?

We submit that the overly succinct three-word answer is: “chronic psychological stress”, plus deadly institutional aggression and neglect of the sick elderly regarding the March-June 2020 catastrophe (cvp1). “Chronic psychological stress” is a powerful determinant of individual health (see below), which is essentially ignored by all those who accept the promoted dominant view that the virulence and contagiousness of the viral respiratory pathogens are predominantly determined by viral genetics, with only secondary influence from host characteristics and social determinants of host characteristics. The dominant view is contradicted by more than a century of hard mortality data, as explained above (Figures 1 through 4), where the declared pandemics are undetected

and all the detected major mortality excesses are tied to socio-economic periods and events.

Researchers considering mortality from diseases must make themselves aware that ordinary psychological stress significantly impacts immune response, and that psychoneuroimmunology is a large field of research (Ader and Cohen, 1993).

Social status, within a specific dominance hierarchy, is a major predictor of chronic stress, in social animals including humans (Cohen et al., 1997a) (Sapolsky, 2005), which, in turn, may be the dominant determinant of individual health, disease burden, and longevity (Cohen et al., 2007).

Ordinary psychological stress is known to be a dominant factor in making an individual susceptible to viral respiratory disease symptomatic infection, and to increase the severity of the infection (Cohen et al., 1991). Also, social isolation (paucity of social-network interactions), in addition to individual psychological stress, is known to have an added impact on the individual's susceptibility to viral respiratory diseases (Cohen et al., 1997b).

Furthermore, there is a large age gradient for stress endurance: extended periods of psychological stress are known to have more deleterious health effects in elderly persons than in younger persons (Prenderville et al., 2015).

The stress-immune relationship, however, is not simply a monotonic function of integrated intensity. Frequency and duration are pivotal: chronic or long-term stress harms immune response, whereas short-term adaptive stress enhances immune response. The often-cited review by Dhabhar (2014) has:

> Short-term (i.e., lasting for minutes to hours) stress experienced during immune activation enhances innate/primary and adaptive/secondary immune responses. Mechanisms of immuno-enhancement include changes in dendritic cell, neutrophil,

> macrophage, and lymphocyte trafficking, maturation, and function as well as local and systemic production of cytokines. In contrast, long-term stress suppresses or dysregulates innate and adaptive immune responses by altering the Type 1–Type 2 cytokine balance, inducing low-grade chronic inflammation, and suppressing numbers, trafficking, and function of immunoprotective cells.

Peters et al. (2021) have reviewed these concepts and the known science for the relevance to COVID-19. They pointed out that “the socioeconomic issues and various aspects of the Western type lifestyle that are closely associated with psychosocial stress have recently been reported to contribute to COVID-19”. Their ultimate aim is to “clarify whether psychosocial interventions have the potential to optimize neuroendocrine-immune responses against respiratory viral infections during and beyond the COVID-19 pandemic.”

Therefore, it is not difficult to imagine that the massive socio-economic disruptions of the COVID-era would have caused undue chronic psychological stress and amplified dominance-hierarchy stress predominantly against those who are already at the bottom of the societal dominance hierarchy, and have the least means to adjust to dramatically new circumstances. The new circumstances include: loss of sources of income, both legitimate and illegal, increased social isolation, increased hierarchical impositions, constant fear propaganda, severe mobility restrictions, closing of public and corporate-public spaces previously used, enforcement and intimidation against private or informal gatherings, mobbing against those who do not cheerfully accept the “new reality”, and increased aggressions from equally stressed individuals. The missing means to adjust would include: undisturbed salary and ability to work from home, means to stay connected by Zoom (by video conferencing applications), large comfortable air-conditioned homes, means to home-school children in an adapted environment, nearby facilities for outside exercise, private facilities for physical exercise, undisturbed shopping by home delivery, undisturbed self-medication, continued access to health care, and so on.

It follows, from the science reviewed above, that the “undue chronic psychological stress and amplified dominance-hierarchy stress”, generally applied to entire populations, would cause death in those most likely to experience the stress and already in higher risk categories. It appears, for example, that populations normally adapted to summer heatwaves in the Southern USA were either prevented from practicing their usual adaptations to the heat or became more vulnerable to this physiological stress, or both.

It is evident also that the type of weakening of the immune system caused by chronic psychological stress would lessen the body’s ability to fight bacterial pneumonia, and that the populations hardest hit during the COVID-era are already disproportionately susceptible to bacterial pneumonia (Figure 38).

At this stage (Figure 34, Figure 38), and given the state of science and practice in this regard (Ginsburg and Klugman, 2020), it is not unreasonable to ask whether the logic has not been inverted: Is COVID-19-assignment an incorrect cause-assignment for what is in fact bacterial pneumonia? From this perspective, it becomes relevant to point out that Ivermectin is probably an effective antibacterial agent against tuberculosis, for example (Crump, 2017) (Lim et al., 2013), which would have been prescribed where the mainstream protocols call for avoiding antibiotics (Beovic et al., 2020) (CDC, 2021h) (Karami et al., 2021).

Karami et al. (2021) put it this way:

> Conclusions: On presentation to the hospital bacterial co-infections are rare, while empiric antibiotic use is abundant. This implies that in patients with COVID-19 empiric antibiotic should be withheld. This has the potential to dramatically reduce the current overuse of antibiotics in the COVID-19 pandemic.

Buehrle et al. (2020) pointed out that, at the same time, outpatient antibiotic prescriptions dropped significantly in the USA:

Abstract: In April 2020, there were significant reductions in prescription fills of each of the 10 most prescribed outpatient antibiotics in the United States. Monthly azithromycin, amoxicillin-clavulanate, and levofloxacin fills did not rebound significantly from April through July 2020. Coronavirus disease 2019 had an immediate and sustained impact on US outpatient antibiotic prescribing.

The CDC (2021h) shows this graph:

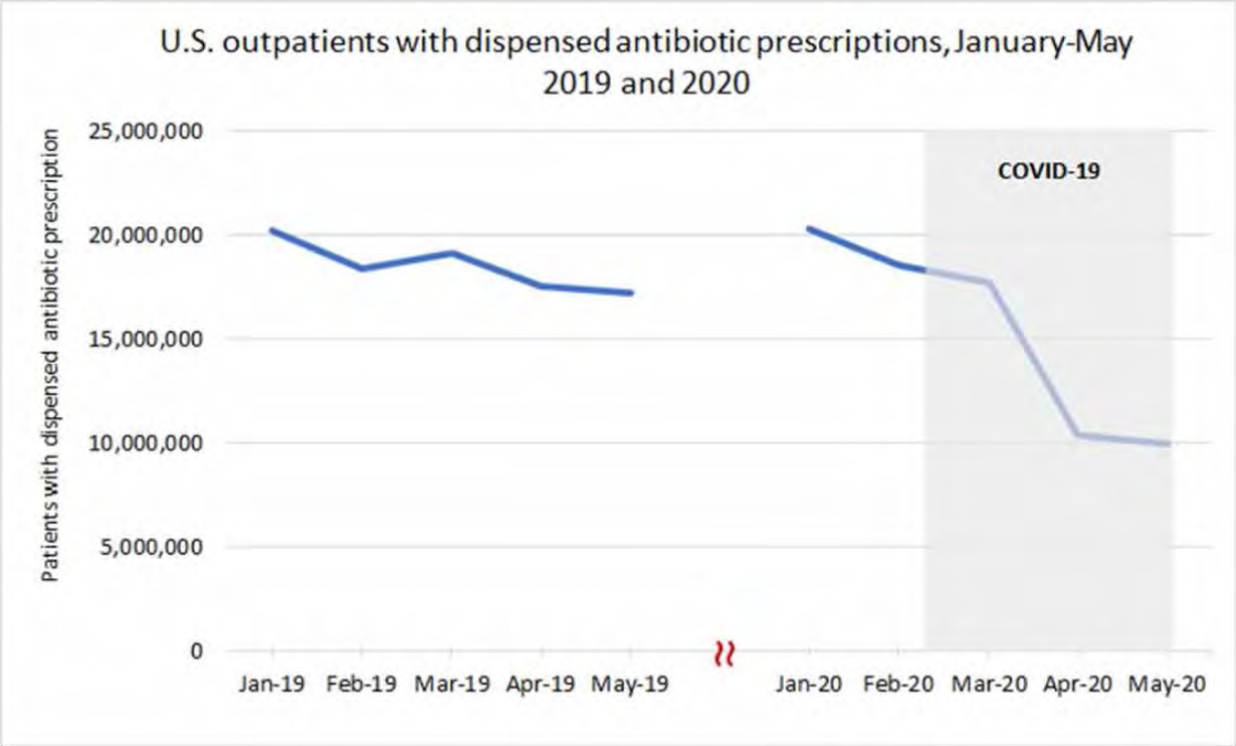


Figure 39. Estimated number of outpatients with dispensed antibiotic prescriptions, USA, 2019-2020. (CDC, 2021h).

If COVID-19 is largely misdiagnosed bacterial pneumonia (using a faulty PCR test: Borger et al., 2021; or not using any laboratory test), or if co-infection with bacterial pneumonia is not appropriately recognized (Ginsburg and Klugman, 2020), or if bacterial pneumonia itself goes otherwise untreated, while antibiotics (and Ivermectin) are withdrawn, in circumstances where large populations of vulnerable and susceptible residents have suppressed immune systems from chronic psychological stress induced

by large-scale socio-economic disruption, then the state has recreated the conditions that produced the horrendous bacterial pneumonia epidemic of 1918 (Morens et al., 2008) (Chien et al., 2009) (Sheng et al., 2011), in COVID-era USA.

6. Conclusion

By examining the socio-jurisdictional and temporal structure of the ACM/w data, and by comparing to socio-geo-economic and climatic data, we conclude that the massive above-trend COVID-era mortality in the USA is not the result of a pandemic, but instead is caused by the large-scale medical and government responses, which transformed the domestic economy and living conditions, and the associated long-term chronic psychological stress effects on the most vulnerable populations (regarding poverty and obesity), in a context of ordinary seasonal respiratory diseases and typical summer heat-wave climatic effects.

In light of the results presented herein, the view that a new respiratory disease virus caused the excess deaths in the COVID-era (March-2020 to present) in the USA has to be considered an extravagant theory, contrary to empirical data and viral respiratory disease phenomenology:

- No declared pandemic (1957-58, 1968, 2009) has ever caused a detectable increase in yearly all-cause mortality in the USA, since 1900, except 1918, which has been incorrectly assigned as an influenza pandemic.
- All the detected anomalies in yearly all-cause mortality in the USA, since 1900, have been associated with major socio-economic upheavals: the First World War, The Great Depression and Dust Bowl, the Second World War, and the medical and government response to the declared COVID-19 pandemic.
- None of the recently declared viral respiratory disease pandemics (1957-58, 1968, 2009), and none of the ubiquitous seasonal (winter) epidemics of the last

century or more, in all Northern hemisphere countries having sufficiently good data, exhibit large jurisdictional heterogeneity (in both time and location) in all-cause mortality of the magnitude seen during the COVID-era.

- On the contrary, viral respiratory disease epidemics, never mind declared pandemics, never stop at jurisdictional boundaries or national or state or provincial or regional or county borders. Instead, seasonal (winter) all-cause mortality is always synchronous across mid-latitude Northern hemispheric jurisdictions, while showing similar to statistically identical patterns of temporal variation within any given year.
- The jurisdictional and temporal heterogeneity of all-cause mortality during the COVID-era in the USA (and other nations) is of unprecedented character and magnitude (Figures 5-11, 13-16, and Table 2), which can only be due to local and time-dependent forces and vulnerability to those forces, not viral respiratory diseases as the primary driver.
- The extraordinary mortality spike that occurred in New York City and some North-East coastal states in March-June 2020 (cvp1) and virtually nowhere else (some 34 USA states did not significantly exhibit this feature in all-cause mortality) is impossible for a virulent and contagious respiratory disease virus acting in a society free from local aggression or local environmental disaster. To our knowledge, no such intense feature, this late in the cycle-year, has ever occurred in the world epidemiological record.
- Viral respiratory diseases never give rise to all-cause mortality by time peaks (maxima) in the summer. The unprecedented summer peaks seen in the USA in the COVID-era are contrary to known viral respiratory disease epidemiology.
- Pre-COVID-era viral-respiratory-disease burden mortality (winter burden) does not correlate with obesity, whereas the state-wise heterogeneous summer-2020, fall-winter-2020-2021 and summer-2021 excess (above-SB) mortalities do correlate with obesity.
- Pre-COVID-era viral-respiratory-disease burden mortality (winter burden) does not correlate with poverty, whereas the state-wise heterogeneous summer-2020,

fall-winter-2020-2021 and summer-2021 excess (above-SB) mortalities do correlate with poverty.

- Pre-COVID-era viral-respiratory-disease burden mortality (winter burden) does not correlate with climatic temperature, whereas the state-wise heterogeneous summer-2020, fall-winter-2020-2021 and summer-2021 excess (above-SB) mortalities do correlate with climatic temperature.
- In the correlations that we identified, the 2020 and 2021 summer excess (above-SB) mortalities extend to zero values for sufficiently small values of poverty, obesity or summer temperatures, or their combinations, such as the product of poverty and obesity, suggesting that the presumed new pathogen requires sufficiently high state-wise average poverty, obesity and/or temperatures in order to spread and be lethal in the summer.
- Pre-COVID-era viral-respiratory-disease burden mortality (winter burden) always correlates with the proportion of the population that is elderly, whereas the state-wise heterogeneous summer-2020, fall-winter-2020-2021 and summer-2021 excess (above-SB) mortalities anti-correlate with the proportion of the population that is elderly, strongly so for summer mortality.
- No known respiratory disease virus has ever caused a permanent (1.5 years and counting) step-wise time-independent increase in mortality of 15-34 year olds, which appears to have occurred in the COVID-era (Figures 33b to 33e).
- Pre-COVID-era viral-respiratory-disease burden mortality (winter burden) does not correlate with population density (Figure 29), whereas the state-wise heterogeneous March-June 2020 excess mortality (cvp1) strongly correlates with population density; and summer-2020, fall-winter-2020-2021 and summer-2021 excess (above-SB) mortalities anti-correlate with population density (Figure 30). (This is a consequence of the localities of the March-June 2020 anomaly, and that poor states tend to have low population density.)
- The largest high-tech vaccination campaign in history, targeted against the presumed pathogen, had no detectable benefit in all-cause mortality, given the post-vaccination-campaign summer-2021 surge that is observed.

- It is extremely unlikely that a virulent and contagious viral respiratory pathogen that would have caused the exceedingly large COVID-era excess mortality in the USA, could not have crossed the border into Canada, the world's longest international land border (8,890 km) between two major trading partners; where both countries are normally (pre-COVID-era) continuously subject to seasonal (winter) viral respiratory disease epidemics having virtually identical mortality characteristics.

Finally, our examination of plausible mechanisms for the exceptionally large COVID-era mortality in the USA, given all our empirical observations, leads us to postulate that COVID-19 may largely be misdiagnosed bacterial pneumonia (using a faulty PCR test: Borger et al., 2021; and see Ginsburg and Klugman, 2020), that correctly assigned bacterial pneumonia itself largely goes untreated, while antibiotics (and Ivermectin) are withdrawn, in circumstances where large populations of vulnerable and susceptible residents have suppressed immune systems from chronic psychological stress induced by (“COVID response”) large-scale socio-economic disruption, and that the USA has, in the COVID-era, thus recreated the conditions that produced the horrendous bacterial pneumonia epidemic of 1918 (Morens et al., 2008) (Chien et al., 2009) (Sheng et al., 2011).

Given the approximately 1 M excess deaths that have occurred in the most vulnerable and underprivileged residents of the USA in the COVID-era, given the evidence from empirical and statistical data on the causes of the excess mortality, and in view of our research and general observations, we feel justified in making the following comment. We believe that genetic-sequencing-centered virologists and mathematical modellers (as opposed to other and broad disciplines connected to epidemiology, biology, psychology and health), pharmaceutical-industry lobbyists, politicized public health officials (WHO, national, and local), biased media, and approval-seeking politicians, have had far too much influence on public policy in the events surrounding the proclaimed pandemic, and in establishing the questionable dominant narrative, without regard for the hard data that is all-cause mortality by time, jurisdiction, age group, sex,

and so forth; without regard for robust measures of population-level actual harm, while allowing tunnel-vision assignation of cause. The resulting practice has been mostly contrary to public health principles of objectively, scientifically, equally and independently assessing risks and benefits of any impactful policy, within a framework of transparency and accountability; and has caused great societal harm, beyond significant excess mortality itself, which is difficult to fully quantify.

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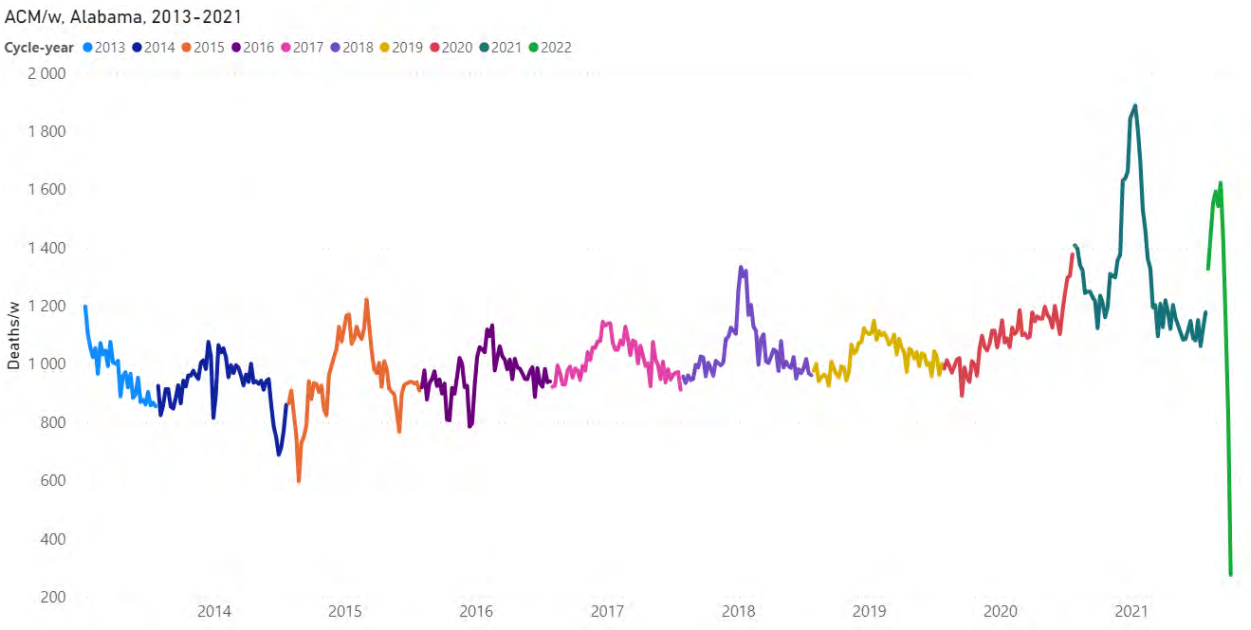
Appendix:

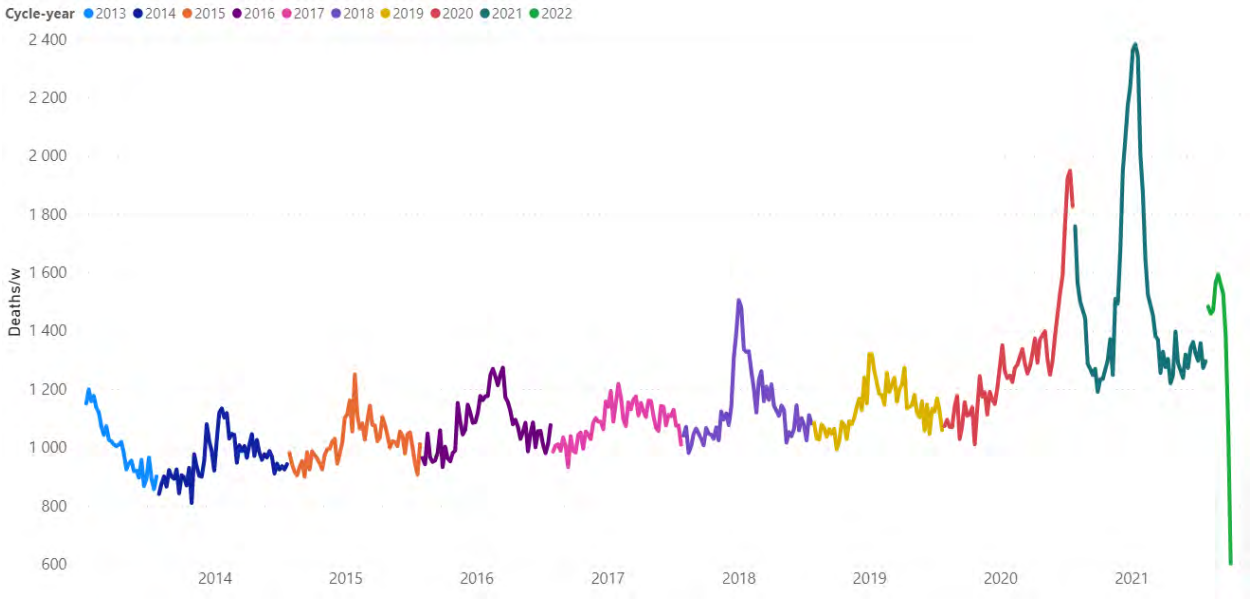
ACM/w, 2013-2021, with colour-differentiated cycle-years, for all the individual states of continental USA

The following graphs represent the all-cause mortality by week in each state of the continental USA from 2013 to 2021. Data are displayed from week-1 of 2013 to week-40 of 2021 (last available data point at the date of access, unless otherwise stated). The different colours are for the different cycle-years. The cycle-year starts on week-31 of a calendar-year (beginning of August) and ends on week-30 of the next calendar-year (end of July). Cycle-years 2013 and 2022 are then not completed. Data were retrieved from CDC (CDC, 2021a), as described in Table 1 of section 2 of the article.

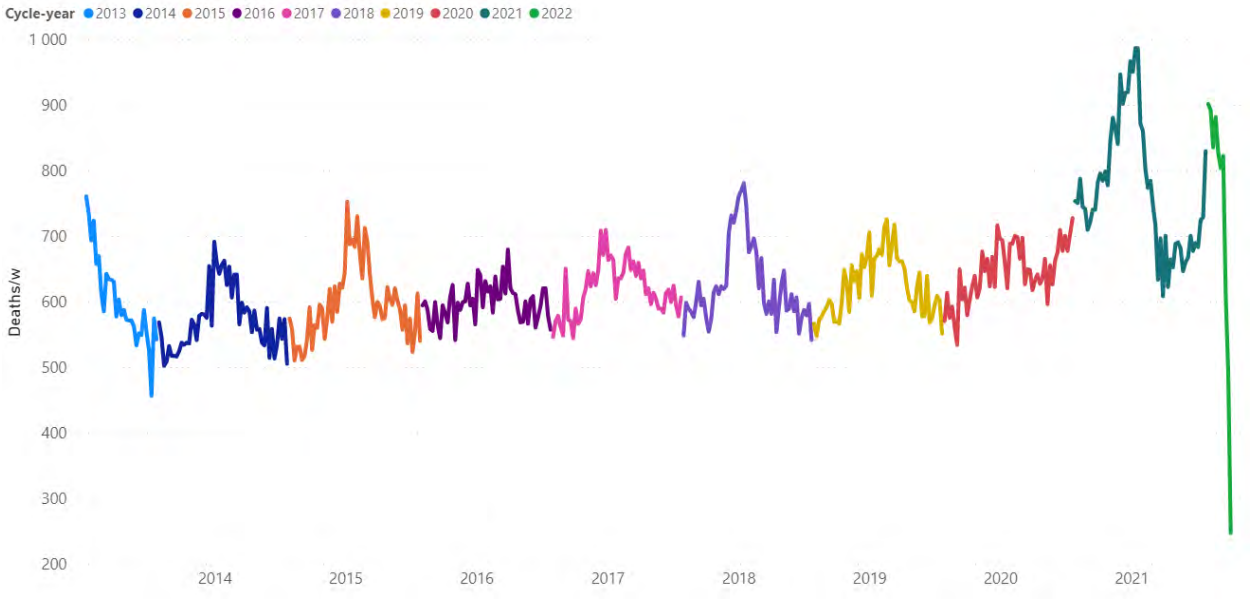
The 49 continental USA states, including District of Columbia and excluding Alaska and Hawaii, are presented by alphabetical order.

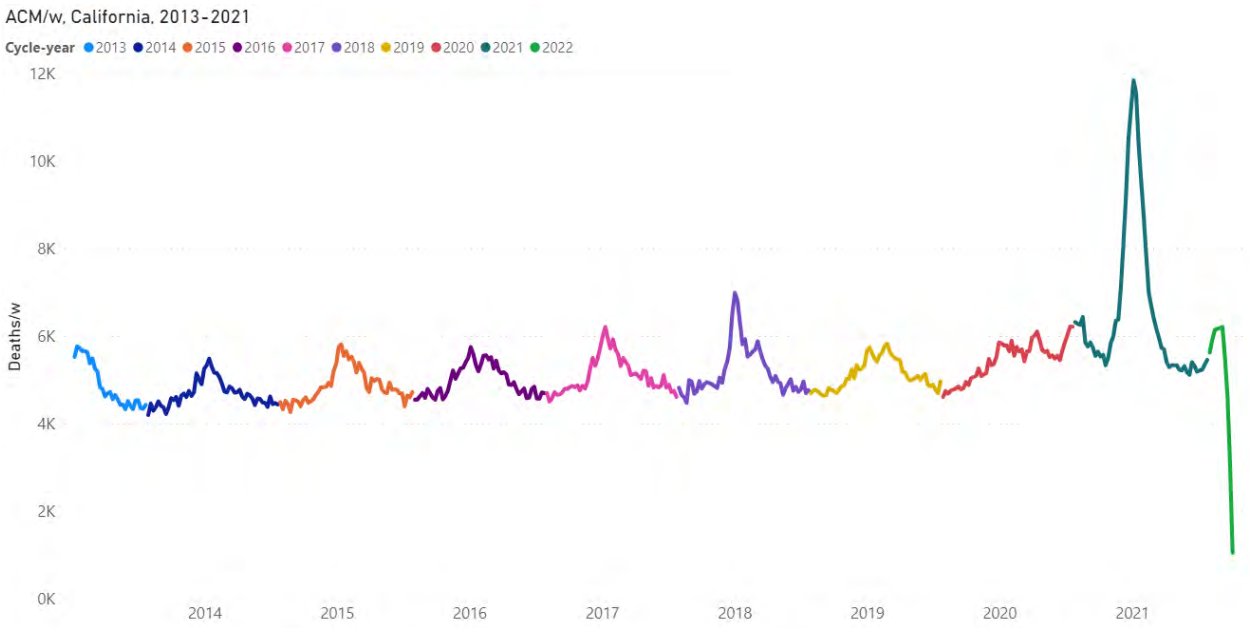


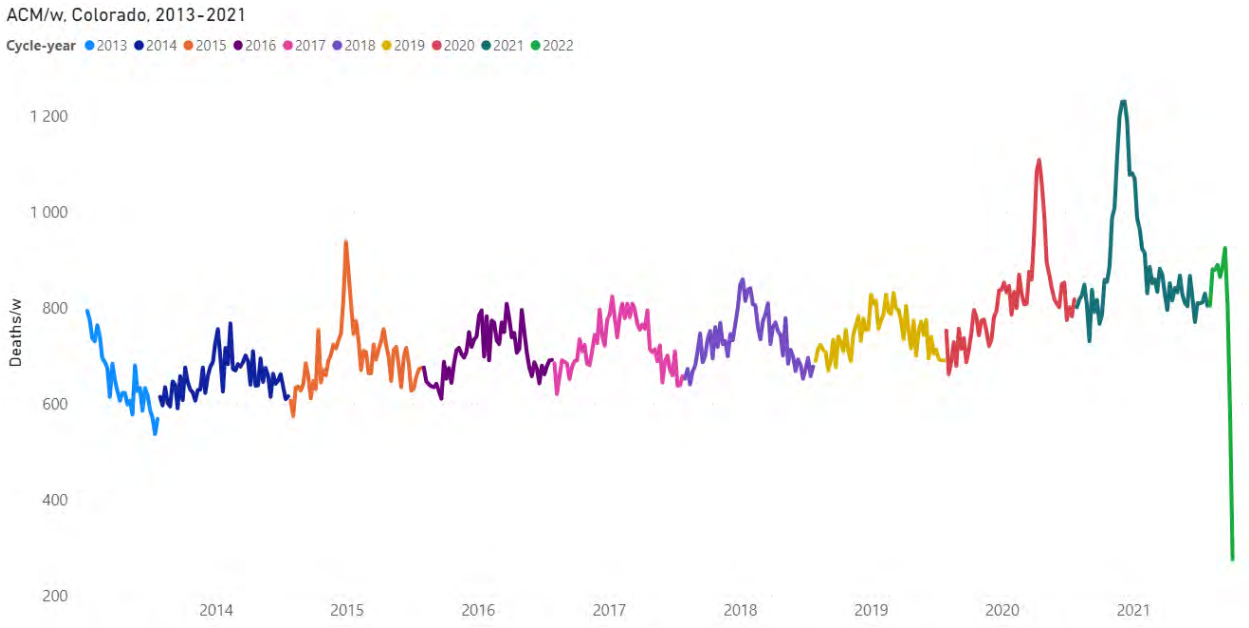
ACM/w, Arizona, 2013-2021

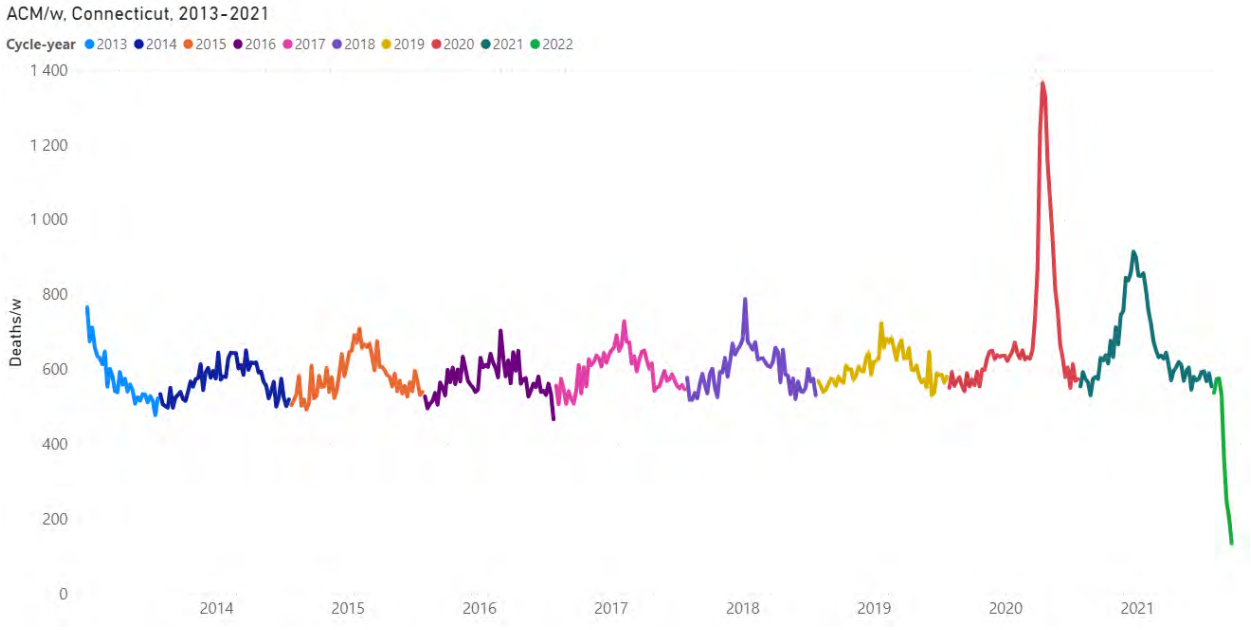


ACM/w, Arkansas, 2013-2021

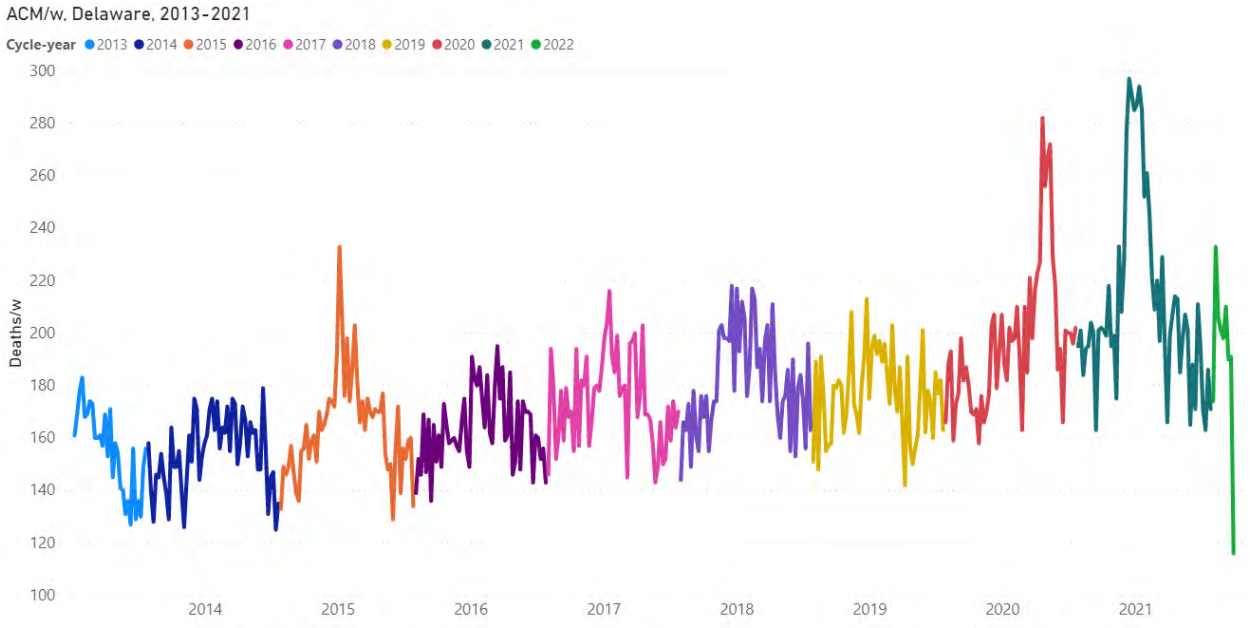



ACM/w, California, 2013-2021
Cycle-year 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
12K
10K
8K
6K
4K
2K
0K
Deaths/w
2014
2015
2016
2017
2018
2019
2020
2021


ACM/w, Colorado, 2013-2021
Cycle-year 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
1 200
1 000
800
600
400
200
Deaths/w
2014
2015
2016
2017
2018
2019
2020
2021

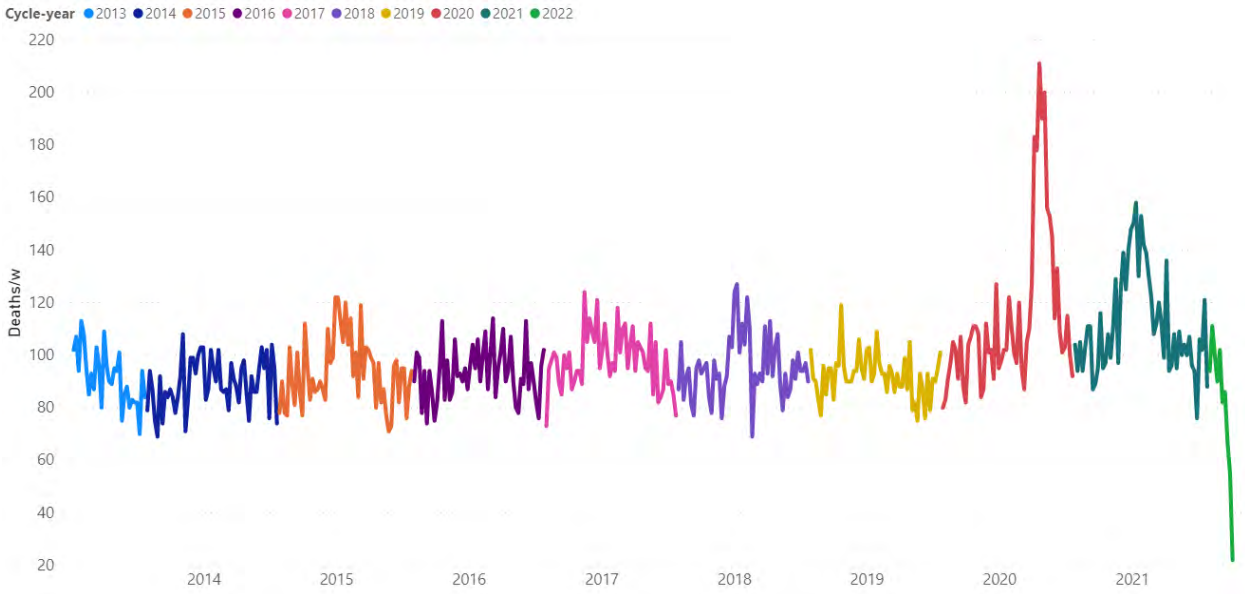


The last data point of Connecticut is week-38 of 2021.

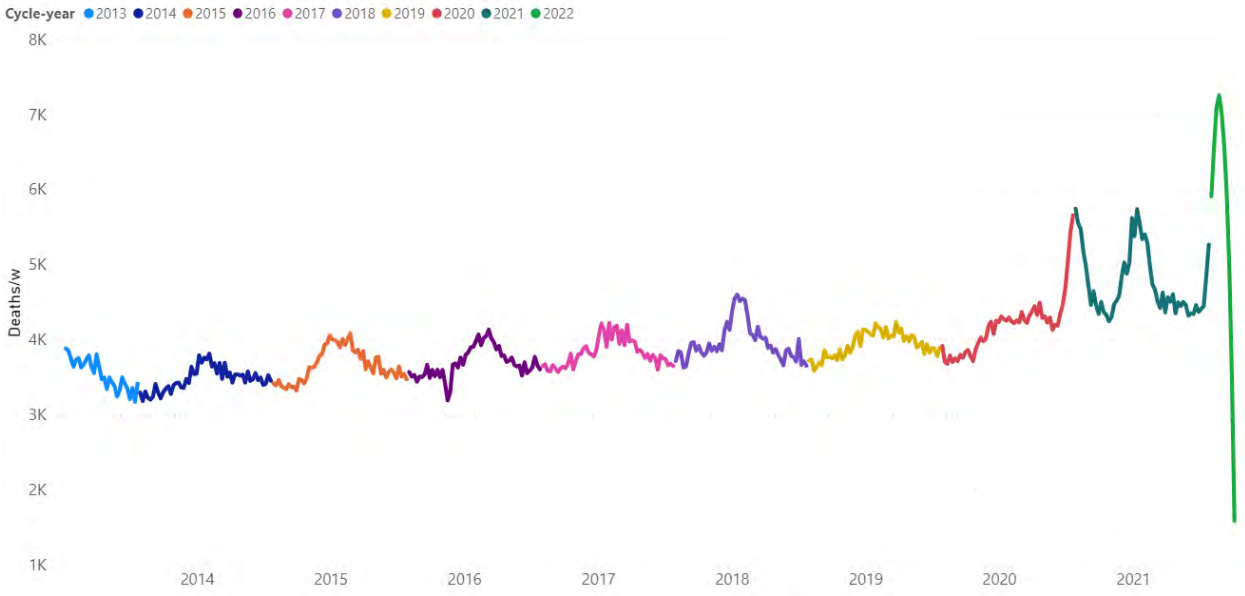


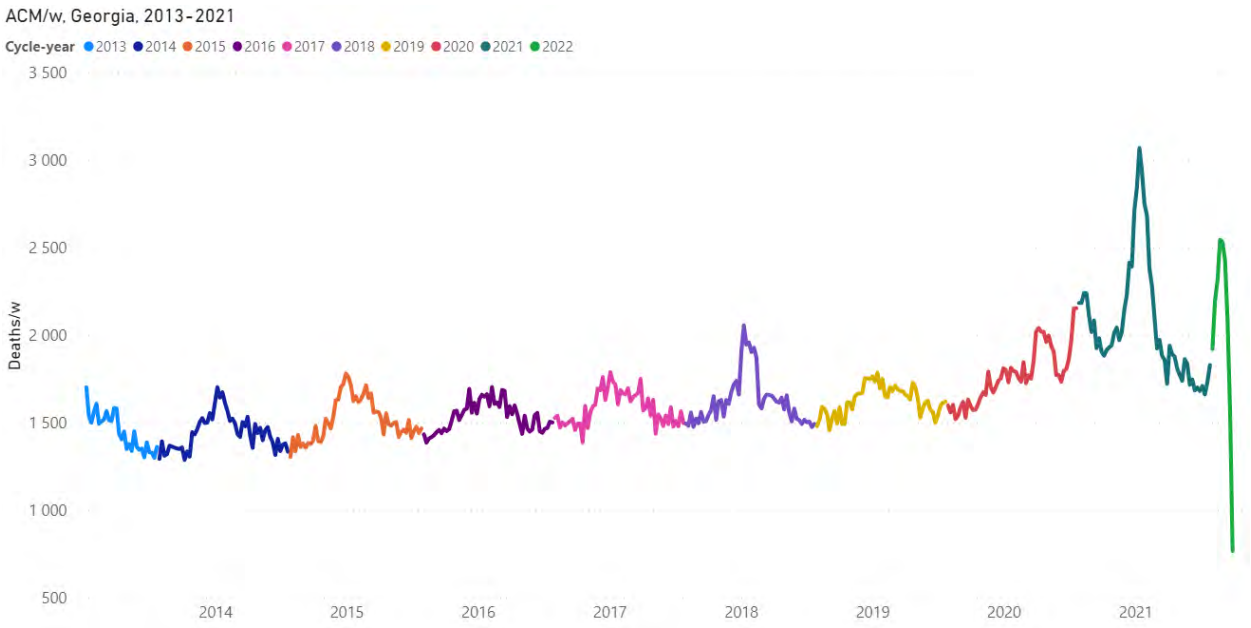
The last data point of Delaware is week-39 of 2021.

ACM/w, District of Columbia, 2013-2021

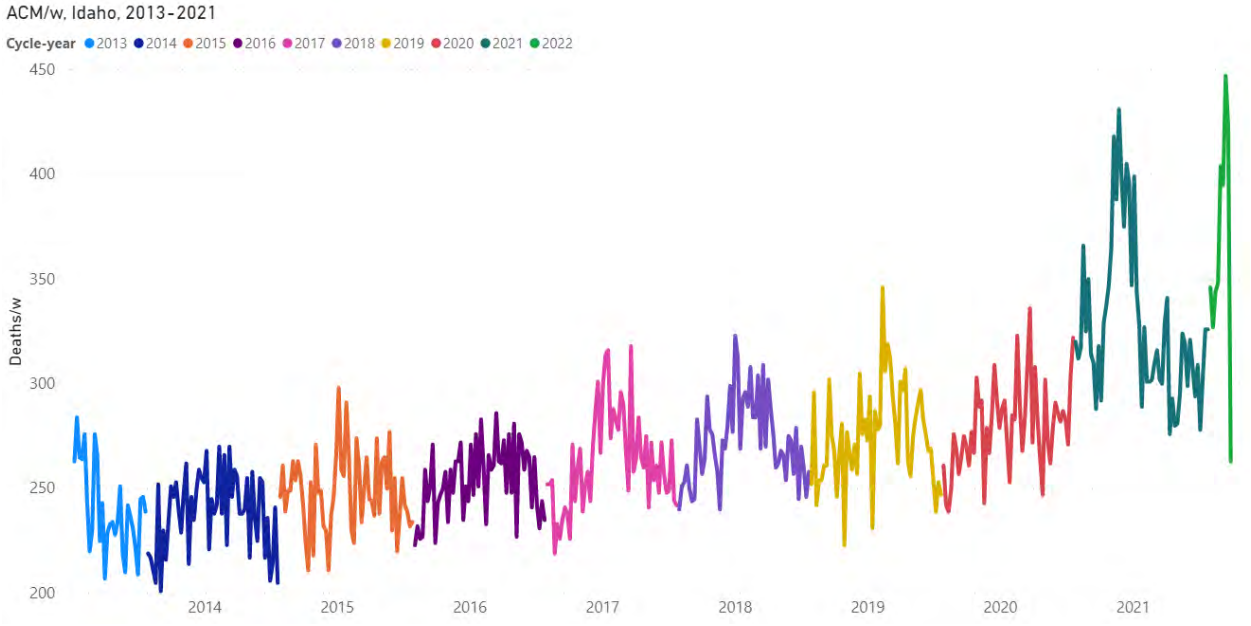


ACM/w, Florida, 2013-2021

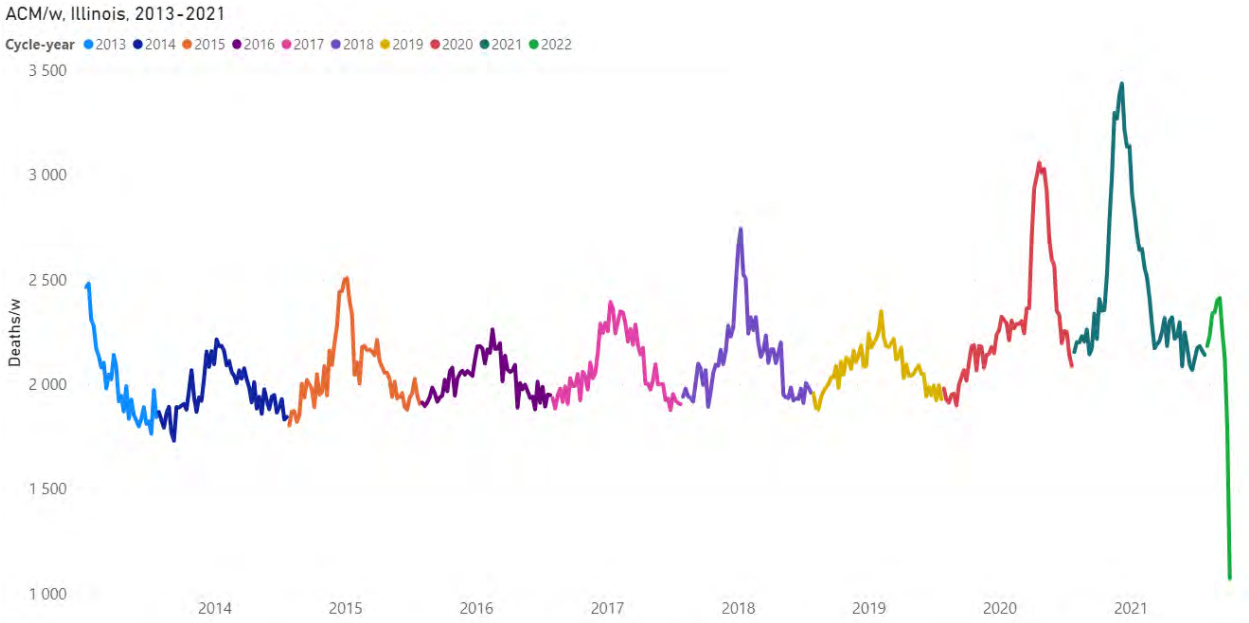


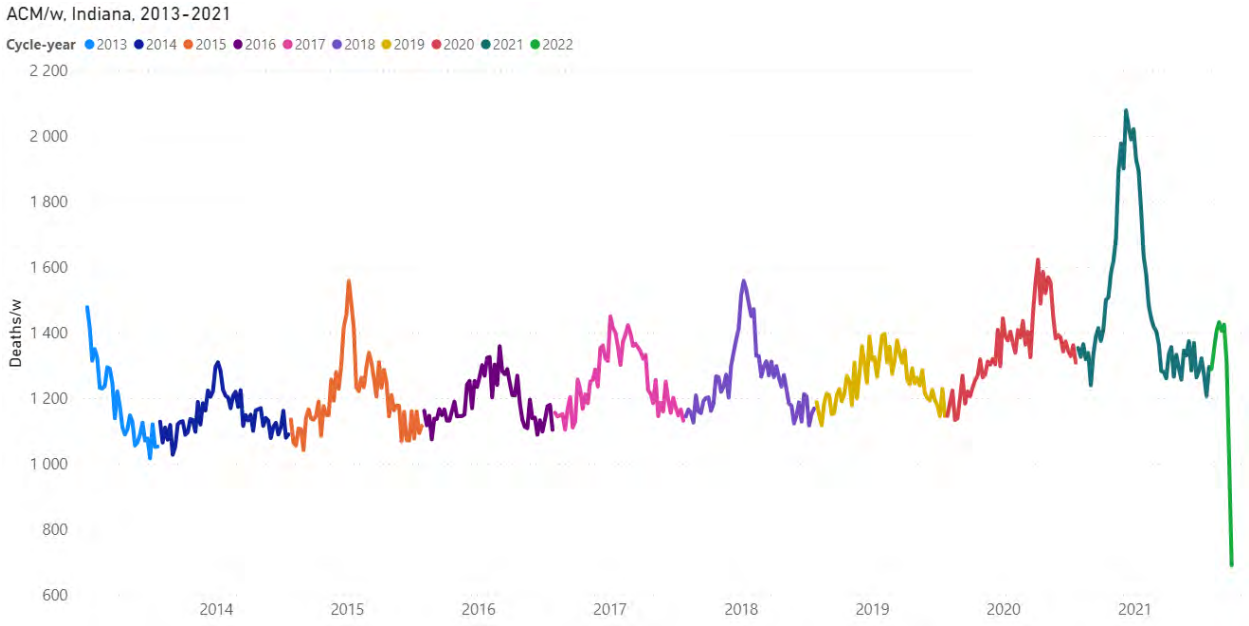


The last data point of Georgia is week-39 of 2021.



The last data point of Idaho is week-39 of 2021.

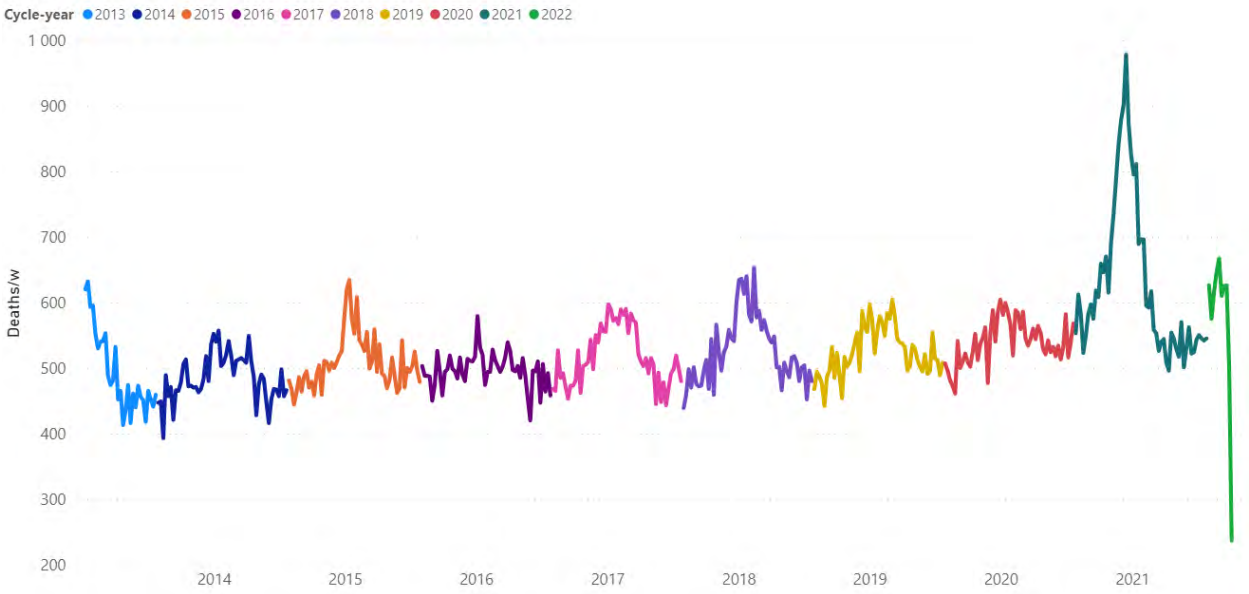


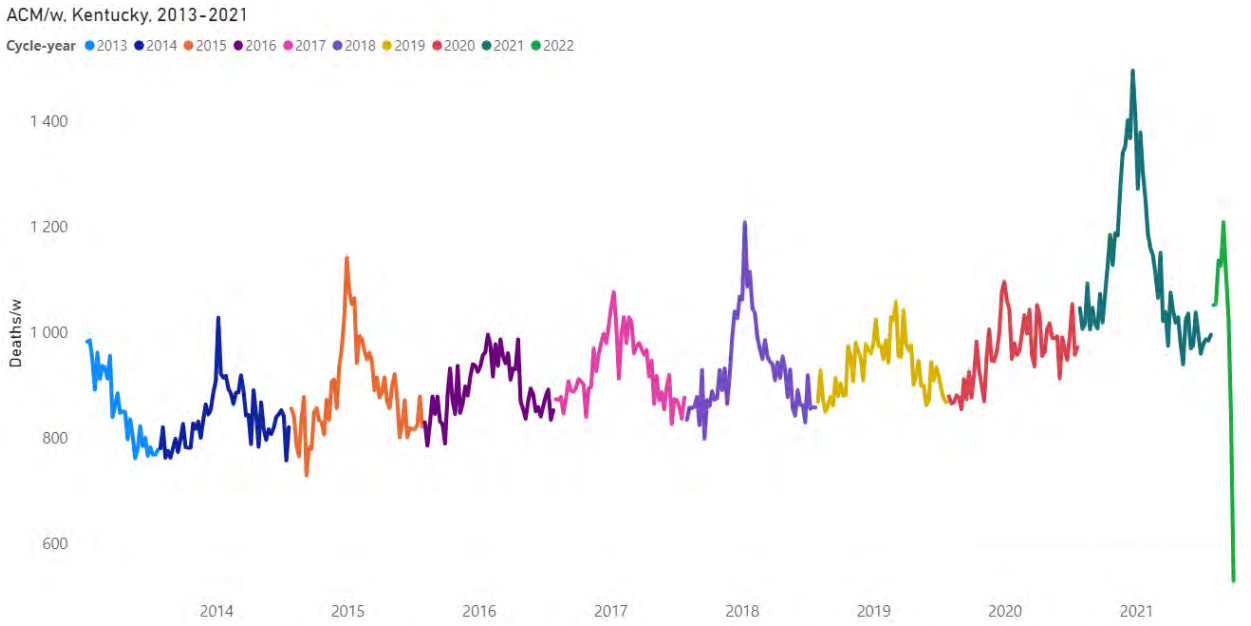


The last data point of Indiana is week-39 of 2021.

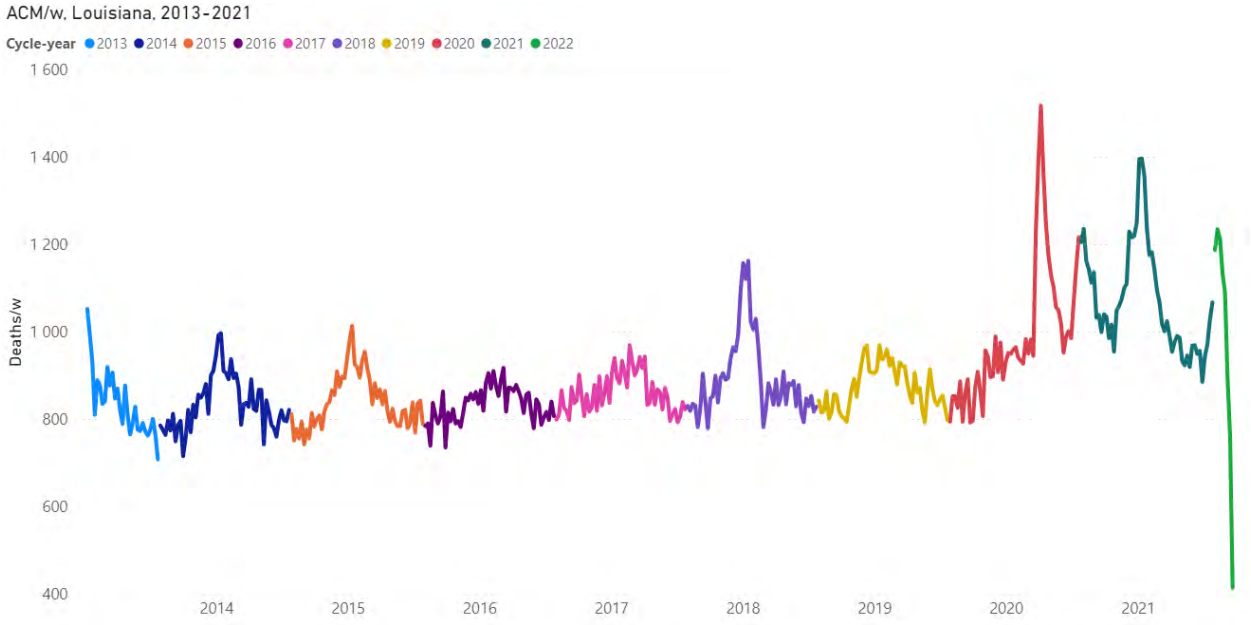
ACM/w, Iowa, 2013-2021

ACM/w, Kansas, 2013-2021



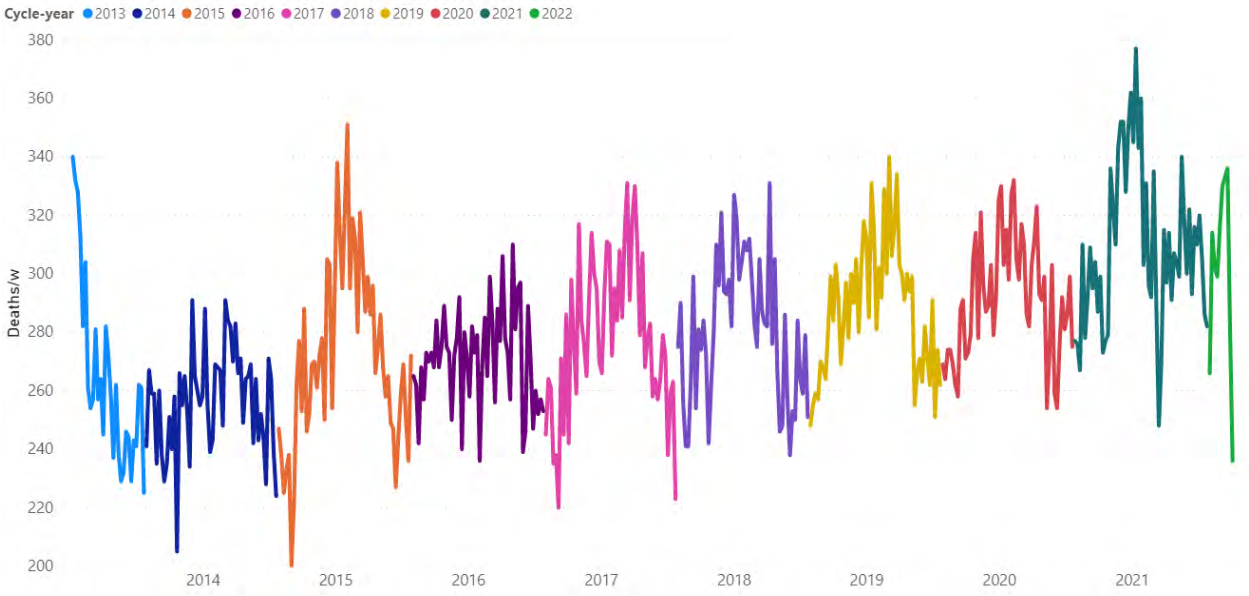


The last data point of Kentucky is week-39 of 2021.



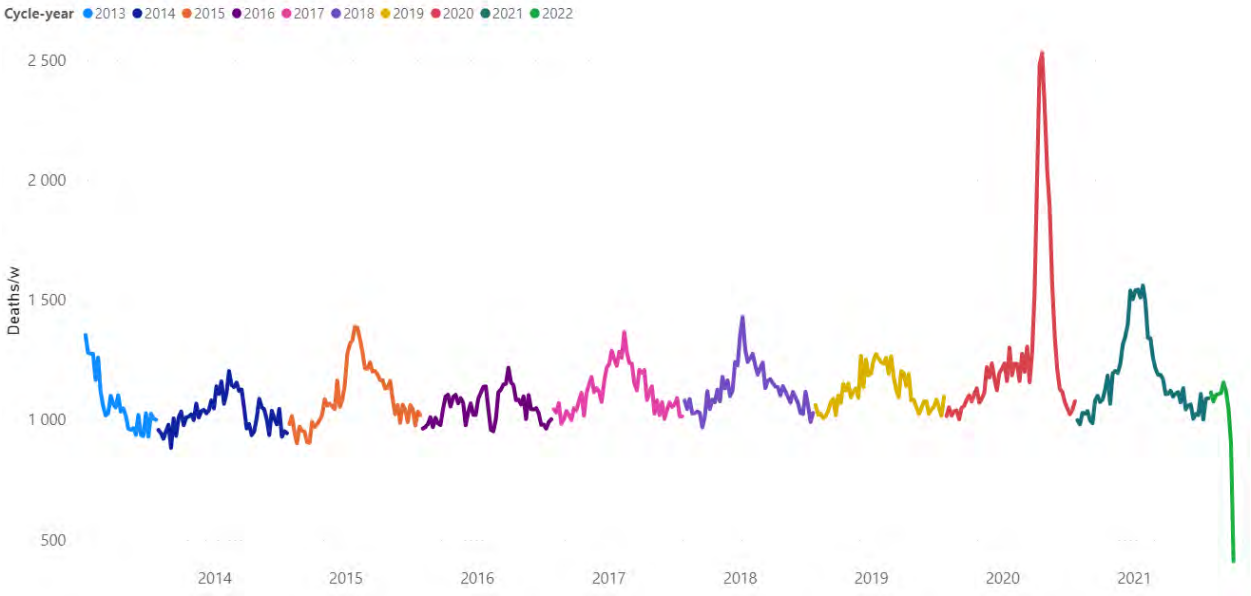
The last data point of Louisiana is week-38 of 2021.

ACM/w, Maine, 2013-2021



ACM/w, Maryland, 2013-2021

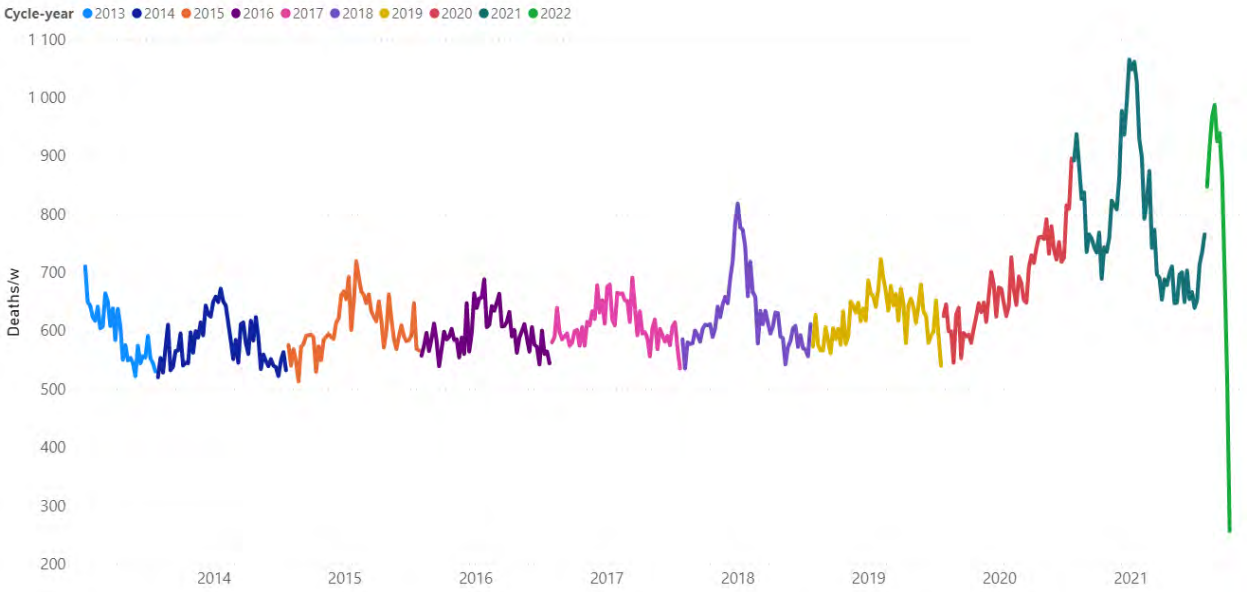
ACM/w, Massachusetts, 2013-2021

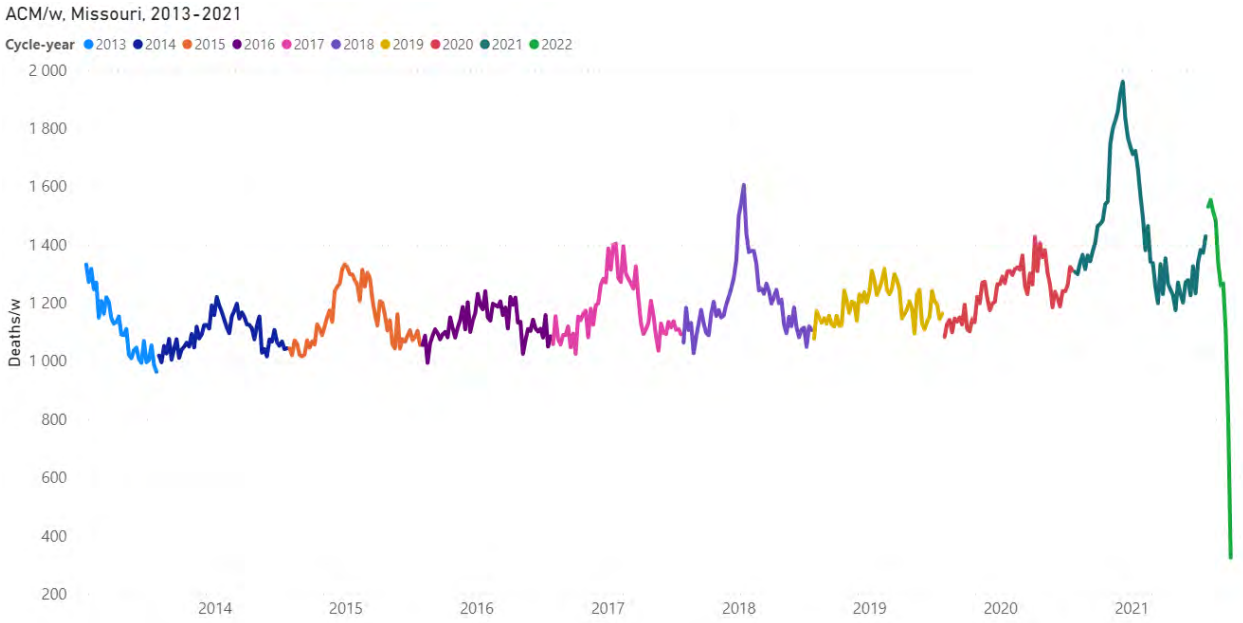


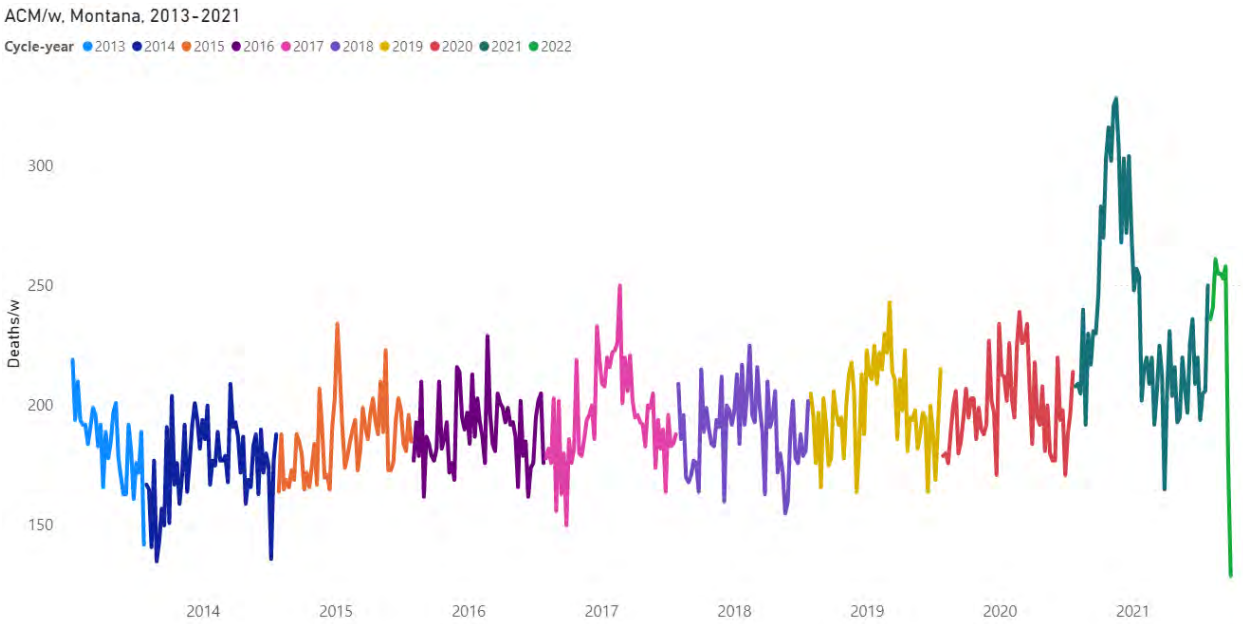
ACM/w, Michigan, 2013-2021

ACM/w, Minnesota, 2013-2021

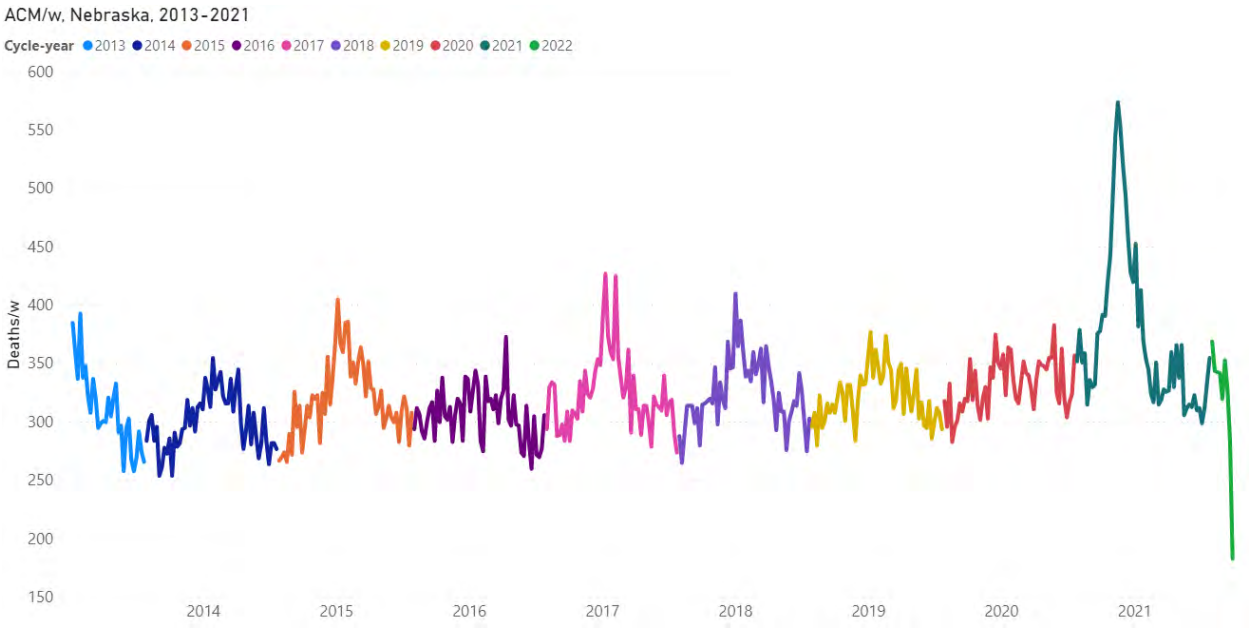
ACM/w, Mississippi, 2013-2021







The last data point of Montana is week-39 of 2021.



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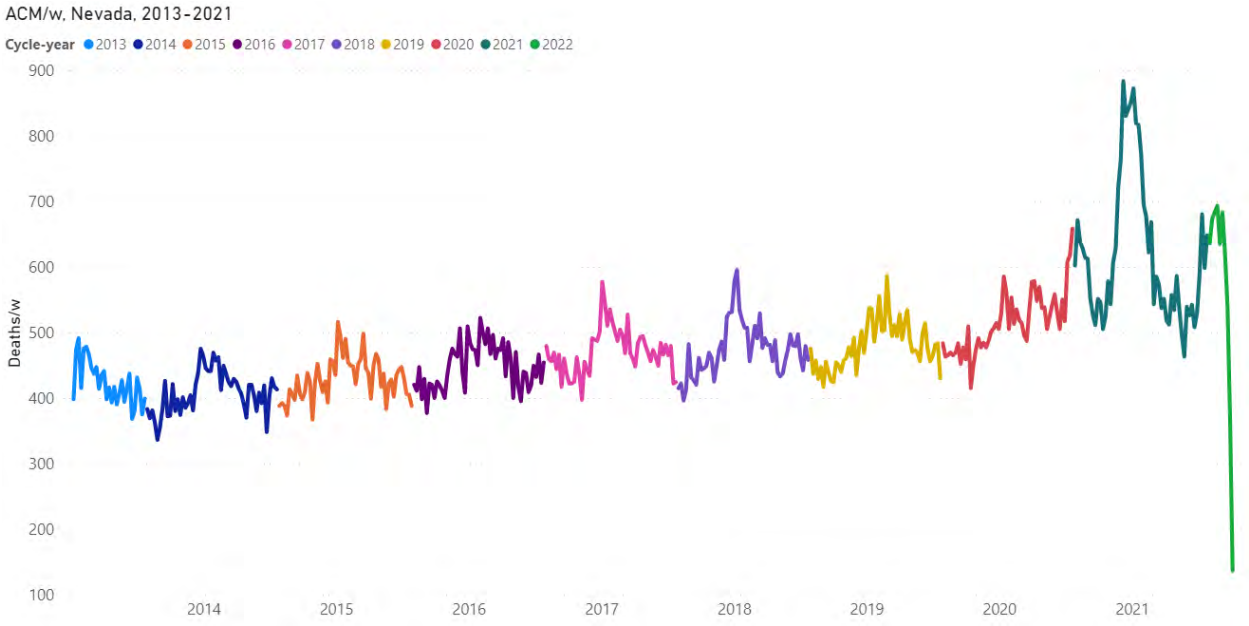
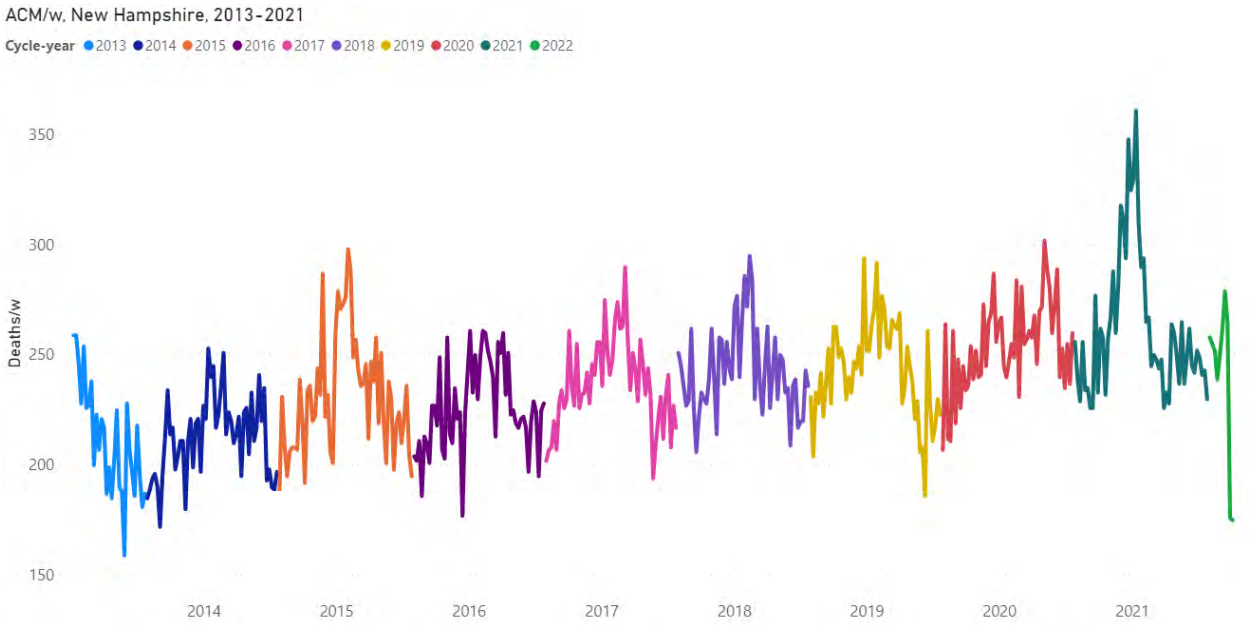
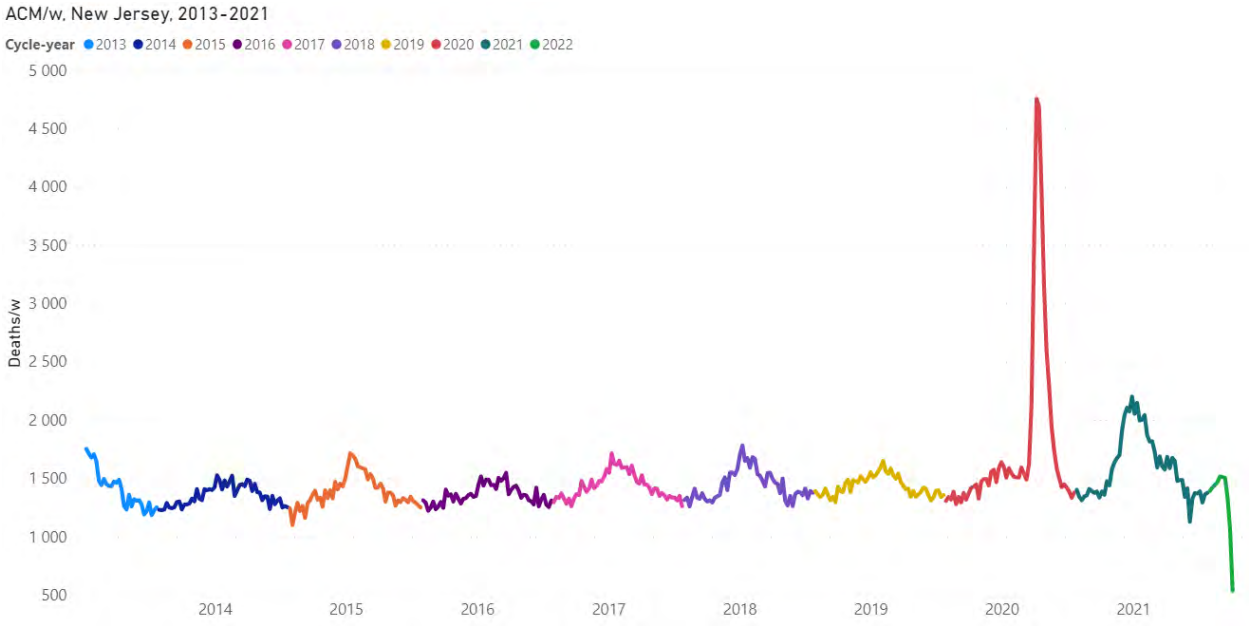
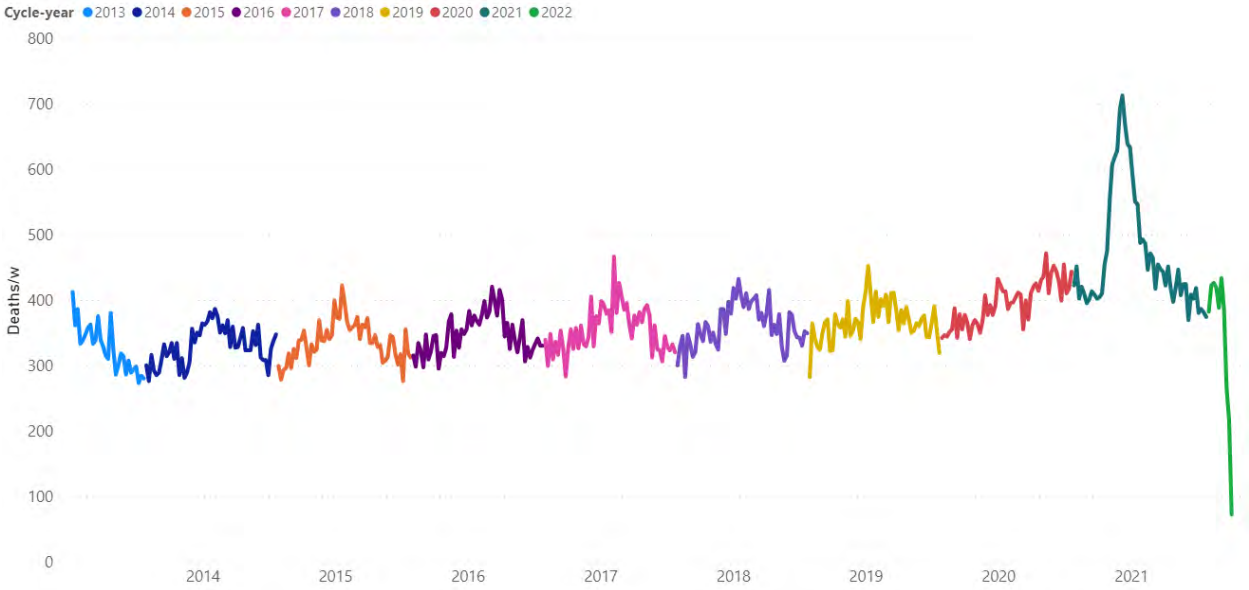


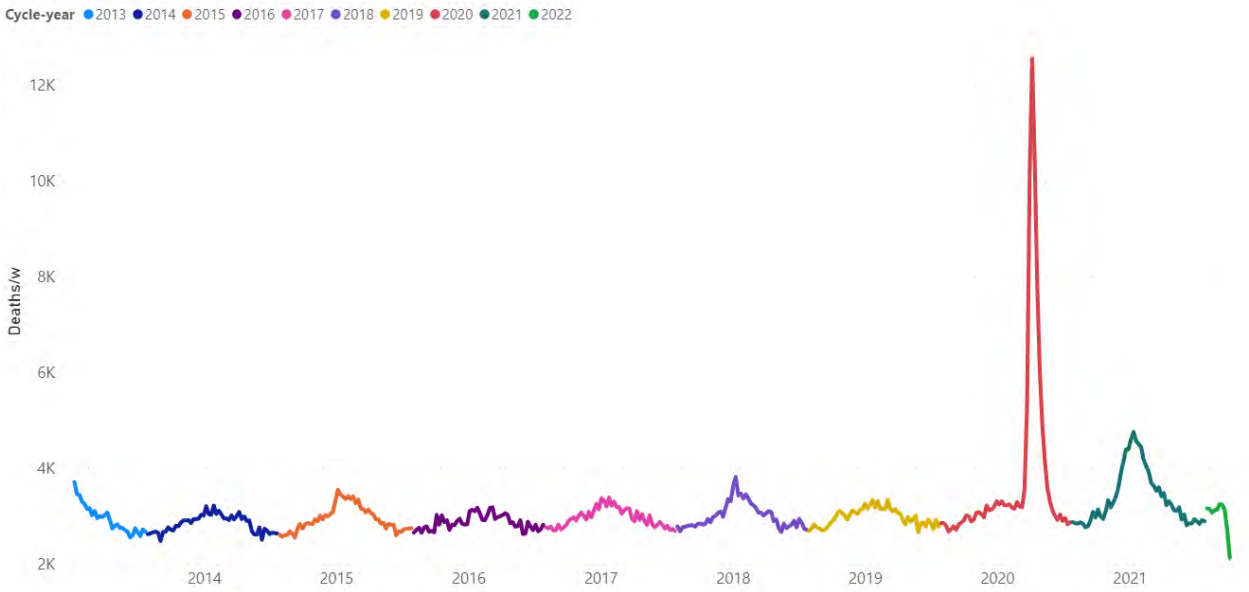

ACM/w, New Hampshire, 2013-2021
Cycle-year 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
Deaths/w
350
300
250
200
150
2014
2015
2016
2017
2018
2019
2020
2021

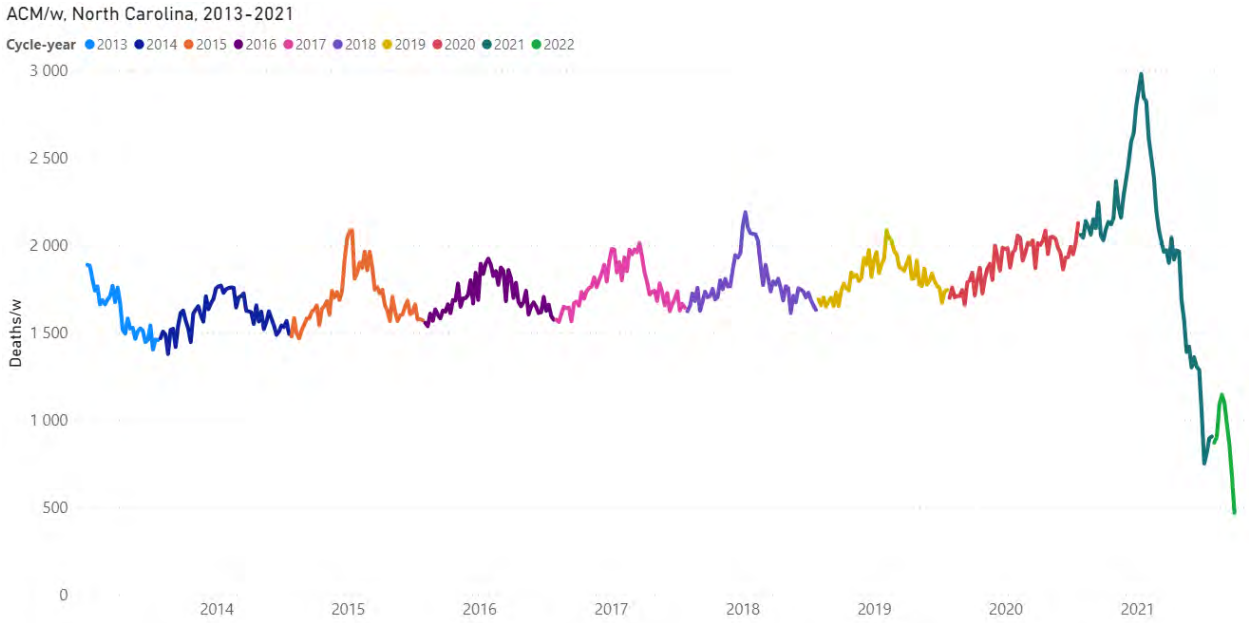

ACM/w, New Jersey, 2013-2021
Cycle-year 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
Deaths/w
5 000
4 500
4 000
3 500
3 000
2 500
2 000
1 500
1 000
500
2014
2015
2016
2017
2018
2019
2020
2021

ACM/w, New Mexico, 2013-2021



ACM/w, New York, 2013-2021





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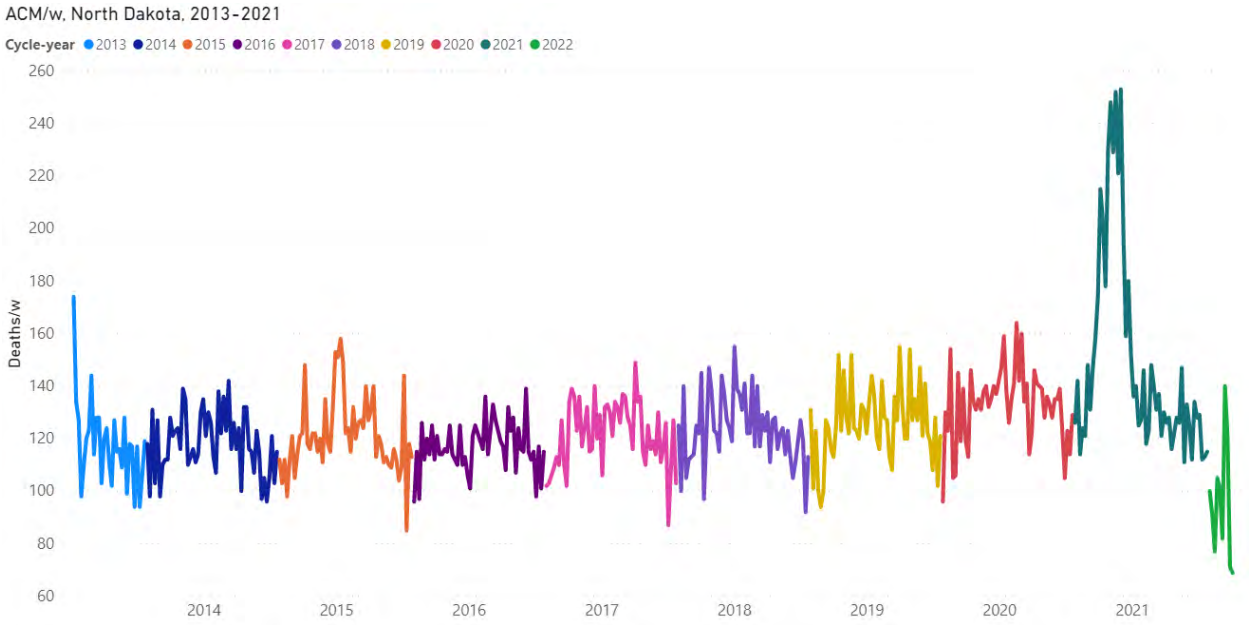
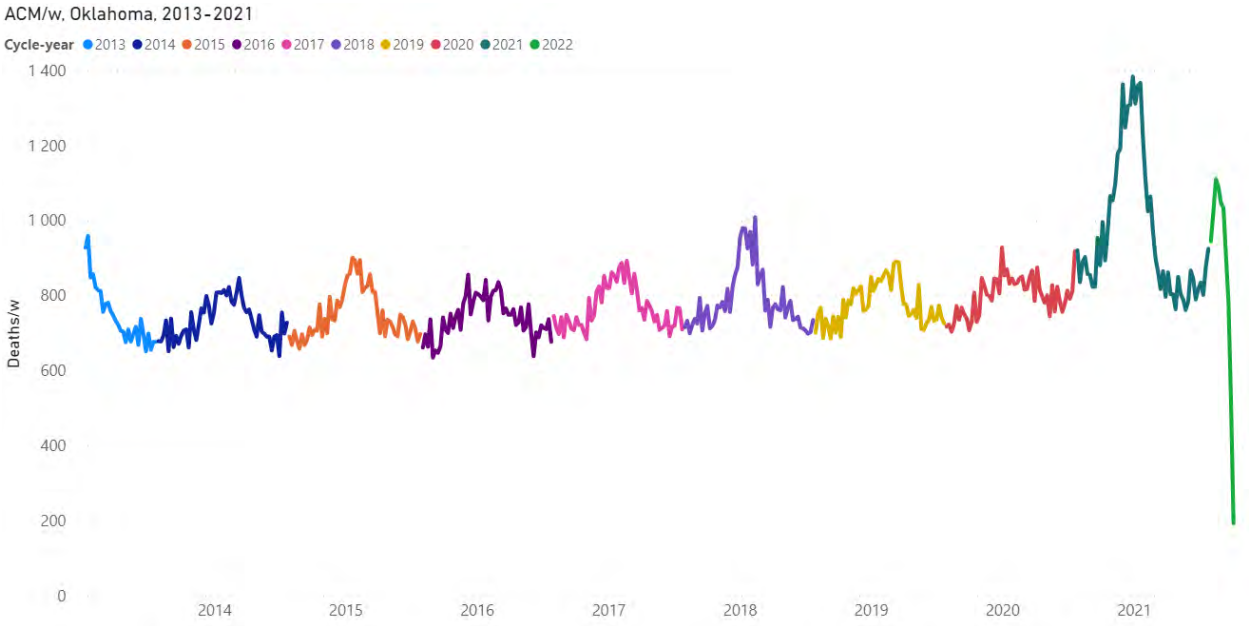
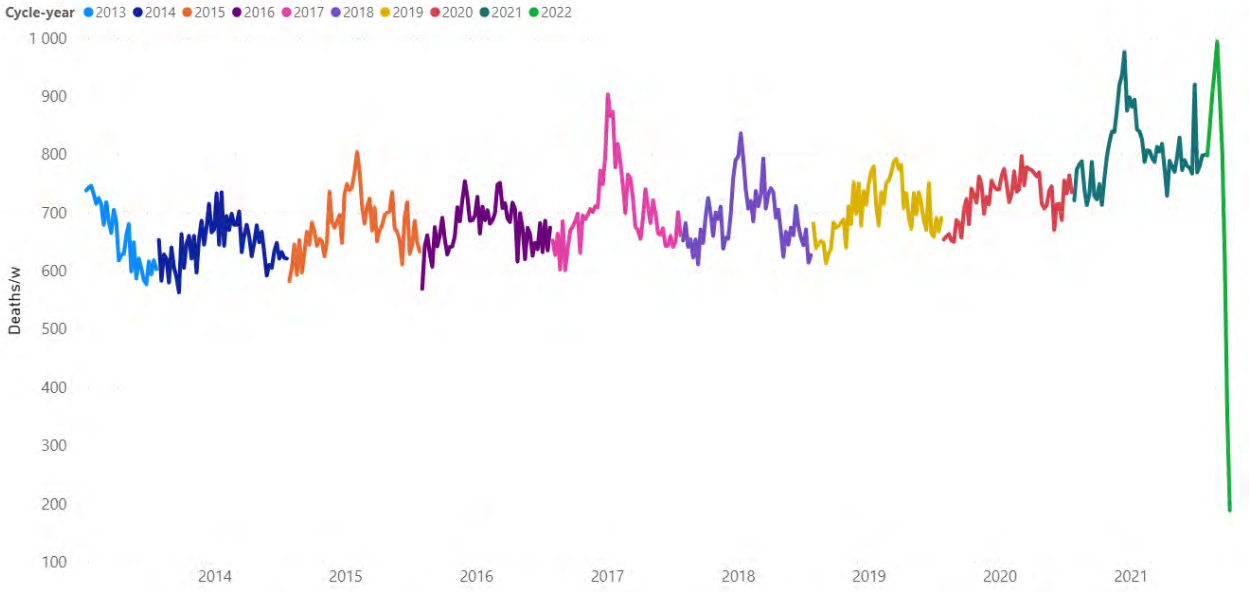


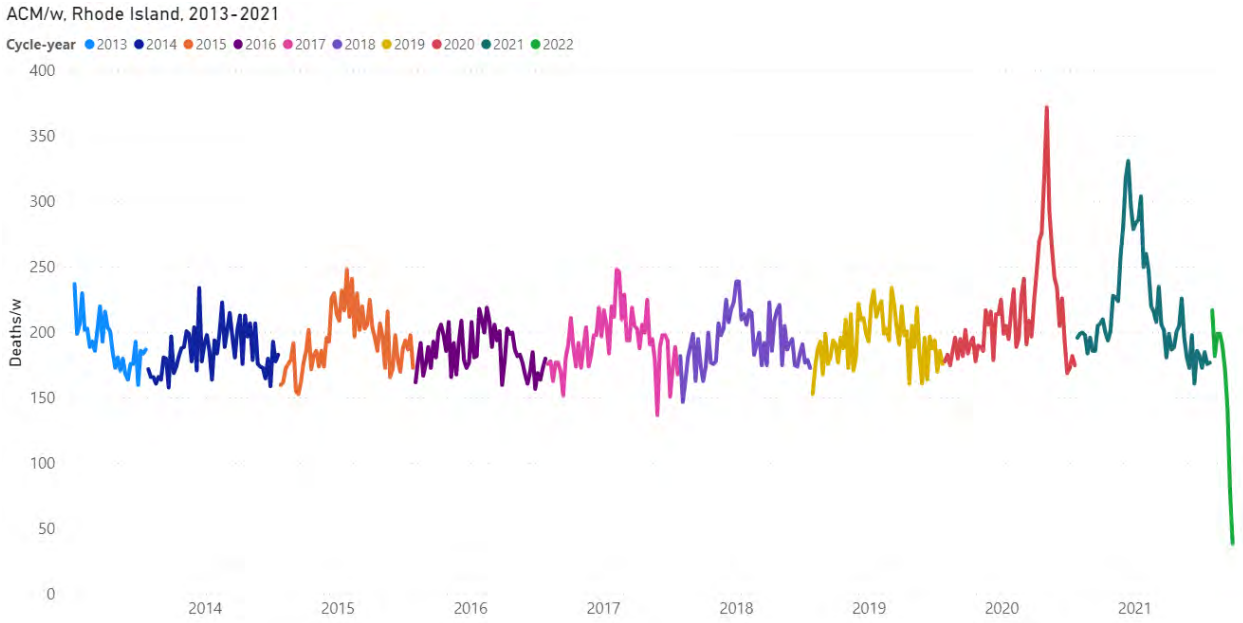
The last data point of Ohio is week-39 of 2021.



ACM/w, Oregon, 2013-2021



ACM/w, Pennsylvania, 2013-2021



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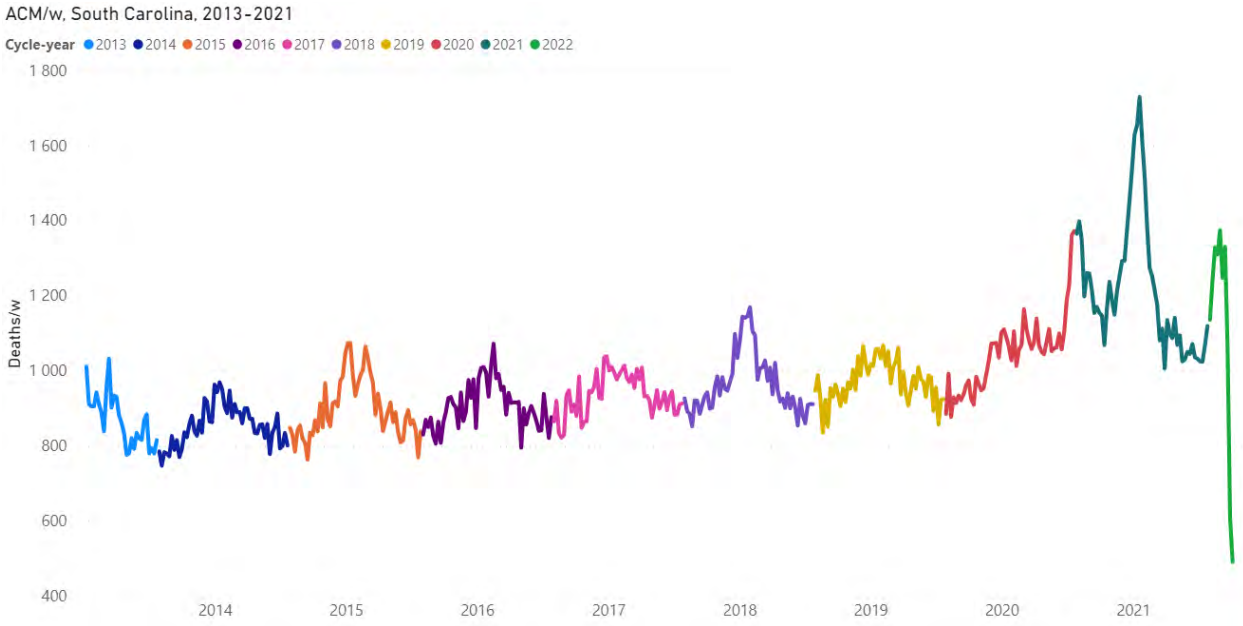
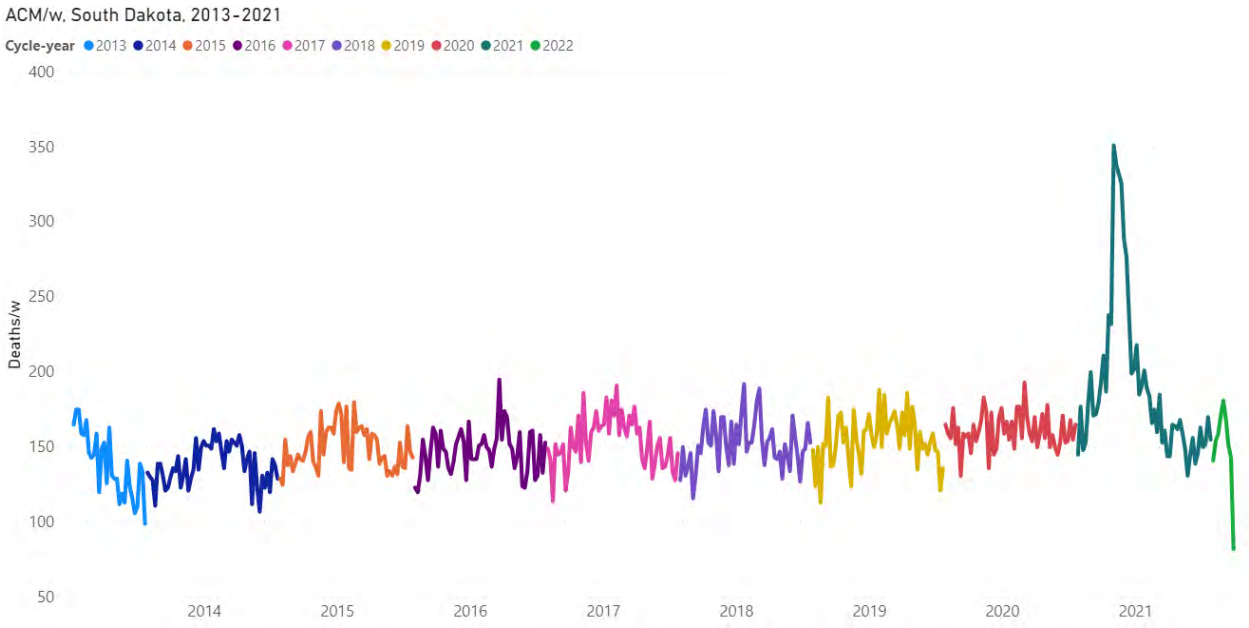
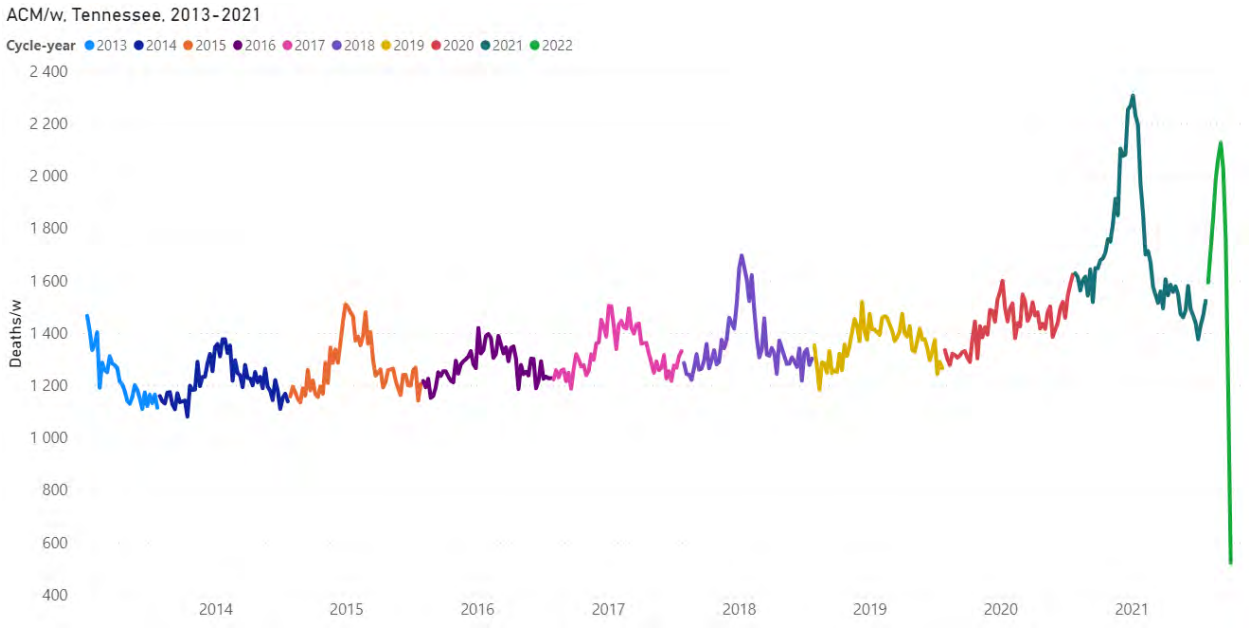
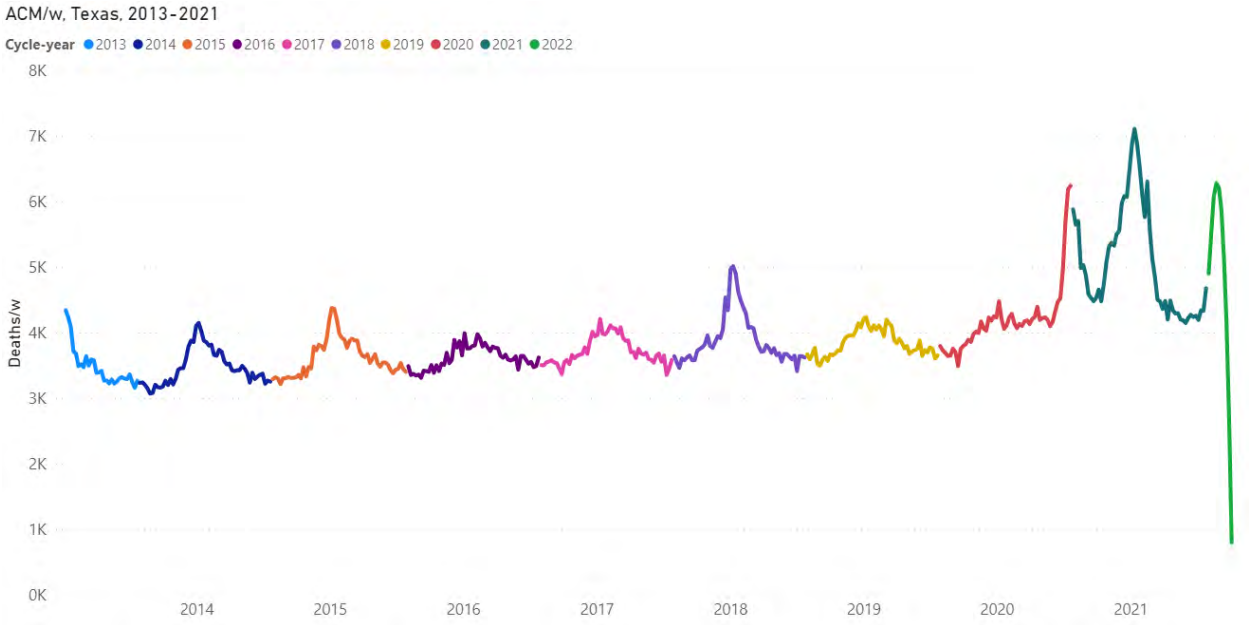
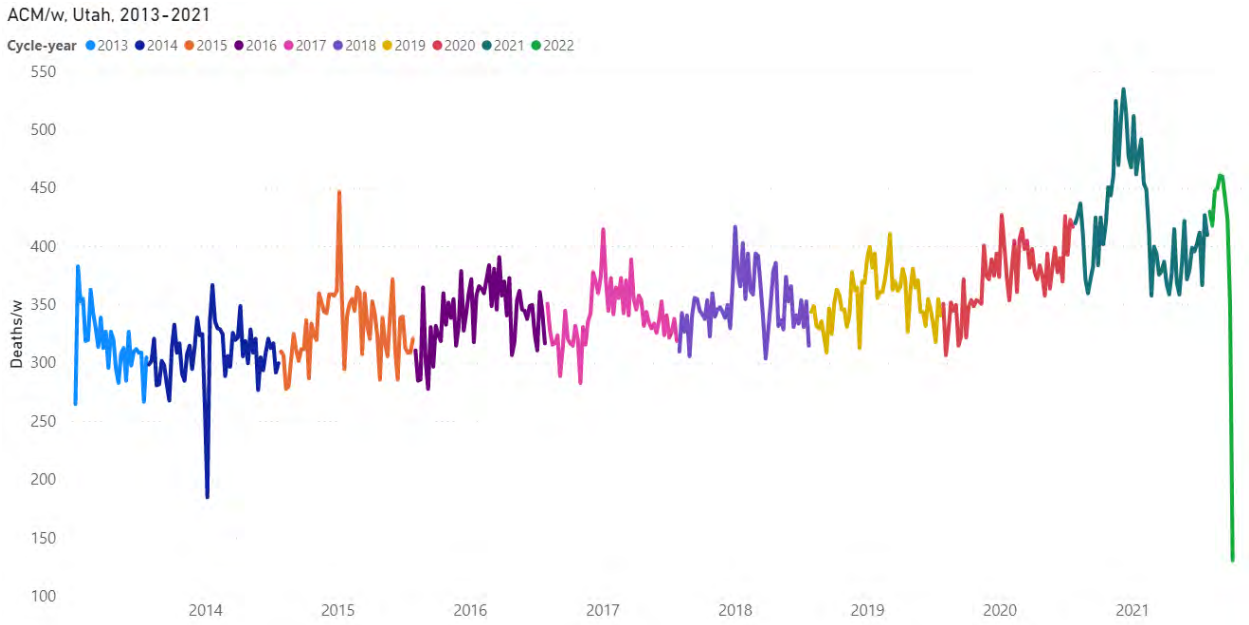




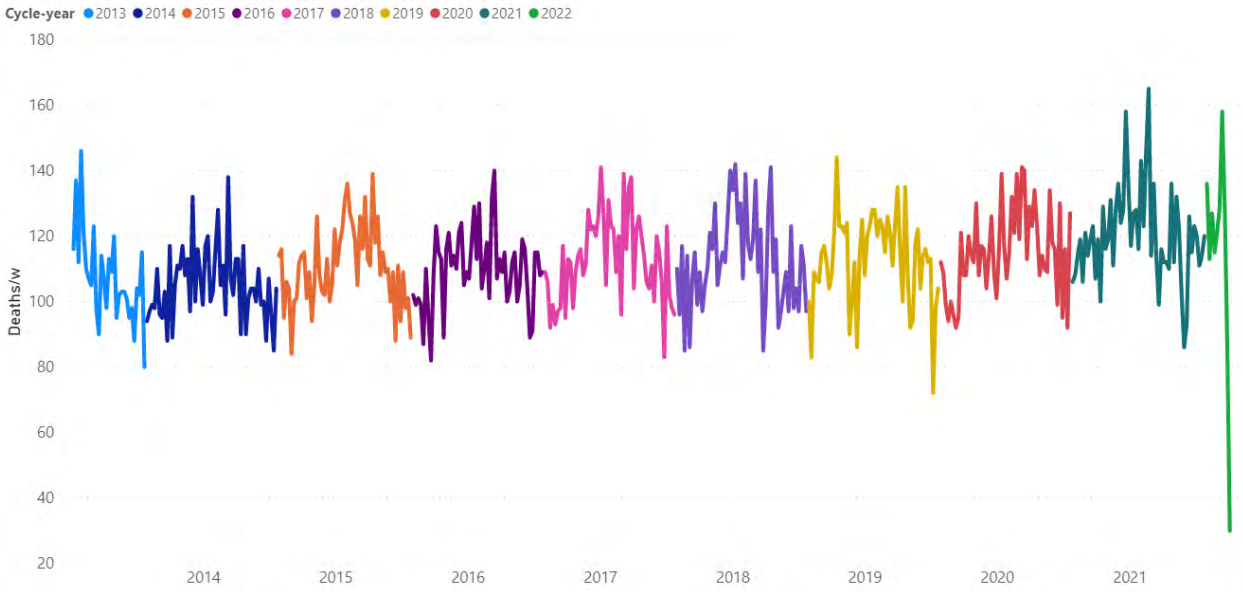
The last data point of South Dakota is week-39 of 2021.



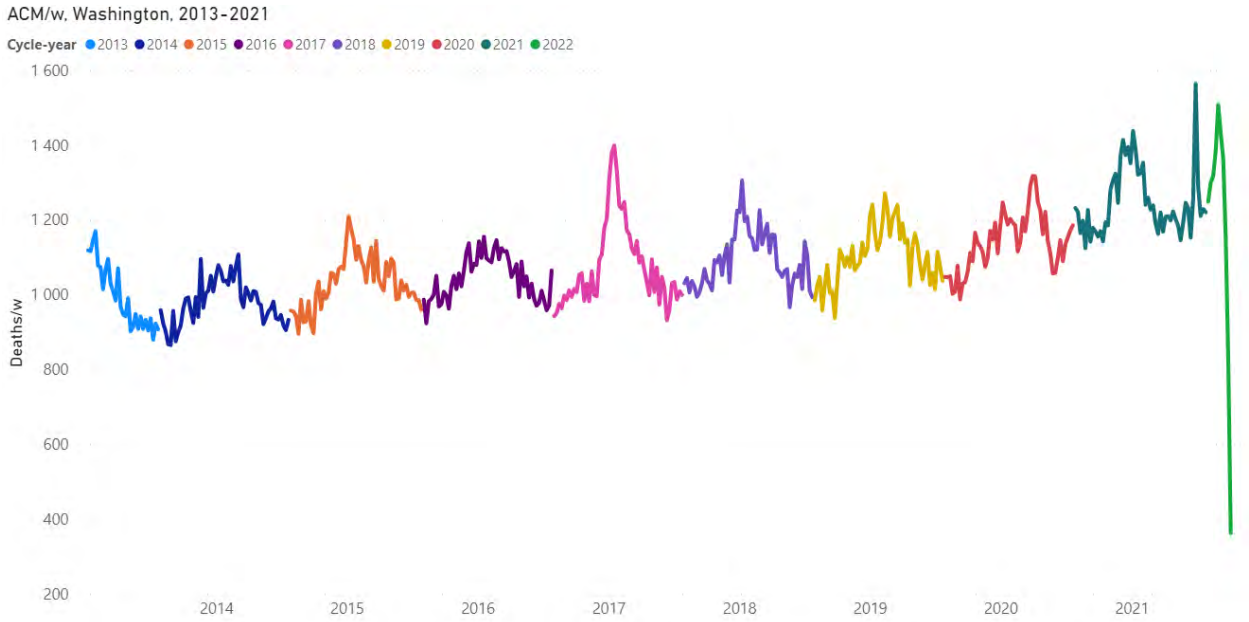

ACM/w, Texas, 2013-2021
Cycle-year 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
Deaths/w
8K
7K
6K
5K
4K
3K
2K
1K
0K
2014
2015
2016
2017
2018
2019
2020
2021

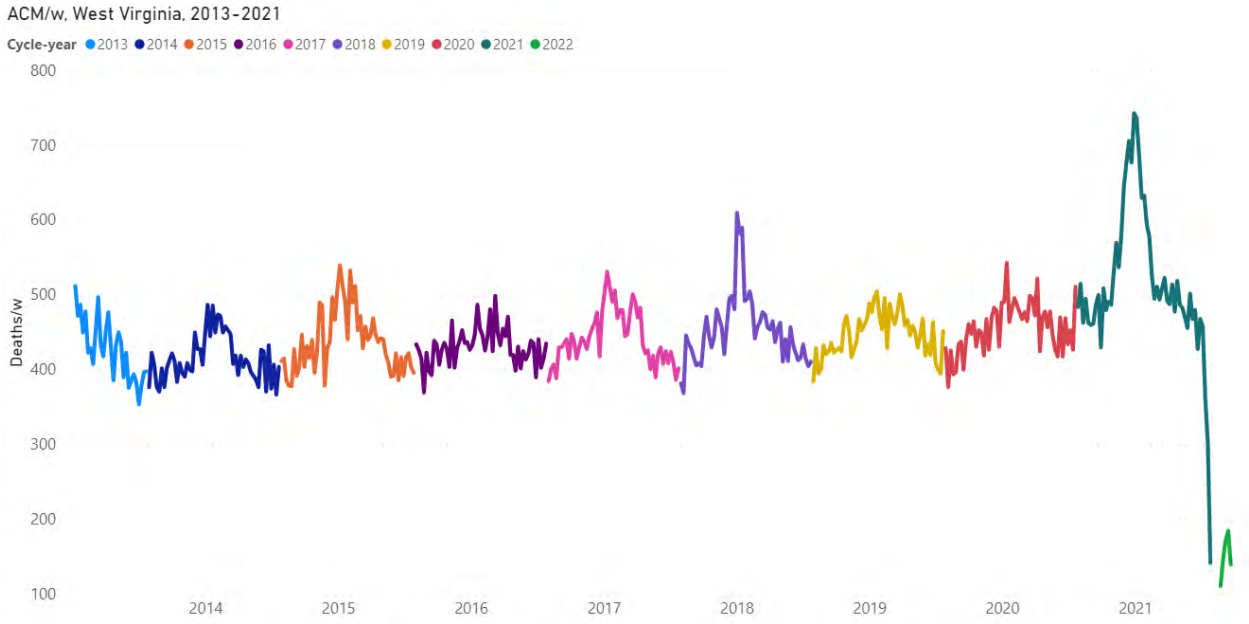

ACM/w, Utah, 2013-2021
Cycle-year 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
Deaths/w
550
500
450
400
350
300
250
200
150
100
2014
2015
2016
2017
2018
2019
2020
2021

ACM/w, Vermont, 2013-2021



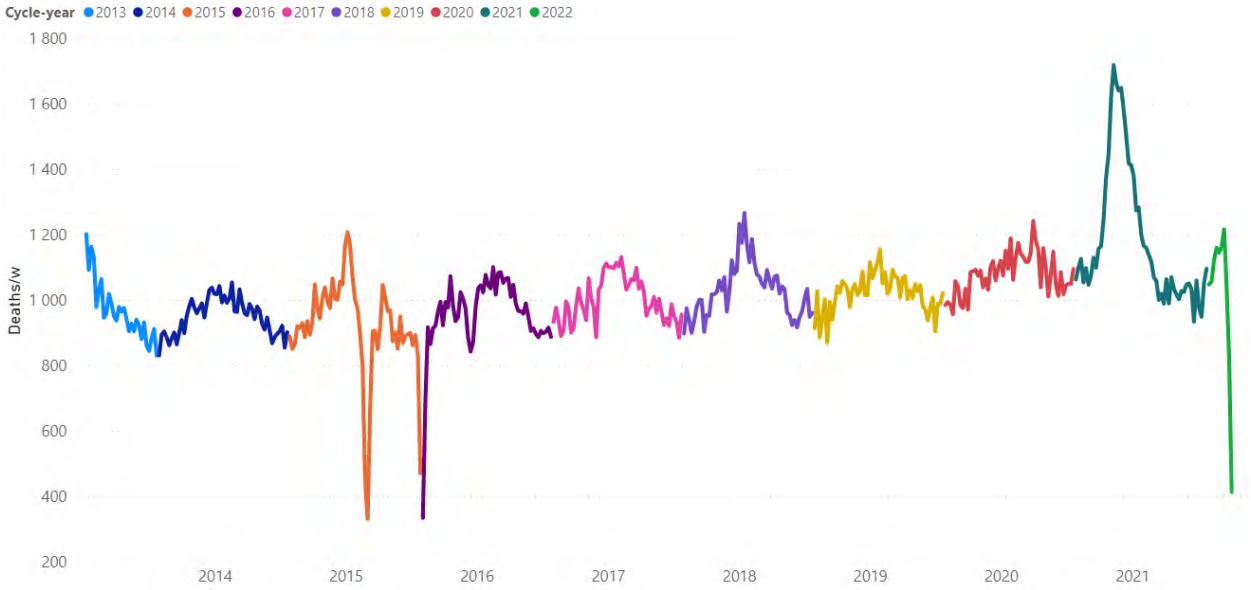
ACM/w, Virginia, 2013-2021



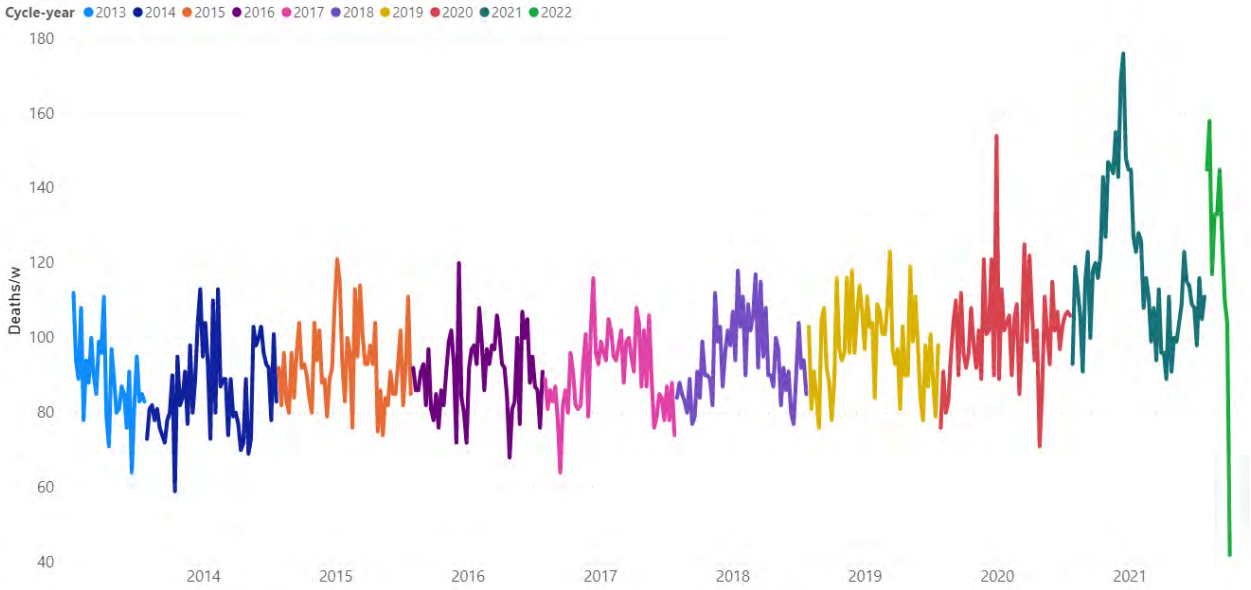


The last data point of West Virginia is week-38 of 2021.

ACM/w, Wisconsin, 2013-2021



ACM/w, Wyoming, 2013-2021



Tab 10

THE PFIZER INOCULATIONS FOR COVID-19

MORE HARM
THAN GOOD

Canadian Covid Care Alliance
Alliance canadienne pour la prévention
et prise-en-charge de la covid

Contact us
info@canadiancovidcarealliance.org
www.canadiancovidcarealliance.org

WHO WE ARE

Our alliance of **over 500 independent Canadian doctors, scientists, and health care practitioners** is committed to providing quality, balanced, evidence-based information to the Canadian public about COVID-19 so that hospitalizations can be reduced, lives saved, and our country safely restored to normal as quickly as possible.

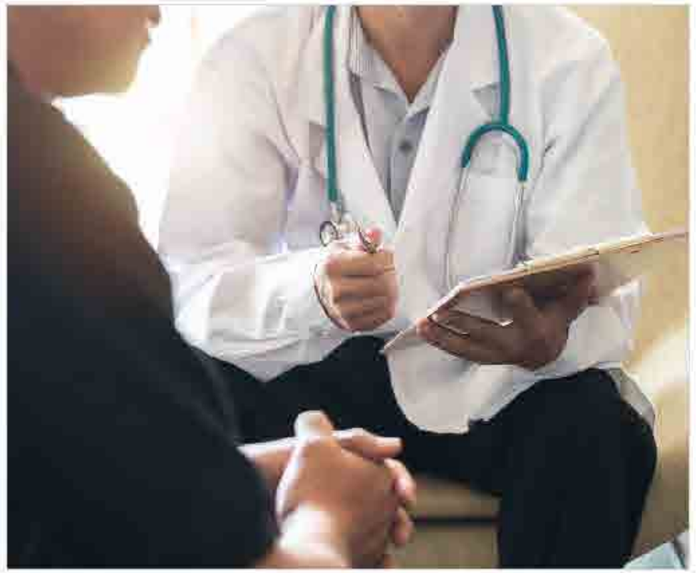
WE SUPPORT

The doctor/patient relationship and personalized care

Informed consent and treatment options

Free and open **scientific discourse**

Safe & effective vaccines



FIRST, DO NO HARM

The federal, provincial and municipal governments in Canada have a **responsibility to protect the health of Canadians as well as our Charter Rights and Freedoms. Any medical interventions approved by Health Canada must first be PROVEN SAFE.**

Due diligence in research, as well as **adherence to established protocols of the doctor/patient relationship, informed consent and scientific inquiry** are essential to carrying out that responsibility.

Deviating from those practices, causing harm and failing to disclose risks of harm is negligent at best.

OVERVIEW

Hierarchy of evidence

Pfizer's 2 month data report, Dec 31 2020

- ARR vs RRR explained - VIDEO
- Early unblinding of Pfizer's randomized control trial

Pfizer's 6 month data report, Sep 15 2021

- Increased risk of illness
- Increased risk of death

The Pfizer Trials - What went wrong

- Pfizer did not follow established protocols
- Misleading demographics - Wrong age
- Misleading demographics - Tested on healthy, given to sick
- Inadequate control groups
- Did not track biomarkers
- Wrong clinical endpoints
- Not tested for spread reduction
- Subjective testing
- Missing data - Lost to follow up and Suspected, but unconfirmed
- Failure to test - Why it matters
- 12 - 15 trial - All risk, no benefit
- 12 - 15 trial - Failure to report serious adverse events
- 5 - 11 year olds - Risking their health
- Myocarditis is serious
- The FDA abandons "First, do no harm"
- 5 - 11 year olds - No informed consent
- The BMJ Pfizer trial whistleblower article

A critical eye on the Sep 15 2020 report

- 6 month data manipulation - Mixed cohorts
- The Pfizer trials did not prove safety - they proved harm

How this is playing out in the real world

- Roll out surveillance - You don't find what you don't look for
- Rising incidents of heart issues in young people (Ontario Public Health Report)
- This is not normal - High incidences of deaths in athletes (German, Israeli news articles)
- This is supposed to be rare - VIDEO of athletes collapsing
- Pfizer's post marketing pharmacovigilance report

Considerable evidence of conflict of interest

- Pfizer is making billions
- The public record of Pfizer's corporate culture
- Links to articles on Pfizer's past behaviour
- Conflicts of interest among Pfizer report authors
- The CDC has redefined "vaccine"
- The media has been captured - VIDEO

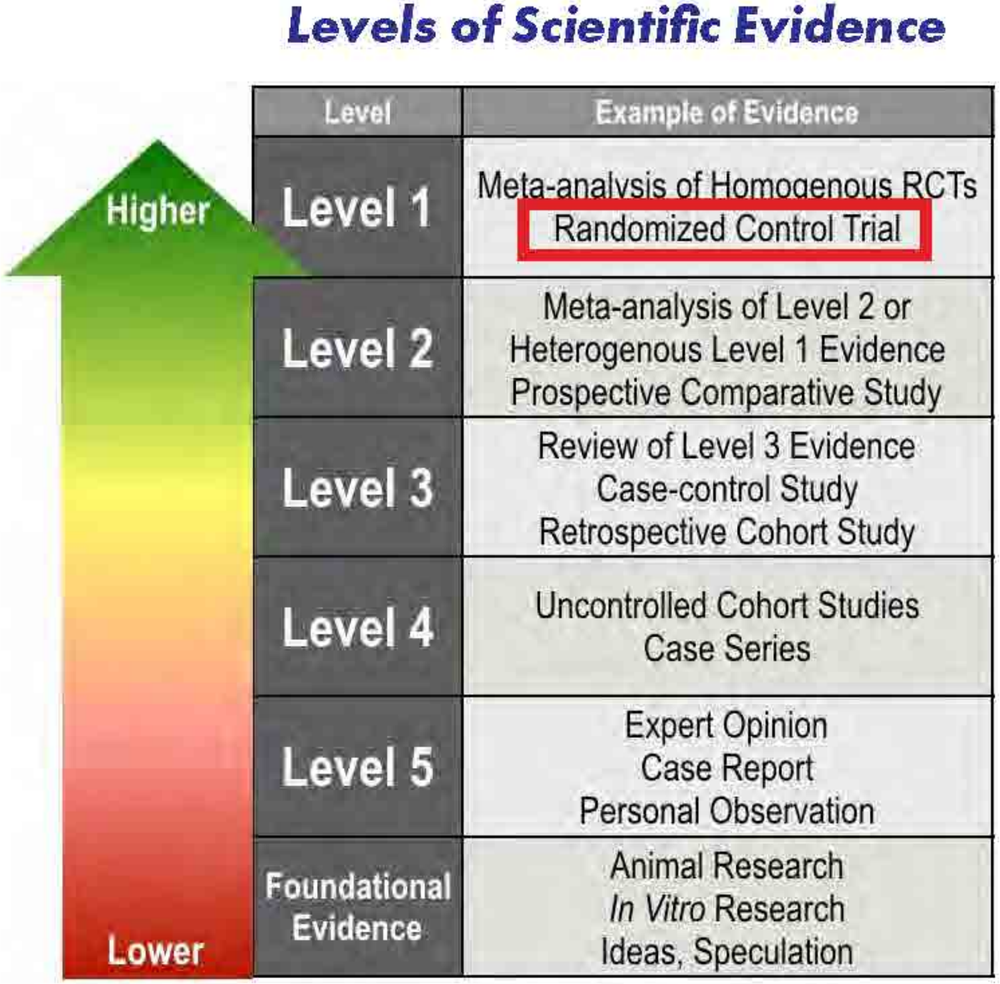
This is no way to manage a supplier

The inoculations should be withdrawn immediately

Recommended reading & viewing

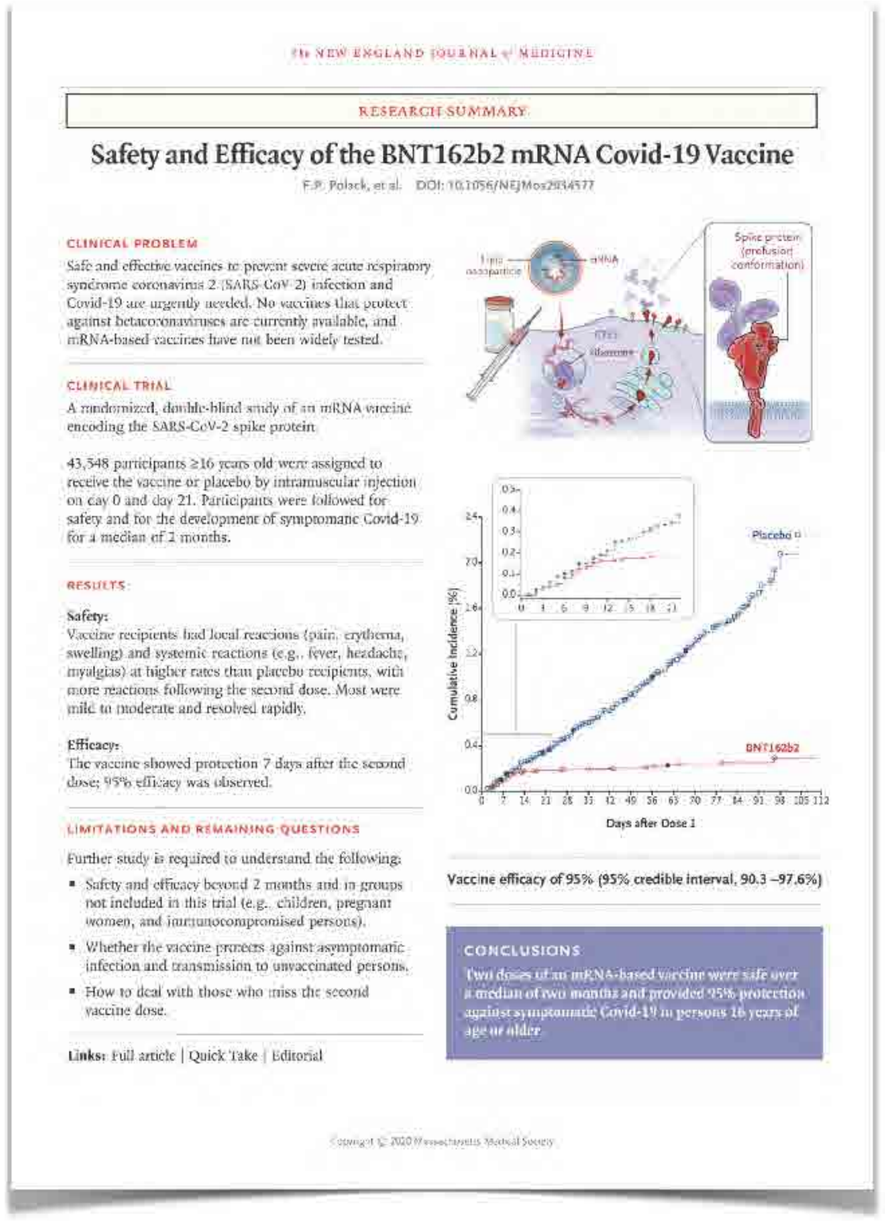
THE HIERARCHY OF EVIDENCE

- **A randomized control trial is LEVEL 1 Evidence**, the highest form of evidence there is. It is considered the Gold Standard and is the only way to prove something is true.
- **Models are LEVEL 5 or lower** as they are expert opinion/speculation.
- **Policy should be determined by the highest level of evidence available, LEVEL 1.**



PFIZER'S ORIGINAL TRIAL REPORT DECEMBER 31 2020

- Published in New England Journal of Medicine
- Showed **2 months worth of safety & efficacy data**
- Described starting with 43,548 people divided into:
  1. **Treatment group** (received inoculation)
  2. **Control group** (received saline)
  for 2 months to see who developed COVID-19
- The claim was that the inoculations were safe and showed **95% efficacy 7 days after the 2nd dose**. But that 95% was actually **Relative Risk Reduction. Absolute Risk Reduction** was only **0.84%.**



THE NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

CLINICAL PROBLEM

Safe and effective vaccines to prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and Covid-19 are urgently needed. No vaccines that protect against betacoronaviruses are currently available, and mRNA-based vaccines have not been widely tested.

CLINICAL TRIAL

A randomized, double-blind study of an mRNA vaccine encoding the SARS-CoV-2 spike protein

43,548 participants ≥16 years old were assigned to receive the vaccine or placebo by intramuscular injection on day 0 and day 21. Participants were followed for safety and for the development of symptomatic Covid-19 for a median of 2 months.

RESULTS

Safety:
Vaccine recipients had local reactions (pain, erythema, swelling) and systemic reactions (e.g., fever, headache, myalgias) at higher rates than placebo recipients, with more reactions following the second dose. Most were mild to moderate and resolved rapidly.

Efficacy:
The vaccine showed protection 7 days after the second dose; 95% efficacy was observed.

LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy beyond 2 months and in groups not included in this trial (e.g., children, pregnant women, and immunocompromised persons).
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to deal with those who miss the second vaccine dose.

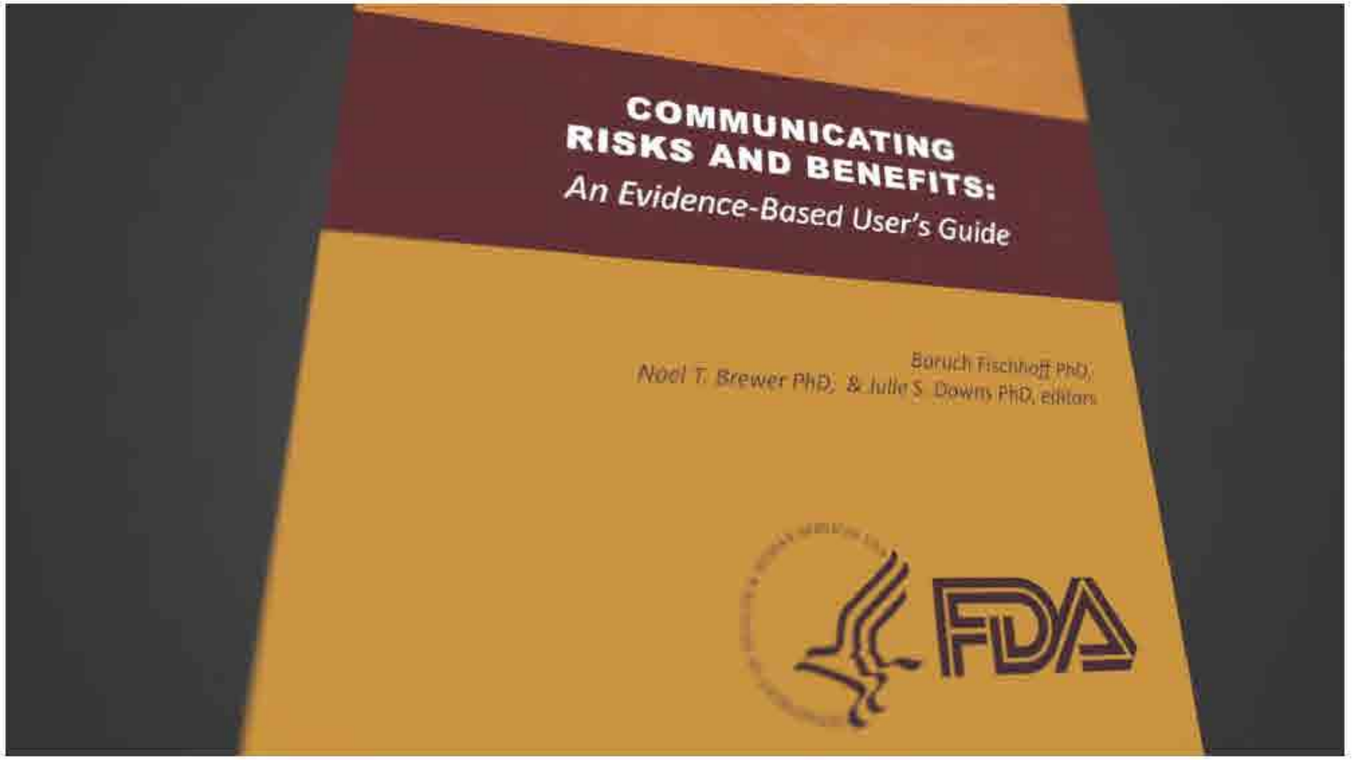
Links: Full article | Quick Take | Editorial

Vaccine efficacy of 95% (95% credible interval, 90.3 –97.6%)

CONCLUSIONS

Two doses of an mRNA-based vaccine were safe over a median of two months and provided 95% protection against symptomatic Covid-19 in persons 16 years of age or older.

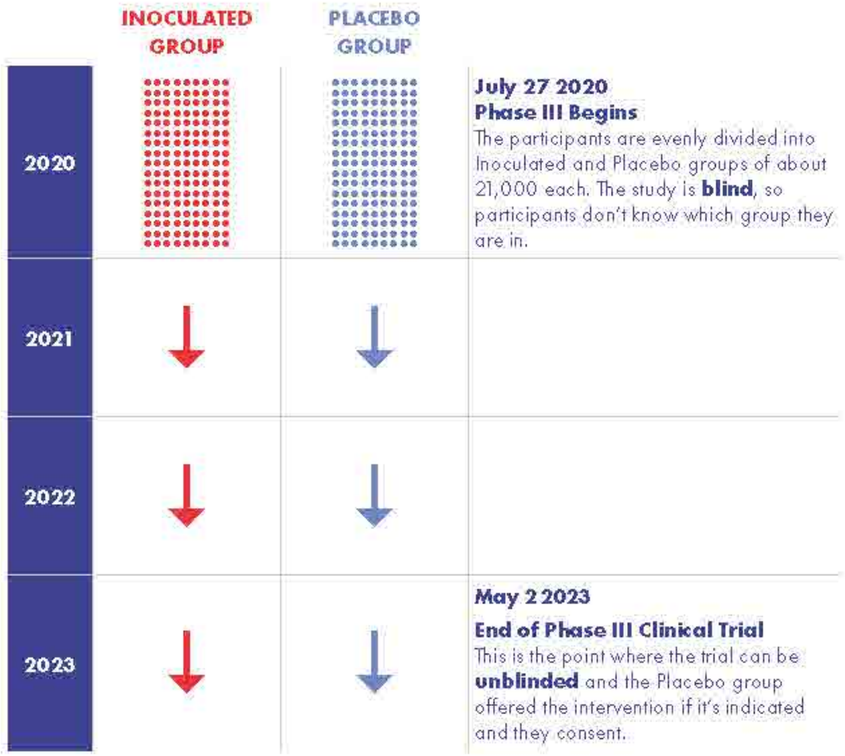
ABSOLUTE RISK REDUCTION VS RELATIVE RISK REDUCTION



https://rumble.com/vobcg5-relative-vs-absolute-risk-reduction.html

EARLY UNBLINDING OF RANDOMIZED CONTROL TRIAL = NO LONG TERM SAFETY DATA

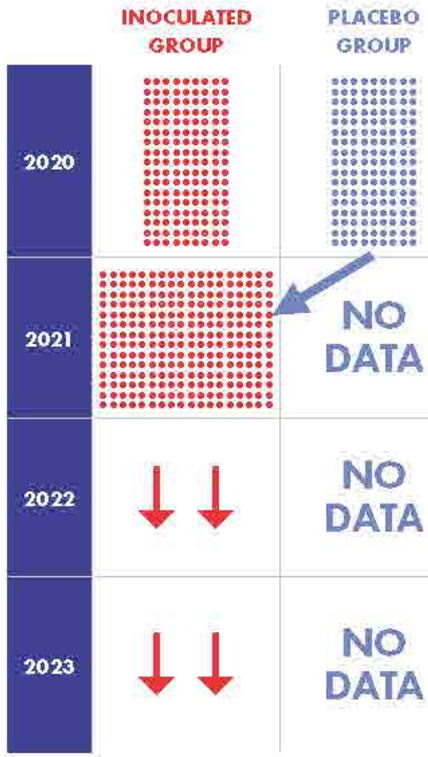
WHAT WAS SUPPOSED TO HAPPEN



July 27 2020
Phase III Begins
The participants are evenly divided into Inoculated and Placebo groups of about 21,000 each. The study is **blind**, so participants don't know which group they are in.

May 2 2023
End of Phase III Clinical Trial
This is the point where the trial can be **unblinded** and the Placebo group offered the intervention if it's indicated and they consent.

WHAT ACTUALLY HAPPENED



July 27 2020
Phase III Begins
The participants are evenly divided into Inoculated and Placebo groups of about 21,000 each. The study is **blind.**

Dec 31 2020
Release 2 month data report. The trial is unblinded early.

Crossover Occurs
The participants from the **Placebo Group** are given the opportunity to take the inoculation and by early 2021, the majority of them have crossed over to the inoculated group. **It's no longer a randomized control trial, as control group is gone.**

May 2 2023
End of Phase III Clinical Trial
The long term safety data that was supposed to be assessed at this point is **no longer possible to ascertain as the placebo group crossed over two years previously.**

PFIZER'S 6 MONTH REPORT DATA
LEVEL 1 EVIDENCE OF HARM

- Pfizer's most recent report indicates an **Efficacy of 91.3%**. (Which means **a reduction in positive cases** compared to placebo group.)
- **But it also showed**, compared to the placebo group, **an increase in illness and deaths.**
- There is **no benefit to a reduction in cases** if it comes at the cost of **increased sickness and death.**

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

S.J. Thomas, E.D. Moreira, Jr., N. Kitchin, J. Absalon, A. Gurtman, S. Lockhart, J.L. Perez, G. Pérez Marc, F.P. Polack, C. Zeldis, R. Bailey, K.A. Swanson, X. Xu, S. Roychoudhury, K. Koury, S. Bouguermouh, W.V. Kalina, D. Cooper, R.W. Frenck, Jr., L.L. Hammitt, Ö. Türeci, H. Nell, A. Schaefer, S. Ünal, Q. Yang, P. Liberator, D.B. Tresnan, S. Mather, P.R. Dormitzer, U. Şahin, W.C. Gruber, and K.U. Jansen, for the C4591001 Clinical Trial Group*

ABSTRACT

BACKGROUND

BNT162b2 is a lipid nanoparticle–formulated, nucleoside-modified RNA vaccine encoding a prefusion-stabilized, membrane-anchored severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) full-length spike protein. BNT162b2 is highly efficacious against coronavirus disease 2019 (Covid-19) and is currently approved, conditionally approved, or authorized for emergency use worldwide. At the time of initial authorization, data beyond 2 months after vaccination were unavailable.

METHODS

In an ongoing, placebo-controlled, observer-blinded, multinational, pivotal efficacy trial, we randomly assigned 44,165 participants 16 years of age or older and 2264 participants 12 to 15 years of age to receive two 30-μg doses, at 21 days apart, of BNT162b2 or placebo. The trial end points were vaccine efficacy against laboratory-confirmed Covid-19 and safety, which were both evaluated through 6 months after vaccination.

RESULTS

BNT162b2 continued to be safe and have an acceptable adverse-event profile. Few participants had adverse events leading to withdrawal from the trial. Vaccine efficacy against Covid-19 was 91.3% (95% confidence interval [CI], 89.0 to 93.2) through 6 months of follow-up among the participants without evidence of previous SARS-CoV-2 infection who could be evaluated. There was a gradual decline in vaccine efficacy. Vaccine efficacy of 86 to 100% was seen across countries and in populations with diverse ages, sexes, race or ethnic groups, and risk factors for Covid-19 among participants without evidence of previous infection with SARS-CoV-2. Vaccine efficacy against severe disease was 96.7% (95% CI, 80.3 to 99.9). In South Africa, where the SARS-CoV-2 variant of concern B.1.351 (or beta) was predominant, a vaccine efficacy of 100% (95% CI, 53.5 to 100) was observed.

CONCLUSIONS

Through 6 months of follow-up and despite a gradual decline in vaccine efficacy, BNT162b2 had a favorable safety profile and was highly efficacious in preventing Covid-19. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Dormitzer can be contacted at philip.dormitzer@pfizer.com or at Pfizer, 401 N. Middletown Rd., Pearl River, NY 10965.

*A list of the investigators in the C4591001 Clinical Trial Group is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on September 15, 2021, at NEJM.org.

N Engl J Med 2021;385:1761-1773.
DOI: 10.1056/NEJMoa2110345

CME at NEJM.org

https://www.nejm.org/doi/pdf/10.1056/NEJMoa2110345?articleTools=true

INCREASED RISK OF ILLNESS

Screen capture from Pfizer 6 Month Supplementary Appendix

Adverse Event	BNT162b2 (N[a]=21,926) n[b] (%)	Placebo (N[a]=21,921) n[b] (%)
Any event	6617 (30.2)	3048 (13.9)
Related[c]	5241 (23.9)	1311 (6.0)
Severe	262 (1.2)	150 (0.7)
Life-threatening	21 (0.1)	26 (0.1)
Any serious adverse event	127 (0.6)	116 (0.5)
Related[c,d]	3 (0.0)	0
Severe	71 (0.3)	66 (0.3)
Life-threatening	21 (0.1)	26 (0.1)
Any adverse event leading to withdrawal	32 (0.1)	36 (0.2)
Related[c]	13 (0.1)	11 (0.1)
Severe	10 (0.0)	10 (0.0)
Life-threatening	3 (0.0)	7 (0.0)
Death	3 (0.0)	5 (0.0)

Table S3 | Participants Reporting at Least 1 Adverse Event from Dose 1 to 1 Month After Dose 2 During the Blinded Follow-up Period. The population included all ≥16-year-old participants who received ≥1 dose of vaccine irrespective of follow-up time. a. N=number of participants in the specified group. This value is the denominator for the percentage calculations. b. n=Number of participants reporting ≥1 occurrence of the specified event category. For 'any event', n=number of participants reporting ≥1 occurrence of any event. c. Assessed by the investigator as related to investigational product. d. Shoulder injury related to vaccine administration, right axillary lymphadenopathy, and paroxysmal ventricular arrhythmia (as previously reported). Adverse events for 12–15-year-old participants were reported previously.[11]

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months - Supplementary Appendix

*A **significant increase in illness,** which the Pfizer inoculations were supposed to reduce.*

	BNT162b2	Placebo	Risk Change
Efficacy (Meaning number of people diagnosed with COVID-19.)	77	850	**-91%**
Related Adverse Event (Meaning an investigator has assessed it as related to the BNT162b2 injection.)	5,241	1,311	**+300%**
Any Severe Adverse Event (Interferes significantly with normal function.)	262	150	**+75%**
Any Serious Adverse Event (Involves visit to ER or hospitalization.)	127	116	**+10%**

INCREASED RISK OF DEATH

Screen capture from Pfizer 6 Month Supplementary Appendix

Reported Cause of Death*	BNT162b2 (N=21,926) n	Placebo (N=21,921) n
Deaths	15	14
Acute respiratory failure	0	1
Aortic rupture	0	1
Arteriosclerosis	2	0
Biliary cancer metastatic	0	1
COVID-19	0	2
COVID-19 pneumonia	1	0
Cardiac arrest	4	1
Cardiac failure congestive	1	0
Cardiorespiratory arrest	1	1
Chronic obstructive pulmonary disease	1	0
Death	0	1
Dementia	0	1
Emphysematous cholecystitis	1	0
Hemorrhagic stroke	0	1
Hypertensive heart disease	1	0
Lung cancer metastatic	1	0
Metastases to liver	0	1
Missing	0	1
Multiple organ dysfunction syndrome	0	2
Myocardial infarction	0	2
Overdose	0	1
Pneumonia	0	2
Sepsis	1	0
Septic shock	1	0
Shigella sepsis	1	0
Unevaluable event	1	0

Table S4 | Causes of Death from Dose 1 to Unblinding (Safety Population, ≥16 Years Old). a. Multiple causes of death could be reported for each participant. There were no deaths among 12–15-year-old participants.

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months - Supplementary Appendix

	BNT162b2	Placebo
Deaths before unblinding (In Table S4 of Supplementary Appendix)	15	14
Deaths after unblinding (Not in table, but mentioned in text of 6 month report. See quote below.)	5	
Total Deaths	20	14

"After unblinding" means when the Placebo participants were given the opportunity to "cross over" and take the BNT162b2 inoculation.*

"...3 participants in the BNT162b2 group and 2 in the original placebo group who received BNT162b2 after unblinding died."

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

Concerning Causes of Death

	BNT162b2	Placebo
Total COVID-19 Related Deaths	1	2
Deaths Related to Cardiovascular Events	9	5

*A total of 19,525 subjects originally randomized to placebo received at least one dose of BNT162b2 after unblinding (Dose 3 and Dose 4) and before the March 13, 2021 data cutoff

THE PFIZER TRIALS

WHAT WENT WRONG

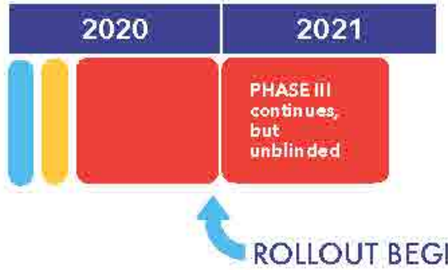
PFIZER DID NOT FOLLOW ESTABLISHED PROTOCOLS

Regarding the persistent claim that the COVID-19 inoculation products do not need to be tested, because mRNA technology has already undergone testing: mRNA technology is the delivery mechanism, not the inoculation. That's like saying that since we've used syringes safely before, anything injected via syringe is safe. (And in fact, there are still a lot of unknowns about the effects of the mRNA delivery mechanism.)

NORMALLY, VACCINE DEVELOPMENT LOOKS LIKE THIS, WITH A TIMELINE OF 5 TO 10 YEARS.

RARELY, IT CAN BE DONE IN AS LITTLE AS 5 YEARS.

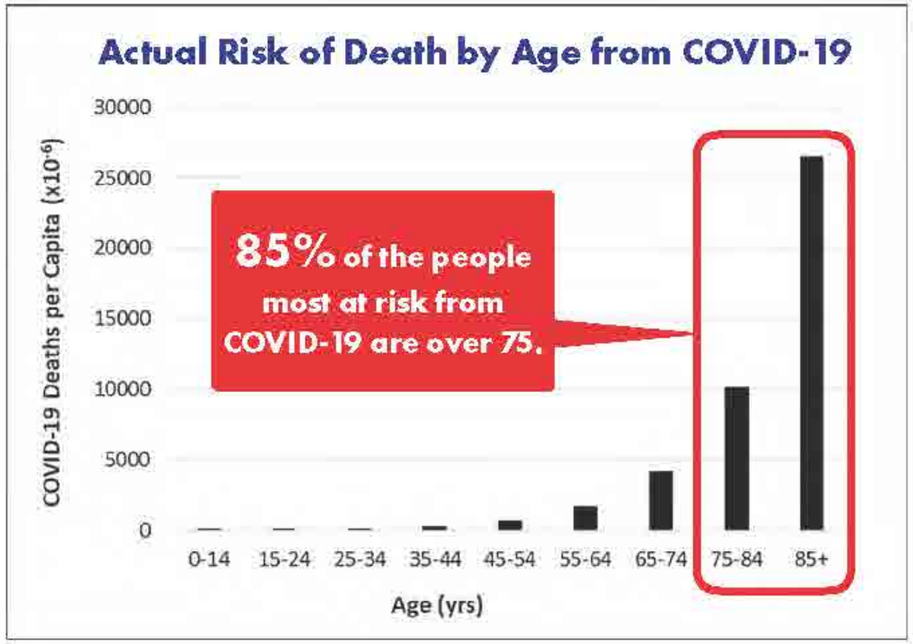
FOR THE COVID-19 INOCULATIONS, IT WAS DONE IN 1 YEAR.



- Animal testing was skipped
- Phases II/III were combined
- After 2 months of Phase II/III, Emergency Use Authorized
- The trials were unblinded
- Phase III trials are ongoing until 2023

MISLEADING DEMOGRAPHICS
WRONG AGE FOR TARGET POPULATION

When designing a trial for the efficacy and safety of a potential treatment, **the focus should be on the target population who could most benefit from that treatment.** Instead Pfizer chose participants from younger demographic that would be a) less likely to need a vaccine, b) less likely to suffer an adverse event during a trial, c) more likely to respond well to a vaccine, as the elderly have comparatively poor immune responses.



COVID-19 Deaths per capita by age in the United States (as of Jun 5, 2021). Population-based on U.S. CDC WONDER Bridge-Race Population Estimate 2019. Data obtained from https://wonder.cdc.gov/bridged-race-v2019.html

Pfizer Trial Demographics

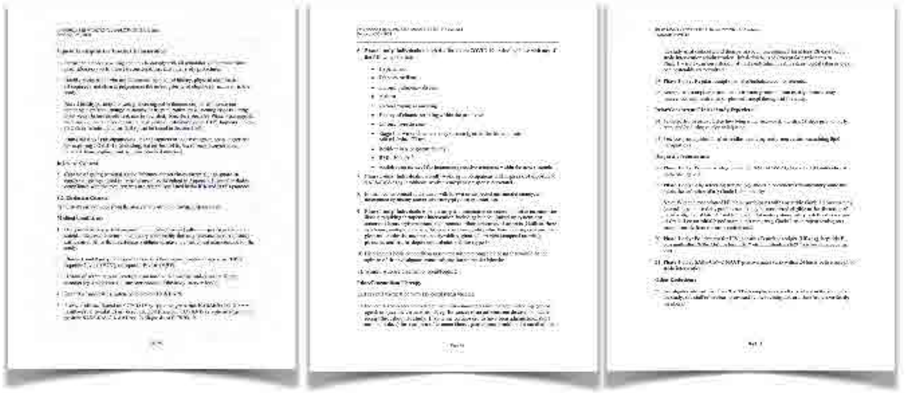
Demographics (population for the primary efficacy endpoint). The number of participants who received vaccine and placebo, stratified by age.

AGE GROUP	Pfizer-BioNTech COVID-19 Vaccine (N = 18,242) n (%)	Placebo (N = 18,379) n (%)
≥12 through 15 years[b]	46 (0.3 %)	42 (0.2 %)
≥16 through 17 years	66 (0.4 %)	68 (0.4 %)
≥16 through 64 years	14,216 (77.9 %)	14,299 (77.8 %)
≥65 through 74 years	3176 (17.4 %)	3226 (17.6 %)
≥75 years	804 (4.4 %)	812 (4.4 %)

Yet 75+ year olds represent only 4% of trial subjects.

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)
https://labeling.pfizer.com/ShowLabeling.aspx?id=14471

MISLEADING DEMOGRAPHICS
TESTED ON HEALTHY, GIVEN TO SICK



Pfizer Trial Protocols - Exclusions

REAL WORLD CO-MORBIDITIES

95% of people who have died with COVID-19 have had **at least 1 co-morbidity** listed as cause of death. The **average is 4 co-morbidities**.

https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm?fbclid=IwAR3-vmg3ffKK5-9tOHPGAHWFVO3DfslkJ0KsDEPQpWmPbKtp6EsoYY2Qs1Q#Comorbidities

PFIZER TRIAL CO-CONDITIONS

Only **21% had a co-existing condition.**

https://www.nejm.org/doi/pdf/10.1056/NEJMoa2034577?articleTools=true

IMPLICATIONS FOR ROLL OUT

- We are told the inoculations are "safe." Yet **many health conditions** - in fact a list several pages long - **were excluded from the trials**, including pregnant or breastfeeding women, people with allergies, with psychiatric conditions, immunocompromised people, people with bleeding disorders, people who had previously tested positive for COVID-19, people who had been prescribed steroids, etc., so there has never been any data to make safety claims about those people. Yet **they are also not excluded from mandates and vaccine passports.**
- The vaccines were **tested on the healthy**, and then immediately **given to the frailest members of the society** - the elderly with multiple health conditions. This is unscientific and unethical.

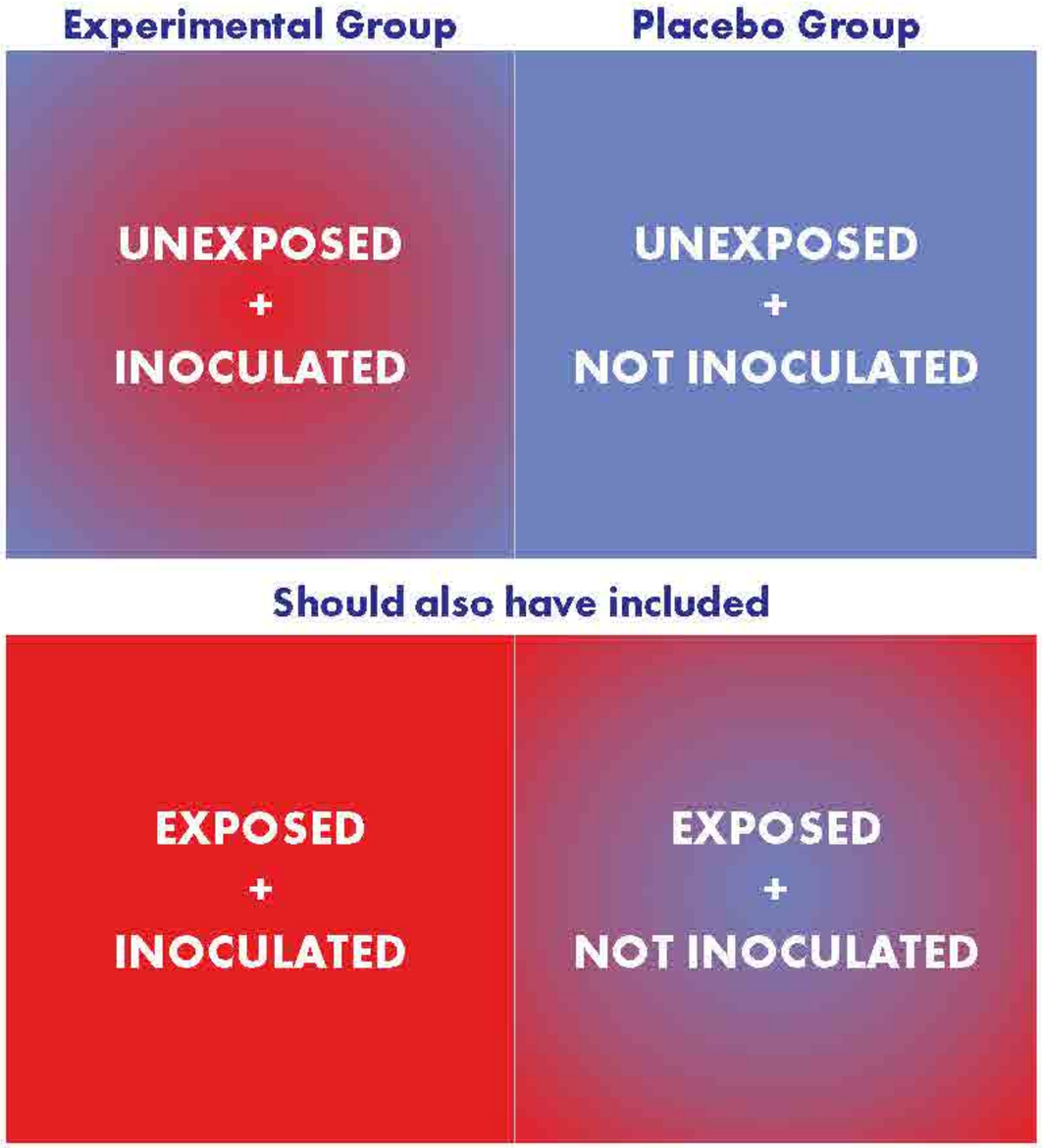
INADEQUATE CONTROL GROUPS

Pfizer only observed 2 groups:

- **UNEXPOSED** & **INOCULATED**
- **UNEXPOSED** & **NOT INOCULATED**

They should have included two more groups:

- **EXPOSED** & **INOCULATED**, people who had recovered, then got the inoculation, to see if the inoculation was safe for them
- **EXPOSED** & **NOT INOCULATED** people who were recovered and not inoculated to see how the inoculations stacked up against natural immunity



LOW QUALITY SAFETY SCIENCE DIDN'T TRACK BIOMARKERS

As Kostoff *et al.* highlighted in a recent paper, "Why are we vaccinating children against COVID-19?" (highly recommended), that while the Pfizer trials tested for antibodies and tracked adverse events in terms of symptoms, **they didn't test for adverse events at the subclinical (pre-symptom) level.**

This was extremely unsafe, because **symptoms/ diseases are typically end points of processes** that can take months, years, or decades to surface. By the time you get to symptoms, things can have gone pretty wrong. (Think diabetes or high blood pressure, where the disease can be quite advanced before any symptoms occur.) **Pfizer should have been tracking biomarkers that would have been early warning indicators for disease caused by the inoculations.**

High quality safety science would have meant they should have tested before & after inoculation for:

- d-dimers for evidence of enhanced **coagulation/ clotting** *(several of our doctors have noticed increased levels of d-dimers in inoculated patients presenting with stroke like symptoms - video available here)*
- C-reactive protein for evidence of enhanced **inflammation**
- troponins for evidence of **cardiac damage**
- occludin and claudin for evidence of enhanced **barrier permeability**
- blood oxygen levels for evidence of enhanced **hypoxia**
- amyloid-beta and phosphorylated tau for evidence of increased **predisposition to Alzheimer's** disease
- Serum HMGB1, CXCL13, Dickkopf-1 for evidence of an **increased disposition to autoimmune disease**, etc.

WRONG CLINICAL ENDPOINTS
SHOULD HAVE FOCUSED ON ALL CAUSE MORTALITY & ILLNESS

The fear with COVID-19, was that it was going to **a) kill people, b) make them sick.**

So any COVID-19 vaccine clinical trial should set out to ask the question **"Do people who take the vaccines have less illness and death than those who don't?"**

Illness + Death should be the CLINICAL ENDPOINTS. And not just illness + death with COVID-19, but **any and all illness and death,** in order to make sure that the vaccines are not causing harm.

This is well known. It was learned decades ago with cancer drug trials. At first, they used a clinical endpoint of "Did the drug shrink the cancer?" If it did, they called it effective. **But it turned out the drugs were not only killing cancer, they were killing patients.** They were forced to change the design of their trials and switch to "all cause mortality" as the primary endpoint instead and show that people receiving the drug actually live longer than those who don't. (J. Bart Classen has written an excellent research article on the subject. Read **here**.)

WHAT SHOULD HAVE HAPPENED

(After the proper early safety phases of development were completed.)

"Do people who take the vaccines have **less illness and death** than those who don't?"

- **YES**. Proceed to long terms safety studies.
- **NO**. Go back to the drawing board.

WHAT ACTUALLY HAPPENED

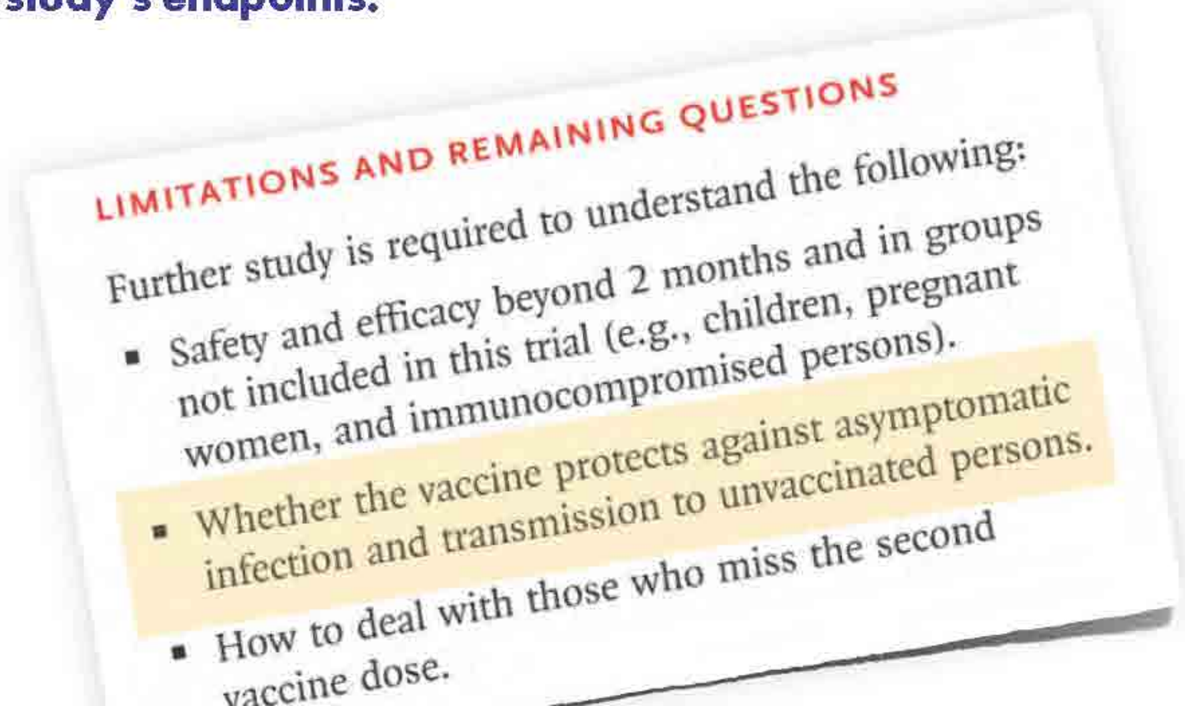
(Without the proper early safety phases of development having been completed.)

"Do people who take the vaccines **test positive for COVID-19 less often**?"

- **YES**. Proceed to world wide roll out.
- **NO**. (The trial set up made this result unlikely).

NOT TESTED FOR SPREAD REDUCTION
VACCINE PASSPORTS UNJUSTIFIED

Although vaccine passports are now being used to ostensibly prevent or reduce transmission of COVID-19, this outcome was never studied in the trial and it is inappropriate to assign that capability to these inoculations. **There is no evidence at all that they reduce the spread of disease and transmission was never one of the study's endpoints.**



LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy beyond 2 months and in groups not included in this trial (e.g., children, pregnant women, and immunocompromised persons).
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to deal with those who miss the second vaccine dose.

TESTING FAILURES
SUBJECTIVE TESTING

The Pfizer trials DID NOT test all participants for COVID-19. Instead, they instructed their investigators to test only those with a COVID-19 symptom and **left it up to their discretion** to decide what those were.

This means that:

- **Asymptomatic infection would be missed entirely**
- A high level of **subjectivity was introduced to the study - an investigator had the ability to sway the results**
- The lack of objective systematic testing **makes results unreliable**

All participants should have been tested.

MISSING DATA

- LOST TO FOLLOW UP
- SUSPECTED, BUT UNCONFIRMED

	INOCULATED GROUP	PLACEBO GROUP
ENDPOINT DATA - Confirmed COVID Cases	8	162
Participants Lost to Follow Up	80	86
Suspected, but Unconfirmed Cases	1,594	1,816

The basis for the Emergency Use Authorization was the Confirmed COVID cases of 8 vs 162, which meant a Relative Risk Reduction of 95%. But **when dealing with such a small number of cases, any change can impact the results significantly.**

Lost to follow up means **they lost touch with those subjects** and can't confirm whether they got sick or not. They don't know.

Suspected, but unconfirmed means these people were **symptomatic for COVID-19,** but were **never tested**. (Discretion for testing was left up to the investigator.)

The fact that the Lost to Follow Up and Suspected but Unconfirmed numbers are higher - and here they are even significantly higher - than the End Point numbers means that **this data is unreliable. The study should not have been accepted in this state.** In normal scientific practice they should have returned to investigate further.

Confirmed Cases

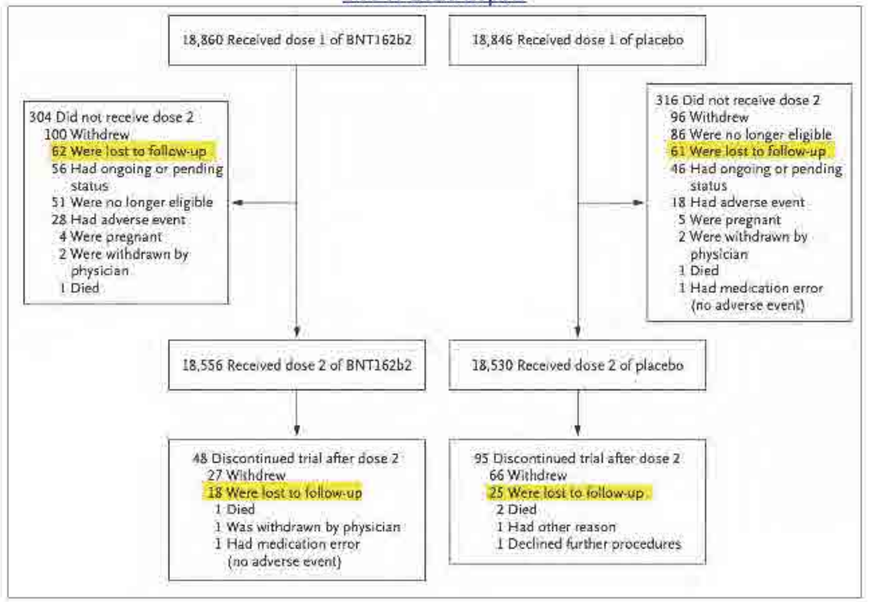
Dec 31 2020 Report

Table 3. Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection before 7 Days after Dose 2.

Efficacy End-Point Subgroup	BNT162b2 (N=18,198)		Placebo (N=18,325)		Vaccine Efficacy, % (95% CI)†
	No. of Cases	Surveillance Time (No. at Risk)*	No. of Cases	Surveillance Time (No. at Risk)*	
Overall	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.0–97.9)

Lost to Follow Up

Dec 31 2020 Report



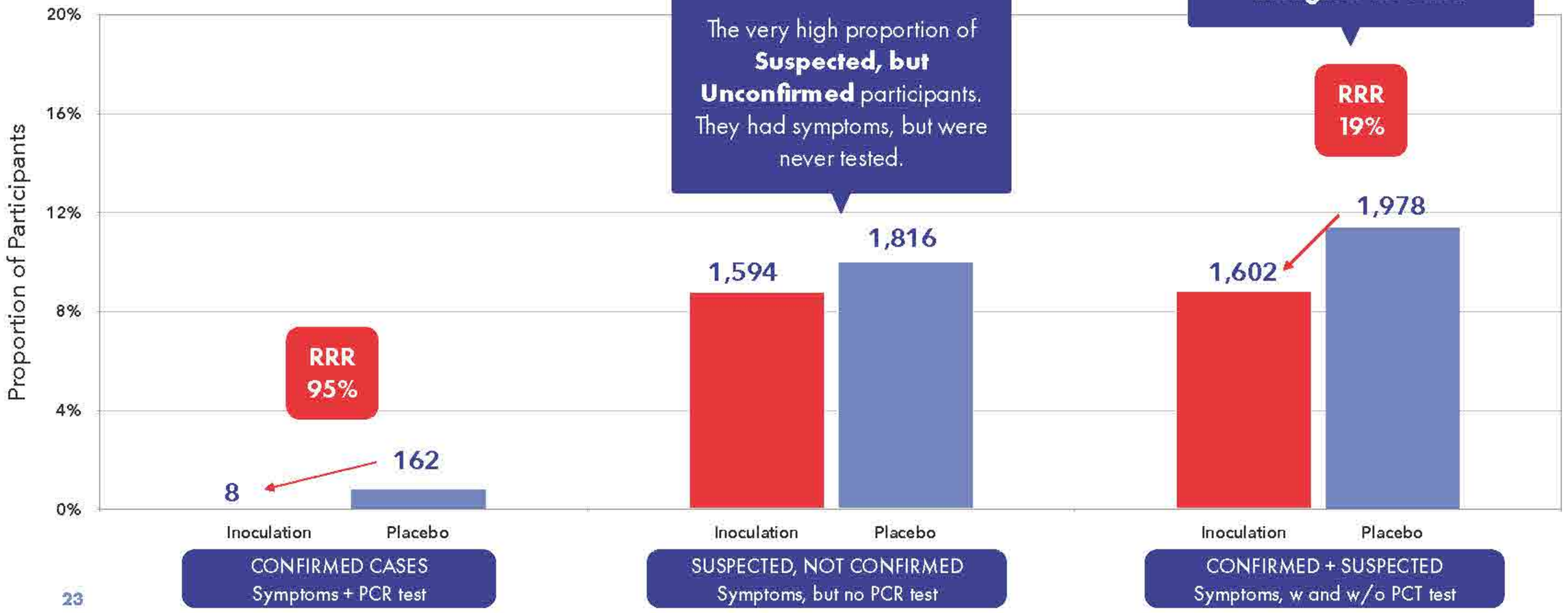
Suspected but Unconfirmed

Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020

FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine

Among 3410 total cases of suspected but unconfirmed COVID-19 in the overall study population, 1594 occurred in the vaccine group vs. 1816 in the placebo group. Suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. 287 in the placebo group. It is possible that the imbalance in suspected COVID-19 cases occurring in the 7 days postvaccination represents vaccine reactogenicity with symptoms that overlap with those of COVID-19. Overall though, these data do not raise a concern that protocol-specified reporting of suspected, but unconfirmed COVID-19 cases could have masked clinically significant adverse events that would not have otherwise been detected.

FAILURE TO TEST
WHY IT MATTERS



12-15 ADOLESCENT TRIAL
ALL RISK, NO BENEFIT

- This study was severely underpowered, as **a study this small will not show up risk**.
  - Inoculated group - **1,005** (**0** tested positive for COVID-19)
  - Placebo group - **978** (**18** tested positive for COVID-19)

- Pfizer claimed these were great results, but since adolescents are at statistically 0% risk of death from COVID-19, and very low risk of severe illness, **the inoculation is of little benefit to them.** Instead, it presents a very real risk of adverse events.

- But the adolescent Pfizer study wasn't actually designed to find those. **A serious adverse event**, including death, that occurred at a 1/800 rate **might not even show up in a sample of 1,005** people.

- But in this case, it did. **Among the 1,005 adolescents, there WAS at least one serious adverse event - Maddie de Garay.**

"For children without a serious medical condition, the danger of severe Covid is so low as to be difficult to quantify."
-COVID AND AGE, Oct 12, 2021, New York Times

12 -15 ADOLESCENT TRIAL
FAILURE TO REPORT SERIOUS ADVERSE EVENTS

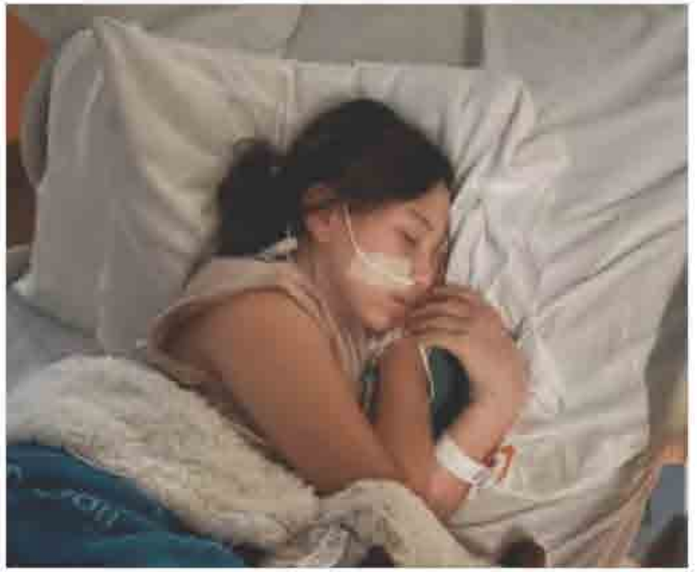
Maddie de Garay is a 12 year old trial participant who developed a serious reaction after her second dose and was hospitalized within 24 hours.

Maddie developed gastroparesis, nausea and vomiting, erratic blood pressure, memory loss, brain fog, headaches, dizziness, fainting, seizures, verbal and motor tics, menstrual cycle issues, lost feeling from the waist down, lost bowel and bladder control and had an nasogastric tube placed because she lost her ability to eat. She has been hospitalized many times, and for the past **10 months she has been wheelchair bound and fed via tube.**

In their report to the FDA, **Pfizer described her injuries as "functional abdominal pain."**

- One participant experienced an SAE reported as generalized neuralgia, and also reported 3 concurrent non-serious AEs (abdominal pain, abscess, gastritis) and 1 concurrent SAE (constipation) within the same week. The participant was eventually diagnosed with functional abdominal pain. The event was reported as ongoing at the time of the cutoff date.

Emergency Use Authorization Amendment



5 - 11 YEAR OLDS RISKING THEIR HEALTH

Re: the 5 to 11 year old cohort

In this table, **Pfizer, using predictive modelling acknowledges that their inoculations WILL cause myocarditis**, but optimistically **claims there will be zero deaths** from myocarditis in any of their modelled (speculation, level 5 evidence) scenarios.

But **even if it were true,** there is no justification for causing harm to children this way. **FIRST, DO NO HARM.**

There is now such a high expectation of heart problems from the inoculations among children that **Sick Kids is putting out brochures on how to deal with them.**

FDA BRIEFING DOCUMENT
EUA AMENDMENT REQUEST FOR PFIZER-BIONTECH COVID-19 VACCINE
FOR USE IN CHILDREN 5 THROUGH 11 YEARS OF AGE

Table 14. Model-Predicted Benefit-Risk Outcomes of Scenarios 1-6 per One Million Fully Vaccinated Children 5-11 Years Old

	Benefits				Risks			
Sex	Prevented COVID-19 Cases	Prevented COVID-19 Hospitalizations	Prevented COVID-19 ICU Admissions	Prevented COVID-19 Deaths	Excess Myocarditis Cases	Excess Myocarditis Hospitalizations	Excess Myocarditis ICU Admissions	Excess Myocarditis Deaths
Males & Females								
Scenario 1	45,773	192	62	1	106	58	34	0
Scenario 2	54,345	250	80	1	106	58	34	0
Scenario 3	2,639	21	7	0	106	58	34	0
Scenario 4	58,851	241	77	1	106	58	34	0
Scenario 5	45,773	192	62	3	106	58	34	0
Scenario 6	45,773	192	62	1	53	29	17	0
Males only								
Scenario 1	44,790	203	67	1	179	98	57	0
Scenario 2	54,345	250	82	1	179	98	57	0
Scenario 3	2,639	21	7	0	179	98	57	0
Scenario 4	57,857	254	83	1	179	98	57	0
Scenario 5	44,790	203	67	3	179	98	57	0
Scenario 6	44,790	203	67	1	89	49	29	0
Females only								
Scenario 1	45,063	172	54	1	32	18	10	0
Scenario 2	54,345	250	78	2	32	18	10	0
Scenario 3	2,639	21	7	0	32	18	10	0
Scenario 4	57,938	215	67	2	32	18	10	0
Scenario 5	45,063	172	54	4	32	18	10	0
Scenario 6	45,063	172	54	1	16	9	5	0

cenario 1: COVID-19 incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
cenario 2: COVID-19 incidence at peak of U.S. Delta variant surge at end of August 2021, VE 70% vs. COVID-19 cases and 80%
COVID-19 hospitalization.
enario 3: COVID-19 incidence as of na
enario 4: COVID-19 incidence as of Se
nario 5: COVID-19 case incidence as
pitalization, COVID-19 death rate 300
ario 6: COVID-19 incidence as of Se
ss myocarditis cases 50% of Scenari

Low Level (Level 5 Evidence)
SPECULATION - A Predictive Model

MYOCARDITIS IS SERIOUS

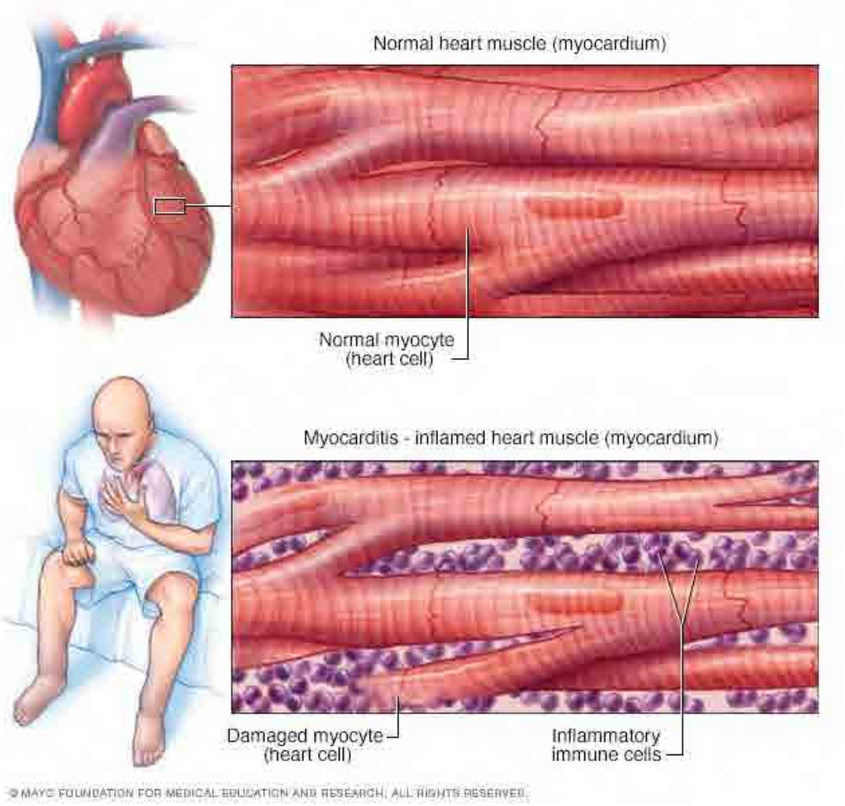
MYOCARDITIS

"Myocarditis is an inflammatory process of the myocardium. (Heart muscle.) **Severe myocarditis weakens your heart** so that the rest of your body doesn't get enough blood. Clots can form in your heart, **leading to a stroke or heart attack."**

THE US NATIONAL CENTRE FOR BIOTECHNOLOGY INFORMATION

"The mortality rate is up to 20% at 6.5 years."

https://jcmr-online.biomedcentral.com/articles/10.1186/1532-429X-13-S1-M7

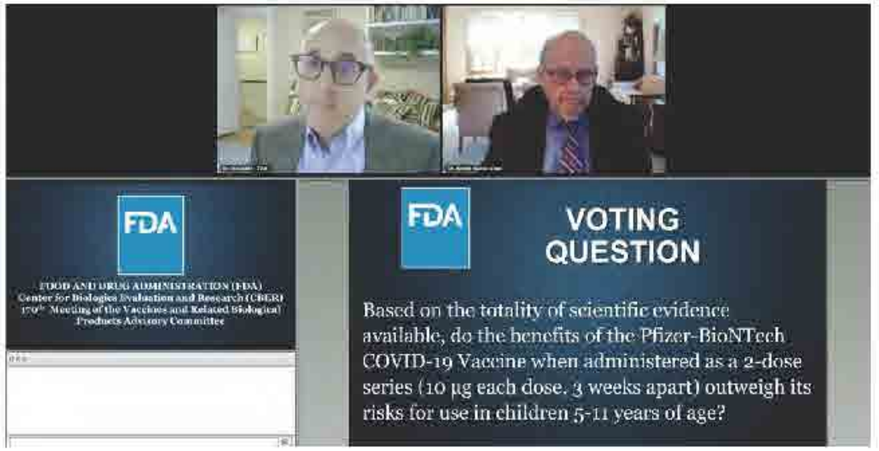


THE FDA ABANDONS FIRST, DO NO HARM

Medical interventions are supposed to be **PROVEN SAFE BEFORE** the are rolled out in the population.

Yet **Dr. Eric Rubin**, one of the 18 members of the **FDA advisory panel** who voted, to approve the inoculations for children 5 - 11, actually said the opposite, and suggested that **a population level roll out was an appropriate way to test for adverse events.**

It's worth noting that Dr. Eric Rubin is the **editor-in-chief of the New England Journal of Medicine, which publishes the Pfizer trial reports.**



"We're never going to learn about how safe this vaccine is unless we start giving it. That's just the way it goes. That's how we found out about rare complications of other vaccines like the rotavirus vaccine. And I do think we should vote to approve it."

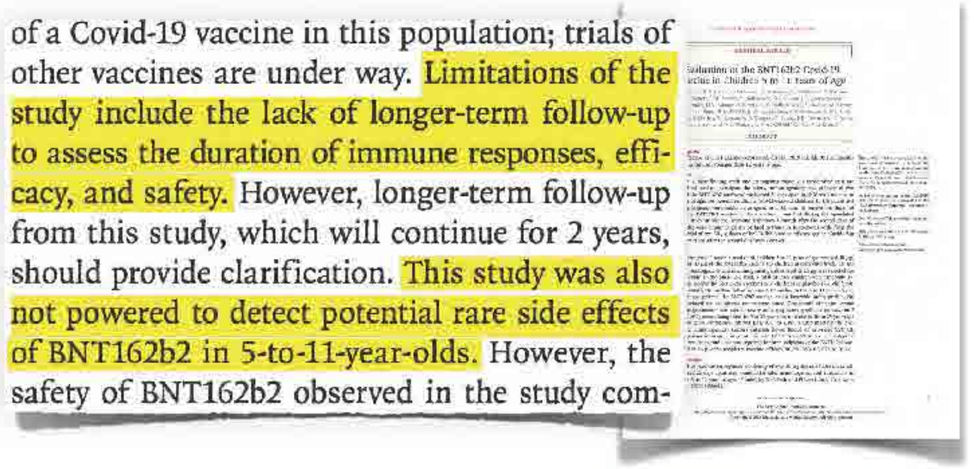
Dr. Eric Rubin, FDA advisory panel member,
Harvard professor & editor-in-chief of the New England Journal of Medicine
Vaccines and Related Biological Products Advisory Committee – 10/26/2021

5 - 11 YEAR OLDS
NO INFORMED CONSENT

- **Direct-to-consumer advertising of prescription drugs is illegal in Canada,** yet politicians from all levels of government are marketing inoculations to children, using cartoons and mascots.

- **They are proclaiming the inoculations to be safe, yet the data is not there to back that up.** In addition to admitting that their inoculations can cause myocarditis, Pfizer also admits, right in their report, that **their long term immune response, efficacy & safety data is limited and that their studies weren't powered to find "rare" side effects** as only 1,517 kids got the inoculation.

- How many parents would take their kids to get this shot if they were informed of this? **The law of informed consent says they should be, but it's not happening.**



of a Covid-19 vaccine in this population; trials of other vaccines are under way. Limitations of the study include the lack of longer-term follow-up to assess the duration of immune responses, efficacy, and safety. However, longer-term follow-up from this study, which will continue for 2 years, should provide clarification. This study was also not powered to detect potential rare side effects of BNT162b2 in 5-to-11-year-olds. However, the safety of BNT162b2 observed in the study com-

https://www.nejm.org/doi/full/10.1056/NEJMoa2116298

THE BRITISH MEDICAL JOURNAL PUBLISHES WHISTLEBLOWER STORY

On November 2nd, the British Medical Journal released an article about their investigation into Ventavia, one of the research companies Pfizer hired to conduct the trials.

It's quite damning. **The whistleblower is a Regional Director** who actually reported her company to the FDA for:

- **Falsifying data**
- **Unblinding participants**
- **Not following up and testing participants who reported symptoms**
- **Mislabelling specimens**

Several other employees backed up her account. Despite all this, **neither Pfizer, nor the FDA ever audited or investigated** the research company, Pfizer never disclosed the problems in its EUA application, and in fact, Pfizer has now hired that same Researcher, Ventavia, to run four more COVID-19 clinical trials.

FEATURE

Check for updates

Madrid, Spain
Cite this as: BMJ 2021;375:n2635
http://dx.doi.org/10.1136/bmj.n2635
Published: 2 November 2021

BMJ INVESTIGATION

Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial

Revelations of poor practices at a contract research company helping to carry out Pfizer's pivotal covid-19 vaccine trial raise questions about data integrity and regulatory oversight. Paul D Thacker reports

Paul D Thacker *investigative journalist*

In autumn 2020 Pfizer's chairman and chief executive, Albert Bourla, released an open letter to the billions of people around the world who were investing their hopes in a safe and effective covid-19 vaccine to end the pandemic. "As I've said before, we are operating at the speed of science," Bourla wrote, explaining to the public when they could expect a Pfizer vaccine to be authorised in the United States.[1]

But, for researchers who were testing Pfizer's vaccine at several sites in Texas during that autumn, speed may have come at the cost of data integrity and patient safety. A regional director who was employed at the research organisation Ventavia Research Group has told *The BMJ* that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson, emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson has provided *The BMJ* with dozens of internal company documents, photos, audio

executives later questioned Jackson for taking the photos.

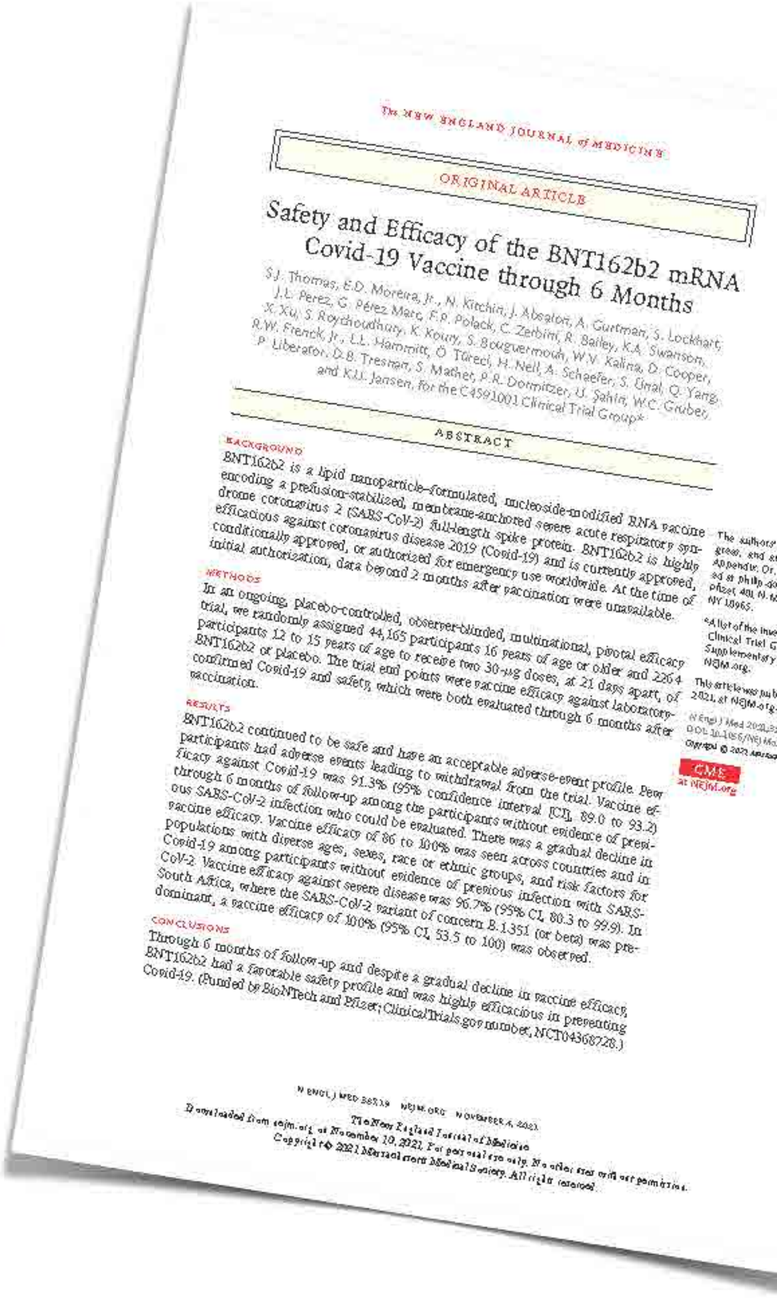
Early and inadvertent unblinding may have occurred on a far wider scale. According to the trial's design, unblinded staff were responsible for preparing and administering the study drug (Pfizer's vaccine or a placebo). This was to be done to preserve the blinding of trial participants and all other site staff, including the principal investigator. However, at Ventavia, Jackson told *The BMJ* that drug assignment confirmation printouts were being left in participants' charts, accessible to blinded personnel. As a corrective action taken in September, two months into trial recruitment and with around 1000 participants already enrolled, quality assurance checklists were updated with instructions for staff to remove drug assignments from charts.

In a recording of a meeting in late September 2020 between Jackson and two directors a Ventavia executive can be heard explaining that the company wasn't able to quantify the types and number of errors they were finding when examining the trial paperwork for quality control. "In my mind, it's something new every day," a Ventavia executive says. "We know that it's significant."

Ventavia was not keeping up with data entry queries,

BMJ: first published as 10.1136/bmj.n2635 on 2 November 2021

A CRITICAL EYE BACK ON
THE SEP 15 2021 REPORT



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

S.J. Thomas, E.D. Moreira, Jr., N. Kitchin, J. Absalon, A. Gurtman, S. Lockhart, J.L. Perez, G. Pérez Marc, F.P. Polack, C. Zerbini, R. Bailey, K.A. Swanson, X. Xu, S. Roychoudhury, K. Koury, S. Bouguermouh, W.V. Kalina, D. Cooper, R.W. Frenck, Jr., L.L. Hammitt, Ö. Türeci, H. Nell, A. Schaefer, S. Ünal, Q. Yang, P. Liberator, D.B. Tresnan, S. Mather, P.R. Dormitzer, U. Şahin, W.C. Gruber, and K.U. Jansen, for the C4591001 Clinical Trial Group*

ABSTRACT

BACKGROUND

BNT162b2 is a lipid nanoparticle–formulated, nucleoside-modified RNA vaccine encoding a prefusion-stabilized, membrane-anchored severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) full-length spike protein. BNT162b2 is highly efficacious against coronavirus disease 2019 (Covid-19) and is currently approved, conditionally approved, or authorized for emergency use worldwide. At the time of initial authorization, data beyond 2 months after vaccination were unavailable.

METHODS

In an ongoing, placebo-controlled, observer-blinded, multinational, pivotal efficacy trial, we randomly assigned 44,165 participants 16 years of age or older and 2264 participants 12 to 15 years of age to receive two 30-μg doses, at 21 days apart, of BNT162b2 or placebo. The trial end points were vaccine efficacy against laboratory-confirmed Covid-19 and safety, which were both evaluated through 6 months after vaccination.

RESULTS

BNT162b2 continued to be safe and have an acceptable adverse-event profile. Few participants had adverse events leading to withdrawal from the trial. Vaccine efficacy against Covid-19 was 91.3% (95% confidence interval [CI], 89.0 to 93.2) through 6 months of follow-up among the participants without evidence of previous SARS-CoV-2 infection who could be evaluated. There was a gradual decline in vaccine efficacy. Vaccine efficacy of 86 to 100% was seen across countries and in populations with diverse ages, sexes, race or ethnic groups, and risk factors for Covid-19 among participants without evidence of previous infection with SARS-CoV-2. Vaccine efficacy against severe disease was 96.7% (95% CI, 80.3 to 99.9). In South Africa, where the SARS-CoV-2 variant of concern B.1.351 (or beta) was predominant, a vaccine efficacy of 100% (95% CI, 53.5 to 100) was observed.

CONCLUSIONS

Through 6 months of follow-up and despite a gradual decline in vaccine efficacy, BNT162b2 had a favorable safety profile and was highly efficacious in preventing Covid-19. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.)

N Engl J Med 385:1–12. NEJM.ORG NOVEMBER 4, 2021

The New England Journal of Medicine

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6 MONTH DATA MANIPULATION
MIXED COHORTS

Pfizer took the results from their adult trial, which started July 27, 2020, and then added the results from the 12 - 15 year olds' trial, **despite the fact that the adolescent trial started four months later.**

Since it's well known that the efficacy of the inoculations wanes over time, **this gives a false boost to the efficacy numbers.** The efficacy for these two cohorts should have been reported separately, not presented as one combined result. Without this boost, their efficacy number would likely have fallen.

Jul 27
Adult Trial (16+) Begins

Dec
Adolescent Trial (12 - 15) Begins

Mar 13
Data Cutoff Date for Efficacy Reported in 6 Month Study

2020						2021		
JULY	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR

PFIZER TRIALS DID NOT PROVE SAFETY
THEY PROVED HARM

ILLNESS

	BNT162b2	Placebo	Risk Change
Efficacy (Meaning number of people diagnosed with COVID-19.)	77	850	**-91%**
Related Adverse Event (Meaning an investigator has assessed it as related to the BNT162b2 injection.)	5,241	1,311	**+300%**
Any Severe Adverse Event (Interferes significantly with normal function.)	262	150	**+75%**
Any Serious Adverse Event (Involves visit to ER or hospitalization.)	127	116	**+10%**

DEATHS

BNT162b2	Placebo
20	14

These are the results of Pfizer's own randomized control trial.

LEVEL 1 EVIDENCE OF HARM.

HOW THIS IS PLAYING OUT IN THE REAL WORLD

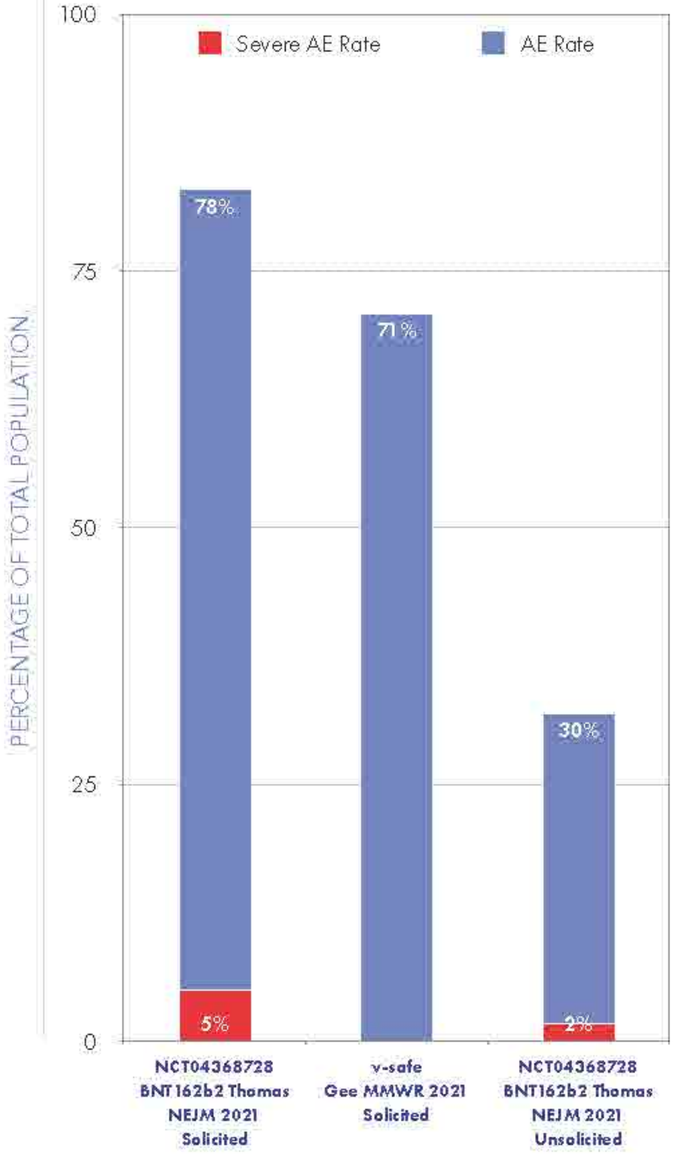
ROLL OUT SURVEILLANCE YOU DON'T FIND WHAT YOU DON'T LOOK FOR

There is a dramatic difference between passive vs active monitoring of adverse events

1. When participants were **actively** followed for adverse events (AEs) in the trials, high percentages of adverse events were reported.

2. Once the vaccine was rolled out at the population level, **passive** surveillance was used with Health Canada, VAERS or the European Yellow Card system.

When that happened, the **signal was completely lost**.



VS

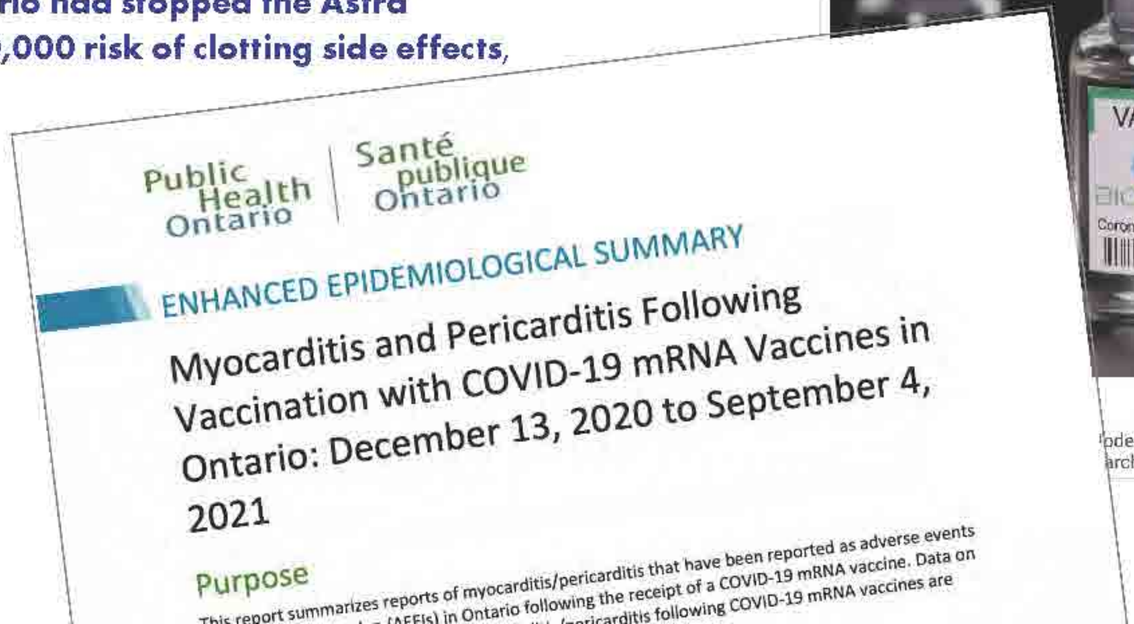
RISING INCIDENTS OF HEART ISSUES IN YOUNG PEOPLE

Ontario Public Health is well aware of this, as they published a report on it, but they seem inconsistent in their concerns.

- On Sep 29, 2021, Ontario Public Health recommended **young men 18-24** not take the **Moderna shot**, because of a **1 in 5,000 risk of myocarditis.** They suggested **Pfizer shot** instead, which has a **1 in 28,000 risk of myocarditis.**

- But as recently as May 8, 2021, **Ontario had stopped the Astra Zeneca shot because of a 1 in 60,000 risk of clotting side effects**, which was considered too high.

- **Their priorities are inconsistent.**



Public Health Ontario | Santé publique Ontario

ENHANCED EPIDEMIOLOGICAL SUMMARY

Myocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to September 4, 2021

Purpose

This report summarizes reports of myocarditis/pericarditis that have been reported as adverse events (AEFIs) in Ontario following the receipt of a COVID-19 mRNA vaccine. Data on myocarditis/pericarditis following COVID-19 mRNA vaccines are

TORONTO SUN

Ontario

More than 100 Ontario youth sent to hospital for vaccine-related heart problems: Report

There were 54 persons aged 25-39 included in the tally and 44 persons aged 40 and over

Anthony Furey
Sep 03, 2021 · September 3, 2021 · 2 minute read · 314 Comments

oderna coronavirus disease (COVID-19) vaccine labels are seen
arch 19, 2021. PHOTO BY DADO RUVIC /REUTERS

THIS IS NOT NORMAL

Health News , Vaccine Injury Stories , Vaccines

Grieving Father Ernest Ramirez Shares Heartbreaking Story of His Teen Son's Death 5 Days After Pfizer Vaccine

Isaiah Harris Aged 18 – Pfizer May 2021

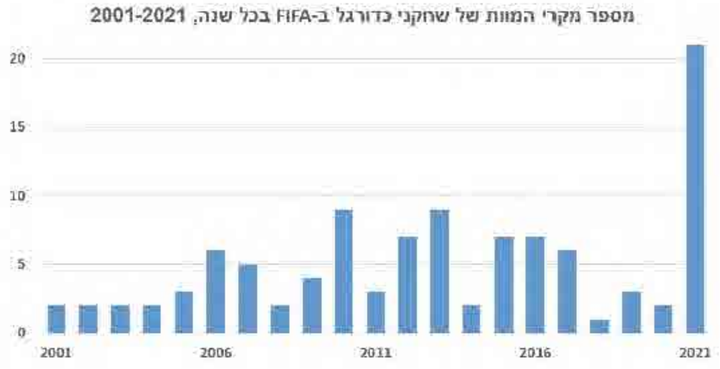
Severe Adverse Reaction: Myocarditis (Inflammation of the Heart) Resulting in a Heart Attack

A German news site put together a list of over **75 known cases of athletes collapsing - and even dying - in the last 5 months.**

https://report24.news/ab-13-jahren-lange-liste-ploetzlich-verstorbener-oder-schwerkranker-sportler/

An Israeli news site analyzed the number of sudden deaths "on the pitch" of members of the International Football Association (FIFA) over the past 20 years.

The average number of FIFA sudden deaths between 2000 - 2020 was 4.2. In 2021, it was 21.



https://www.rtnews.co.il/?view=article&id=49&catid=22

THIS IS SUPPOSED TO BE RARE

https://rumble.com/vpnxkr-are-these-side-effects-extremely-rare.html

PFIZER'S POST MARKETING PHARMACOVIGILANCE REPORT

- On Nov 17, 2021, the FDA released the first batch of what will ultimately be **329,000 pages** they were ordered by a court to provide to satisfy a Freedom of Information request by a group called Public Health and Medical Professionals for Transparency who want access to the **data used by the FDA to approve Pfizer's COVID-19 inoculations**. (The FDA asked in court to have over 50 years to release the documents.)

- One **post marketing pharmacovigilance report** submitted to the FDA, where Pfizer tracked real world adverse events occurring in the first 2.5 months after Emergency Use Authorization, was particularly disturbing.
  - **Over 1,200 deaths**
  - **Over 25,000 nervous system adverse events**
  - Under "Safety concerns" Pfizer listed **Anaphylaxis** and **Vaccine-Associated Enhanced Disease**

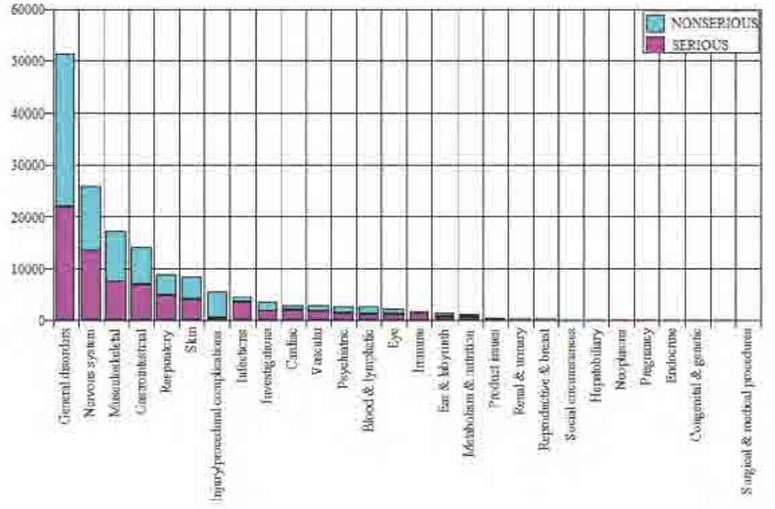
- **This document should be incriminating for any agency who saw it and called these inoculations "safe."**

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 - 107 years Mean = 50.9 years n = 34952	≤ 17	175[a]
	18-30	4953
	31-50	13886
	51-64	7884
	65-74	3098
	≥ 75	5214
	Unknown	6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness



3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

CONSIDERABLE EVIDENCE OF CONFLICT OF INTEREST

PFIZER IS MAKING BILLIONS

$33.5B+ in 2021 alone.

When the incentive is such an astronomical sum of money, it only makes sense to **ensure rigorous oversight** of the process and to ensure **as many safeguards as possible** are in place.

Their agenda is **their shareholders and their bottom line**, not public health.

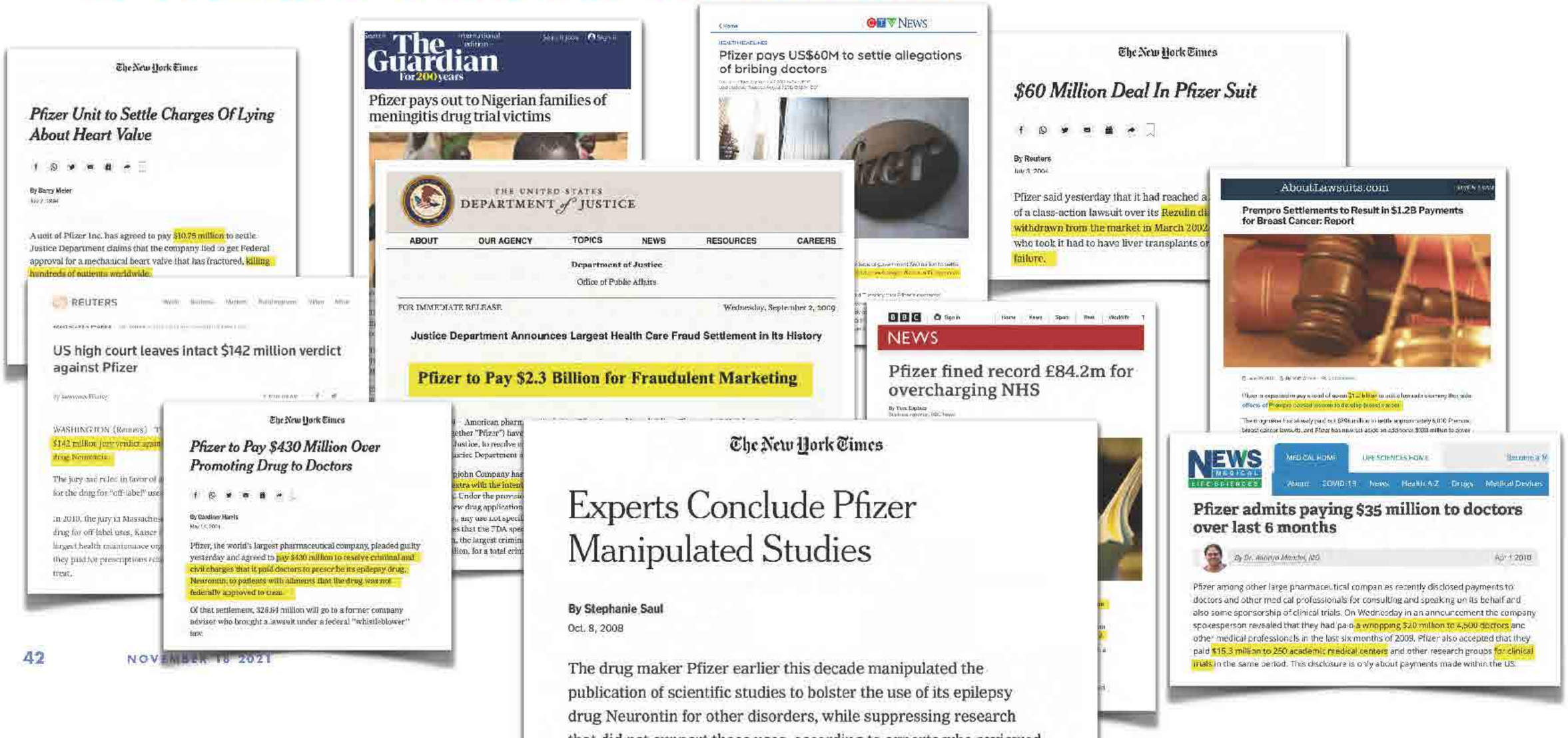
Forbes

Pfizer Expects $33.5 Billion In Vaccine Revenue In 2021

Albert Bourla, CEO of Pfizer, photographed in June 2020. JAMEL TOPPIN FOR FORBES

Biotech giant Pfizer expects to generate $33.5 billion in Covid-19 vaccine sales in 2021, up from previous estimates of $26 billion, according to its second quarter earnings reports. These projections are based on the 2.1 billion doses of the Pfizer/BioNTech vaccine which the company expects to manufacture and deliver by the end of the year.

THE PUBLIC RECORD OF PFIZER'S CORPORATE CULTURE



The New York Times

Pfizer Unit to Settle Charges Of Lying About Heart Valve

By Barry Meier

A unit of Pfizer Inc. has agreed to pay $10.75 million to settle Justice Department claims that the company lied to get Federal approval for a mechanical heart valve that has fractured, killing hundreds of patients worldwide.

The Guardian For 200 years

Pfizer pays out to Nigerian families of meningitis drug trial victims

CTV NEWS

Pfizer pays US$60M to settle allegations of bribing doctors

The New York Times

$60 Million Deal In Pfizer Suit

By Reuters

Pfizer said yesterday that it had reached a
of a class-action lawsuit over its Rezulin di
withdrawn from the market in March 2002
who took it had to have liver transplants or
failure.

THE UNITED STATES DEPARTMENT of JUSTICE

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Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Wednesday, September 2, 2009

Justice Department Announces Largest Health Care Fraud Settlement in Its History

Pfizer to Pay $2.3 Billion for Fraudulent Marketing

AboutLawsuits.com

Prempro Settlements to Result in $1.2B Payments for Breast Cancer: Report

REUTERS

US high court leaves intact $142 million verdict against Pfizer

WASHINGTON (Reuters)
$142 million jury verdict again
drug Neurontin.
The jury and ruled in favor of
for the drug for "off-label" use
in 2010, the jury in Massachus
drug for off-label uses, Kaiser
largest health maintenance or
they paid for prescriptions rel
treat.

BBC NEWS

Pfizer fined record £84.2m for overcharging NHS

The New York Times

Pfizer to Pay $430 Million Over Promoting Drug to Doctors

By Gardiner Harris

Pfizer, the world's largest pharmaceutical company, pleaded guilty yesterday and agreed to pay $430 million to resolve criminal and civil charges that it paid doctors to prescribe its epilepsy drug, Neurontin, to patients with ailments that the drug was not federally approved to treat.

Of that settlement, $28.84 million will go to a former company adviser who brought a lawsuit under a federal "whistleblower" law.

The New York Times

Experts Conclude Pfizer Manipulated Studies

By Stephanie Saul

Oct. 8, 2008

The drug maker Pfizer earlier this decade manipulated the publication of scientific studies to bolster the use of its epilepsy drug Neurontin for other disorders, while suppressing research

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Pfizer admits paying $35 million to doctors over last 6 months

By Dr. Maryam Mandavi, MD Apr 1 2010

Pfizer among other large pharmaceutical companies recently disclosed payments to doctors and other medical professionals for consulting and speaking on its behalf and also some sponsorship of clinical trials. On Wednesday in an announcement the company spokesperson revealed that they had paid a whopping $20 million to 4,500 doctors and other medical professionals in the last six months of 2009. Pfizer also accepted that they paid $15.3 million to 250 academic medical centers and other research groups for clinical trials in the same period. This disclosure is only about payments made within the US.

LINKS TO THE PUBLIC RECORD OF PFIZER'S CORPORATE CULTURE

- **Pfizer Unit to Settle Charges Of Lying About Heart Valve, Jul 2, 1994** https://www.nytimes.com/1994/07/02/business/pfizer-unit-to-settle-charges-of-lying-about-heart-valve.html
- **Pfizer to Pay $430 Million Over Promoting Drug to Doctors, May 14, 2004** https://www.nytimes.com/2004/05/14/business/pfizer-to-pay-430-million-over-promoting-drug-to-doctors.html
- **$60 Million Deal In Pfizer Suit over Rezulin, July 3, 2004** https://www.nytimes.com/2004/07/03/business/60-million-deal-in-pfizer-suit.html
- **Experts Conclude Pfizer Manipulated Studies, Oct 8, 2008** https://www.nytimes.com/2008/10/08/health/research/08drug.html
- **Pfizer to Pay $2.3 Billion for Fraudulent Marketing, Sep 2, 2009** https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history
- **Pfizer Admits Paying $35 Million to Doctors Over Last 6 Months, Apr 1, 2010** https://www.news-medical.net/news/20100401/Pfizer-admits-paying-2435-million-to-doctors-over-last-6-months.aspx
- **Pfizer Pays Out to Nigerian Families of Meningitis Drug Trial Victims, Aug 12, 2011** https://www.theguardian.com/world/2011/aug/11/pfizer-nigeria-meningitis-drug-compensation
- **Pfizer Pays US$60M to Settle Allegations of Bribing Doctors, Aug 7, 2012** https://www.ctvnews.ca/health/health-headlines/pfizer-pays-us-60m-to-settle-allegations-of-bribing-doctors-1.906216
- **SEC Charges Pfizer with FCPA Violations, Aug 7, 2012** https://www.sec.gov/news/press-release/2012-2012-152htm
- **US High Court Leaves Intact $142 million Verdict Against Pfizer, Dec 9, 2013** https://www.reuters.com/article/us-usa-court-pfizer-idUSBRE9B80K020131209
- **Pfizer Fined Record £84.2m for Overcharging NHS, Dec 7, 2016** https://www.bbc.com/news/business-38233852
- **Sanofi, FSK, Pfizer, Boehringer Must Face Zantac Class-Action Lawsuits: Court Oct 15, 2021** https://medicaldialogues.in/news/industry/pharma/sanofi-gsk-pfizer-boehringer-must-face-zantac-class-action-lawsuits-court-83138

CONFLICTS OF INTEREST AMONG PFIZER REPORT AUTHORS

6 MONTH REPORT AUTHORS

Employment + Stock

N. Kitchin
J. Absalon — Corresponding Author
S. Lockhart
R. Bailey
K.A. Swanson — Last Author
S. Roychoudhury
K. Koury
W.V. Kalina
D. Cooper
D.B. Tresnan
S. Mather
P.R. Dormitzer
U. Şahin — BioNTech founders whose stock value increased by $9 billion
W.C. Gruber
K.U. Jansen
Ö. Türeci — BioNTech founders whose stock value increased by $9 billion

Employment

A. Gurtman
J.L. Perez
S. Bouguermouh
P. Liberator
X. Xu

Grant/Consultant/Clinical Trial

R.W. Frenck, Jr.
L.L. Hammitt
S. Ünal
S.J. Thomas — Lead Author
G. Pérez Marc
F.P. Polack

No Conflict

E.D. Moreira, Jr
H. Nell
A. Schaefer
C. Zerbini
Q. Yang

THE CDC HAS REDEFINED "VACCINE" TO SUIT POLITICAL & PHARMACEUTICAL INTERESTS

For many years	Jul 27, 2021	Aug 18, 2021	Starting Sep 2, 2021
CDC Definition of VACCINE *"A product that stimulates a person's immune system* ***to produce immunity to a specific disease, protecting the person from that disease."***	Head of CDC Rochelle Walensky went on CNN and admitted the COVID-19 vaccines do not provide immunity - they don't stop people from catching or transmitting COVID-19. 	Joe Biden announced booster shots for all Americans. 	**CDC Definition of VACCINE CHANGED** *"A preparation that is used* ***to stimulate the body's immune response against diseases."*** **This looks like fraud.**

THE MEDIA HAS BEEN CAPTURED

https://rumble.com/voz64j-brought-to-you-by-pfizer.html

THIS IS NO WAY TO MANAGE A SUPPLIER

Pfizer has been **indemnified for damages** in case their inoculations hurt and kill people, and Pfizer **profits to the tune of billions** if the trials are successful.

No reasonable, responsible person would have given Pfizer carte blanche in such a situation.

Instead, **you would engage in rigorous oversight** and **hold them to the highest scientific standards**. This was not done.

THE INOCULATIONS SHOULD BE WITHDRAWN IMMEDIATELY

- It's clear that Pfizer - and the agencies overseeing their trials - failed to follow established, high quality safety and efficacy protocols right from the beginning.
- We have presented **Level 1 evidence of harm from Pfizer's own trial data**. Any government which has approved these inoculations, much less mandated them, **knew or should have known from the available data that harm would be caused to its citizens.**
- Any government that approved this medical intervention for its citizens should have ensured that the trial had used the **appropriate clinical endpoints** and **high quality safety science**.
- **Any government official who possesses this evidence and continues to allow its citizens to be inoculated with a toxic agent is, at the very least, negligent.**

RECOMMENDED READING/VIEWING

PUBLISHED PAPERS REFUTING PFIZER INOCULATIONS

- **Why Are We Vaccinating Children Against COVID-19?** https://www.sciencedirect.com/science/article/pii/S221475002100161X

- **US COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint, "All Cause Severe Morbidity"** https://www.scivisionpub.com/pdfs/us-covid19-vaccines-proven-to-cause-more-harm-than-good-based-on-pivotal-clinical-trial-data-analyzed-using-the-proper-scientific--1811.pdf

PFIZER'S NEJM PUBLISHED RESULTS

- **Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine** https://www.nejm.org/doi/full/10.1056/nejmoa2034577

- **FDA Briefing Document, Dec 10, 2020** https://www.fda.gov/media/144245/download

- **Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months** https://www.nejm.org/doi/full/10.1056/NEJMoa2110345

- **The 6 Month Supplementary Appendix** https://www.nejm.org/doi/suppl/10.1056/NEJMoa2110345/suppl_file/nejmoa2110345_appendix.pdf

BRITISH MEDICAL JOURNAL

- **Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial** https://www.bmj.com/content/375/bmj.n2635

ONTARIO PUBLIC HEALTH EPIDEMIOLOGICAL SUMMARY

- **Myocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to September 4, 2021** https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-myocarditis-pericarditis-vaccines-epi.pdf?sc_lang=en

SHORT VIDEOS

- **Informed Consent - It's Your Right (3 minutes)** https://rumble.com/vleq43-informed-consent-its-your-right.html

- **Brought to You by Pfizer (1 minute)** https://rumble.com/voz64j-brought-to-you-by-pfizer.html

- **Why Do We Need Vaccine Passports? (2 minutes)** https://rumble.com/vn1zof-why-do-we-need-vaccine-passports.html

- **COVID-19 Vaccines and D-Dimer levels (9 minutes)** https://rumble.com/voeisj-dr-rochagn-kilian-blowing-the-whistle-on-covid-19-vaccines-and-d-dimer-leve.html

- **How Reliable Is the PCR Test? (2 minutes)** https://youtu.be/gL7Z5JmRIM4

WE NEED YOU TO HOLD THEM ACCOUNTABLE

- This evidence is a tool you can use. It represents a real opportunity to hold our leaders accountable as it is not opinion, or modelling, or real world evidence that can be dismissed or manipulated, but LEVEL 1 EVIDENCE from a randomized control trial. As such, it has high evidentiary value.
- We're asking that you call your MP and MPP and that you ask for a 1 hour meeting. Preferably in person, but Zoom will work too.
- During the meeting, play them the video and provide them with the PDF version. Ask them questions, like whether or not they were aware of all the issues with the Pfizer trial. Or what they plan to do now that they are. Get them to agree to a follow up meeting where they will provide you with answers.
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- This presentation is available in PDF and video format on our website at www.canadiancovidcarealliance.org

THE PFIZER INOCULATIONS FOR COVID-19

MORE HARM
THAN GOOD

Canadian Covid Care Alliance
Alliance canadienne pour la prévention
et prise-en-charge de la covid

Contact us
info@canadiancovidcarealliance.org
www.canadiancovidcarealliance.org

Tab 11

World

Pfizer, BioNTech and Moderna making $1,000 profit every second while world's poorest countries remain largely unvaccinated

News and Press Release

Source: Oxfam

Posted: 16 Nov 2021

Originally published: 16 Nov 2021

Origin: View original

Demand grows for firms to share vaccine recipes and technology as billionaire pharma bosses convene for 'Big Pharma Davos'

New figures from the Peoples Vaccine Alliance reveal that the companies behind two of the most successful COVID-19 vaccines —Pfizer, BioNTech and Moderna— are making combined profits of $65,000 every minute. The figures based on the latest company reports are released as CEOs from pharmaceutical industry meet for the annual STAT summit —the equivalent of a 'Big Pharma Davos'— from 16-18 November.

These companies have sold the majority of doses to rich countries, leaving low-income countries out in the cold. Pfizer and BioNTech have delivered less than one percent of their total vaccine supplies to low-income countries, while Moderna has delivered just 0.2 percent. Meanwhile 98 percent of people in low income countries have not been fully vaccinated.

Maaza Seyoum of the African Alliance and People's Vaccine Alliance Africa said: "It is obscene that just a few companies are making millions of dollars in profit every single hour, while just two percent of people in low-income countries have been fully vaccinated against coronavirus.

"Pfizer, BioNTech and Moderna have used their monopolies to prioritise the most profitable

contracts with the richest governments, leaving low income countries out in the cold."

Despite receiving public funding of over $8 billion, the three corporations have refused calls to urgently transfer vaccine technology and know-how with capable producers in low- and middle-income countries via the World Health Organisation (WHO), a move that could increase global supply, drive down prices and save millions of lives In Moderna's case, this is despite explicit pressure from the White House and requests from the WHO that the company collaborate in and help accelerate its plan to replicate the Moderna vaccine for wider production at its mRNA hub in South Africa.

While Albert Bourla, the CEO of Pfizer, described the call to share vaccine recipes 'dangerous nonsense,' the WHO emergency use approval of the Indian vaccine Covaxin earlier this month is clear evidence that developing countries have the capacity and expertise.

Anna Marriott, Oxfam's Health Policy Manager said: "Contrary to what Pfizer's CEO says, the real nonsense is claiming the experience and expertise to develop and manufacture life-saving medicines and vaccines does not exist in developing countries. This is just a false excuse that pharmaceutical companies are hiding behind to protect their astronomical profits

"It is also a complete failure of government to allow these companies to maintain monopoly control and artificially constrain supply in the midst of a pandemic while so many people in the world are yet to be vaccinated."

Based on company financial statements, the Alliance estimates that Pfizer, BioNTech and Moderna will make pre tax profits of $34 billion this year between them, which works out as over a thousand dollars a second, $65,000 a minute or $93.5 million a day. The monopolies these companies hold have produced five new billionaires during the pandemic, with a combined net wealth of $35 1 billion

The People's Vaccine Alliance, which has 80 members including the African Alliance, Global Justice Now, Oxfam, and UNAIDS, is calling for the pharmaceutical corporations to immediately suspend intellectual property rights for COVID-19 vaccines, tests, treatments, and other medical tools by agreeing to the proposed waiver of the TRIPS Agreement at the World Trade Organisation

They are also calling on governments, including the United States, to use all their legal and policy tool to dem nd th t ph rm euti l omp nie h re COVID-19 d t know-how nd te hnology

tools to demand that pharmaceutical companies share COVID-19 data, know-how, and technology with the WHO's COVID-19 Technology Access Pool and South Africa mRNA Technology Transfer Hub.

More than 100 nations, led by South Africa and India —with the support of the US— have been calling for the TRIPS waiver, which also has the support of over 100 past and present world leaders and Nobel laureates.

Despite this, other rich nations, including the UK and Germany, are still blocking the proposal, putting the interest of pharmaceutical companies over what's best for the world. This issue is set to dominate the World Trade Organisation Ministerial Summit to be held in Geneva from 30 November to 3 December.

Notes to editors

A People's Vaccine Alliance report from 21 October found that Moderna has only delivered 0 2 percent of their total vaccine supply to low-income countries and Pfizer/BioNTech has delivered less than 1 percent.

In their Q3 financial statement, Pfizer forecast $36 billion in vaccine revenue for 2021. Gross profit from the revenue is split 50/50 with BioNTech. Pfizer guidance for their income before tax (after splitting profit with BioNTech) is 'High 20s as a Percentage of Revenues ' A conservative 25 percent margin would bring Pfizer's profit before tax to $9 billion in 2021 from the Comirnaty COVID-19 vaccine.

In BioNTech's Q3 financial statement they forecast €16-17 billion in vaccine revenue for 2021. In the 9 months ending September 30 the company made € 10.3 billion profit before tax on €13.4 billion, revenue giving a 77 percent profit margin Using a conservative €16 billion forecasted revenue for the full year, we therefore estimate that at a 77 percent profit margin, BioNTech will make €12.3 billion in pre-tax profit in 2021 —or $14.7 billion using the 2021 average exchange rate

Moderna's Q3 profit before tax for 9 months ending September 30 is $7.8 billion on $11.2 billion revenue giving a pre tax profit margin of 70 percent The company projects full year 2021 sales to be "between $15 billion and $18 billion". Using the lower end of the estimate —70 percent of $15 billion is $10.5 billion in profit for 2021. The vaccine is Moderna's only commercial product.

We therefore estimate the combined 2021 profit before tax for Moderna and Pfizer and BioNTech as $34 billion. There are 525600 minutes in a year giving $ 64,961 profit before tax per minute or

$1,083 per second Pre tax, rather than net, profit is used as Pfizer only report the guidance for pre-tax profit margin.

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External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results.

Pieter Borger [1*], Rajesh K. Malhotra [2], Michael Yeadon [3], Clare Craig [4], Kevin McKernan [5]
Klaus Steger [6], Paul McSheehy [7], Lidiya Angelova [8], Fabio Franchi [9], Thomas Binder [10]
Henrik Ullrich [11], Makoto Ohashi [12], Stefano Scoglio [13], Marjolein Doesburg-van Kleffens [14]
Dorothea Gilbert [15], Rainer J. Klement [16], Ruth Schruefer [17], Berber W. Pieksma [18], Jan Bonte [19],
Bruno H. Dalle Carbonara[20], Kevin P. Corbett [21], Ulrike Kämmerer [22].

* Corresponding author

ABSTRACT

In the publication entitled “Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR” (Eurosurveillance 25(8) 2020) the authors present a diagnostic workflow and RT-qPCR protocol for detection and diagnostics of 2019-nCoV (now known as SARS-CoV-2), which they claim to be validated, as well as being a *robust diagnostic methodology for use in public-health laboratory settings*.

In light of all the consequences resulting from this very publication for societies worldwide, a group of independent researchers performed a point-by-point review of the aforesaid publication in which 1) all components of the presented test design were cross checked, 2) the RT-qPCR protocol-recommendations were assesses w.r.t. good laboratory practice, and 3) parameters examined against relevant scientific literature covering the field.

The published RT-qPCR protocol for detection and diagnostics of 2019-nCoV and the manuscript suffer from numerous technical and scientific errors, including insufficient primer design, a problematic and insufficient RT-qPCR protocol, and the absence of an accurate test validation. Neither the presented test nor the manuscript itself fulfils the requirements for an acceptable scientific publication. Further, serious conflicts of interest of the authors are not mentioned. Finally, the very short timescale between submission and acceptance of the publication (24 hours) signifies that a systematic peer review process was either not performed here, or of problematic poor quality.

We provide compelling evidence of several scientific inadequacies, errors and flaws. Considering the scientific and methodological blemishes presented here, we are confident that the editorial board of Eurosurveillance has no other choice but to retract the publication.

CONCISE REVIEW REPORT

This paper will show numerous serious flaws in the Corman-Drosten paper, the significance of which has led to worldwide misdiagnosis of infections attributed to SARS-CoV-2 and associated with the disease COVID-19. We are confronted with stringent lockdowns which have destroyed many people's lives and livelihoods, limited access to education and these imposed restrictions by governments around the world are a direct attack on people's basic rights and their personal freedoms, resulting in collateral damage for entire economies on a global scale.

There are ten fatal problems with the Corman-Drosten paper which we will outline and explain in greater detail in the following sections.

The first and major issue is that the *novel* Coronavirus SARS-CoV-2 (in the publication named 2019-nCoV and in February 2020 named SARS-CoV-2 by an international consortium of virus experts) is based on *in silico* (theoretical) sequences, supplied by a laboratory in China [1], because at the time neither control material of infectious ("live") or inactivated SARS-CoV-2 nor isolated genomic RNA of the virus was available to the authors. To date no validation has been performed by the authorship based on isolated SARS-CoV-2 viruses or full length RNA thereof.

According to Corman et al.: *"We aimed to develop and deploy robust diagnostic methodology for use in public health laboratory settings without having virus material available."* [1]

The focus here should be placed upon the two stated aims: a) *development* and b) *deployment* of a *diagnostic test for use in public health laboratory settings*. These aims are not achievable without having any actual virus material available (e.g. for determining the infectious viral load). In any case, only a protocol with maximal accuracy can be the mandatory and primary goal in any scenario-outcome of this magnitude. Critical viral load determination is mandatory information, and it is in Christian Drosten's group responsibility to perform these experiments and provide the crucial data.

Nevertheless these *in silico* sequences were used to develop a RT-PCR test methodology to identify the aforesaid virus. This model was based on the assumption that the *novel* virus is very similar to SARS-CoV from 2003 (Hereafter named SARS-CoV-1) as both are beta-coronaviruses.

The PCR test was therefore designed using the genomic sequence of SARS-CoV-1 as a control material for the Sarbeco component; we know this from our personal email-communication with [2] one of the co-authors of the Corman-Drosten paper. This method to model SARS-CoV-2 was described in the Corman-Drosten paper as follows:
"the establishment and validation of a diagnostic workflow for 2019-nCoV screening and specific confirmation, designed in absence of available virus isolates or original patient specimens. Design and validation were enabled by the close genetic relatedness to the 2003 SARS-CoV, and aided by the use of synthetic nucleic acid technology."

In short, a design relying merely on close genetic relatives does not fulfill the aim for a "robust diagnostic test" as cross reactivity and therefore false-positive results will inevitably occur.
Validation was only done in regards to *in silico* (theoretical) sequences and within the laboratory-setting, and not as required for in-vitro diagnostics with isolated genomic viral RNA. This very fact hasn't changed even after 10 months of introduction of the test into routine diagnostics.
There are numerous other severe scientific errors regarding the biomolecular design of the primers, the PCR method, as well as the molecular validation of the PCR products and methods described in the Corman-Drosten paper which are examined in detail in the following chapters. The paper itself already signifies that a large number of false positive results are generated by this test, even under controlled laboratory conditions, making it completely unsuitable as a reliable virus screening method for entire populations in an ongoing pandemic. Given the far-reaching implications, including quarantine measures, lockdowns, curfews and impacts on education etc., this paper must be immediately retracted.

DESIGN AND ERRORS in RT-PCR

The Reverse Transcription-Polymerase Chain Reaction (RT-PCR) is an important biomolecular technology to rapidly detect rare RNA fragments, which are known in advance. In the first step, RNA molecules present in the sample are reverse transcribed to yield cDNA. The cDNA is then amplified in the polymerase chain reaction using a specific primer pair and a thermostable DNA polymerase enzyme. The technology is highly sensitive and its detection limit is theoretically 1 molecule of cDNA. The specificity of the PCR is highly influenced by biomolecular design errors.

What is important when designing an RT-PCR Test and the quantitative RT-qPCR test described in the Corman-Drosten publication?

1. The primers and probes:

   a) the concentration of primers and probes must be of optimal range (100-200 nM)
   b) must be specific to the target-gene you want to amplify
   c) must have an optimal percentage of GC content relative to the total nitrogenous bases (minimum 40%, maximum 60%)
   d) for virus diagnostics at least 3 primer pairs must detect 3 viral genes (preferably as far apart as possible in the viral genome)

2. The temperature at which all reactions take place:

   a) DNA melting temperature (>92°)
   b) DNA amplification temperature (TaqPol specific)
   c) Tm; the annealing temperature (the temperature at which the primers and probes reach the target binding/detachment, not to exceed 2˚C per primer pair).
   Tm heavily depends on GC content of the primers

3. The number of amplification cycles (less than 35; preferably 25-30 cycles); In case of virus detection, >35 cycles only detects signals which do not correlate with infectious virus as determined by isolation in cell culture [reviewed in 2]; if someone is tested by PCR as positive when a threshold of 35 cycles or higher is used (as is the case in most laboratories in Europe & the US), the probability that said person is actually infected is less than 3%, the probability that said result is a false positive is 97%

[reviewed in 3]

4. Molecular biological validations; amplified PCR products must be validated either by running the products in a gel with a DNA ruler, or by direct DNA sequencing

5. Positive and negative controls should be specified to confirm/refute specific virus detection

6. There should be a Standard Operational Procedure (SOP) available, which unequivocally specifies the above parameters, so that all laboratories are able to set up the exact same test conditions. To have a validated universal SOP is essential, because it enables the comparison of data within and between countries.

MINOR CONCERNS WITH THE CORMAN-DROSTEN PAPER

1. In Table 1 of the Corman-Drosten paper, different abbreviations are stated - “nM” is specified, “nm” isn’t. Further in regards to correct nomenclature, nm means “nanometer” therefore nm should read nM here.

2. It is the general consensus to write genetic sequences always in the 5’-3’ direction, including the reverse primers. It is highly unusual to do alignment with reverse complementary writing of the primer sequence as the authors did in figure 2 of the Corman-Drosten paper. Here, in addition, a wobble base is marked as “y” without description of the bases the Y stands for.

3. Two misleading pitfalls in the Corman-Drosten paper are that their Table 1 does not include Tm-values (annealing-temperature values), neither does it show GC-values (number of G and C in the sequences as %-value of total bases).

MAJOR CONCERNS WITH THE CORMAN-DROSTEN PAPER

A) BACKGROUND

The authors introduce the background for their scientific work as: "*The ongoing outbreak of the recently emerged novel coronavirus (2019-nCoV) poses a challenge for public health laboratories as virus isolates are unavailable while there is growing evidence that the outbreak is more widespread than initially thought, and international spread through travelers does already occur".*

According to BBC News [4] and Google Statistics [5] there were 6 deaths world-wide on January 21st 2020 - the day when the manuscript was submitted. Why did the authors assume a challenge for public health laboratories while there was no substantial evidence at that time to indicate that the outbreak was more widespread than initially thought?

As an aim the authors declared to develop and deploy robust diagnostic methodology for use in public health laboratory settings without having virus material available. Further, they acknowledge that "The present study demonstrates the enormous response capacity achieved through coordination of academic and public laboratories in national and European research networks."

B) Methods and Results

1. Primer & Probe Design

1a) Erroneous primer concentrations

Reliable and accurate PCR-test protocols are normally designed using between 100 nM and 200 nM per primer [7]. In the Corman-Drosten paper, we observe unusually high and varying primer concentrations for several primers (table 1). For the RdRp_SARSr-F and RdRp_SARSr-R primer pairs, 600 nM and 800 nM are described, respectively. Similarly, for the N_Sarbeco_F and N_Sarbeco_R primer set, they advise 600 nM and 800 nM, respectively [1]. It should be clear that these concentrations are far too high to be optimal for specific amplifications of target genes. *There exists no specified reason to use these extremely high*

concentrations of primers in this protocol. Rather, these concentrations lead to increased unspecific binding and PCR product amplification.

Table1: Primers and probes (adapted from Corman-Drosten paper; erroneous primer concentrations are highlighted)

Assay/use	Oligonucleotide	Sequence[a]	Concentration[b]
RdRP gene	RdRp_SARSr-F	GTGARATGGTCATGTGTGGCGG	Use 600 nM per reaction
	RdRp_SARSr-P2	FAM-CAGGTGGAACCTCATCAGGAGATGC-BBQ	Specific for 2019-nCoV, will not detect SARS-CoV. Use 100 nM per reaction and mix with P1
	RdRP_SARSr-P1	FAM-CCAGGTGGWACRTCATCMGGTGATGC-BBQ	Pan Sarbeco-Probe will detect 2019-nCoV, SARS-CoV and bat-SARS-related CoVs. Use 100 nM per reaction and mix with P2
	RdRp_SARSr-R	CARATGTTAAASACACTATTAGCATA	Use 800 nM per reaction
E gene	E_Sarbeco_F	ACAGGTACGTTAATAGTTAATAGCGT	Use 400 nm per reaction
	E_Sarbeco_P1	FAM-ACACTAGCCATCCTTACTGCGCTTCG-BBQ	Use 200 nm per reaction
	E_Sarbeco_R	ATATTGCAGCAGTACGCACACA	Use 400 nm per reaction
N gene	N_Sarbeco_F	CACATTGGCACCCGCAATC	Use 600 nm per reaction
	N_Sarbeco_P	FAM-ACTTCCTCAAGGAACAACATTGCCA-BBQ	Use 200 nm per reaction
	N_Sarbeco_R	GAGGAACGAGAAGAGGCTTG	Use 800 nm per reaction

[a] W is A/T; R is G/A; M is A/C; S is G/C. FAM: 6-carboxyfluorescein; BBQ: blackberry quencher.
[b] Optimised concentrations are given in nanomol per litre (nM) based on the final reaction mix, e.g. 1.5 µL of a 10 µM primer stock solution per 25 µL total reaction volume yields a final concentration of 600 nM as indicated in the table.

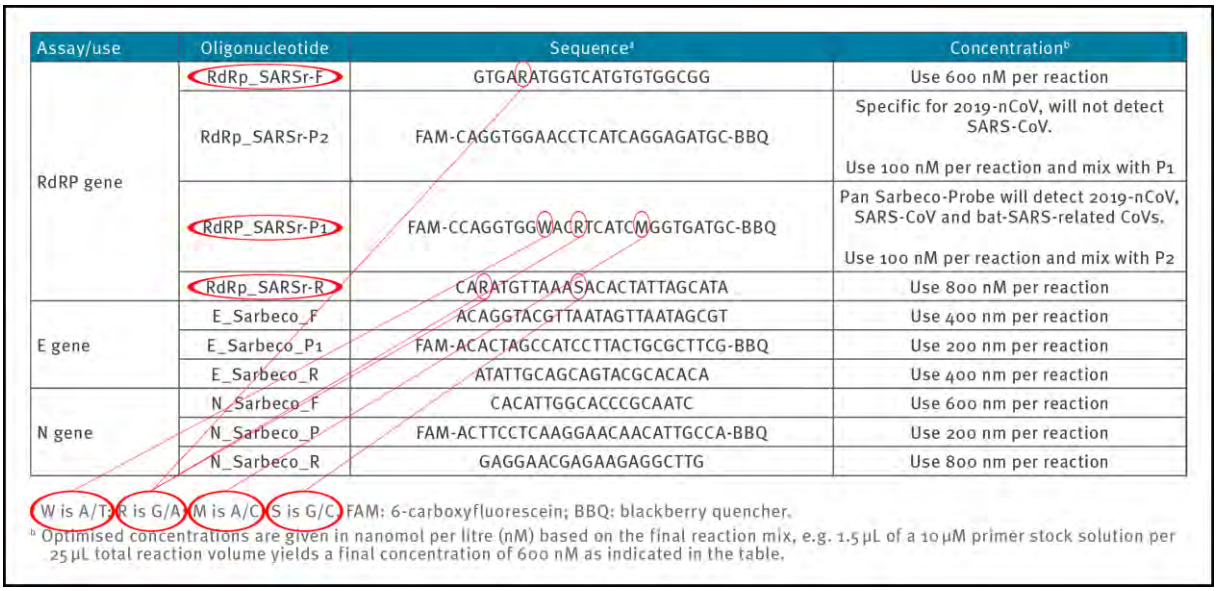
1b) Unspecified ("Wobbly") primer and probe sequences

To obtain reproducible and comparable results, it is essential to distinctively define the primer pairs. In the Corman-Drosten paper we observed six unspecified positions, indicated by the letters R, W, M and S (Table 2). The letter W means that at this position there can be either an A or a T; R signifies there can be either a G or an A; M indicates that the position may either be an A or a C; the letter S indicates there can be either a G or a C on this position.

This high number of variants not only is unusual, but it also is highly confusing for laboratories. These six unspecified positions could easily result in the design of several different alternative primer sequences which do not relate to SARS-CoV-2 (2 distinct RdRp_SARSr_F primers + 8 distinct RdRp_SARS_P1 probes + 4 distinct RdRp_SARSr_R). *The design variations will inevitably lead to results that are not even SARS-CoV-2 related. Therefore, the confusing unspecific description in the Corman-Drosten paper is not suitable as a Standard Operational Protocol. These unspecified positions should have been designed unequivocally.*

These wobbly sequences have already created a source of concern in the field and resulted in a Letter to the Editor authored by Pillonel *et al.* [8] regarding blatant errors in the described sequences. These errors are self-evident in the Corman *et al.* supplement as well.

Table 2: Primers and probes (adapted from Corman-Drosten paper; unspecified ("Wobbly") nucleotides in the primers are highlighted)



Assay/use	Oligonucleotide	Sequence[a]	Concentration[b]
RdRP gene	RdRp_SARSr-F	GTGARATGGTCATGTGTGGCGG	Use 600 nM per reaction
	RdRp_SARSr-P2	FAM-CAGGTGGAACCTCATCAGGAGATGC-BBQ	Specific for 2019-nCoV, will not detect SARS-CoV. Use 100 nM per reaction and mix with P1
	RdRP_SARSr-P1	FAM-CCAGGTGGWACRTCATCMGGTGATGC-BBQ	Pan Sarbeco-Probe will detect 2019-nCoV, SARS-CoV and bat-SARS-related CoVs. Use 100 nM per reaction and mix with P2
	RdRp_SARSr-R	CARATGTTAAASACACTATTAGCATA	Use 800 nM per reaction
E gene	E_Sarbeco_F	ACAGGTACGTTAATAGTTAATAGCGT	Use 400 nm per reaction
	E_Sarbeco_P1	FAM-ACACTAGCCATCCTTACTGCGCTTCG-BBQ	Use 200 nm per reaction
	E_Sarbeco_R	ATATTGCAGCAGTACGCACACA	Use 400 nm per reaction
N gene	N_Sarbeco_F	CACATTGGCACCCGCAATC	Use 600 nm per reaction
	N_Sarbeco_P	FAM-ACTTCCTCAAGGAACAACATTGCCA-BBQ	Use 200 nm per reaction
	N_Sarbeco_R	GAGGAACGAGAAGAGGCTTG	Use 800 nm per reaction

W is A/T; R is G/A; M is A/C; S is G/C; FAM: 6-carboxyfluorescein; BBQ: blackberry quencher.
[b] Optimised concentrations are given in nanomol per litre (nM) based on the final reaction mix, e.g. 1.5 µL of a 10 µM primer stock solution per 25 µL total reaction volume yields a final concentration of 600 nM as indicated in the table.

The WHO-protocol (Figure 1), which directly derives from the Corman-Drosten paper, concludes that in order to confirm the presence of SARS-CoV-2, two control genes (the E- and the RdRp-genes) must be identified in the assay. It should be noted, that the RdPd-gene has one uncertain position ("wobbly") in the forward-primer (R=G/A), two uncertain positions in the reverse-primer (R=G/A; S=G/C) and it has three uncertain positions in the RdRp-probe (W=A/T; R=G/A; M=A/C). So, two different forward primers, four different reverse primers, and eight distinct probes can be synthesized for the RdPd-gene. Together, there are 64 possible combinations of primers and probes!

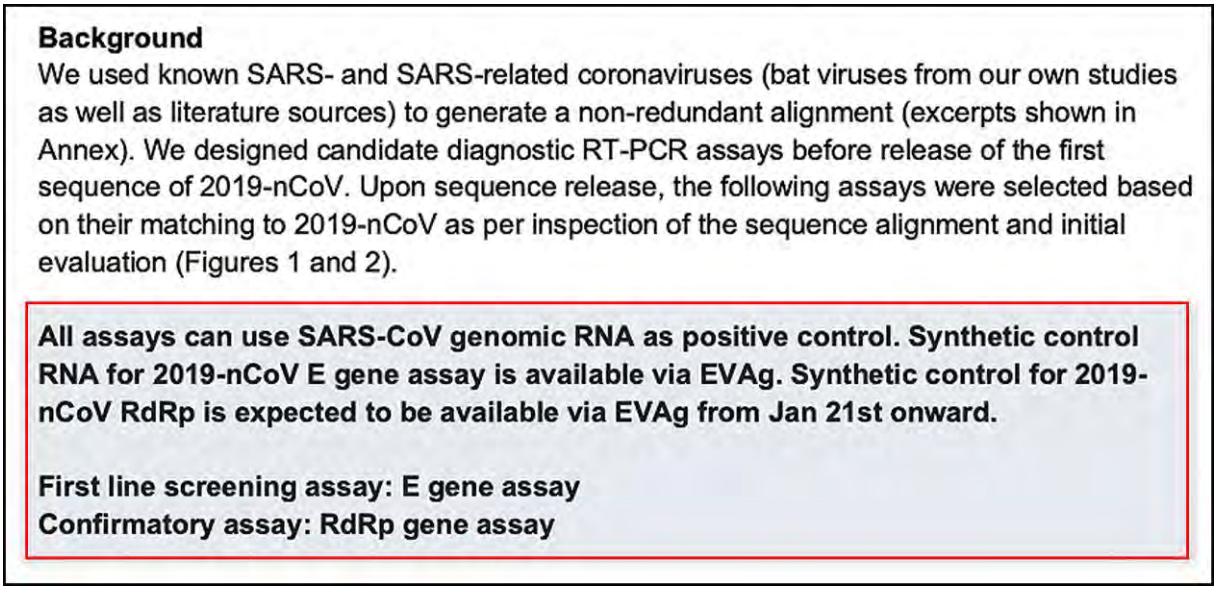
The Corman-Drosten paper further identifies a third gene which, according to the WHO protocol, was not further validated and deemed unnecessary: *"Of note, the N gene assay also performed well but was not subjected to intensive further validation because it was slightly less sensitive."*

This was an unfortunate omission as it would be best to use all three gene PCRs as

confirmatory assays, and this would have resulted in an almost sufficient virus RNA detection diagnostic tool protocol. Three confirmatory assay-steps would at least minimize-out errors & uncertainties at every fold-step in regards to “Wobbly”-spots. (Nonetheless, the protocol would still fall short of any “good laboratory practice”, when factoring in all the other design-errors).

As it stands, the N gene assay is regrettably neither proposed in the WHO-recommendation (Figure 1) as a mandatory and crucial third confirmatory step, nor is it emphasized in the Corman-Drosten paper as important optional reassurance “for a routine workflow” (Table 2).

Consequently, in nearly all test procedures worldwide, merely 2 primer-matches were used instead of all three. This oversight renders the entire test-protocol useless with regards to delivering accurate test-results of real significance in an ongoing pandemic.



Background

We used known SARS- and SARS-related coronaviruses (bat viruses from our own studies as well as literature sources) to generate a non-redundant alignment (excerpts shown in Annex). We designed candidate diagnostic RT-PCR assays before release of the first sequence of 2019-nCoV. Upon sequence release, the following assays were selected based on their matching to 2019-nCoV as per inspection of the sequence alignment and initial evaluation (Figures 1 and 2).

All assays can use SARS-CoV genomic RNA as positive control. Synthetic control RNA for 2019-nCoV E gene assay is available via EVAg. Synthetic control for 2019-nCoV RdRp is expected to be available via EVAg from Jan 21st onward.

First line screening assay: E gene assay
Confirmatory assay: RdRp gene assay

Figure 1: The N-Gene confirmatory-assay is neither emphasized as necessary third step in the official WHO Drosten-Corman protocol-recommendation [8] nor is it required as a crucial step for higher test-accuracy in the Eurosurveillance publication.

1c) Erroneous GC-content (discussed in 2c, together with annealing temperature (Tm))

1d) Detection of viral genes

RT-PCR is not recommended for primary diagnostics of infection. This is why the RT-PCR Test

used in clinical routine for detection of COVID-19 is not indicated for COVID-19 diagnosis on a regulatory basis.

"Clinicians need to recognize the enhanced accuracy and speed of the molecular diagnostic techniques for the diagnosis of infections, but also to understand their limitations. Laboratory results should always be interpreted in the context of the clinical presentation of the patient, and appropriate site, quality, and timing of specimen collection are required for reliable test results". [9]

However, it may be used to help the physician's differential diagnosis when he or she has to discriminate between different infections of the lung (Flu, Covid-19 and SARS have very similar symptoms). For a confirmative diagnosis of a specific virus, at least 3 specific primer pairs must be applied to detect 3 virus-specific genes. Preferably, these target genes should be located with the greatest distance possible in the viral genome (opposite ends included). Although the Corman-Drosten paper describes 3 primers, these primers only cover roughly half of the virus' genome. This is another factor that decreases specificity for detection of intact COVID-19 virus RNA and increases the quote of false positive test results.

Therefore, even if we obtain three positive signals (i.e. the three primer pairs give 3 different amplification products) in a sample, this does not prove the presence of a virus. A better primer design would have terminal primers on both ends of the viral genome. This is because the whole viral genome would be covered and three positive signals can better discriminate between a complete (and thus potentially infectious) virus and fragmented viral genomes (without infectious potency). In order to infer anything of significance about the infectivity of the virus, the Orf1 gene, which encodes the essential replicase enzyme of SARS-CoV-1 and SARS-CoV-2 viruses, should have been included as a target (Figure 2). The positioning of the targets in the region of the viral genome that is most heavily and variably transcribed is another weakness of the protocol.

Kim *et al.* demonstrate a highly variable 3' expression of subgenomic RNA in Sars-CoV-2 [23]. These RNAs are actively monitored as signatures for asymptomatic and non-infectious patients [10]. It is highly questionable to screen a population of asymptomatic people with qPCR primers that have 6 base pairs primer-dimer on the 3 prime end of a primer (Figure 3). Apparently the WHO recommends these primers. We tested all the wobble derivatives from

the Corman-Drosten paper with Thermofisher's primer dimer web tool [11]. The RdRp forward primer has 6bp 3prime homology with Sarbeco E Reverse. At high primer concentrations this is enough to create inaccuracies.

Of note: There is a perfect match of one of the N primers to a clinical pathogen (*Pantoea*), found in immuno-compromised patients. The reverse primer hits *Pantoea* as well but not in the same region (Figure 3).

<u>These are severe design errors, since the test cannot discriminate between the whole virus and viral fragments. The test cannot be used as a diagnostic for SARS-CoV-2 viruses.</u>

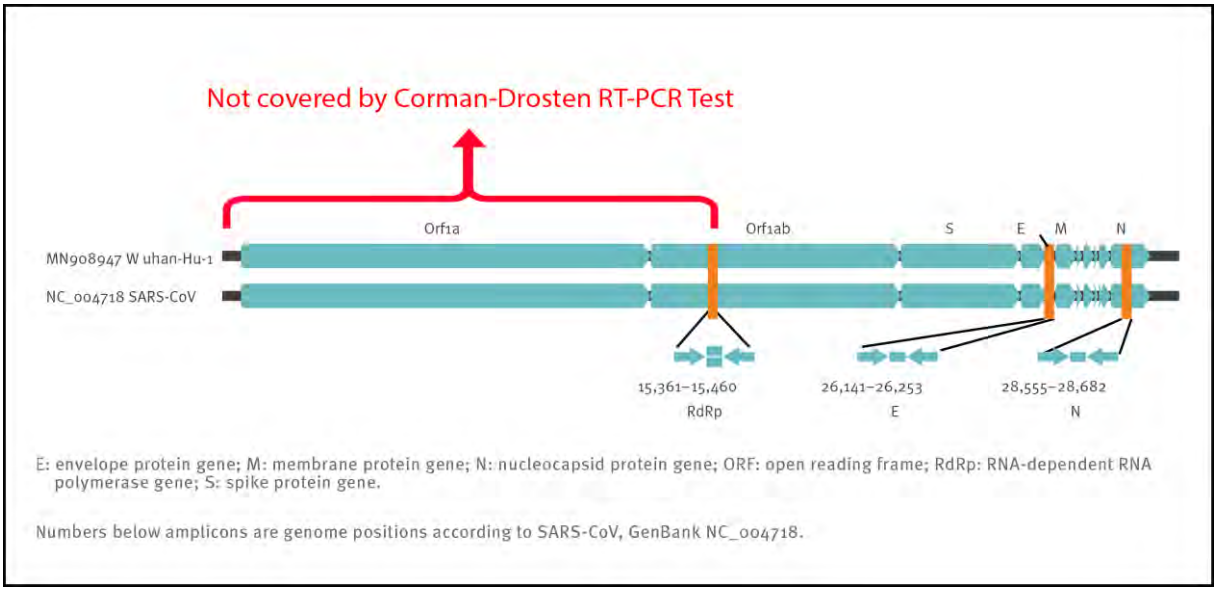


Figure 2: Relative positions of amplicon targets on the SARS-CoV-1 coronavirus and the 2019 novel coronavirus genome. ORF: open reading frame; RdRp: RNA-dependent RNA polymerase. Numbers below amplicon are genome positions according to SARS-CoV-1, NC_004718 [1];

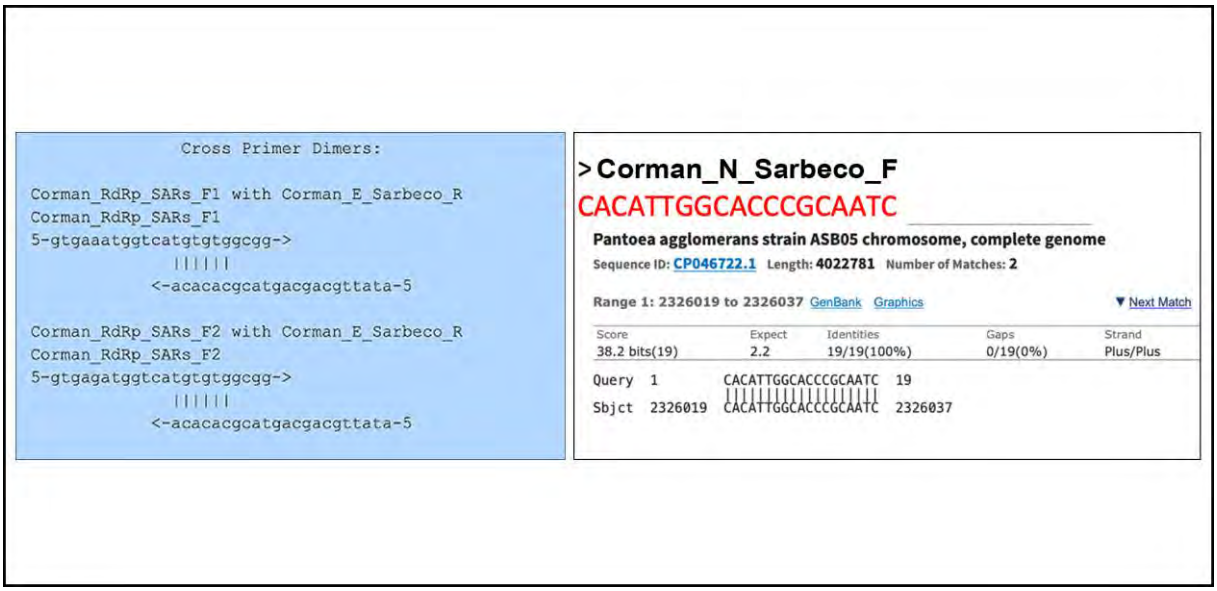


Figure 3: A test with Thermofischer's primer dimer web tool reveals that the RdRp forward primer has a 6bp 3`prime homology with Sarbeco E Reverse (left box). Another test reveals that there is a perfect match for one of the N-primers to a clinical pathogen (*Pantoea*) found in immuno-compromised patients (right box).

2. Reaction temperatures

2a) DNA melting temperature (>92°).

Adequately addressed in the Corman-Drosten paper.

2b) DNA amplification temperature.

Adequately addressed in the Corman-Drosten paper.

2c) Erroneous GC-contents and Tm

The annealing-temperature determines at which temperature the primer attaches/detaches from the target sequence. For an efficient and specific amplification, GC content of primers should meet a minimum of 40% and a maximum of 60% amplification. As indicated in table 3, three of the primers described in the Corman-Drosten paper are not within the normal range for GC-content. Two primers (RdRp_SARSr_F and RdRp_SARSr_R) have unusual and very low GC-values of 28%-31% for all possible variants of wobble bases, whereas primer E_Sarbeco_F has a GC-value of 34.6% (Table 3 and second panel of Table 3).

It should be noted that the GC-content largely determines the binding to its specific target due to its three hydrogen bonds in base pairing. Thus, the lower the GC-content of the primer, the lower its binding-capability to its specific target gene sequence (i.e. the gene to

be detected). This means for a target-sequence to be recognized we have to choose a temperature which is as close as possible to the actual annealing-temperature (best practise-value) for the primer not to detach again, while at the same time specifically selecting the target sequence.

If the Tm-value is very low, as observed for all wobbly-variants of the RdRp reverse primers, the primers can bind non-specifically to several targets, decreasing specificity and increasing potential false positive results.

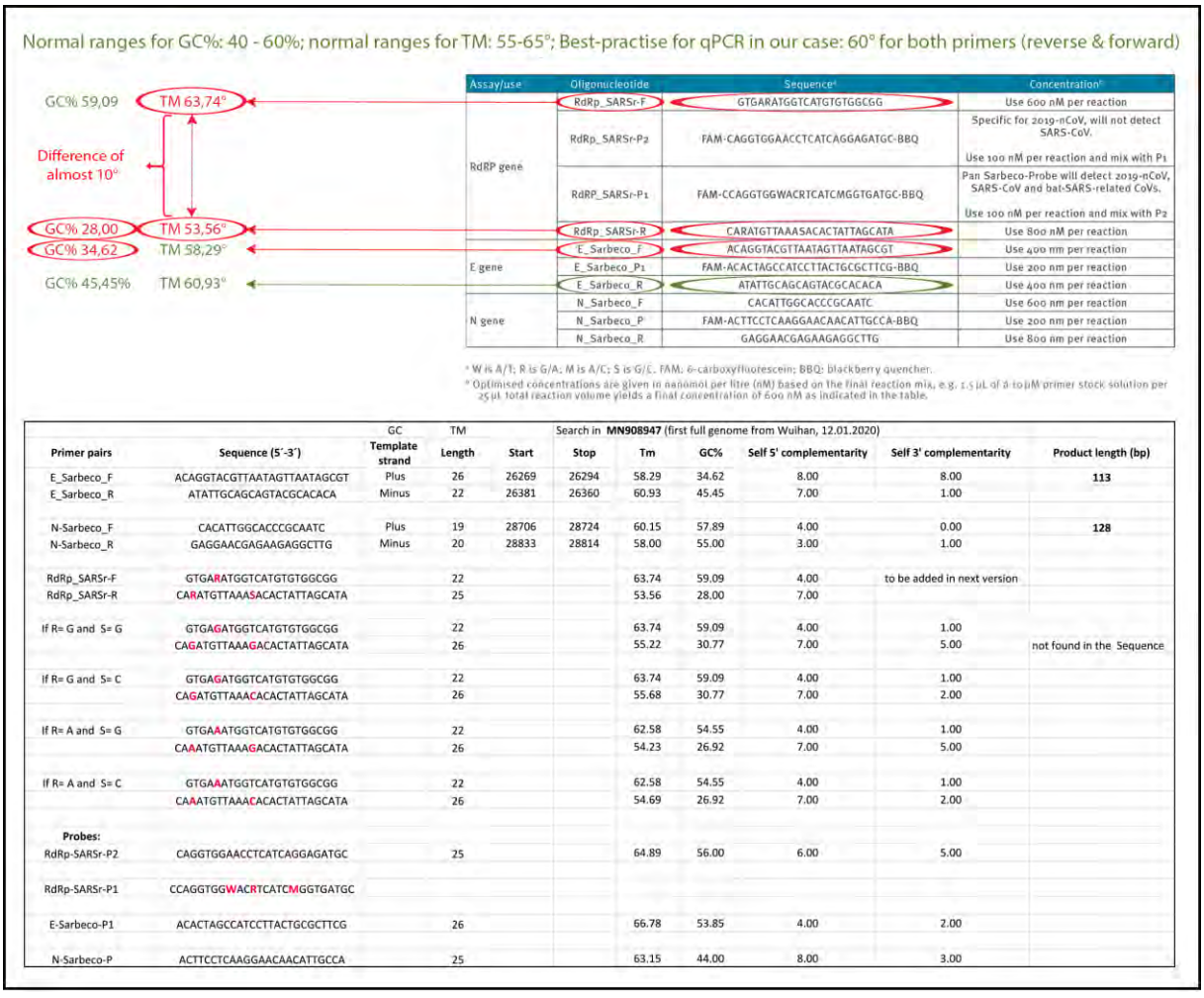
The annealing temperature (Tm) is a crucial factor for the determination of the specificity /accuracy of the qPCR procedure and essential for evaluating the accuracy of qPCR-protocols. Best-practice recommendation: Both primers (forward and reverse) should have an almost similar value, preferably the identical value.

We used the freely available primer design software Primer-BLAST [12, 25] to evaluable the best-practise values for all primers used in the Corman-Drosten paper (Table 3). We attempted to find a Tm-value of 60° C, while similarly seeking the highest possible GC%-value for all primers. A maximal Tm difference of 2° C within primer pairs was considered acceptable. Testing the primer pairs specified in the Corman-Drosten paper, we observed a difference of 10° C with respect to the annealing temperature Tm for primer pair1 (RdRp_SARSr_F and RdRp_SARSr_R). *This is a very serious error and makes the protocol useless as a specific diagnostic tool.*

Additional testing demonstrated that only the primer pair designed to amplify the N-gene (N_Sarbeco_F and N_Sarbeco_R) reached the adequate standard to operate in a diagnostic test, since it has a sufficient GC-content and the Tm difference between the primers (N_Sarbeco_F and N_Sarbeco_R) is 1.85° C (below the crucial maximum of 2° C difference). Importantly, this is the gene which was neither tested in the virus samples (Table 2) nor emphasized as a confirmatory test. In addition to highly variable melting temperatures and degenerate sequences in these primers, there is another factor impacting specificity of the procedure: the dNTPs (0.4uM) are 2x higher than recommended for a highly specific amplification. There is additional magnesium sulphate added to the reaction as well. This procedure combined with a low annealing temperature can create non-specific amplifications. When additional magnesium is required for qPCR, specificity of the assay should be further scrutinized.

The design errors described here are so severe that it is highly unlikely that specific amplification of SARS-CoV-2 genetic material will occur using the protocol of the Corman-Drosten paper.

Table 3: GC-content of the primers and probes (adapted from Corman-Drosten paper; aberrations from optimized GC-contents are highlighted. Second Panel shows a table-listing of all Primer-BLAST best practices values for all primers and probes used in the Corman-Drosten paper by Prof. Dr. Ulrike Kämmerer & her team



Assay/use	Oligonucleotide	Sequence[a]	Concentration[b]
RdRP gene	RdRp_SARSr-F	GTGARATGGTCATGTGTGGCGG	Use 600 nM per reaction
	RdRp_SARSr-P2	FAM-CAGGTGGAACCTCATCAGGAGATGC-BBQ	Specific for 2019-nCoV, will not detect SARS-CoV. Use 100 nM per reaction and mix with P1
	RdRP_SARSr-P1	FAM-CCAGGTGGWACRTCATCMGGTGATGC-BBQ	Pan Sarbeco-Probe will detect 2019-nCoV, SARS-CoV and bat-SARS-related CoVs. Use 100 nM per reaction and mix with P2
	RdRp_SARSr-R	CARATGTTAAASACACTATTAGCATA	Use 800 nM per reaction
E gene	E_Sarbeco_F	ACAGGTACGTTAATAGTTAATAGCGT	Use 400 nm per reaction
	E_Sarbeco_P1	FAM-ACACTAGCCATCCTTACTGCGCTTCG-BBQ	Use 200 nm per reaction
	E_Sarbeco_R	ATATTGCAGCAGTACGCACACA	Use 400 nm per reaction
N gene	N_Sarbeco_F	CACATTGGCACCCGCAATC	Use 600 nm per reaction
	N_Sarbeco_P	FAM-ACTTCCTCAAGGAACAACATTGCCA-BBQ	Use 200 nm per reaction
	N_Sarbeco_R	GAGGAACGAGAAGAGGCTTG	Use 800 nm per reaction

[a] W is A/T; R is G/A; M is A/C; S is G/C. FAM: 6-carboxyfluorescein; BBQ: blackberry quencher.
[b] Optimised concentrations are given in nanomol per litre (nM) based on the final reaction mix, e.g. 1.5 µL of a 10 µM primer stock solution per 25 µL total reaction volume yields a final concentration of 600 nM as indicated in the table.

		GC	TM	Search in **MN908947** (first full genome from Wuihan, 12.01.2020)						
Primer pairs	**Sequence (5'-3')**	**Template strand**	**Length**	**Start**	**Stop**	**Tm**	**GC%**	**Self 5' complementarity**	**Self 3' complementarity**	**Product length (bp)**
E_Sarbeco_F	ACAGGTACGTTAATAGTTAATAGCGT	Plus	26	26269	26294	58.29	34.62	8.00	8.00	**113**
E_Sarbeco_R	ATATTGCAGCAGTACGCACACA	Minus	22	26381	26360	60.93	45.45	7.00	1.00	
N-Sarbeco_F	CACATTGGCACCCGCAATC	Plus	19	28706	28724	60.15	57.89	4.00	0.00	**128**
N-Sarbeco_R	GAGGAACGAGAAGAGGCTTG	Minus	20	28833	28814	58.00	55.00	3.00	1.00	
RdRp_SARSr-F	GTGARATGGTCATGTGTGGCGG		22			63.74	59.09	4.00	to be added in next version	
RdRp_SARSr-R	CARATGTTAAASACACTATTAGCATA		25			53.56	28.00	7.00		
If R= G and S= G	GTGAGATGGTCATGTGTGGCGG		22			63.74	59.09	4.00	1.00	
	CAGATGTTAAAGACACTATTAGCATA		26			55.22	30.77	7.00	5.00	not found in the Sequence
If R= G and S= C	GTGAGATGGTCATGTGTGGCGG		22			63.74	59.09	4.00	1.00	
	CAGATGTTAAACACACTATTAGCATA		26			55.68	30.77	7.00	2.00	
If R= A and S= G	GTGAAATGGTCATGTGTGGCGG		22			62.58	54.55	4.00	1.00	
	CAAATGTTAAAGACACTATTAGCATA		26			54.23	26.92	7.00	5.00	
If R= A and S= C	GTGAAATGGTCATGTGTGGCGG		22			62.58	54.55	4.00	1.00	
	CAAATGTTAAACACACTATTAGCATA		26			54.69	26.92	7.00	2.00	
Probes:										
RdRp-SARSr-P2	CAGGTGGAACCTCATCAGGAGATGC		25			64.89	56.00	6.00	5.00	
RdRp-SARSr-P1	CCAGGTGGWACRTCATCMGGTGATGC									
E-Sarbeco-P1	ACACTAGCCATCCTTACTGCGCTTCG		26			66.78	53.85	4.00	2.00	
N-Sarbeco-P	ACTTCCTCAAGGAACAACATTGCCA		25			63.15	44.00	8.00	3.00	

3. The number of amplification cycles

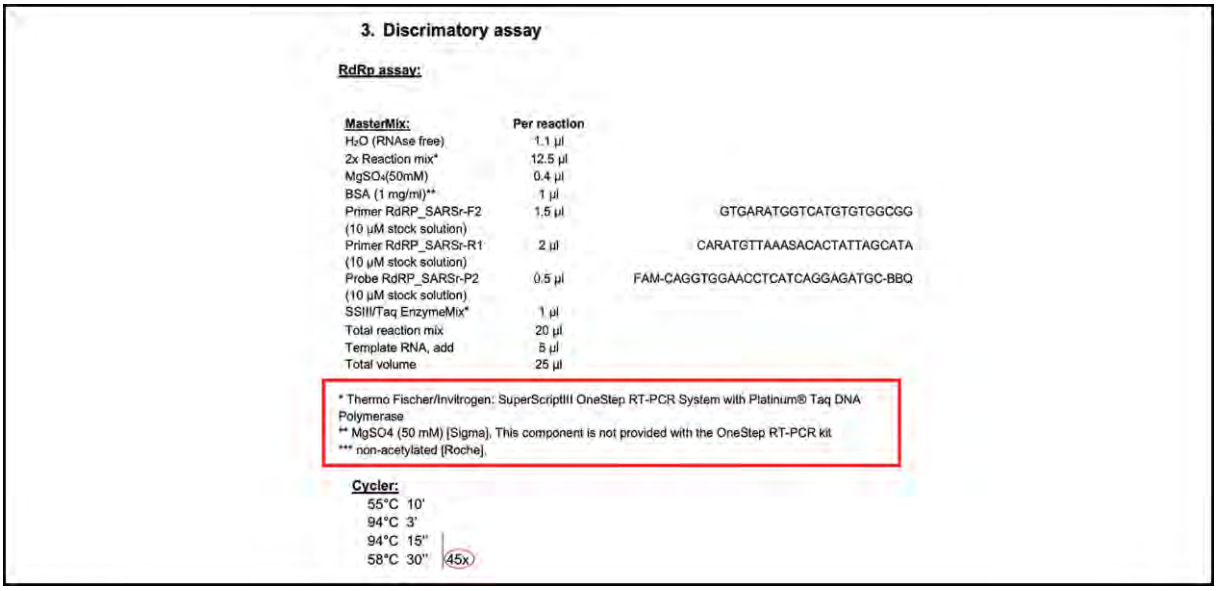
It should be noted that there is no mention anywhere in the Corman-Drosten paper of a test being positive or negative, or indeed what defines a positive or negative result. These types of virological diagnostic tests must be based on a SOP, including a validated and fixed number of PCR cycles (Ct value) after which a sample is deemed positive or negative. The maximum reasonably reliable Ct value is 30 cycles. Above a Ct of 35 cycles, rapidly increasing numbers of false positives must be expected .

PCR data evaluated as positive after a Ct value of 35 cycles are completely unreliable.

Citing Jaafar *et al.* 2020 [3]: *"At Ct = 35, the value we used to report a positive result for PCR, <3% of cultures are positive."* In other words, there was no successful virus isolation of SARS-CoV-2 at those high Ct values.

Further, scientific studies show that only non-infectious (dead) viruses are detected with Ct values of 35 [22].

Between 30 and 35 there is a grey area, where a positive test cannot be established with certainty. This area should be excluded. Of course, one could perform 45 PCR cycles, as recommended in the Corman-Drosten WHO-protocol (Figure 4), but then you also have to define a reasonable Ct-value (which should not exceed 30). But an analytical result with a Ct value of 45 is scientifically and diagnostically absolutely meaningless (a reasonable Ct-value should not exceed 30). All this should be communicated very clearly. *It is a significant mistake that the Corman-Drosten paper does not mention the maximum Ct value at which a sample can be unambiguously considered as a positive or a negative test-result. This important cycle threshold limit is also not specified in any follow-up submissions to date.*



3. Discrimatory assay

RdRp assay:

MasterMix:	**Per reaction**	
H_2O (RNAse free)	1.1 µl	
2x Reaction mix*	12.5 µl	
$MgSO_4$(50mM)	0.4 µl	
BSA (1 mg/ml)**	1 µl	
Primer RdRP_SARSr-F2 (10 µM stock solution)	1.5 µl	GTGARATGGTCATGTGTGGCGG
Primer RdRP_SARSr-R1 (10 µM stock solution)	2 µl	CARATGTTAAASACACTATTAGCATA
Probe RdRP_SARSr-P2 (10 µM stock solution)	0.5 µl	FAM-CAGGTGGAACCTCATCAGGAGATGC-BBQ
SSIII/Taq EnzymeMix*	1 µl	
Total reaction mix	20 µl	
Template RNA, add	5 µl	
Total volume	25 µl	

* Thermo Fischer/Invitrogen: SuperScriptIII OneStep RT-PCR System with Platinum® Taq DNA Polymerase
** MgSO4 (50 mM) [Sigma], This component is not provided with the OneStep RT-PCR kit
*** non-acetylated [Roche].

Cycler:
55°C 10'
94°C 3'
94°C 15"
58°C 30" 45x

Figure 4: RT-PCR Kit recommendation in the official Corman-Drosten WHO-protocol [8]. Only a "Cycler"-value (cycles) is to be found without corresponding and scientifically reasonable Ct (Cutoff-value). This or any other cycles-value is nowhere to be found in the actual Corman-Drosten paper.

4. Biomolecular validations

To determine whether the amplified products are indeed SARS-CoV-2 genes, biomolecular validation of amplified PCR products is essential. For a diagnostic test, this validation is an absolute must.

Validation of PCR products should be performed by either running the PCR product in a 1% agarose-EtBr gel together with a size indicator (DNA ruler or DNA ladder) so that the size of the product can be estimated. The size must correspond to the calculated size of the amplification product. But it is even better to sequence the amplification product. The latter will give 100% certainty about the identity of the amplification product. Without molecular validation one can not be sure about the identity of the amplified PCR products. Considering the severe design errors described earlier, the amplified PCR products can be anything.

Also not mentioned in the Corman-Drosten paper is the case of small fragments of qPCR (around 100bp): It could be either 1,5% agarose gel or even an acrylamide gel.
The fact that these PCR products have not been validated at molecular level is another striking error of the protocol, making any test based upon it useless as a specific diagnostic tool to identify the SARS-CoV-2 virus.

5. Positive and negative controls to confirm/refute specific virus detection.

The unconfirmed assumption described in the Corman-Drosten paper is that SARS-CoV-2 is the only virus from the SARS-like beta-coronavirus group that currently causes infections in humans. The sequences on which their PCR method is based are *in silico* sequences, supplied by a laboratory in China [23], because at the time of development of the PCR test no control material of infectious ("live") or inactivated SARS-CoV-2 was available to the authors. The PCR test was therefore designed using the sequence of the known SARS-CoV-1 as a control material for the Sarbeco component (Dr. Meijer, co-author Corman-Drosten paper in an email exchange with Dr. Peter Borger) [2].

All individuals testing positive with the RT-PCR test, as described in the Corman-Drosten paper, are assumed to be positive for SARS-CoV-2 infections. There are three severe flaws in their assumption. First, a positive test for the RNA molecules described in the Corman-Drosten paper cannot be equated to "infection with a virus". A positive RT-PCR test merely indicates the presence of viral RNA molecules. As demonstrated under point 1d (above), the Corman-Drosten test was not designed to detect the full-length virus, but only a fragment of the virus. We already concluded that this classifies the test as unsuitable as a diagnostic test for SARS-virus infections.

Secondly and of major relevance, the functionality of the published RT-PCR Test was not demonstrated with the use of a positive control (isolated SARS-CoV-2 RNA) which is an essential scientific gold standard.

Third, the Corman-Drosten paper states:

"To show that the assays can detect other bat-associated SARS-related viruses, we used the E gene assay to test six bat-derived faecal samples available from Drexler et al. [...] und Muth et al. […]. These virus-positive samples stemmed from European rhinolophid bats. Detection of these phylogenetic outliers within the SARS-related CoV clade suggests that all Asian viruses are likely to be detected. This would, theoretically, ensure broad sensitivity even in case of multiple independent acquisitions of variant viruses from an animal reservoir."

This statement demonstrates that the E gene used in RT-PCR test, as described in the Corman-Drosten paper, is not specific to SARS-CoV-2. The E gene primers also detect a broad spectrum of other SARS viruses.

The genome of the coronavirus is the largest of all RNA viruses that infect humans and they all have a very similar molecular structure. Still, SARS-CoV-1 and SARS-CoV-2 have two highly specific genetic fingerprints, which set them apart from the other coronaviruses. First, a unique fingerprint-sequence (KTFPPTEPKKDKKKK) is present in the N-protein of SARS-CoV-1 and SARS-CoV-2 [13,14,15]. Second, both SARS-CoV-1 and SARS-CoV-2 do not contain the HE protein, whereas all other coronaviruses possess this gene [13, 14]. So, in order to specifically detect a SARS-CoV-1 and SARS-CoV-2 PCR product the above region in the N gene should have been chosen as the amplification target. A reliable diagnostic test should focus on this specific region in the N gene as a confirmatory test. The PCR for this N gene was not further validated nor recommended as a test gene by the Drosten-Corman paper, because of

being “not so sensitive” with the SARS-CoV original probe [1].

Furthermore, the absence of the HE gene in both SARS-CoV-1 and SARS-CoV-2 makes this gene the ideal negative control to exclude other coronaviruses. The Corman-Drosten paper does not contain this negative control, nor does it contain any other negative controls. The PCR test in the Corman-Drosten paper therefore contains neither a unique positive control nor a negative control to exclude the presence of other coronaviruses. This is another major design flaw which classifies the test as unsuitable for diagnosis.

6. Standard Operational Procedure (SOP) is not available

There should be a Standard Operational Procedure (SOP) available, which unequivocally specifies the above parameters, so that all laboratories are able to set up the identical same test conditions. To have a validated universal SOP is essential, because it facilitates data comparison within and between countries. It is very important to specify all primer parameters unequivocally. We note that this has not been done. Further, the Ct value to indicate when a sample should be considered positive or negative is not specified. It is also not specified when a sample is considered infected with SARS-CoV viruses. As shown above, the test cannot discern between virus and virus fragments, so the Ct value indicating positivity is crucially important. This Ct value should have been specified in the Standard Operational Procedure (SOP) and put on-line so that all laboratories carrying out this test have exactly the same boundary conditions. It points to flawed science that such an SOP does not exist. The laboratories are thus free to conduct the test as they consider appropriate, resulting in an enormous amount of variation. Laboratories all over Europe are left with a multitude of questions; which primers to order? which nucleotides to fill in the undefined places? which Tm value to choose? How many PCR cycles to run? At what Ct value is the sample positive? And when is it negative? And how many genes to test? Should all genes be tested, or just the E and RpRd gene as shown in Table 2 of the Corman-Drosten paper? Should the N gene be tested as well? And what is their negative control? What is their positive control? The protocol as described is unfortunately very vague and erroneous in its design that one can go in dozens of different directions. There does not appear to be any standardization nor an SOP, so it is not clear how this test can be implemented.

7. Consequences of the errors described under 1-5: false positive results.

The RT-PCR test described in the Corman-Drosten paper contains so many molecular biological design errors (see 1-5) that it is not possible to obtain unambiguous results. It is inevitable that this test will generate a tremendous number of so-called “false positives”. The definition of false positives is a negative sample, which initially scores positive, but which is negative after retesting with the same test. False positives are erroneous positive test-results, i.e. negative samples that test positive. And this is indeed what is found in the Corman-Drosten paper. On page 6 of the manuscript PDF the authors demonstrate, that even under well-controlled laboratory conditions, a considerable percentage of false positives is generated with this test:

“In four individual test reactions, weak initial reactivity was seen however they were negative upon retesting with the same assay. These signals were not associated with any particular virus, and for each virus with which initial positive reactivity occurred, there were other samples that contained the same virus at a higher concentration but did not test positive. Given the results from the extensive technical qualification described above, it was concluded that this initial reactivity was not due to chemical instability of real-time PCR probes and most probably to handling issues caused by the rapid introduction of new diagnostic tests and controls during this evaluation study.” [1]

The first sentence of this excerpt is clear evidence that the PCR test described in the Corman-Drosten paper generates false positives. Even under the well-controlled conditions of the state-of-the-art Charité-laboratory, 4 out of 310 primary-tests are false positives per definition. Four negative samples initially tested positive, then were negative upon retesting. This is the classical example of a false positive. In this case the authors do not identify them as false positives, which is intellectually dishonest.

Another telltale observation in the excerpt above is that the authors explain the false positives away as "handling issues caused by the rapid introduction of new diagnostic tests". Imagine the laboratories that have to introduce the test without all the necessary information normally described in an SOP.

8. The Corman-Drosten paper was not peer-reviewed

Before formal publication in a scholarly journal, scientific and medical articles are traditionally certified by "peer review." In this process, the journal's editors take advice from various experts ("referees") who have assessed the paper and may identify weaknesses in its assumptions, methods, and conclusions. Typically a journal will only publish an article once the editors are satisfied that the authors have addressed referees' concerns and that the data presented supports the conclusions drawn in the paper." This process is as well described for Eurosurveillance [16].

The Corman-Drosten paper was submitted to Eurosurveillance on January 21st 2020 and accepted for publication on January 22nd 2020. On January 23rd 2020 the paper was online. On January 13th 2020 version 1-0 of the protocol was published at the official WHO website [17], updated on January 17th 2020 as document version 2-1 [18], even before the Corman-Drosten paper was published on January 23rd at Eurosurveillance.

Normally, peer review is a time-consuming process since at least two experts from the field have to critically read and comment on the submitted paper. In our opinion, this paper was not peer-reviewed. Twenty-four hours are simply not enough to carry out a thorough peer review. Our conclusion is supported by the fact that a tremendous number of very serious design flaws were found by us, which make the PCR test completely unsuitable as a diagnostic tool to identify the SARS-CoV-2 virus. Any molecular biologist familiar with RT-PCR design would have easily observed the grave errors present in the Corman-Drosten paper before the actual review process. We asked Eurosurveillance on October 26th 2020 to send us a copy of the peer review report. To date, we have not received this report and in a letter dated November 18th 2020, the ECDC as host for Eurosurveillance declined to provide access without providing substantial scientific reasons for their decision. On the contrary, they write that "disclosure would undermine the purpose of scientific investigations." [24].

9. Authors as the editors

A final point is one of major concern. It turns out that two authors of the Corman-Drosten paper, Christian Drosten and Chantal Reusken, are also members of the editorial board of this journal [19]. Hence there is a severe conflict of interest which strengthens suspicions

that the paper was not peer-reviewed. It has the appearance that the rapid publication was possible simply because the authors were also part of the editorial board at Eurosurveillance. This practice is categorized as compromising scientific integrity .

SUMMARY CATALOGUE OF ERRORS FOUND IN THE PAPER

The Corman-Drosten paper contains the following specific errors:

1. There exists no specified reason to use these extremely high concentrations of primers in this protocol. The described concentrations lead to increased nonspecific bindings and PCR product amplifications, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

2. Six unspecified wobbly positions will introduce an enormous variability in the real world laboratory implementations of this test; the confusing nonspecific description in the Corman-Drosten paper is not suitable as a Standard Operational Protocol making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

3. The test cannot discriminate between the whole virus and viral fragments. Therefore, the test cannot be used as a diagnostic for intact (infectious) viruses, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus and make inferences about the presence of an infection.

4. A difference of 10° C with respect to the annealing temperature Tm for primer pair1 (RdRp_SARSr_F and RdRp_SARSr_R) also makes the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

5. A severe error is the omission of a Ct value at which a sample is considered positive and negative. This Ct value is also not found in follow-up submissions making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

6. The PCR products have not been validated at the molecular level. This fact makes the protocol useless as a specific diagnostic tool to identify the SARS-CoV-2 virus.

7. The PCR test contains neither a unique positive control to evaluate its specificity for SARS-CoV-2 nor a negative control to exclude the presence of other coronaviruses, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

8. The test design in the Corman-Drosten paper is so vague and flawed that one can go in dozens of different directions; nothing is standardized and there is no SOP. This highly questions the scientific validity of the test and makes it unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

9. Most likely, the Corman-Drosten paper was not peer-reviewed making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

10. We find severe conflicts of interest for at least four authors, in addition to the fact that two of the authors of the Corman-Drosten paper (Christian Drosten and Chantal Reusken) are members of the editorial board of Eurosurveillance. A conflict of interest was added on July 29 2020 (Olfert Landt is CEO of TIB-Molbiol; Marco Kaiser is senior researcher at GenExpress and serves as scientific advisor for TIB-Molbiol), that was not declared in the original version (and still is missing in the PubMed version); TIB-Molbiol is the company which was “the first” to produce PCR kits (Light Mix) based on the protocol published in the Corman-Drosten manuscript, and according to their own words, they distributed these PCR-test kits before the publication was even submitted [20]; further, Victor Corman & Christian Drosten failed to mention their second affiliation: the commercial test laboratory “Labor Berlin”. Both are responsible for the virus diagnostics there [21] and the company operates in the realm of real time PCR-testing.

CONCLUSION

In light of our re-examination of the test protocol to identify SARS-CoV-2 described in the Corman-Drosten paper we have identified concerning errors and inherent fallacies which render the SARS-CoV-2 PCR test useless.

The decision as to which test protocols are published and made widely available lies squarely in the hands of Eurosurveillance. A decision to recognise the errors apparent in the Corman-Drosten paper has the benefit to greatly minimise human cost and suffering going forward. Is it not in the best interest of Eurosurveillance to retract this paper? Our conclusion is clear. In the face of all the tremendous PCR-protocol design flaws and errors described here, we conclude: There is not much of a choice left in the framework of scientific integrity and responsibility.

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To the Federal Chancellor of the Federal Republic of Germany

Platz der Republik 1
11011 Berlin

December 13, 2021

Copy to:

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- German Ethics Council, Office Jägerstr. 22/23, 10117 Berlin
- the parties represented in the German Bundestag
- Press Office of the German Medical Association, Herbert-Lewin-Platz 1, 10623 Berlin
- Press Office of the National Association of Statutory Health Insurance Physicians, Herbert-Lewin-Platz 2, 10623 Berlin
- German Press Agency, Markgrafenstr. 20, 10969 Berlin
- also to: die Zeit, Süddeutsche, Welt, Handelsblatt, FAZ, Frankfurter Rundschau, taz, BILD, Neue Züricher Zeitung (NZZ), multipolar, NachDenkSeiten

Open letter

Little benefit and still unclear risks from COVID vaccinations

Dear Members of Parliament,

Dear Federal Chancellor,

We perceive with great concern that our society is divided into those vaccinated against COVID and unvaccinated, and that there is growing pressure exerted on unvaccinated to cause them to get vaccinated.

We call on the government to put a stop to this division and not only to stop all direct and indirect compulsory measures aimed at vaccinating the previously unvaccinated, but also to actively prevent them.

In the following, we explain why compulsion or pressure of any kind is neither justified nor ethically justifiable.

The effectiveness of vaccination in protecting against severe COVID-19 disease

The pivotal trials of vaccines against COVID-19 have shown a relative vaccine effectiveness of about 60 to 95% for preventing infection. The Follow-up, however, was only 10 to 14 weeks [1-4]. Due to the short observation period and the insufficient number of events, it is neither possible to make statements about long-term efficacy, nor conclusions regarding the prevention of severe disease progressions or deaths can be drawn. Here, observational studies with vaccinated and non-vaccinated persons are necessary.

An important example of such a study is a large matched cohort study from Israel, in which 596,618 vaccinated and unvaccinated individuals were compared with respect to the risk of COVID-related hospitalization or death [5]. The relative risk reduction of vaccinated individuals with respect to hospitalization was 58% - which is already much less than the registration studies suggested. However, the absolute risk reduction was only 0.025%. This means that approximately 4000 people need to be vaccinated to prevent *one* hospitalization. With regard to the prevention of one death, the absolute risk is reduced by only 0.0039% by vaccination. This means that about 26,000 people need to be vaccinated to prevent *one* COVID death. The probability for the individual to be protected by the vaccination is therefore extremely low and must therefore be weighed against the risks of vaccination. In the meantime, there are numerous other observational studies with very similar results.

The effectiveness of vaccines against SARS-CoV-2 mutants over the time

Recent works show that vaccine effectiveness declines over time. In a study published in the New England Journal of Medicine, there was a decline in the relative vaccine efficacy from > 90% immediately after full immunization to about 65% after four months [6]. In addition, the study showed that there was a significant increase of delta variant infections both in vaccinated and unvaccinated individuals in July 2021, suggesting that vaccine effectiveness not only declines over time, but is also lower for the delta variant. Conclusions regarding protection against hospitalization and death were not possible in this study, because only *one* hospitalization and not even one death were observed.

A recently published cohort study from Sweden shows impressively that vaccine efficacy decreases already after six to seven months to such an extent that protection can no longer be assumed [7]. This fact is also reflected in the increasing numbers of vaccinated people among COVID patients treated in hospital and intensive care units.

Even boostering propagated by many in the meantime will not solve the COVID problem. The absolute risk reduction for severe COVID progression by boostering was 0.18% for patients over 60 years of age with an observation period of only one month according to a study from Israel [8]. Corresponding studies in younger and otherwise healthy individuals are completely lacking. In particular, it is unknown whether vaccination and boostering will be effective with respect to emerging variants such as „Omikron“.

The risks of COVID vaccines

No drug or vaccine has experienced so many reports of serious adverse effects and deaths in such a short period of time as the COVID-19 vaccines. In its Safety Report dated Sept. 20, 2021, the Paul-Ehrlich-Institute referred to more than 156,360 reports of incidents in temporal connection with a COVID vaccination in Germany [9]. The estimated number of unreported cases is probably many times higher. Among the reported incidents 1,450 were fatal, and 15,122 (0.015% of all vaccinations) were classified as severe (requiring hospital admission). The serious adverse events whose occurrence is most likely related to vaccination include cardiac muscle inflammation of the heart muscle and pericardium (myo- and pericarditis), severe allergic reactions (anaphylaxis), thromboses (pulmonary embolisms, strokes, heart attacks), deficiency of blood platelets (thrombocytopenia, hemorrhages), and total body paralysis (Guillain-Barré syndrome). The long-term consequences of the already known serious side effects and further, still largely unexplored negative effects such as an antibody-dependent enhancement of inflammatory processes in the event of re-infection [ADE]) and the promotion of the development of immune complex and autoimmune diseases due to the nucleoside-modified mRNA of the mRNA vaccines are not yet foreseeable due to the short observation times so far.

Infectivity of the vaccinated and unvaccinated

Recent studies show that there is no difference in the viral load and in the number of individuals to whom the infection is transmitted between vaccinated and unvaccinated persons [10] [11]. Vaccinated persons are therefore just as infectious as unvaccinated persons and can contribute equally to the spread of the disease as unvaccinated persons. These findings were confirmed by a large population study conducted by Public Health England: both in alpha and in delta variant infections the same PCR-Ct values are found in vaccinated and unvaccinated individuals [12].

Vaccination of recovered persons

There is no study that has demonstrated a benefit of the vaccination for recovered persons with respect to clinically relevant endpoints. Those who have recovered have a very low risk of recurrence of disease and an even lower risk of a severe disease progression. According to a study from Qatar, the risk for a recurrence of disease within one year in unvaccinated recovered persons was 0.37%, and the risk for a severe course of disease was only 0.001%, and there was not a single death [13]. Even if the high relative risk reductions of the studies are transferred to a collective of recovered persons, the NNV value, i.e. the number of those who need to be vaccinated in order to prevent a severe course of the disease is over 100,000.

The benefit-harm balance of COVID-19 vaccines

When considering the benefit-harm balance, the personal risk of a human of becoming severely ill with COVID-19 or dying from the disease, must be taken into account. This risk is determined primarily by age and the presence of chronic diseases. A systematic review has shown that the risk of dying from COVID is about 10,000 times higher for people over 80 years of age than for children under 10 years of age [14]. This factor must be included in considerations of the benefits, as well as the harms of vaccination. The figures in the Safety Report of the Paul-Ehrlich-Institute suggest that serious adverse effects occur about as frequently in children as in adults. However, myocarditis probably occurs even more frequently in children and adolescents. In children, the number of required vaccinations to prevent *one* severe COVID-19 disease or even death from COVID increases to a multiple. It can be concluded from this that the benefit-harm balance of vaccination for children, adolescents and young adults is very likely to be negative, i.e. the vaccination rather causes more harm than prevents severe COVID. At best in elderly people and those with risk factors for a severe course of disease, a possible protective effect of the vaccination could outweigh. The protection of short duration and the negative consequences of booster vaccinations, e.g. in Israel, make even this benefit appear doubtful. In addition, it must be taken into account that many possible long-term damages of the vaccinations are not yet known due to the lack of observation time and the incomplete documentation.

For these reasons, every person must be free to decide in favor of or against a vaccination after honest information about the benefits and risks. A direct or indirect compulsory vaccination is neither justifiable nor ethically justifiable on the basis of the available evidence.

Conclusion

The absolute, individual benefit of vaccination against COVID-19 is marginal in the average population. It may be higher for people with high risk for a severe course of COVID. Even for these individuals, however, the vaccines still carry unknown risks for adverse late effects. Young and healthy people and in particular healthy children and adolescents must be advised against vaccination, since the risks for serious side effects and late effects far exceed the potential benefits.

The assertion that vaccination will protect other people from COVID-19 is not valid and implausible, given the high incidence of diseases in vaccinated individuals and the lack of difference in infectivity between vaccinated and unvaccinated people.

Vaccination of recovered people is neither scientifically nor epidemiological reasonable.

We therefore demand

- the immediate stop of exclusion and restriction of unvaccinated children and adolescents from social participation

- the immediate stop of the one-sided vaccination information playing down the possible damage as well as an end to the coercion of the population to vaccinate
- the immediate end of discrimination of unvaccinated persons and of the unequal treatment of vaccinated and unvaccinated people in public life, at the workplace and in schools and day-care centers
- a return of political and medical decision makers to (scientific) neutrality, away from the lobby-compliant panic politics pursued so far, which deliberately ignores scientific facts and also violates the fundamental values of liberal democracy.

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(Translation: Dr. Ralf Schramm, Attenhofen)

Bhakdi S

Tab 14

Professor im Ruhestand

Infektionen
Immunologie

500

	All	Since 2017
Citations	25733	3339
h-index	87	28
i10-index	277	97

11 articles not available

20 articles available

Based on funding mandates

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On COVID vaccines: why they cannot work, and irrefutable evidence of their causative role in deaths after vaccination

Sucharit Bhakdi, MD and Arne Burkhardt, MD

This text is a written summary of Dr. Bhakdi's and Dr. Burkhardt's presentations at the Doctors for COVID Ethics symposium that was live-streamed by UKColumn on December 10th, 2021. The two presentations can be viewed at the very beginning of the video recording of the symposium.

The authors

Dr. Bhakdi has spent his life practicing, teaching and researching medical microbiology and infectious diseases. He chaired the Institute of Medical Microbiology and Hygiene at the Johannes Gutenberg Unversity of Mainz, Germany, from 1990 until his retirement in 2012. He has published over 300 research articles in the fields of immunology, bacteriology, virology and parasitology, and served from 1990 to 2012 as Editor-in-Chief of Medical Microbiology and Immunology, one of the first scientific journals of this field that was founded by Robert Koch in 1887.

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The evidence

We herewith present scientific evidence that calls for an immediate stop of the use of gene-based COVID-19 vaccines. We first lay out why the agents cannot protect against viral infection. While no positive effects can be expected, we show that the vaccines can trigger self-destructive processes that lead to debilitating illness and death.

Why the vaccines cannot protect against infection

A fundamental mistake underlying the development of the COVID-19 vaccines was to neglect the functional distinction between the two major categories of antibodies which the body produces in order to protect itself from pathogenic microbes.

The first category (secretory IgA) is produced by immune cells (lymphocytes) which are located directly underneath the mucous membranes that line the respiratory and intestinal tract. The antibodies produced by these lymphocytes are secreted through and to the surface of the mucous membranes.

These antibodies are thus on site to meet air-borne viruses, and they may be able to prevent viral binding and infection of the cells.

The second category of antibodies (IgG and circulating IgA) occur in the bloodstream. These antibodies protect the internal organs of the body from infectious agents that try to spread via the bloodstream.

Vaccines that are injected into the muscle – i.e., the interior of the body – will only induce IgG and circulating IgA, not secretory IgA. Such antibodies cannot and will not effectively protect the mucous membranes from infection by SARS-CoV-2. Thus, the currently observed "breakthrough infections" among vaccinated individuals merely confirm the fundamental design flaws of the vaccines. Measurements of antibodies in the blood can never yield any information on the true status of immunity against infection of the respiratory tract.

The inability of vaccine-induced antibodies to prevent coronavirus infections has been reported in recent scientific publications.

The vaccines can trigger self-destruction

A natural infection with SARS-CoV-2 (coronavirus) will in most individuals remain localized to the respiratory tract. In contrast, the vaccines cause cells deep inside our body to express the viral spike protein, which they were never meant to do by nature. Any cell which expresses this foreign antigen will come under attack by the immune system, which will involve both IgG antibodies and cytotoxic T-lymphocytes. This may occur in any organ. We are seeing now that the heart is affected in many young people, leading to myocarditis or even sudden cardiac arrest and death. How and why such tragedies might causally be linked to vaccination has remained a matter of conjecture because scientific evidence has been lacking. This situation has now been rectified.

Histopathologic studies: the patients

Histopathologic analyses have been performed on the organs of 15 persons who died after vaccination. The age, gender, vaccination record, and time of death after injection of each patient are listed in the table on the next page. The following points are of utmost importance:

- Prior to death, only 4 of the 15 patients had been treated in the ICU for more than 2 days. The majority were never hospitalized and died at home (5), on the street (1), at work (1), in the car (1), or in home-care facilities (1). Therefore, in most cases, therapeutic intervention is unlikely to have significantly influenced the post-mortem findings.
- Not a single death was brought into any possible association with the vaccination by the coroner or the public prosecutor; this association was only established by our autopsy findings.
- The initially performed conventional post-mortems also uncovered no obvious hints to a possible role of vaccination, since the macroscopic appearance of the organs was overall unremarkable. In most cases, "rhythmogenic heart failure" was postulated as the cause of death.

But our subsequent histopathological analyses then brought about a complete turnaround. A summary of the fundamental findings follows.

Case #	Gender	Age (years)	Vaccine (injections)	Time of death after last injection
1	female	82	Moderna (1. and 2.)	37 days
2	male	72	Pfizer (1.)	31 days
3	female	95	Moderna (1. and 2.)	68 days
4	female	73	Pfizer (1.)	unknown
5	male	54	Janssen (1.)	65 days
6	female	55	Pfizer (1. and 2.)	11 days
7	male	56	Pfizer (1. and 2.)	8 days
8	male	80	Pfizer (1. and 2.)	37 days
9	female	89	Unknown (1. and 2.)	6 months
10	female	81	Unknown (1. and 2.)	unknown
11	male	64	AstraZeneca (1. and 2.)	7 days
12	female	71	Pfizer (1. and 2.)	20 days
13	male	28	AstraZeneca (1.), Pfizer (2.)	4 weeks
14	male	78	Pfizer (1. and 2.)	65 days
15	female	60	Pfizer (1.)	23 days

Histopathologic studies: findings

Histopathologic findings of a similar nature were detected in organs of 14 of the 15 deceased. Most frequently afflicted were the heart (14 of 15 cases) and the lung (13 of 15 cases). Pathologic alterations were furthermore observed in the liver (2 cases), thyroid gland (Hashimoto’s thyroiditis, 2 cases), salivary glands (Sjögren`s Syndrome; 2 cases) and brain (2 cases).

A number of salient aspects dominated in all affected tissues of all cases:

1. inflammatory events in small blood vessels (endothelitis), characterized by an abundance of T-lymphocytes and sequestered, dead endothelial cells within the vessel lumen;

2. the extensive perivascular accumulation of T-lymphocytes;
3. a massive lymphocytic infiltration of surrounding non-lymphatic organs or tissue with T-lymphocytes.

Lymphocytic infiltration occasionally occurred in combination with intense lymphocytic activation and follicle formation. Where these were present, they were usually accompanied by tissue destruction.

This combination of multifocal, T-lymphocyte-dominated pathology that clearly reflects the process of immunological self-attack is without precedent. Because vaccination was the single common denominator between all cases, there can be no doubt that it was the trigger of self-destruction in these deceased individuals.

Conclusion

Histopathologic analysis show clear evidence of vaccine-induced autoimmune-like pathology in multiple organs. That myriad adverse events deriving from such auto-attack processes must be expected to very frequently occur in all individuals, particularly following booster injections, is self-evident.

Beyond any doubt, injection of gene-based COVID-19 vaccines places lives under threat of illness and death. We note that both mRNA and vector-based vaccines are represented among these cases, as are all four major manufacturers.

Why intramuscular COVID-19 vaccination must fail

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Abstract

Many countries are currently experiencing a wave of COVID-19 "breakthrough cases" in spite of high vaccination rates. In this paper, we explain the fundamental reason why such cases had to be expected: the antibodies induced by intramuscular vaccination will only circulate in the bloodstream, but they will not reach the surface of the mucous membranes in the upper airways. We also briefly discuss possible mechanisms of vaccine-induced immunopathology.

1 Introduction: All antibodies are not created equal

There are different types of antibodies utilized by the human immune system. The major ones are IgM, IgG and IgA [1]; there are two other classes, IgD and IgE, but there is no need to discuss them here.

IgM is generated in the early stages of an adaptive immune response and is then gradually replaced with IgG antibodies. Both IgM and IgG circulate mainly in the bloodstream. IgG is the most abundant antibody in the blood. On the other hand, while some IgA is found in the bloodstream as well, most IgA is secreted across the mucous membranes of the respiratory tract and the gut, which it then covers and protects.

When our immune system is confronted with an invading pathogenic microbe, the predominant type of antibody it produces depends on the location of that pathogen. If the pathogen is encountered in the bloodstream or inside of tissues within the body, e.g. the muscle, then the immune system will produce mainly IgG antibodies, which will accumulate in the bloodstream. On the other hand, if the pathogen is introduced through the respiratory tract (e.g. the nostrils), then the immune system will produce mainly IgA antibodies—to be more specific, *secretory IgA*, or sIgA.

While sIgA dominates in the upper airways, some IgG is found along with IgA in the lower airways, that is, the bronchi and lung alveoli. In addition to sIgA, an immune response triggered by a respiratory tract infection will also generate both IgG and IgA within the bloodstream, which provides a safeguard in case the barriers of the respiratory tract are breached and the pathogens enter the tissues. In short, sIgA is the main antibody the immune system relies on in the upper respiratory tract (URT), and it forms the first line of defense against respiratory pathogens.

*The first draft of this document was written by a colleague who prefers to remain anonymous.

†In this updated version, a misleading statement in Section 4, pertaining to the location of IgG in the airways, has been amended.

2 Why is sIgA antibody important?

The key reason why an sIgA-based antibody response is desired against respiratory pathogens is that sIgA does not promote inflammation. Binding of sIgA antibodies to the antigens (such as viruses or bacteria) leads to "quiet" expulsion of these pathogens from the body, but it does not elicit any additional damaging immune responses. In contrast, an IgG-based response is followed by an inflammatory immune reaction. This reaction is triggered by a change in the molecular shape of the F_c region (the tail end) of IgG antibodies, which causes them to activate inflammatory cells as well as the serum complement system.

Since our respiratory tract constantly encounters viruses and bacteria within the air we inhale, IgA-based immune responses help avoid unnecessary and repeated inflammations in our airways. sIgA in the mucous membranes of the respiratory tract can subdue the infection and stop the transmission of these germs safely.

Considering these well-established scientific facts, it is beyond perplexing that people only talk about antibodies (mainly IgG antibodies) in the bloodstream after COVID vaccination. If a vaccine should protect us from respiratory viruses and from transmitting them to others, it should elicit an IgA-based immunity in our respiratory tract, especially in the upper airways.

3 What is really damaging our body: viruses, or our own immune system?

Respiratory viruses rarely cause direct damage to our body. It is typically the overreaction of our immune system against those viruses that does the damage [2, 3]. With respect to COVID-19, a recent paper on the causation of clinically severe disease sums it up as follows [4]:

> *[Severity of COVID-19] is suggested not to be a direct effect of viral infection but instead to be caused by the over-activation of the immune system in response to infection, because worsening of disease coincides with the activation of adaptive immunity. This excessive immune response is frequently described as a "cytokine storm" ... Together, high pro-inflammatory cytokines, known to induce collateral damage to tissues, and muted anti-viral responses suggest that an unfavorable immune response may be driving disease in patients with severe cases of COVID-19.*

4 The route of vaccination matters

A vaccine that is given by intramuscular (IM) injection will mainly induce IgG antibodies in the blood; this matches the body's response to pathogens introduced by the same route. It is well known that IM vaccines generate very little or no sIgA in the respiratory tract. Therefore, IM injection is not an efficient way of prepping our immune system against respiratory viruses. Should a full-blown pneumonia develop, circulating IgG antibodies will seep out of the capillaries into the alveoli and there help with viral clearance; therefore, conceivably an IM injection might afford some measure of protection against severe disease. On the other hand, vaccine-induced IgG antibodies may also cause exacerbate the disease (see next section). In any case, prior to inflammation, practically no IgG will be present on the respiratory mucous membranes, which leaves them vulnerable to infection. This is why the current COVID-19 vaccines cannot prevent infection or transmission of the virus [5, 6]. Below is a direct quote from the review paper by McGhee et al. [6]:

> *It is surprising that despite our current level of understanding of the common mucosal immune system, almost all current vaccines are given to humans by the parenteral route. Systemic immunization is essentially ineffective for induction of mucosal immune responses. Since the majority of infectious microorganisms are encountered through mucosal surface areas, it is logical to consider the induction of protective antibodies and T cell responses in mucosal tissues.*

Note that this statement was made already three decades ago—yet nothing has changed, and the same flawed, outdated approach of intramuscular injection has been adopted yet again with the "modern" and "high-tech" COVID-19 vaccines.

We can conclude that either the natural infection through our respiratory tract or nasal vaccination is required to induce effective immunity against respiratory viruses. With COVID-19, this is borne out by a recent animal study [7], which confirmed that the AstraZeneca COVID vaccine administered by the intramuscular route failed to protect hamsters from the infection by SARS-COV-2 or to prevent the transmission of this virus. When the vaccinated animals were challenged with the virus through the airways, they still became infected, and their lungs were damaged. On the other hand, the animals that were vaccinated by the nasal route were able to clear the viruses in the URT and prevent the infection in the lower respiratory tract (LRT).

The lack of protection against infection of the airways by serum IgG is not limited to SARS-CoV-2 and COVID. As early as 1984, Liew et al. demonstrated that the IgG found in the bloodstream is quite irrelevant for the protection against influenza virus; it is the sIgA on the mucous membranes that prevents the virus from establishing infection.

In conclusion, sIgA on the mucous membranes, especially in the URT, is necessary for effective and protective immunity against respiratory viruses, and it is induced only when the antigen is introduced via the natural route—into the URT itself. This rule applies to both natural pathogens and vaccines.

5 An IgG response can be a bad thing

Not only does IgG circulating in the bloodstream fail to prevent infection with respiratory viruses, but an IgG-based immune response can even elicit harmful inflammatory responses, causing serious tissue damage within the respiratory tract. In their recent review article on mucosal immunity to COVID-19, Russell et al. state [8]:

> *Most attention has been given to virus-neutralizing antibodies, especially circulating antibodies. However, these can only be effective in the prevention of infection or disease if [the antibodies] reach the mucosal surfaces where the virus is present, and it should be noted that circulating IgA, even in polymeric form, is not effectively transported into secretions. While plasma-derived IgG occurs in the URT and especially the lower respiratory tract (LRT), IgG is inflammatory in its mode of action, by the induction of such effector mechanisms as complement activation and the engagement of phagocytes such as macrophages and neutrophils as well as natural killer (NK) cells. The serious pathology of COVID-19 occurs in the terminal airways of the lungs, where circulating IgG is the dominant immunoglobulin. The resulting intense inflammation involves multiple molecular and cellular factors, including cells recruited by virus-induced chemo-attractants.*
>
> *...*
>
> *In practical terms this means that intranasal immunization should be an effective means of generating predominantly sIgA antibody responses in the URT and LRT, where SARS-CoV-2 could be neutralized and eliminated without inflammatory consequences. In addition, it implies*

that assaying IgA antibodies in nasal secretions or saliva should be a more informative way of assessing effective immune responses against SARS-CoV-2, whether induced by the natural infection or by intranasal immunization. Assaying serum IgA antibodies, while of additional interest, is not a substitute, because serum IgA comes from a different source (mainly the bone marrow) and consists mostly of monomeric IgA1. This is distinct from mucosal sIgA, which ... is locally synthesized by pIgA-secreting plasma cells resident in the subepithelial spaces (lamina propria) of mucosal tissues and glands ... Moreover, sIgA is essentially non-inflammatory, even anti-inflammatory, in its mode of action. IgA does not activate complement ...

An association of excessive IgG-based immune responses with negative clinical outcomes has also been observed after natural infection with SARS [9] and COVID-19 [4, 10]. IgG antibodies will bind to virus particles first and then, via their F_c moieties (see Section 2), to F_c receptors on immune cells. The virus may then enter those cells and subsequently replicate within them. This disease mechanism is known as *antibody-dependent enhancement* and also occurs with other virus families [11].

In addition to aggravating acute lung disease such as in SARS and COVID-19, high concentrations of IgG are also associated with chronic inflammatory lung diseases such as idiopathic pulmonary fibrosis and chronic hypertensive pneumonitis [12]. In summary, too little IgG is a bad thing, but too much IgG is equally a bad thing.

6 Vaccination and M1/M2 macrophages

Macrophages are an important type of innate immune cells; their role is to ingest and destroy pathogenic microbes. Macrophages can adopt either an M1 or M2 type, depending on the inflammatory state of the tissue. M1 macrophages promote inflammation, whereas M2 macrophages promote wound-healing. Thus, the balance between M1 and M2 macrophages is essential for a healthy immune system.

A recent study in monkeys has demonstrated that the intramuscular injection of a vaccine against SARS-COV—the original SARS virus from 2003, which is highly homologous to the causative agent of COVID (SARS-CoV-2)—promoted the elimination of virus particles that were injected directly into the trachea, but also caused severe inflammatory injuries in the lung tissues. Inflammation was exacerbated by a shift of macrophage polarization from wound-healing M2 toward inflammatory M1 macrophages [13]. Priming the lung macrophages into M1 type leads to dangerous inflammatory diseases and tissue damages, and that's what the IM vaccination does according to this paper.

7 Vaccination and Th2-type immunopathology

T helper cells are a type of lymphocytes that plays a key role in the stimulation and regulation of immune responses. Again, there are two major subsets of this cell type, referred to as Th1 and Th2, respectively. Th1 cells activate immune responses against intracellular pathogens, including protozoa, bacteria, and viruses. Th2 cells, on the other hand, help mount a defense against infections with worm parasites, but they also promote allergic diseases such as asthma, atopic dermatitis, and hay fever [14]. A hallmark of Th2-activated responses is an increased abundance in blood and tissues of eosinophil granulocytes. These effector cells are useful for combating worm parasites, but for little else; in allergic disease, they merely contribute to the tissue damage.

It is therefore significant that several experimental vaccines against the original SARS virus, while inhibiting proliferation of the virus within the lungs to some degree, caused Th2-type lung pathology, characterized by increased numbers of eosinophil granulocytes within and aggravated injury to the lungs [15–17]. These results indicate that the experimental vaccines against SARS-CoV may cause more severe illnesses when the vaccinated person is challenged with the real virus.

We must stress again that SARS-CoV and SARS-CoV-2 are highly homologous, which means that any risk or problem known with SARS-CoV must be considered with SARS-CoV-2 also. While the manufacturers Pfizer, Moderna, and Johnson & Johnson claim that their vaccines preferentially induce Th1 responses, supporting data from human vaccinees are scarce or lacking altogether [18–20].

8 Conclusion

All of the currently used COVID vaccines are applied by intramuscular injection, and they are therefore unable to prevent infection of the upper airways with the SARS-CoV-2 virus. In fact, in their clinical trials, none of the manufacturers even attempted to demonstrate efficacy against infection or transmission in their clinical trials [18–21], and the total lack of efficacy in the real world has since been documented in a large study published by the CDC [22]. The vaccines can, however, lead to severe respiratory immune disease, including Th2-type immunopathology and autoimmunity. When factoring in the large number of adverse events that are being reported with the current vaccines and the low case fatality rate of COVID-19, which we have discussed elsewhere [23], it is clearly more scientific and more reasonable to strive for herd immunity by natural infection rather than vaccination.

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Nature of the toxicity of the COVID-19 vaccines in the USA

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In this study of the Vaccine Adverse Event Reporting System data (VAERS data, USA) for COVID-19 vaccines we examine the broad features of the data, resolved by:

- major adverse effect (AE) category (death, life-threatening reaction, hospitalization, disability, and all categories),
- vaccine manufacturer (Janssen, Moderna, Pfizer),
- type of injection (shot number in primary series, booster),
- date of injection,
- date of onset or finality of AE, and
- age of the person suffering the AE;

compared to the dates of administration of all the injections, for the different manufacturers and types of injections (see Figure S1), and compared to population characteristics (age structure, poverty, life expectancy, obesity).

We elucidate fundamental aspects of the body's response to these kinds of pulses of toxic charges, related to age-dependent immune efficiency and age-dependent spread of vulnerability, and we identify exponential time decay components in the induced mortalities, with half-life values in the range 13-30 days, possibly arising from the spike protein.

A next version of this report will contain more content, detail, and supplementary materials. Supporting figures illustrating the data and analyses are provided at the end of this report.

We make the following observations and conclusions.

→ The priority targeting of the population “most at risk” at the start of the COVID-19 vaccination campaign had disastrous consequences for that population, with disproportionately large vaccine-induced mortality and AEs (Figure S2).

→ Graphs of AE frequency versus time of onset or finality of the AE in days since injection all show the same time structure (for all resolved AEs and resolved injection characteristics):

- a large initial peak in the first 5 days or less, which is larger and sharper for the mRNA multi-dose injections (Moderna, Pfizer) compared to the virus-vector single-dose injection (Janssen),
- an exponential decay, from ~5 days to ~60 days, with a fitted half-life decay time typically falling in the range 13-30 days, with this same behaviour occurring for all three manufacturers and for all the main categories of AEs, and
- a plateau or “second wave” of AEs at long times, beyond ~60 days and up to ~350 days since injection, which largely consists of AEs having associations with COVID-19 itself. (Figures S3 through S5)

→ Furthermore, the large initial peak in the first 5 days or less ($x < 5$ days) is significantly smaller for a first dose than for a second or third dose, for both Pfizer and Moderna, while the half-life for the exponential part ($5 \text{ days} \leq x < 60$ days) is concomitantly larger for the later doses (Figure S5).

→ The observed exponential decay implies a causal link between death (or AE) and injection, up to ~60 days. Accidental deaths would have a uniform (constant) distribution versus time since injection (versus “x”), mathematically corresponding to an infinite decay time.

→ It is reasonable to postulate that the 13-30 day half-life corresponds to the half-life in the body of a toxic component present in or produced by the vaccines, such as the spike protein; and that the initial peak (< 5 days) is due to a toxic component or adjuvant mostly present in the mRNA injections, such as the cationic lipids.

→ It is also reasonable to postulate that there is an enhanced immune response against the vaccine component that causes the initial ($x < 5$ days) peak of deaths, in the later doses compared to a first dose (Figure S5). If the initial immune response partially debilitates mRNA delivery to cells and organs in the body, then spike-protein cumulative toxicity leading to death could be delayed, with relatively less deaths in the exponential decay phase ($5 \text{ days} \leq x < 60$ days) and longer decay half-lives, for doses in addition to a first dose, as observed (Figure S5).

→ Thus, it would appear that the enhanced initial (< 5 days) immune response partially disables spike protein production and spread, which, in theory, would make the vaccine both less toxic and less effective (if it ever is effective) in doses and boosters beyond

the first dose. In fact, we do observe reductions of overall toxicity with increasing doses and boosters, as per Table 1.

	Pfizer	Moderna	Janssen
first	8.08 (0.48)	15.08 (0.82)	20.4 (2.2)
second	5.76 (0.44)	10.37 (0.75)	-
primary	7.03 (0.33)	12.96 (0.56)	20.4 (2.2)
booster	3.20 (0.58)	3.18 (0.66)	3.8 (3.8)
all	7.77 (0.32)	13.38 (0.53)	26.7 (2.5)
12 to 17	0.60 (0.42)	-	-
18 to 64	2.64 (0.37)	3.47 (0.52)	10.6 (1.7)
65 plus	19.7 (1.9)	25.5 (2.1)	79. (12.)

Table 1. Total number of VAERS deaths divided by total number of doses delivered in the same period (2021) to the same group (all values and errors $\times 10^{-6}$), by dose series and by age group. The age-group rows show, for Pfizer and Moderna (Janssen) the total number of deaths following the second (first) dose divided by the total number of administered second (first) doses. Estimated 2σ errors in parentheses: two times the square-root of the number of deaths divided by the number of doses.

→ We produce graphs of toxicity (number of AEs / number of doses) by vaccination date or by AE date (not shown), using the independent-database administered dose data, which demonstrate strong correlations of toxicity with median age of those injected on the vaccination or AE dates, and which show a gradation of manufacturer-specific age-accounted toxicity (and see Table 1):

Janssen > Moderna > Pfizer,

approximately in the ratio (deaths per dose)

Janssen : Moderna : Pfizer = 4 : 1.3 : 1

→ We find that the number of deaths per administered dose (e.g., < 60 days since injection) increases exponentially with age, with doubling time ~9-10 years, which is approximately the known doubling time (in lived years) of the mortality rate for adults in the general population of the USA. We interpret this to mean that the same age-dependent repair/immune efficiency is in play defending against the assault of the injection as is active protecting against the usual array of environmental and internal assaults that cause death in adults (see discussion below about batches, and Figure S6).

→ We find that the VAERS deaths by 5-year age groups (per general-population of each USA age group) vary exponentially, again, with a doubling time approximately equal to the known doubling time for risk of death per time (per year) for adults in the general population of the USA. This supports our hypothesis that survival from the assault of the vaccine is determined by the same age-dependent limiting kinetics of the protective repair/immune mechanisms that ensure survival of adults subjected to the current array of dominant life-expectancy-limiting challenges in the USA.

→ We find no evidence that supports the hypothesis of “toxic batches” (batch-to-batch heterogeneity in lethality). The vaccine itself, as designed, is toxic.

→ In looking for “toxic batches”, we instead found natural distributions of age-dependent vulnerability to assault, as follows. Graphs of number of VAERS deaths by batch versus

median age of those who died (per batch) have an upper threshold given by the usual exponential (doubling time ~ 9-10 years), and a breadth of distribution of values that also increases exponentially with age, with approximately the same doubling time (Figure S6). We postulate that this behaviour arises from the natural age-dependent spread of vulnerably to assault, not from batch heterogeneity. Indeed, essentially the same behaviour (exponential increase in spread of sub-sample mortality with age, and similar doubling time) is displayed if we make such plots on the basis of the state jurisdictions or on the basis of vaccination date, rather than on the basis of the batch number (not shown).

Supporting figures are as follows.

Figure S1. Daily number of doses administered of the Pfizer (blue), Moderna (orange), and Janssen (green) products throughout 2021. Data is from Centers for Disease Control and Prevention (2022). Administered doses show a strong weekly cycle, with fewer doses administered on Sundays. The large dip occurring in December 2021 is due to an artifact present in the CDC data. Details will be given elsewhere. Note: The doses in a primary series, and boosters are also resolved in the data (not shown).

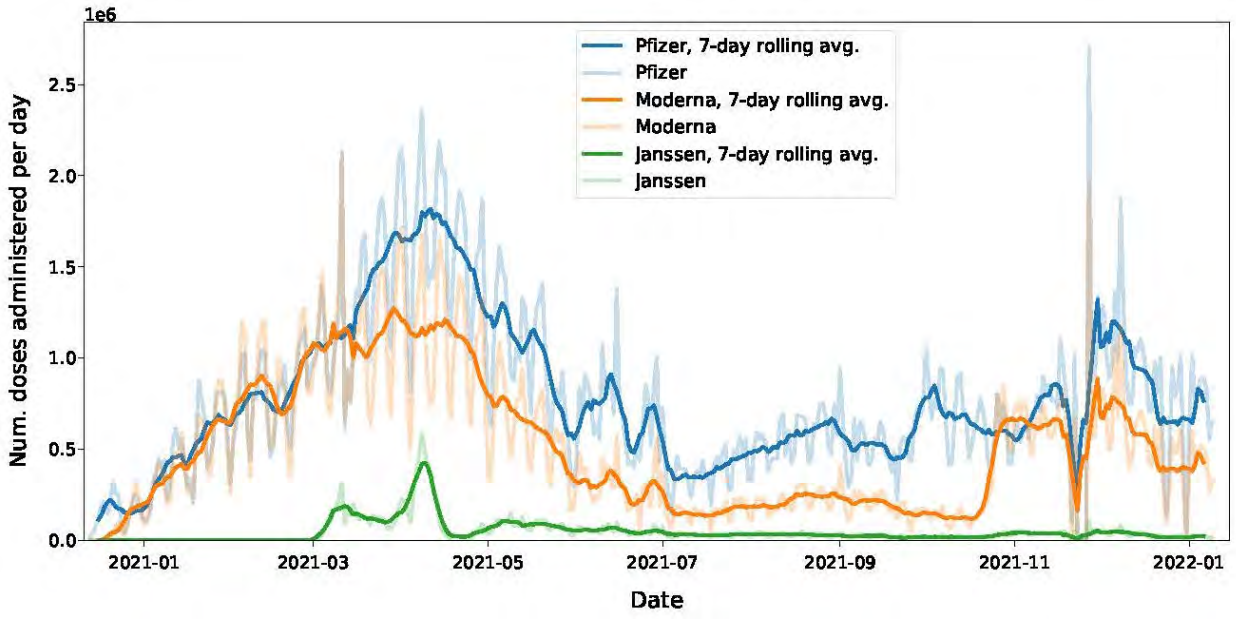
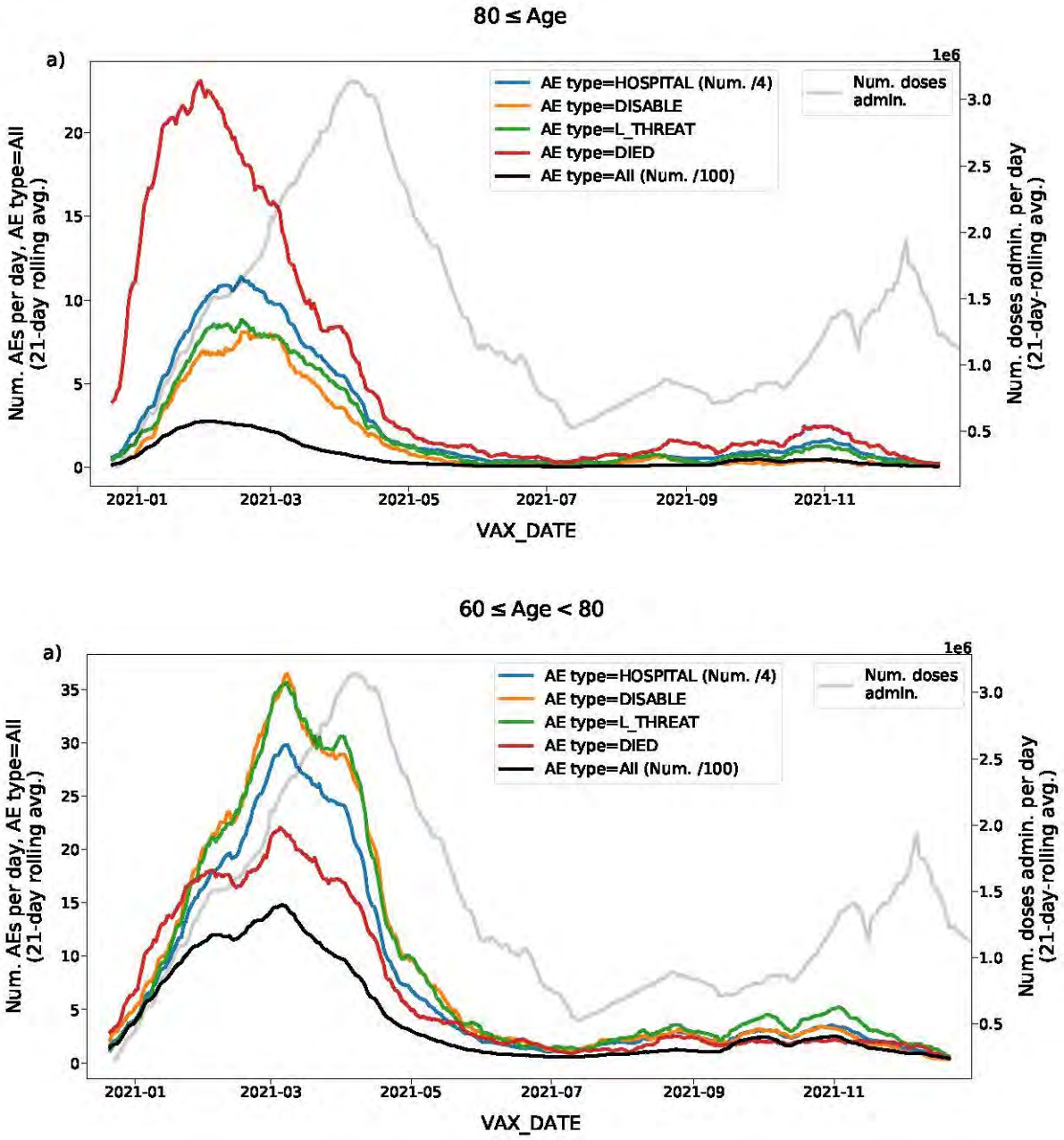
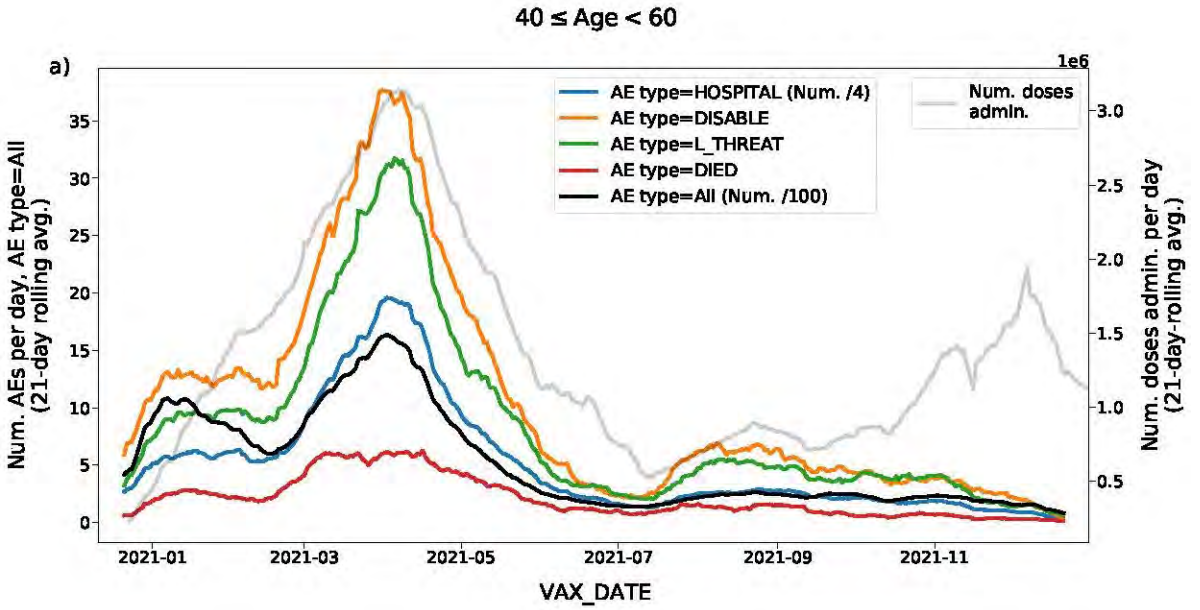


Figure S2. Number of adverse effects (AEs) of different types (hospitalization, disabled, life-threatening, death, all-AEs, as indicated) per day versus date of vaccination, for different age groups (80+, 60-79, 40-59, 0-39 years, as indicated). Grey curve shows number of doses administered per vaccination date (right y-axes).




40 ≤ Age < 60
a)
1e6
AE type=HOSPITAL (Num. /4)
AE type=DISABLE
AE type=L_THREAT
AE type=DIED
AE type=All (Num. /100)
Num. doses admin.
Num. AEs per day, AE type=All (21-day rolling avg.)
Num. doses admin. per day (21-day-rolling avg.)
VAX_DATE

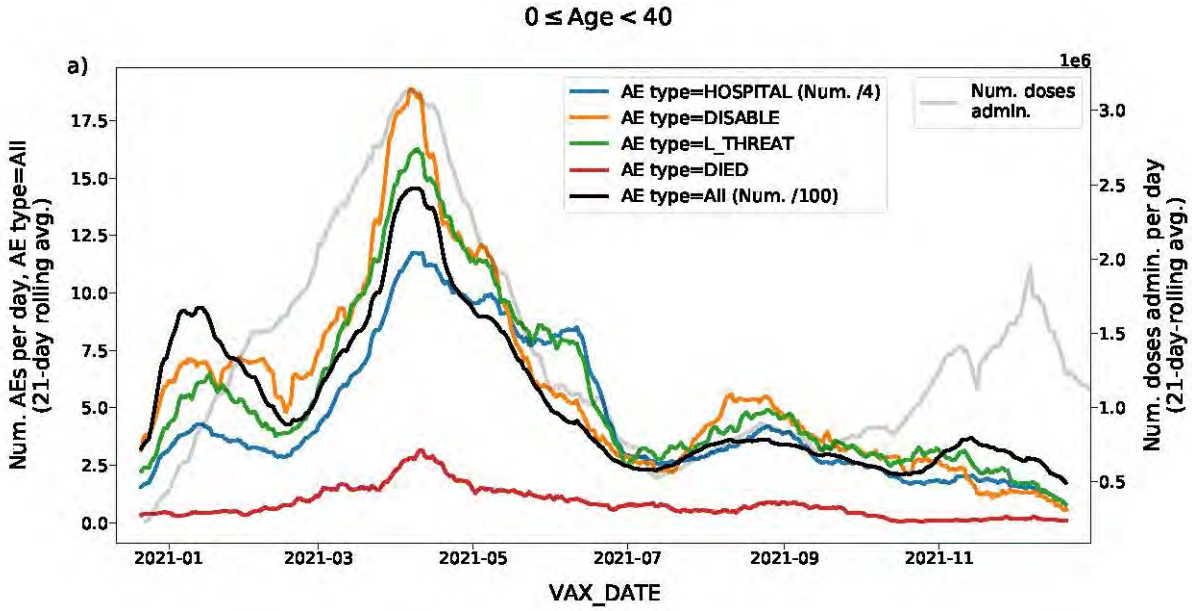

0 ≤ Age < 40
a)
1e6
AE type=HOSPITAL (Num. /4)
AE type=DISABLE
AE type=L_THREAT
AE type=DIED
AE type=All (Num. /100)
Num. doses admin.
Num. AEs per day, AE type=All (21-day rolling avg.)
Num. doses admin. per day (21-day-rolling avg.)
VAX_DATE

Figure S3. Histograms showing the share of VAERS deaths occurring x days after vaccination. (a) shows the full distribution, and its inset shows the same data but zoomed-in on the y-axis. (b) shows the same data but zoomed-in on the x-axis.

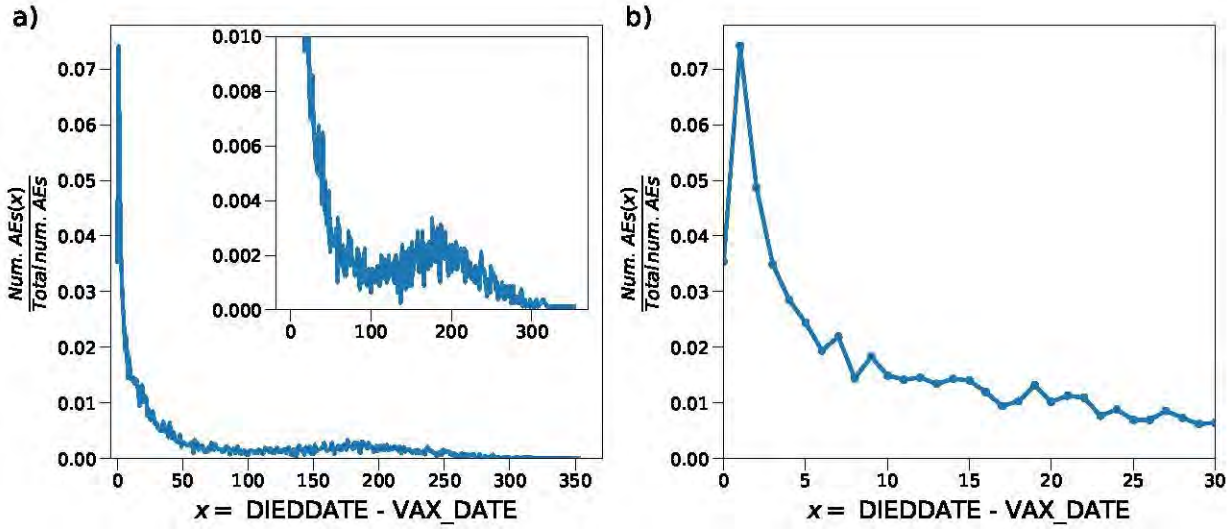


Figure S4. Histograms showing the share of VAERS deaths occurring x days after vaccination, for each manufacturer separately. y-axes are linear on the top row and logarithmic on the bottom row. In the plots in the left column (a and c), deaths at all x values are included in the calculation (but the plots are truncated for better visualization), whereas in the right column (b and d), only deaths for which x < 60 were used. The y-axis in (a) was also truncated for better visualization. Note: The exponential fit (d) gives a half-life equal to 14 days, as indicated.

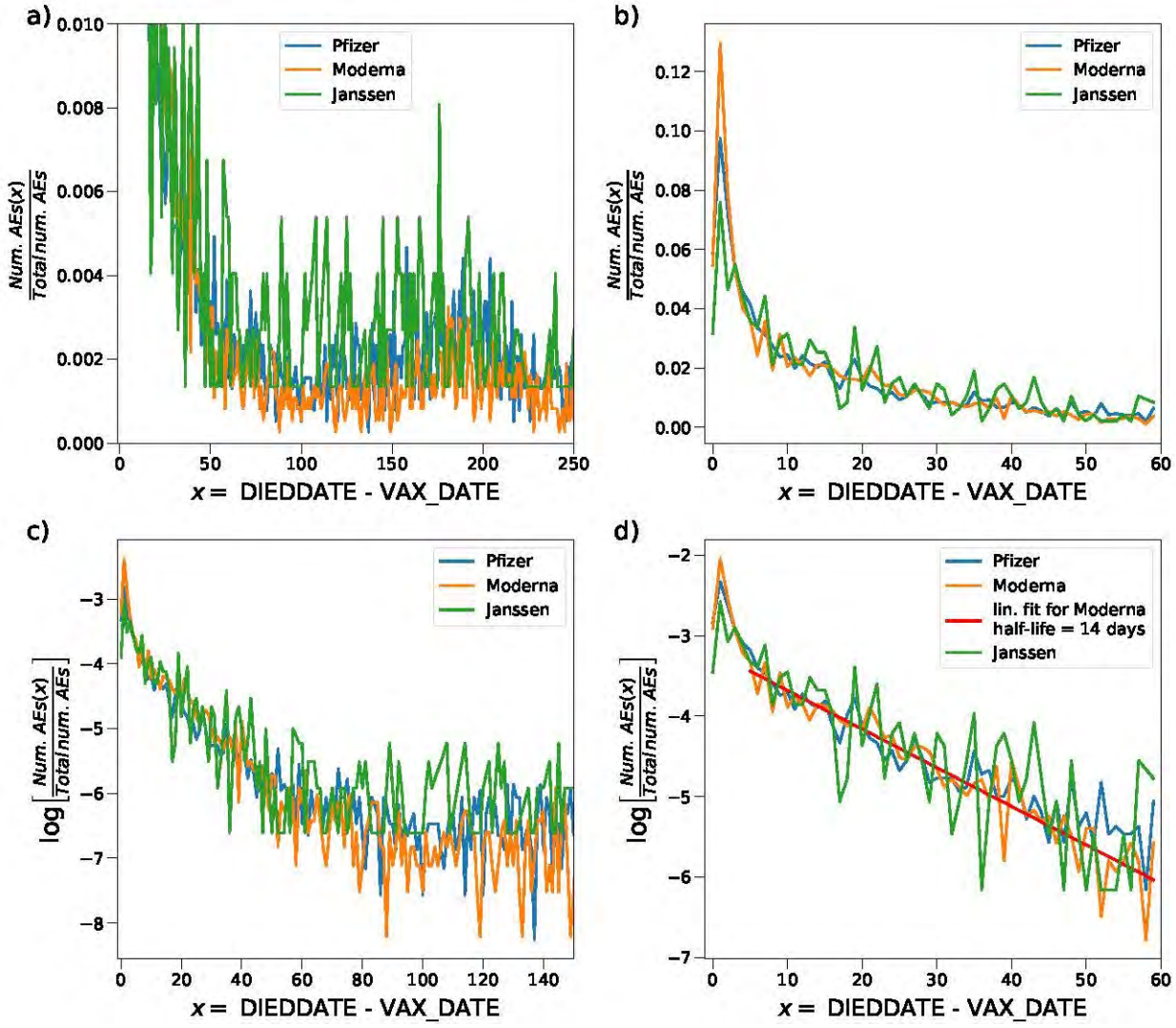


Figure S5. Histograms showing the share of VAERS deaths occurring x days after vaccination, for each manufacturer separately: Pfizer (P) (top row), Moderna (M) (middle row), Janssen (J) (bottom row). The left-most column is for the first dose in a primary series; the second column is for the second dose; and the right-most column is for a third dose. Data for x < 60 days is used. The mean time to death and the total deaths in the graph are as indicated. The exponential fits (red lines) have the following half-life value estimates: 16 days (P1), 25 days (P2), 30 days (P3); 13 days (M1), 21 days (M2), 14 days (M3); 18 days (J1).

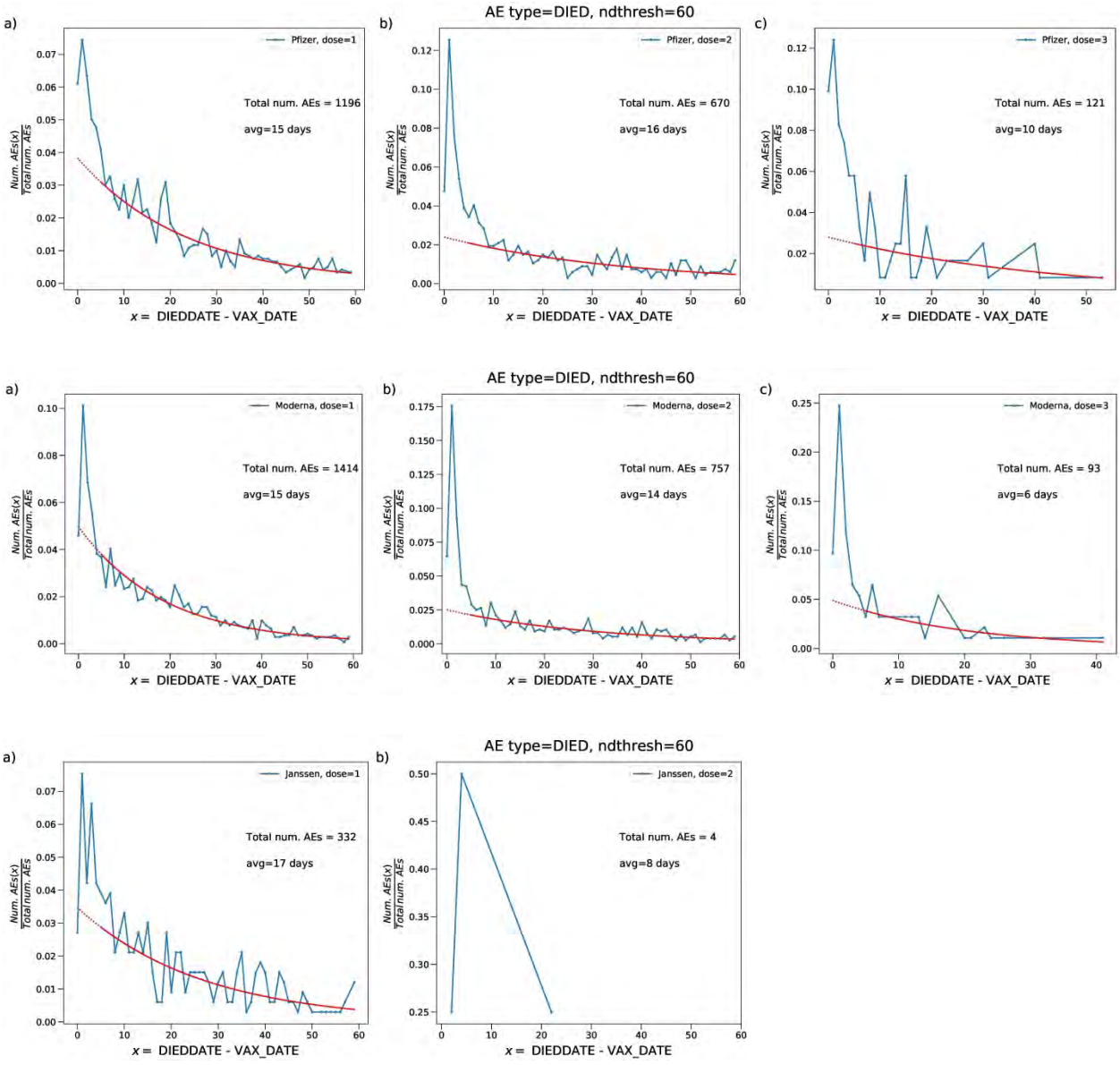
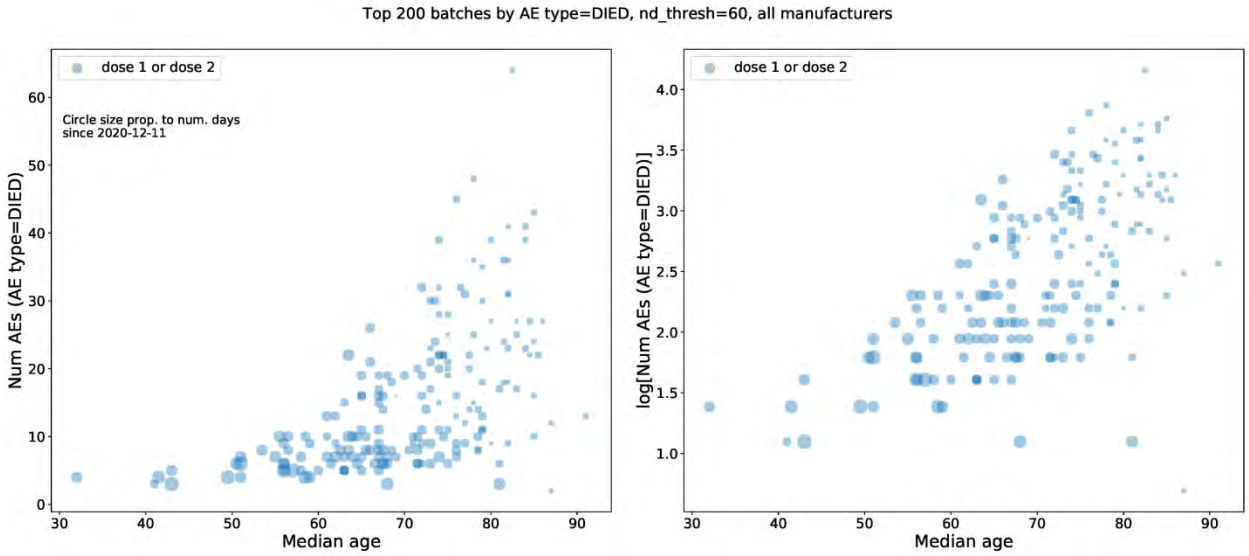


Figure S6. Number of VAERS deaths by batch for the 200 top batches versus median age of those who died (per batch): Linear Y-scale (left), log Y-scale (right). Symbol size is scaled to time (in days) since 11 December 2020.



Tab 18

CDC confirms record doses of flu vaccine were given

Filed Under: H1N1 2009 Pandemic Influenza (/infectious-disease-topics/h1n1-2009-pandemic-influenza) ; Public Health (/infectious-disease-topics/public-health) ; Influenza Vaccines (/infectious-disease-topics/influenza-vaccines)

By: Lisa Schnirring | Oct 08, 2010

Oct 8, 2010 (CIDRAP News) – The US Centers for Disease Control and Prevention (CDC) yesterday issued final estimates for last season's flu vaccine and the 2009 H1N1 monovalent vaccine, confirming a record number of flu vaccine doses distributed.

The CDC's report on the vaccines, published yesterday on its Web site, is a follow-up to preliminary and state-by-state coverage estimates that it issued in April.

The agency had anticipated that uptake of seasonal flu vaccine last fall and winter would be influenced by heightened interest in flu due to pandemic flu activity, which came with public health recommendations to get the seasonal vaccine early. Manufacturers rushed to roll out the seasonal flu vaccine to make way for the pandemic vaccine, which came more slowly and with fewer early doses than first projected.

The 2009-10 flu season was also the first full year that seasonal flu vaccines were formally recommended for all school-aged children.

Health officials are eager to see how a new universal flu vaccination recommendation for everyone age 6 months and older that takes effect this season will influence uptake levels for the coming flu season.

The CDC based its estimates for the two vaccines on two surveys, the Behavioral Risk Factor Surveillance System, an ongoing state-based phone survey of about 400,000 adults, and the National 2009 H1N1 Flu Survey (NHFS), which began last October and ended in June. It based its final estimates for the vaccines on vaccinations reported through May 2010 and interviews conducted through June.

Estimates are a little higher than previous projections for both vaccines because the data includes a broader vaccination period that extended through May 2010.

Seasonal flu vaccine patterns

For the seasonal vaccine, the CDC estimates that national coverage for all people ages 6 months and older was 41.2%, slightly higher than its earlier projection of 39.7% for the population as a whole. It said about 123 million people received the seasonal flu vaccine through May 2010, an increase from the previous estimate of 118.8 million.

Rates were highest for seniors at 69.6%, followed by adults between the ages of 50 and 64 (45%), children ages 6 months through 17 years (43.7%), younger adults with underlying conditions

(38.2%), and healthy younger adults (28.4%).

The CDC cautioned that the seasonal flu vaccine coverage is an overestimate, because the reported coverage level of 123 million exceeds the 114 million doses of seasonal vaccine that were distributed. In its early estimate the CDC had said that respondent confusion over the two types of flu vaccines might have contributed to some overreporting.

Compared with the 2008-2009 flu season, coverage rates rose for all groups except for adults ages 50 through 64.

Pandemic flu vaccine findings

For the pandemic vaccine, the CDC estimates that national coverage for all groups was 27%, which is slightly higher than the April estimate of 24%. About 80.8 million people received the 2009 H1N1 vaccine, according to the latest estimate, compared with the earlier estimate of 72 million.

Coverage was highest in children ages 6 months through age 17 at 40.5% followed by seniors (28.9%), people ages 25 through 64 in high-risk groups (28.6%), and healthy people ages 25 through 64 (18.7%). Pandemic vaccine coverage was 34.2% in the CDC's initial target group: children, younger adults, people with underlying medical conditions, pregnant women, and healthcare workers.

The CDC said high uptake of the pandemic vaccine in children probably reflects the focus many states had on childhood vaccinations, the use of school-based vaccination clinics, and a recognition that children were at risk for severe disease.

See also:

Oct 7 CDC seasonal and pandemic flu vaccine report (http://www.cdc.gov/flu/professionals/vaccination/coverage_0910estimates.htm)

Apr 29 CIDRAP News story "Seasonal flu vaccine uptake rose in 2009-10 (/cidrap/content/influenza/general/news/apr2910seasonal-jw.html)"

Apr 2 CIDRAP News story "CDC estimates 24% of Americans received H1N1 vaccine (/cidrap/content/influenza/swineflu/news/apr0110coverage.html)"

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CIDRAP - Center for Infectious Disease Research and Policy
Office of the Vice Pre ident for Re earch, Univer ity of Minne ota, Minneapoli , MN

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Report Prepared by:

Worldwide Safety

Pfizer

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APPENDICES

LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
AESI	adverse event of special interest
BC	Brighton Collaboration
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease 2019
DLP	data lock point
EUA	emergency use authorisation
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
PCR	Polymerase Chain Reaction
PT	(MedDRA) Preferred Term
PVP	pharmacovigilance plan
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standardised MedDRA query
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system

1. INTRODUCTION

Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency.

"Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission."

This document provides an integrated analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

2. METHODOLOGY

Pfizer is responsible for the management post-authorization safety data on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these

proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

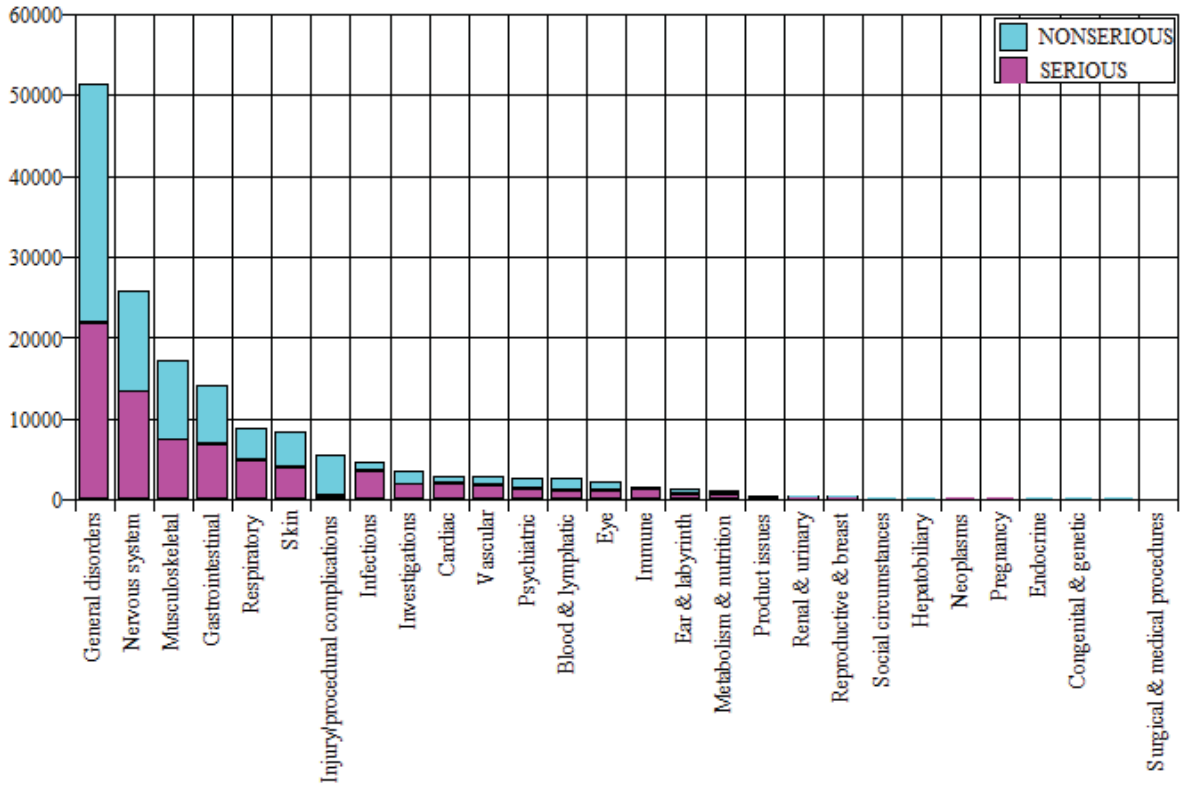

Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
	Pain	3691 (8.8%)
	Malaise	2897 (6.9%)
	Asthenia	2285 (5.4%)
	Drug ineffective	2201 (5.2%)
	Vaccination site erythema	930 (2.2%)
	Vaccination site swelling	913 (2.2%)
	Influenza like illness	835 (2%)
Infections and infestations		
	COVID-19	1927 (4.6%)
Injury, poisoning and procedural complications		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
Musculoskeletal and connective tissue disorders		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
Nervous system disorders		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Paraesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
Respiratory, thoracic and mediastinal disorders		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
Skin and subcutaneous tissue disorders		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
Total number of events		**93473**

3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

Table 4. Important Identified Risk

<table>
<tr><th>Topic</th><th>Description</th></tr>
<tr><td>Important Identified Risk</td><td>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)
Total Number of Cases in the Reporting Period (N=42086)</td></tr>
<tr><td>Anaphylaxis</td><td>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:

<table>
<tr><td>Brighton Collaboration Level</td><td>Number of cases</td></tr>
<tr><td>BC 1</td><td>290</td></tr>
<tr><td>BC 2</td><td>311</td></tr>
<tr><td>BC 3</td><td>10</td></tr>
<tr><td>BC 4</td><td>391</td></tr>
<tr><td>BC 5</td><td>831</td></tr>
<tr><td>Total</td><td>1833</td></tr>
</table>
Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.

There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:

Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.
Relevant event seriousness: Serious (2341), Non-Serious (617);
Gender: Females (876), Males (106), Unknown (20);
Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);
Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);
Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).

Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</td></tr>
</table>

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.
b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

Table 5. Important Potential Risk

Topic	Description
Important Potential Risk	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)	No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue. The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a]. Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved: Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries; Cases Seriousness: 138; Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38). Gender: Females (73), Males (57), Unknown (8); Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5); Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8); Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7). Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD. In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.

a. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Use in Pregnancy and lactation	• Number of cases: 413[a] (0.98% of the total PM dataset); 84 serious and 329 non-serious; • Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. Pregnancy cases: 274 cases including: • 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins). • Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). • 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). • 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. Breast feeding baby cases: 133, of which: • 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events; • 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each). Breast feeding mother cases (6): • 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia • 1 non-serious case reported with very limited information and without associated AEs.

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	• In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each). Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.
Use in Paediatric Individuals <12 Years of Age	<u>Paediatric individuals <12 years of age</u> • Number of cases: 34[d] (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age; • Country of incidence: UK (29), US (3), Germany and Andorra (1 each); • Cases Seriousness: Serious (24), Non-Serious (10); • Gender: Females (25), Males (7), Unknown (2); • Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0; • Case outcome: resolved/resolving (16), not resolved (13), and unknown (5). • Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each). Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population.
Vaccine Effectiveness	Company conventions for coding cases indicative of lack of efficacy: The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below: • PT "Vaccination failure" is coded when ALL of the following criteria are met: o The subject has received the series of two doses per the dosing regimen in local labeling. o At least 7 days have elapsed since the second dose of vaccine has been administered. o The subject experiences SARS-CoV-2 infection (confirmed laboratory tests). • PT "Drug ineffective" is coded when either of the following applies: o The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., "the vaccine did not work", "I got COVID-19". o It is unknown: ▪ Whether the subject has received the series of two doses per the dosing regimen in local labeling; ▪ How many days have passed since the first dose (including unspecified number of days like" a few days", "some days", etc.); ▪ If 7 days have passed since the second dose; o The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose. Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete. Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**

1st dose (day 1-13)	From day 14 post 1st dose to day 6 post 2nd dose	Day 7 post 2nd dose
Code only the events describing the SARS-CoV-2 infection	Code "Drug ineffective"	Code "Vaccination failure"
Scenario Not considered LOE	Scenario considered LOE as "Drug ineffective"	Scenario considered LOE as "Vaccination failure"

Lack of efficacy cases

- Number of cases: 1665[b] (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;
- Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)[f]].
- Country of incidence: US (665), UK (405), Germany (181), France (85), Italy (58), Romania (47), Belgium (33), Israel (30), Poland (28), Spain (21), Austria (18), Portugal (17), Greece (15), Mexico (13), Denmark (8), Canada (7), Hungary, Sweden and United Arab Emirates (5 each), Czech Republic (4), Switzerland (3); the remaining 12 cases originated from 9 different countries.
- COVID-19 infection was suspected in 155 cases, confirmed in 228 cases, in 1 case it was reported that the first dose was not effective (no other information).
- COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (165), not resolved (205) or unknown (1230) at the time of the reporting; there were 65 cases where a fatal outcome was reported.

Drug ineffective cases (1649)

- Drug ineffective event seriousness: serious (1625), non-serious (21)[e];
- Lack of efficacy term was reported:
  - after the 1st dose in 788 cases
  - after the 2nd dose in 139 cases
  - in 722 cases it was unknown after which dose the lack of efficacy occurred.
- Latency of lack of efficacy term reported after the first dose was known for 176 cases:
  - Within 9 days: 2 subjects;
  - Within 14 and 21 days: 154 subjects;
  - Within 22 and 50 days: 20 subjects;
- Latency of lack of efficacy term reported after the second dose was known for 69 cases:
  - Within 0 and 7 days: 42 subjects;
  - Within 8 and 21 days: 22 subjects;
  - Within 23 and 36 days: 5 subjects.
- Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases:
  - Within 0 and 7 days after vaccination: 281 subjects.
  - Within 8 and 14 days after vaccination: 89 subjects.
  - Within 15 and 44 days after vaccination: 39 subjects.

According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1649 cases where lack of efficacy was reported after the 1st dose or the

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness. ***Vaccination failure cases (16)*** • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose: • Latency of lack of efficacy was known for 14 cases: o Within 7 and 13 days: 8 subjects; o Within 15 and 29 days: 6 subjects. COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases. Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.

a. From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed that a 33-year-old and two unspecified age pregnant female patients were scheduled to receive bnt162b2 (PT reported Off label use and Product use issue in 2 cases; Circumstance or information capable of leading to medication error in one case). One case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.
b. 558 additional cases retrieved in this dataset were excluded from the analysis; upon review, 546 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after data lock point (DLP) because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 5 cases have been invalidated in the safety database after DLP; 1 case has been deleted from the discussion because the PTs reported Pathogen resistance and Product preparation issue were not indicative of a lack of efficacy. to be eliminated.
c. Upon review, 31 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects
d. Upon review, 28 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects.
e. Different clinical outcomes may be reported for an event that occurred more than once to the same individual
f. In 2 cases the PT Vaccination failure was replaced with Drug ineffective after DLP. Another case was not included in the discussion of the Vaccination failure cases because correct scheduling (21 days apart between the first and second dose) cannot be confirmed.

3.1.3. Review of Adverse Events of Special Interest (AESIs)

Please refer to Appendix 1 for the list of the company's AESIs for BNT162b2.

The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list is comprised of MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Table 7 provides a summary review of cumulative cases within AESI categories in the Pfizer safety database. This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities.

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
Anaphylactic Reactions *Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria*	Please refer to the Risk 'Anaphylaxis' included above in Table 4.
Cardiovascular AESIs *Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia*	• Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed; • Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries; • Subjects' gender: female (1076), male (291) and unknown (36); • Subjects' age group (n = 1346): Adult[c] (1078), Elderly[d] (266) Child[e] and Adolescent[f] (1 each); • Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6); • Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome[g]: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
COVID-19 AESIs *Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia*	• Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; • Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries; • Subjects' gender: female (1650), male (844) and unknown (573); • Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant[h] and Adolescent (2 each), Child (1); • Number of relevant events: 3359, of which 2585 serious, 774 non-serious; • Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2); • Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days; • Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Dermatological AESIs *Search criteria: PT Chillblains; Erythema multiforme*	• Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed; • Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries; • Subjects' gender: female (17) male and unknown (1 each); • Subjects' age group (n=19): Adult (18), Elderly (1); • Number of relevant events: 20 events, 16 serious, 4 non-serious

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Reported relevant PTs: Erythema multiforme (13) and Chillblains (7) • Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; • Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Haematological AESIs *Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms*	• Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed; • Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=898): female (676) and male (222); • Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1); • Number of relevant events: 1080, of which 681 serious, 399 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Hepatic AESIs *Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury*	• Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed; • Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (43), male (26) and unknown (1); • Subjects' age group (n=64): Adult (37), Elderly (27);

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Number of relevant events: 94, of which 53 serious, 41 non-serious; • Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each); • Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days; • Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Facial Paralysis *Search criteria: PTs Facial paralysis, Facial paresis*	• Number of cases: 449[i] (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed; • Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3),Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (295), male (133), unknown (21); • Subjects' age group (n=411): Adult (313), Elderly (96), Infant[j] and Child (1 each); • Number of relevant events[k]: 453, of which 399 serious, 54 non-serious; • Reported relevant PTs: Facial paralysis (401), Facial paresis (64); • Relevant event onset latency (n = 404): Range from <24 hours to 46 days, median 2 days; • Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97); Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.
Immune-Mediated/Autoimmune AESIs *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity*	• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome[l]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Musculoskeletal AESIs *Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial[n]; Chronic fatigue syndrome; Polyarthritis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis*	• Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed; • Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries; • Subjects' gender (n=3471): female (2760), male (711); • Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1); • Number of relevant events: 3640, of which 1614 serious, 2026 non-serious; • Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1); • Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Neurological AESIs (including demyelination) *Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy*	• Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed. • Country of incidence (≥9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries. • Subjects' gender (n=478): female (328), male (150). • Subjects' age group (n=478): Adult (329), Elderly (149); • Number of relevant events: 542, of which 515 serious, 27 non-serious. • Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each); • Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day; • Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Other AESIs *Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient*	• Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed; • Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries; • Subjects' gender (n=7829): female (5969), male (1860); • Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6);

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive	• Number of relevant events: 8241, of which 3674 serious, 4568 non-serious; • Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each); • Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day; • Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Pregnancy Related AESIs *Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia*	For relevant cases, please refer to Table 6, Description of Missing Information, *Use in Pregnancy and While Breast Feeding*
Renal AESIs *Search criteria: PTs Acute kidney injury; Renal failure.*	• Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed; • Country of incidence: Germany (17), France and UK (13 each), US (6), Belgium, Italy and Spain (4 each), Sweden (2), Austria, Canada, Denmark, Finland, Luxembourg and Norway (1 each); • Subjects' gender: female (46), male (23); • Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1); • Number of relevant events: 70, all serious; • Reported relevant PTs: Acute kidney injury (40) and Renal failure (30); • Relevant event onset latency (n = 42): Range from <24 hours to 15 days, median 4 days; • Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Respiratory AESIs *Search criteria: Lower respiratory tract infections NEC (HLT)*	• Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome	• Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries. • Subjects' gender (n=130): female (72), male (58). • Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1). • Number of relevant events: 137, of which 126 serious, 11 non-serious; • Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). • Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day; • Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Thromboembolic Events *Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism*	• Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed; • Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries; • Subjects' gender (n= 144): female (89), male (55); • Subjects' age group (n=136): Adult (66), Elderly (70); • Number of relevant events: 168, of which 165 serious, 3 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2); • Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days; • Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Stroke *Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents*	• Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed; • Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9),

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)	Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender (n= 273): female (182), male (91); • Subjects' age group (n=265): Adult (59), Elderly (205), Child[m] (1); • Number of relevant events: 300, all serious; • Most frequently reported relevant PTs (>1 occurrence) included: o PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each); o PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each); • Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days; • Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Vasculitic Events *Search criteria: Vasculitides HLT*	• Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed; • Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each); • Subjects' gender: female (26), male (6); • Subjects' age group (n=31): Adult (15), Elderly (16); • Number of relevant events: 34, of which 25 serious, 9 non-serious; • Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each); • Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days; • Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)

a. For the complete list of the AESIs, please refer to Appendix 5;
b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
c. Subjects with age ranged between 18 and 64 years;
d. Subjects with age equal to or above 65 years;
e. Subjects with age ranged between 2 and 11 years;
f. Subjects with age ranged between 12 and less than 18 years;
g. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
h. Subjects with age ranged between 1 (28 days) and 23 months;
i. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report;
k. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
l. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events
m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.
n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;

3.1.4. Medication error

Cases potentially indicative of medication errors[1] that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056[2] (4.9%) of which 1569 (3.7%) are medically confirmed.
- Number of relevant events: 2792
- Top 10 countries of incidence:
  - US (1201), France (171), UK (138), Germany (88), Czech Republic (87), Sweden (49), Israel (45), Italy (42), Canada (35), Romania (33), Finland (21), Portugal (20), Norway (14), Puerto Rico (13), Poland (12), Austria and Spain (10 each).

Medication error case outcomes:

- Fatal (7)[3],
- Recovered/recovering (354, of which 4 are serious),
- Recovered with sequelae (8, of which 3 serious)

[1] MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

[2] Thirty-five (35) cases were exclude from the analysis because describing medication errors occurring in an unspecified number of individuals or describing medication errors occurring with co suspects were determined to be non-contributory.

[3] All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak. .

- Not recovered (189, of which 84 are serious),
- Unknown (1498, of which 33 are serious).

1371 cases reported only MEs without any associated clinical adverse event. The PTs most frequently reported (≥12 occurrences) were: Poor quality product administered (539), Product temperature excursion issue (253), Inappropriate schedule of product administration (225), Product preparation error (206), Underdose (202), Circumstance or information capable of leading to medication error (120), Product preparation issue (119), Wrong technique in product usage process (76), Incorrect route of product administration (66), Accidental overdose (33), Product administered at inappropriate site (27), Incorrect dose administered and Accidental exposure to the product (25 each), Exposure via skin contact (22), Wrong product administered (17), Incomplete course of vaccination, and Product administration error (14 each) Product administered to patient of inappropriate age (12).

In 685 cases, there were co-reported AEs. The most frequently co- associated AEs (> 40 occurrences) were: Headache (187), Pyrexia (161), Fatigue (135), Chills (127), Pain (107), Vaccination site pain (100), Nausea (89), Myalgia (88), Pain in extremity (85) Arthralgia (68), Off label use (57), Dizziness (52), Lymphadenopathy (47), Asthenia (46) and Malaise (41). These cases are summarized in Table 8.

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Accidental exposure to product	0	0	0	5
Accidental overdose	4	1	9	6
Booster dose missed	0	0	0	1
Circumstance or information capable of leading to medication error	0	0	5	11
Contraindicated product administered	1	0	0	2
Expired product administered	0	0	0	2
Exposure via skin contact	0	0	0	5
Inappropriate schedule of product administration	0	2	8	264
Incorrect dose administered	1	1	0	0

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Incorrect route of product administration	2	6	16	127
Lack of vaccination site rotation	1	0	0	0
Medication error	0	0	0	1
Poor quality product administered	1	0	0	34
Product administered at inappropriate site	2	1	13	29
Product administered to patient of inappropriate age	0	4	0	40
Product administration error	1	0	0	3
Product dose omission issue	0	1	0	3
Product preparation error	1	0	4	11
Product preparation issue	1	1	0	14

Overall, there were 68 cases with co-reported AEs reporting Harm and 599 cases with co-reported AEs without harm. Additionally, Intercepted medication errors was reported in 1 case (PTs Malaise, clinical outcome unknow) and Potential medication errors were reported in 17 cases.

4. DISCUSSION

Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

5. SUMMARY AND CONCLUSION

Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

Pfizer will continue routine pharmacovigilance activities on behalf of BioNTech according to the Pharmacovigilance Agreement in place, in order to assure patient safety and will inform the Agency if an evaluation of the safety data yields significant new information for BNT162b2.

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

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Tab 20

Consent: A guide for Canadian physicians

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Introduction

In the shorter *Oxford dictionary*, consent is defined as "the voluntary agreement to or acquiescence in what another person proposes or desires; agreement as to a course of action."

In the medical context and as the law on consent to medical treatment has evolved, it has become a basic accepted principle that "every human being of adult years and of sound mind has the right to determine what shall be done with his or her own body." Clearly physicians may do nothing to or for a patient without valid consent. This principle is applicable not only to surgical operations but also to all forms of medical treatment and to diagnostic procedures that involve intentional interference with the person.

That consent to treatment was lacking or inadequate continues to be a frequent claim against physicians. Obviously it is important therefore that physicians be aware of their legal obligations in obtaining consent from patients. It is hoped this booklet will assist in strengthening this awareness. It is not intended as a legal treatise on the subject of consent but rather as a practical guide for physicians in their day-to-day dealings with patients.

Before we begin: Two important issues

Emergency treatment

To the general rule that consent must always be obtained before any treatment is administered, there is an important exception. In cases of medical emergency when the patient (or substitute decision maker) is unable to consent, a physician has the duty to do what is immediately necessary without consent. For the physician to declare any clinical situation an emergency for which consent is not required, there must be demonstrable severe suffering or an imminent threat to the life or health of the patient. It cannot be a question of preference or convenience for the health care provider; there must be undoubted necessity to proceed at the time. Further, under medical emergency situations, treatments should be limited to those necessary to prevent prolonged suffering or to deal with imminent threats to life, limb or health.

Even when unable to communicate in medical emergency situations, the known wishes of the patient must be respected. Therefore, before proceeding, the physician will want to be satisfied there has been no indication in the past by way of Advance Directive or otherwise that the patient does not want the proposed treatment Further, as soon as the patient is able to make decisions and regains the ability to give consent, a proper and "informed" consent must then be obtained from the patient for additional treatment.

In some provinces, legislation permits the designation of substitute decision-makers to provide or refuse consent on behalf of the incapacitated patient. If the substitute decision-maker is immediately available emergency treatment should proceed only with the consent of that individual

In urgent situations, it may be necessary or appropriate to initiate emergency treatment while steps are taken to obtain the informed consent of the patient or the substitute decision-maker, or to determine the availability of advance directions. However, the instructions as to whether to proceed or not must be obtained as quickly as practicably possible.

When a n emergen y di t to the need to pro ced without v lid on ent from the p tient or the

When an emergency dictates the need to proceed without valid consent from the patient or the substitute decision-maker, a contemporaneous record (at the time) should be made explaining the circumstances which forced the physician's hand. If the circumstances are such that the urgency might be questioned at a later date, arranging a second medical opinion would be prudent if possible.

The bottom line:

- When the patient or substitute decision maker is unable to consent and there is demonstrable severe suffering or an imminent threat to the life or health of the patient, a doctor has the duty to do what is immediately necessary without consent. Emergency treatments should be limited to those necessary to prevent prolonged suffering or to deal with imminent threats to life, limb or health. Even when he/she is unable to communicate, the known wishes of the patient must be respected.

Assault and battery

Most legal actions against physicians concerning consent are based on negligence and raise allegations as to the adequacy of the consent discussion with the patient. A claim of assault and battery may, however, be alleged in specific circumstances. A physician may be liable in assault and battery when no consent was given at all or when the treatment went beyond or deviated significantly from that for which the consent was given. Allegations of assault and battery might also be made if consent to treatment was obtained through serious or fraudulent misrepresentation in what was explained to the patient.

Thus, as has happened in various legal actions, it was seen as an assault and battery to carry out an amputation without having received consent to do so; to administer an intravenous anaesthetic agent into the left arm when the patient had specifically forbidden it; to sterilize a patient when consent had been given for a Caesarean section only; to operate on the patient's back when consent had been given only for a procedure on the toe.

In each of these examples, the physicians knew they were proceeding in the medical best interests of the patients and took measures which were clearly medically indicated. However, our courts have repeatedly affirmed that good intentions of the physician cannot be substituted for the will of the patient.

The bottom line:

- A physician may be liable in assault and battery when no consent was given at all, when the treatment went beyond or deviated significantly from that for which the consent was given, or if consent to treatment was obtained through serious or fraudulent misrepresentation in what was explained to the patient.

Types of consent

Consent to treatment may be implied or it may be specifically expressed either orally or in writing. The clinical situation determines the approach required.

Implied consent

Implied consent

Much of a physician's work is done on the basis of consent which is implied either by the words or the behaviour of the patient or by the circumstances under which treatment is given. For example, it is common for a patient to arrange an appointment with a physician, to keep the appointment, to volunteer a history, to answer questions relating to the history and to submit without objection to physical examination. In these circumstances consent for the examination is clearly implied. To avoid misunderstanding, however, it may be prudent to state to the patient an intention to examine the breasts, genitals or rectum.

The foregoing notwithstanding, in many situations the extent to which consent was implied may later become a matter of disagreement. Physicians should be reasonably confident the actions of the patient imply permission for the examinations, investigations and treatments proposed. When there is doubt, it is preferable the consent be expressed, either orally or in writing

Expressed consent

Expressed consent may be in oral or written form. It should be obtained when the treatment is likely to be more than mildly painful, when it carries appreciable risk, or when it will result in ablation of a bodily function.

Although orally expressed consent may be acceptable in many circumstances, frequently there is need for written confirmation. As physicians have often observed, patients can change their minds or may not recall what they authorized; after the procedure or treatment has been carried out, they may attempt to take the position it had not been agreed to or was not acceptable or justified Consent may be confirmed and validated adequately by means of a suitable contemporaneous notation by the treating physician in the patient's record.

Expressed consent in written form should be obtained for surgical operations and invasive investigative procedures. It is prudent to obtain written consent also whenever analgesic, narcotic or anaesthetic agents will significantly affect the patient's level of consciousness during the treatment

Requirements for valid consent

For consent to serve as a defence to allegations of either negligence or assault and battery, it must meet certain requirements. The consent must have been **voluntary**, the patient must have had the **capacity** to consent and the patient must have been **properly informed**.

Voluntary consent

Patients must always be free to consent to or refuse treatment, and be free of any suggestion of duress or coercion. Consent obtained under any suggestion of compulsion either by the actions or words of the physician or others may be no consent at all and therefore may be successfully repudiated In this context physicians must keep clearly in mind there may be circumstances when the initiative to consult a physician was not the patient's, but was rather that of a third party, a friend, an employer, or even a police officer. Under such circumstances the physician may be well aware that the patient is only very reluctantly following the course of action suggested or insisted upon by a third person. Then, physicians should be more than usually careful to assure themselves patients are in

full agreement with what has been suggested, that there has been no coercion and that the will of other persons has not been imposed on the patient.

The bottom line:

- Consent obtained under any suggestion of compulsion either by the actions or words of the doctor or others may be no consent at all and therefore may be successfully repudiated.

Capacity to consent

An individual who is able to understand the nature and anticipated effect of proposed medical treatment and alternatives, and to appreciate the consequences of refusing treatment, is considered to have the necessary capacity to give valid consent. However, there are special circumstances to which particular attention must be given.

Age of consent

The legal age of majority has become progressively irrelevant in determining when a young person may consent to his or her medical treatment. As a result of consideration and recommendations by law reform groups as well as the evolution of the law on consent, the concept of maturity has replaced chronological age. The determinant of capacity in a minor has become the extent to which the young person's physical, mental, and emotional development will allow for a full appreciation of the nature and consequences of the proposed treatment, including the refusal of such treatments

Legislation in a number of provinces and the territories has codified the law on consent, including the reliance on maturity in assessing a young person's capacity to consent to or refuse medical treatment. Only the Province of Quebec has established a fixed age of 14 years, below which the consent of the parent or guardian or of the court is necessary for the purposes of proposed treatment.

Generally, where the minor patient lacks the necessary capacity, the parents or guardian are authorized to consent to treatment on the minor's behalf. In doing so, the parents or guardian must be guided by what is in the best interests of the minor This consideration becomes all the more important when the parent or guardian seeks to refuse treatment the physician regards as medically necessary. In these circumstances, there is an obligation on the part of physicians to report the matter to child protection authorities

Patients must be at least 18 years of age to consent to medical assistance in dying. A minor patient’s parents or guardian cannot consent to assistance in dying on the minor’s behalf

The bottom line:

- The determinant of capacity in a minor has become the extent to which the young person's physical, mental, and emotional development will allow for a full appreciation of the nature and consequences of the proposed treatment, including the refusal of such treatments.
- Generally, where the minor patient lacks the necessary capacity, the parents or guardian are authorized to consent to treatment on the minor's behalf, and must be guided by what is in the best interests of the minor.

Mental incapacity / Substitute decision-making

It is well accepted that a person who is incapable to make decisions regarding certain matters might still have sufficient mental capacity to give valid consent to medical treatment Again, it depends on whether the patient is able to appreciate adequately the nature of the proposed treatment, its anticipated effect and the alternatives. Therefore, many individuals who may be mentally infirm or who have been committed to a psychiatric facility continue to be capable of controlling and directing their own medical care, including the right to consent to treatment or to refuse treatment. It is beyond the scope of this general discussion to comment on the various legal requirements pursuant to mental health legislation, but physicians should be generally familiar with the applicable mental health legislation in their jurisdiction, particularly with reference to formal capacity assessments necessary to declare the patient incapable of consent and the appeal process available to the patient.

In circumstances where it has been determined that a patient is incapable of consenting to a particular medical treatment, the question as to who is authorized to make the decision will arise It is now possible in the majority of provinces for a patient to execute an Advance Directive as to future care in the event that the patient becomes incapacitated or is unable to communicate his or her wishes. Advance Directives are sometimes referred to as living wills. Advance Directives may contain explicit instructions relating to consent or refusal of treatment in specified circumstances. In some provinces, Advance Directives may be contained in Powers of Attorney for personal care An Advance Directive may also be used to appoint or designate an individual who will be authorized to make substitute decisions about consent or refusal of treatment in the event that the patient becomes incapacitated. Again, physicians will want to be generally familiar with any applicable legislation in their particular jurisdiction. Consent to medical assistance in dying cannot be given by way of Advance Directives

In limited circumstances, a patient can waive the requirement that their consent to medical assistance in dying be confirmed at the time it is administered. Before losing capacity, patients who meet all eligibility criteria and safeguards for MAID and for whom natural death is reasonably foreseeable may make advance arrangements in writing with their medical or nurse practitioner. The advance agreement will be invalided if the person subsequently refuses or demonstrates resistance to MAID in their words, sounds, or gestures.

A number of provinces have also enacted legislation for substitute decision-makers which sets out and ranks a list of individuals, usually family members, who are authorized to give or refuse consent to treatment on behalf of an incapable person. The specific legislation in the jurisdiction will generally set out the principles that should guide the substitute decision maker's treatment decision Generally speaking, substitute decision-makers must act in compliance with any prior capable wish of the patient, where possible. Consideration of such factors as the individual's current wishes and his or her known beliefs and values may also be required, depending on the jurisdiction. It is clear that the substitute decision-maker should always be guided by the patient's best interests. Substitute consent, including that of a parent for a child, cannot be utilized for proposed treatment which might be regarded as non-therapeutic, such as non-therapeutic sterilization. Physicians will want to be alert to other circumstances that might raise unique issues such as substitute consent in the context of clinical research. It is also important to remember that a substitute decision-maker cannot consent to MAID on behalf of an incapable patient

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The determination of the patient's best interests, or whether a proposed treatment is "therapeutic" or not can be difficult, and, in circumstances where there are questions or doubts, physicians are encouraged to consult with other physicians and legal counsel. There may be circumstances where an ethical consult would be prudent. Physicians should also be aware that there are legal mechanisms available to address circumstances where concerns exist that a substitute decision-maker may not be acting in the patient's best interests.

In the absence of a valid Advance Directive or duly authorized substitute decision-maker, strictly speaking only the court or someone appointed by the court may properly consent to or refuse medical treatment where the patient lacks the requisite capacity to make the decision. Unfortunately, the legal procedure for the appointment of a guardian of the patient can be lengthy and expensive. As a result, and from a practical standpoint, physicians have often proceeded on the basis of the family's approval where the medical treatment is clearly required, where the patient's condition may deteriorate if not treated promptly, and the treatment is determined to be in the patient's best interests. Should there be any disagreement among family members, or if the proposed treatment carries significant risks, then specific legal advice should probably be sought about that situation.

The bottom line:

- Many individuals who may be mentally infirm or who have been committed to a psychiatric facility continue to be capable of controlling and directing their own medical care, including the right to consent to treatment or to refuse treatment; legal requirements vary with jurisdiction, so physicians should be generally familiar with the applicable mental health legislation in their jurisdiction.
- In circumstances where there are questions or doubts about what is in the patient's best interests or whether a proposed treatment is "therapeutic" or not, physicians are encouraged to consult with other physicians and, when warranted, legal counsel

Informed consent

Disclosure of information

For consent to treatment to be considered valid, it must be an "informed" consent. The patient must have been given an adequate explanation about the nature of the proposed investigation or treatment and its anticipated outcome as well as the significant risks involved and alternatives available. The information must be such as will allow the patient to reach an informed decision. In situations where the patient is not mentally capable, the discussion must take place with the substitute decision maker

The obligation to obtain informed consent must always rest with the physician who is to carry out the treatment or investigative procedure This obligation may be delegated in appropriate circumstances (to a PGY trainee for example) but before assigning this duty to another, the treating physician should be confident the delegate has the knowledge and experience to provide adequate explanations to the patient

In special circumstances, an obligation of pre-treatment disclosure may fall to more than one physician involved in the care For example, a radiologist carrying out an invasive diagnostic

procedure would likely be seen as responsible for explaining how the test will be done and the risks attendant upon it. The physician who ordered the test might also be expected to tell the patient, in general terms, about the nature and purpose of the test and alternatives which might be employed.

The bottom line:

- The patient must have been given an adequate explanation about the nature of the proposed investigation or treatment and its anticipated outcome as well as the significant risks involved and alternatives available.
- The obligation to obtain informed consent must always rest with the physician who is to carry out the treatment or investigative procedure.

Standard of disclosure

Although obtaining a valid consent from patients has always involved explanations about the general nature of the proposed treatment and its anticipated effect, the Supreme Court of Canada, over two decades ago, imposed a more stringent standard of disclosure upon physicians. The adequacy of consent explanations is to be judged by the "reasonable patient" standard, or what a reasonable patient in the particular patient's position would have expected to hear before consenting.

The Supreme Court of Canada has set out in general terms the scope of the physician's duty in informing patients before treatment as follows:

"In summary, decided cases appear to indicate that in obtaining the consent of a patient for the performance upon him of a surgical operation, a surgeon, generally, should answer any specific questions posed by the patient as to the risks involved and should, without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation. However, having said that, it should be added that the scope of the duty of disclosure and whether or not is has been breached are matters which must be decided in relation to the circumstances of each particular case."

In a subsequent decision, the court extended the obligation of disclosure as follows

"... a surgeon must also, where the circumstances require it, explain... alternative means of treatment and their risks."

The foregoing does provide physicians with a general basis for deciding the nature and extent of the pre-treatment information which should be given to patients but it can be difficult to apply legal generalizations to specific clinical situations Therefore, some comment about several of the points raised in these precedent-setting judgments may be helpful.

Throughout these and other legal judgments which have been rendered in more recent years, there is repeated reference to the need to disclose "material" risks to patients. However, there can be some understandable uncertainty as to what in fact does constitute a "material" risk. One court has defined it as follows

"A risk is thus material when a reasonable person in what the physician knows or should know to be

the patient's position would be likely to attach significance to the risk or cluster of risks in determining whether or not to undergo the proposed therapy."

Thus the particular circumstances of the patient are an important determinant of materiality.

It is clear that the materiality of a risk is influenced as well both by the frequency of the possible risk and also by its seriousness should it occur. Generally speaking, the more frequent the risk, the greater the obligation to discuss it beforehand. Further, even uncommon risks of great potential seriousness should be disclosed. In this context the Supreme Court of Canada indicated that even if a risk is "a mere possibility" yet it carries with it serious consequences such as paralysis or death, it should be regarded as material and therefore requires disclosure.

The bottom line:

- The adequacy of consent explanations is judged by the "reasonable patient" standard, or what a reasonable patient in the particular patient's position would have expected to hear before consenting.
- Recent legal judgments repeatedly refer to the need to disclose "material" risks to patients Generally speaking, the more frequent the risk, the greater the obligation to discuss it beforehand. Further, even uncommon risks of great potential seriousness should be disclosed

Patient comprehension

It has been suggested that not only must the physician provide the necessary details about the nature, consequences and material risks of the proposed treatment in order to obtain informed consent, but also the physician has the duty to ensure the patient has understood the information. **This interpretation of the case law goes too far and would place an unfair and unreasonable burden on the physician.** In rejecting this obligation, the court, in a recent Scottish case, commented that such an onus upon the physician could only be discharged through "vigorous and inappropriate cross-examination" of the patient.

There is no doubt, however, that the physician does have a duty to take reasonable steps so as to be relatively satisfied that the patient does understand the information being provided, particularly where there may be language difficulties or emotional issues involved What amounts to "reasonable steps" will very much depend on the individual facts and circumstances of the particular situation.

It seems clear that by engaging in personal dialogue with the patient, the physician will be placed in the best possible position to be reasonably comfortable the patient understands the consent explanation. Personal attendance permits the physician the opportunity to observe the patient's reaction for signs of apparent comprehension or confusion As well, the ability of the patient to ask questions will often assist the physician to assess the level of patient understanding.

The bottom line:

- Physicians have a duty to take reasonable steps so as to be relatively satisfied that the patient does understand the information being provided, particularly where there may be language difficulties or emotional issues involved

Consent disclosure in research and experimentation

The issue of consent merits careful consideration by those physicians who may become involved in any research work in which patients or human volunteers are asked to participate.

In terms of the extent to which risks must be disclosed, there is now less distinction between "therapeutic" and "non-therapeutic" research than in earlier years when requirements for informed consent were less stringent. These days, for any treatment or procedure that is innovative or that could be perceived as experimental, anything which may be interpreted as going beyond the need for prophylaxis, diagnosis or therapy, an element of "research" should be assumed. In such circumstances a standard of full disclosure may be applicable when obtaining consent. The concept of therapeutic privilege is inappropriate and no information about a project or clinical trial may be hidden from a patient on the ground that disclosure would result in undue worry or anxiety. As well, researchers must recognize the potential for what might later appear to have been duress or coercion. This is a particularly important consideration if the subject has a physician-patient relationship with a member of the research team.

A fair explanation must always be given about what is proposed, its risks and discomforts, what, if any, benefits might accrue and, if applicable, what appropriate alternative treatments or procedures might be offered. If a blind study is involved, patients must be aware they could stand to derive no benefit at all. Researchers should offer and make themselves available to answer enquiries about what is proposed and should emphasize to patients or subjects they are free to withdraw consent and discontinue participation in the project at any time without prejudice.

It might be argued that minors or adults with mental disability do not have the capacity to consent when research or experimentation figure to any significant extent in clinical management. Physicians should exercise a great deal of caution in dealing with such situations.

The bottom line:

- When it comes to research and experimentation, a fair explanation must be given about what is proposed, its risks and discomforts, what if any benefits might accrue and, if applicable, what appropriate alternative treatments or procedures might be offered. If a blind study is involved, patients must be aware they could stand to derive no benefit at all

Informed refusal

Our courts have reaffirmed repeatedly a patient's right to refuse treatment even when it is clear treatment is necessary to preserve the life or health of the patient. Justice Robins of the Ontario Court of Appeal explained:

"The right to determine what shall, or shall not, be done with one's own body, and to be free from non-consensual medical treatment, is a right deeply rooted in our common law This right underlines the doctrine of informed consent. With very limited exceptions, every person's body is considered inviolate, and, accordingly, every competent adult has the right to be free from unwanted medical treatment. The fact that serious risks or consequences may result from a refusal of medical treatment

does not vitiate the right of medical self-determination. The doctrine of informed consent ensures the freedom of individuals to make choices about their medical care. It is the patient, not the physician, who ultimately must decide if treatment — any treatment — is to be administered."

However, difficulty may arise if it should later be claimed the refusal had been based on inadequate information about the potential consequences of declining what had been recommended. In the same way as valid consent to treatment must be "informed," so it may be argued a refusal must be similarly "informed." Physicians thus may be seen to have the same obligations of disclosure as when obtaining consent, that is, disclosure of the risk to be accepted.

When patients decide against recommended treatment, particularly urgent or medically necessary treatment, discussions about their decision must be conducted with some sensitivity. While recognizing an individual's right to refuse, physicians must at the same time explain the consequences of the refusal without creating a perception of coercion in seeking consent. Refusal of the recommended treatment does not necessarily constitute refusal for all treatments. Reasonable alternatives should be explained and offered to the patient.

As when documenting the consent discussion, notes should be made about a patient's refusal to accept recommended treatment. Such notes will have evidentiary value if there is any controversy later about why treatment was not given.

The bottom line:

- Our courts have reaffirmed repeatedly a patient's right to refuse treatment even when it is clear treatment is necessary to preserve the life or health of the patient. Physicians must at the same time explain the consequences of the refusal without creating a perception of coercion in seeking consent.

Informed discharge

Although not strictly an element of the pre-operative consent process, the courts have recently elaborated on the duty or obligation of physicians to properly inform patients in the post operative or post-discharge period. Thus a physician must conduct a discussion with a patient of the post-treatment risks or complications, even statistically remote ones that are of a serious nature. The purpose is to inform the patient of clinical signs and symptoms that may indicate the need for immediate treatment such that the patient will know to visit the physician or return to the hospital/facility

The bottom line:

- Physicians have an obligation to properly inform patients in the post-operative or post-discharge period, most specifically about clinical signs and symptoms that may indicate the need for immediate treatment.

Some practical considerations about informed consent

The law on consent will continue to evolve. However, current interpretation of legal judgements dealing with "informed consent" will allow some suggestions which may be of practical assistance to

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physicians in their attempt to meet the legal standards

1. Insofar as may be possible, tell the patient the diagnosis. If there is some uncertainty about the diagnosis mention this uncertainty, the reason for it and what is being considered.

2. The physician should disclose to the patient the nature of the proposed treatment, its gravity, any material risks and any special risks relating to the specific treatment in question Even if a risk is a mere possibility which ordinarily might not be disclosed, if its occurrence carries serious consequences, as for example paralysis or death, it must be regarded as a material risk requiring disclosure.

3 A physician must answer any specific questions posed by the patient as to the risks involved in the proposed treatment. Always the patient must be given the opportunity to ask questions.

4. The patient should be told about the consequences of leaving the ailment untreated. Although there should be no appearance of coercion by unduly frightening patients who refuse treatment, our courts now recognize there is a positive obligation to inform patients about the potential consequences of their refusal.

5. The patient should be told about available alternative forms of treatment and their risks. There is no obligation to discuss what might be clearly regarded as unconventional therapy but patients should know there are other accepted alternatives and why the recommended therapy has been chosen.

6. Physicians must be alert to a patient's individual concerns about the proposed treatment and deal with them. It must be remembered that any particular patient's special circumstances might require disclosure of potential although uncommon hazards of the treatment when ordinarily these might not be seen as material. Courts have made it clear that the duty of disclosure extends to what the physician knows or should know the particular patient deems relevant to a decision whether or not to undergo treatment.

7 Although any particular patient may waive aside all explanations, may have no questions, and may be prepared to submit to the treatment whatever the risks may be without any explanatory discussion, physicians must exercise cautious discretion in accepting such waivers.

8. When, because of emotional factors, the patient may be unable to cope with pre-treatment explanations, the physician may be justified in withholding or generalizing information which otherwise would be required to be given. This so-called "therapeutic privilege" should be exercised with great discretion and only when there are compelling reasons dictated by clinical circumstances.

9 In obtaining consent for cosmetic surgical procedures or for any type of medical or surgical work which might be regarded as less than entirely necessary to the physical health of the patient, physicians must take particular care in explaining fully the risks and anticipated results. As in

experimental research situations, courts may impose on physicians a higher standard of disclosure in such circumstances.

10. Encouragement about optimistic prospects for the results of treatment should not allow for the misinterpretation that results are guaranteed.

11. Where a part or all of the treatment is to be delegated, patients have a right to know about this and who will be involved in their care Consent explanations should include such information

12. A note by the physician on the record at the time of consent explanations can later serve as important confirmation that a patient was appropriately informed, particularly if the note refers to any special points which may have been raised in the discussion.

Consent forms — Documentation of consent

A consent form itself is not consent

Consideration of a consent form to be signed by the patient should not obscure the important fact that the form itself is not the "consent." The explanation given by the physician, the dialogue between physician and patient about the proposed treatment, is the all important element of the consent process. The form is simply evidentiary, written confirmation that explanations were given and the patient agreed to what was proposed. A signed consent form will be of relatively little value later if the patient can convince a court the explanations were inadequate or, worse, were not given at all.

Apart from providing evidence that a patient consented to proposed treatment, there is another important reason for having consent forms signed In many Canadian jurisdictions it has become a legal requirement that such a document must be completed before any surgical procedure is undertaken in a hospital

The bottom line:

- The explanation given by the physician, the dialogue between physician and patient about the proposed treatment, is the all important element of the consent process
- The consent form itself is not the "consent." It is simply evidentiary, written confirmation that the explanations were given and that the patient agreed to what was proposed
- In many Canadian jurisdictions it has become a legal requirement that such a document must be completed before any surgical procedure is undertaken in a hospital.

Basic elements

On the basis of experience in advising and defending its members on matters of consent, the Canadian Medical Protective Association believes a satisfactory consent form, adaptable to most situations, should be a relatively simple document, such as the prototype suggested below

Basic elements of a consent form:
Consent to investigation, treatment or operative procedure

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(1) I,_____ , hereby consent to undergo the investigation, treatment or operative procedure, , ordered by or to be performed by Dr._____.

(2) The nature and anticipated effect of what is proposed including the significant risks and alternatives available have been explained to me. I am satisfied with these explanations and I have understood them

(3) I also consent to such additional or alternative investigations, treatments or operative procedures as in the opinion of Dr._____ are immediately necessary.

(4) I further agree that in his or her discretion, Dr may make use of the assistance of other surgeons, physicians, and hospital medical staff (including trainees) and may permit them to order or perform all or part of the investigation, treatment, or operative procedure, and I agree that they shall have the same discretion in my investigation and treatment as Dr. _____.

Dated_____
day / month / year

Patient_____

Witness_____

Identification and acknowledgement of explanations

The form should name the patient and in general terms the nature of the investigation, treatment or operation. It should name the physician who is to carry out the treatment. There should be included an acknowledgement by the patient that explanations have been given about the nature of the treatment and its anticipated effect, and about any material risks and special or unusual risks Mention should be made also of the patient's acknowledgement that alternative forms of treatment or investigation have been discussed. The form should allow for acknowledgement by the patient that he or she is satisfied with the explanations and has understood them.

Anaesthesia

Again, as a result of its experience with negligence litigation against physicians, the Canadian Medical Protective Association continues to believe that specific consent, except where required by a statute, is unnecessary for the administration of anaesthesia for surgery The need for written consent for anaesthesia is seen as limited because ordinarily it should be implicit in the documentation of the pre-anaesthetic examination by the anaesthetist that the patient was properly informed. The pre-anaesthetic visit by the anaesthetist or the anaesthetist's delegate provides an opportunity for discussion about alternative forms of anaesthesia which might be offered, any exclusions imposed by the patient and any particular risks which the examining anaesthetist feels may be appropriate to

mention in the particular case.

Although usually the record of the pre-anaesthetic examination will adequately confirm the dialogue which occurred between anaesthetist and patient, if specific consent for anaesthesia is included on a form, care should be taken to avoid provision on the document inviting exclusions to be stated by the patient Any such exclusions should have been agreed upon at the pre anaesthetic examination Failing such discussion and decision, and particularly with a form that offers opportunity for the patient to stipulate exclusions, there is greater risk the patient could impose last minute restrictions on the anaesthetist with the possibility that these might be overlooked

Added or alternative procedures

The clause in the prototype form authorizing additional or alternative procedures requires some special comment. In their pre-operative explanations to patients, surgeons will always attempt to anticipate in advance what various conditions might be encountered and what alternative procedures might have to be added during the operation However, not infrequently, circumstances arise which compel the physician to consider an extension of the procedure, something which could not have been anticipated and which was not mentioned to the patient beforehand

In these situations, the physician may exceed the mandate given by the patient only if failure to take the additional or alternative steps would render ineffective the procedure for which the consent was given or would pose a significant risk to the health or life of the patient. If there arises need to proceed with something wholly different from that to which the patient has given consent and if it be reasonable and not harmful to delay, the patient should be allowed to regain consciousness Then additional explanations can be given and consent sought for the different procedure. Only when something additional or alternative is immediately necessary and vital to the health and life of the patient, not merely a matter of convenience, should a physician proceed without expressed consent.

Delegation to others

The final paragraph of the prototype consent form is deemed necessary because of two sets of circumstances which are common in practice. The first is the situation where a number of physicians work as a group and where for various reasons work may be delegated to another member of the same group.

The other circumstances are those found in teaching hospitals where PGY trainees and others participate in the care of patients Delegation of work and responsibility to these post graduate trainees is essential. They must have assigned to them increasing responsibility for reaching decisions and for carrying out progressively more difficult and complex treatments and procedures once they have shown evidence of ability.

Patients must be informed about the involvement of trainees in their care. At the same time they should be reassured about the quality of that care and the measure of supervision which will be exercised. If patients in teaching hospitals are told that other physicians may be involved in their care, if they are given appropriate reassurances and especially if they have already met the other members of the medical team looking after them, patients will likely accede to the proposals and, most important, can never claim they did not know work might be delegated to someone else.

Some clinical teachers may still have concern that if all of this is done routinely and such acknowledgements are set out on a consent form, some patients might refuse to allow the management to be delegated, insisting that their own attending physician provide it all. This, of course, is the patient's prerogative. If there must be difficulty, better it be resolved beforehand than to be faced later with a patient who thinks the result of treatment is less than ideal and who then claims if it had been known the treatment was to be delegated, consent would have been withheld Under such circumstances both physician and post-graduate trainee might be relatively defenceless.

Signatures and witnesses

Remembering that consent forms are simply documentary confirmation of consent explanations and the patient's willingness to proceed with what has been proposed, it is preferable to arrange for a patient's signature on the form as contemporaneously as possible with the pre treatment discussions Sometimes it is convenient to accomplish this in a physician's office or at the bedside with the physician present. More often, however, the signing may occur as an administrative step during the process of admission to hospital or as part of a hospital ward administrative routine. The patient should be given ample opportunity to consider what he or she is signing and be given adequate opportunity to consider the implications of that to which they are consenting

Because of the varying circumstances under which consent forms are frequently signed, nurses or other hospital personnel may be asked to witness the signing. It should be remembered that in witnessing a signature the witness simply confirms the identity of the patient who signed the document and that the person's mental state at the time appeared to allow for an understanding of what was signed The role of the witness has no other legal significance Most important, the witness to a signature on a consent form should not feel he or she has any obligation whatsoever to provide pre-treatment explanations which, in signing the form, the patient acknowledges having received. A nurse or other person witnessing a patient's signature on a consent form does in no way attest to the adequacy of explanations which have been given by the physician. However, if a patient implies or states that he or she has been inadequately informed about the nature of the proposed treatment, a person witnessing the signature or others present should not press for the signature and the treating physician should be notified.

Some consent forms require the signature of the treating physician who, by signing, acknowledges that consent explanations have been given. Clearly, the purpose of this signature is to direct the physician's attention to his or her legal obligations Although the purpose of the treating physician's signature may be commendable, having regard to some of the practical considerations in arranging for the completion of consent forms, it may be preferable that this requirement not be contained on the form and imposed. On most occasions the physician will have held the required discussions with the patient previously and may not be readily available at the time when the form is prepared for the patient's signature Then, if through an administrative failure the physician's signature fails to appear on the form, its absence might be more harmful to the physician's legal interest than if the form did not call for his or her signature in the first place.

Notes in the medical record

A signed consent form has undoubted evidentiary value and is a specific legal requirement in many

situations However, when an informed consent is called into question, a physician's note on the record may be of equal or even greater usefulness for defence purposes. Courts rely heavily on progress notes if it is clear they were made contemporaneously with the events they record

At the time when consent explanations are given it is a relatively simple matter for the physician to note briefly some of the significant points raised in conversation with the patient. Such notations, particularly if they identify questions or special concerns expressed by the patient, can serve to validate the consent process better than any other documentation.

The note need not be voluminous or time consuming If it records on the office or hospital chart something relevant to the discussion with the particular patient, it will be much more credible in evidence than the recollections of any of the parties involved in a lawsuit. The contemporaneous progress note about consent can be invaluable and is highly recommended

Consent forms and medical assistance in dying

In addition to amendments to the *Criminal Code*, all regulatory authorities (Colleges) have developed guidelines for physicians concerning MAID. Physicians should be familiar with the requirements concerning written consent in the *Criminal Code* and the College guidelines, including the requirements concerning witnessing the request for MAID, and other information that must be attested to.

Handouts and materials supplemental to consent explanations

Because the essential element of consent is the dialogue and sharing of information between physician and patient, anything which can conveniently facilitate this process is desirable. The pre-treatment consent discussions with the patient are most important and should not be replaced; however, sometimes these discussions can be more informative if they are supplemented by printed or other recommended materials which are given to the patient in advance and can be reviewed at leisure by the patient

For relatively standardized treatments, investigative or therapeutic procedures, background information about what is being proposed may be provided in the form of, for example, information sheets, printed brochures or electronic resources. This material should outline the nature of the proposed treatment or procedure, its purpose and intended outcome, and should mention significant risks and potential complications which might be of relevance to most patients Such information resources should invite questions from the patient about the treatment and it should be clear that opportunity will be given for such questioning and for further discussion after the resource has been reviewed.

Information sheets, brochures, and similar materials may not be applicable in many circumstances under which consent is obtained but when they are used should be seen only as an adjunct and not a substitute to consent discussions. Frequently consent explanations must be tailored to the particular circumstances of the individual patient.

Because of the wide variety of circumstances under which consent forms are signed, it is preferable that the information sheet or similar document not be an integral part of the consent form. The signing

of a consent form, the acknowledgement that appropriate information has already been given, is often simply an administrative step which does not allow for adequate review of information on which patients must base their decisions for or against treatment. Documents supplementary to consent explanations should be provided well in advance of signing. From time to time when commenting about consent procedures, courts have made it clear, except in urgent and pressing circumstances, patients must be given adequate opportunity to consider the implications of that to which they are consenting.

Consent explanations are sometimes added to in a more elaborate fashion by a videotape recording of the discussion about the proposed treatment or procedure. This adjunct is probably most applicable for cosmetic surgery but may be suitable also in other circumstances.

Regardless of what supplementary methods are employed to provide patients with information prior to consent, it must again be emphasized they can only supplement and not replace dialogue with the patient For evidentiary purposes, a contemporaneous notation should be made confirming that the supplementary material had been provided and that after reviewing it the patient was given an opportunity to ask questions about it before consenting.

Since legal actions often arise many years after clinical treatment, it is wise to keep older versions of information sheets or other materials in an archive file, with the dates noted of when these were in use,in case they are required during medico legal difficulties that arise after they are no longer in use

The bottom line:

- Handouts and materials should be supplemental to consent explanations; the essential element of consent is the dialogue and sharing of information between physician and patient
- Supplementary documents should be provided well in advance of signing the consent form so that patients have adequate opportunity to consider the implications of that to which they are consenting.
- It is wise to keep older versions of materials in an archive file.

Treatment in Canada of U.S. and other foreign residents

It is not unusual that physicians practising in Canada are called upon to provide professional services to patients who are not ordinarily resident in Canada. Many such patients are visitors or tourists who become ill and require urgent or emergent care Increasingly, however, such patients are individuals, mostly United States residents, who have travelled to Canada specifically to receive elective medical care, perhaps attracted by comparative cost benefits.

Every Canadian physician should appreciate that any foreign patient who brings a legal action because of dissatisfaction with the medical care received in Canada may very well seek to bring that legal action back home where the patient resides The risk of a foreign action is very important to physicians, as there may very well be limitations on the legal assistance or protection available from, for example, CMPA to member physicians or insurers to other health professionals in connection with such actions.

When a foreign patient brings a legal action against a Canadian physician, one of the principal issues

When a foreign patient brings a legal action against a Canadian physician, one of the principal issues to be determined is whether the foreign court should accept jurisdiction or defer such that the legal action must be brought in Canada. There is a greater likelihood the foreign court will permit the legal action to proceed in the patient's home jurisdiction:

- the more it appears that a foreign resident was encouraged or invited to attend in Canada for medical care or attention,
- the more it appears that arrangements for such care were initiated while the patient was in the foreign jurisdiction,
- the more elective the care or treatment provided was, or
- the more it appears foreign funding was involved.

Canadian physicians attending foreign patients in Canada should take steps to encourage that any subsequent medico legal action be brought in Canada **Before treating a foreign patient (with the exception of emergency cases), all physicians and health care organizations should make reasonable efforts to ensure a Governing Law and Jurisdiction Agreement is completed.** These forms are designed to assist in establishing Canadian jurisdiction for any potential legal actions that may result from care or treatment provided by Canadian physicians or health care organizations to non residents

Which form do you use?

- Physicians who provide treatment in their private office should ensure the patient completes the form for use by physicians in private practice
- Physicians working in a health care organization setting are specifically included in the health care organization form, and are not required to also have the physician in private practice form completed. Either the physician or a representative of the health care organization can have the patient complete and sign the form; it is not intended that separate forms be obtained by both parties
- In Québec, the Direction des programmes d'assurance du Réseau de la santé et des services sociaux will recommend the use of the form for health care organizations be integrated in the administrative process relating to the examination, treatment and in-hospital stay of all non-residents of Canada. Until this form is in use, the CMPA recommends physicians who treat non-residents of Canada in a Québec public health care institution use the physician in private practice form.
- Physicians who work at a health care organization that is not a HIROC or a Direction des programmes d'assurance subscriber should check with the administration of the facility before using the form for health care organizations.
- Physicians who practice in a clinic or facility that is a recognized legal entity should use the form for health care organizations. This advice does not apply if the entity is simply the physician's personal professional corporation. In such cases, the physician should use the form for a physician in private practice.

The bottom line:

- Any foreign patient who brings a legal action because of dissatisfaction with the medical care

received in Canada may very well seek to bring that legal action back home where the patient resides. There may be limitations on the legal assistance or protection available from the CMPA or insurers in connection with foreign actions.
- Before treating a foreign patient (with the exception of emergency cases), all physicians and health care organizations should make reasonable efforts to ensure a Governing Law and Jurisdiction Agreement is completed.

Click here to view:

- Governing Law and Jurisdiction Agreement (for Health Care Organizations) [PDF]
- Governing Law and Jurisdiction Agreement (for Physician in Private Practice) [PDF]

Gmail [redacted]

RE: {External} Evaluations of accommodation request

Joseph Hickey [redacted] Tue, Dec 7, 2021 at 6:54 PM
To: [redacted]@bank-banque-canada.ca>

Dear [redacted]

I have followed up with RCGT about their procedure for an appeal of the medical evaluation of my accommodation request, and you were in CC to an email I sent a few minutes ago recapping my conversation with [redacted] of RCGT about that.

As I wrote in my email to [redacted], I intend to submit my appeal to RCGT as soon as possible.

Please note that I also intend to appeal regarding the religious and human rights (age & sex) aspects and will send my submission to you as soon as possible.

Sincerely,
Joseph

--
Joseph Hickey, PhD
[redacted]

On Mon, Dec 6, 2021 at 10:22 PM [redacted]@bank-banque-canada.ca> wrote:

Category/Catégorie: Protected A/Protégé A

Dear Joseph,

When I referenced "third party subject matter experts" in relation to your religious, age and sex aspects of your request, I was referring to the external legal experts engaged by the Bank to provide advice on accommodation requests under the Covid-19 Vaccination Policy. The information that you have submitted to date was fully reviewed by the external legal experts.

There are no additional third-party evaluations that were conducted.

Thank you,

[redacted]

[redacted]
Senior Employee Relations Specialist

Spécialiste principal des relations avec les employés

Human Resources| Ressources humaines

Bank of Canada |Banque du Canada

234 rue Wellington Street, Ottawa, ON K1A 0G9
[redacted]

BANK OF CANADA
BANQUE DU CANADA

From: Joseph Hickey [redacted]
Sent: December 3, 2021 2:31 PM
To: [redacted]@bank-banque-canada.ca>
Subject: Re: {External} Evaluations of accommodation request

Dear [redacted]

Thank you for your email of Nov. 29.

In your email, you wrote: "In terms of the request for religious accommodation, unfortunately we are not in a position to release the third party legal advice relating to your request. That said, we can advise that the committee reviewing the request felt that the information that you have submitted to date does not establish a sufficient connection between your request and a religious belief."

In communications to me prior to your Nov. 29 email, including our meeting on MS Teams of Nov. 18, you have said that "third party subject matter experts" evaluated the religious and human rights (age & sex) aspects of my accommodation request.

However, in your Nov. 29 email (passage cited above) you refer only to "third party legal advice". I would like to clarify: are you now saying that no third party subject matter evaluations were made with respect to my accommodation request?

Also, your Nov. 29 email does not mention the human rights (age & sex) aspects of my accommodation request. Will you provide me with the evaluations of that part of my request?

Please provide me with copies of all third party expert or professional opinions ("subject matter evaluations"), irrespective of whether these were used by a lawyer to give you legal advice.

Thank you,
Joseph

--

Joseph Hickey, PhD

[redacted]

[redacted]

On Mon, Nov 29, 2021 at 12:56 PM [redacted]@bank-banque-canada.ca> wrote:

Category/Catégorie: Protected A/Protégé A

Dear Joseph,

Thank you for your email. With respect to your request for medical accommodation, RCGT will be able to provide the documentation prepared by the medical reviewer who made the recommendation on your case. I believe RCGT has already responded to that end.

In terms of the request for religious accommodation, unfortunately we are not in a position to release the third party legal advice relating to your request. That said, we can advise that the committee reviewing the request felt that the information that you have submitted to date does not establish a sufficient connection between your request and a religious belief.

Thank you,

[redacted]

[redacted] [redacted]
Senior Employee Relations Specialist

Spécialiste principal des relations avec les employés

Human Resources| Ressources humaines

Bank of Canada |Banque du Canada

234 rue Wellington Street, Ottawa, ON K1A 0G9

[redacted]

[redacted]

[redacted]

BANK OF CANADA
BANQUE DU CANADA

From: Joseph Hickey [redacted]
Sent: November 25, 2021 4:58 PM
To: [redacted]@bank-banque-canada.ca>
Cc: [redacted]
Subject: {External} Evaluations of accommodation request

Dear [redacted]

Please send me the evaluations of my request for accommodation by the Bank's internal committee and by all of the third parties who were involved in evaluating my request.

Please send those documents to [redacted]

I have included [redacted] in CC here, since you asked me to inquire at that email address for additional information related to the medical aspects of my accommodation request.

Thank you,

Joseph

--

Joseph Hickey, PhD

[redacted]

[redacted]

==========

La version française suit le texte anglais.

Treasury Board of Canada Secretariat | Secrétariat du Conseil du Trésor du Canada

Canada

Managers' Toolkit for the Implementation of the Policy on COVID-19 Vaccination for the Core Public Administration including the Royal Canadian Mounted Police

Version 1.0

October 8, 2021

Contents

1. INTRODUCTION

Vaccination is one of the most effective tools we have at our disposal to protect broader public health in the face of COVID-19, and to prevent future outbreaks. Used in combination with preventative public health measures, it offers the best available protection for Canadians.

As the country's largest employer, the Government of Canada is leading by example on vaccination to protect the health and safety of public servants and the communities where they live and work.

Requiring the vaccination of the federal workforce will contribute to reaching the overall levels of vaccination Canada needs to sustain a resilient economic recovery in the face of more transmissible and dangerous COVID-19 variants of concern, and to protect the millions of children and others who are currently unable to be vaccinated and vulnerable to infection.

The government has announced details of its plans to require vaccination across the federal public service. These plans have been informed by discussions with key stakeholders, including departments, bargaining agents, and the Office of the Privacy Commissioner.

Under the new Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police, federal public servants in the Core Public Administration and members of the RCMP must attest to their vaccination status. The requirement for employees to be vaccinated applies whether they are teleworking, working remotely or working on-site.

As early as November 15, public servants who refuse to disclose their status or who are unwilling to be vaccinated will be placed on administrative leave without pay (LWOP). Employees who have attested to having received a first dose as of the attestation deadline will have a period of up to 10 weeks after the first dose to receive their second dose. If they do not receive their second dose by this time, they will be placed on LWOP. Employees unable to be vaccinated may request accommodation.

Other COVID-19 preventative measures will also continue to be in place, including encouraging remote work as much as possible, maintaining a physical distance of at least two metres, washing hands, wearing masks in common areas indoors or outdoors, and staying home when sick. Measures will be reviewed and adjusted as public health guidance evolves.

In accordance with the *Directive on Leave and Special Working Arrangements*, public servants who work in the Core Public Administration and the RCMP can use "Time off for personal medical and dental appointments" (code 698) for both COVID-19 vaccine appointments.

The collection of all personal information from public servants will be done in accordance with the *Privacy Act,* the *Policy on Privacy Protection* and its related instruments.

2. POLICY AND RELATED FRAMEWORKS

Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police

Framework for Implementation of the Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police

LINK TBD

Framework on Mandatory COVID-19 Testing for Implementation of the Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police

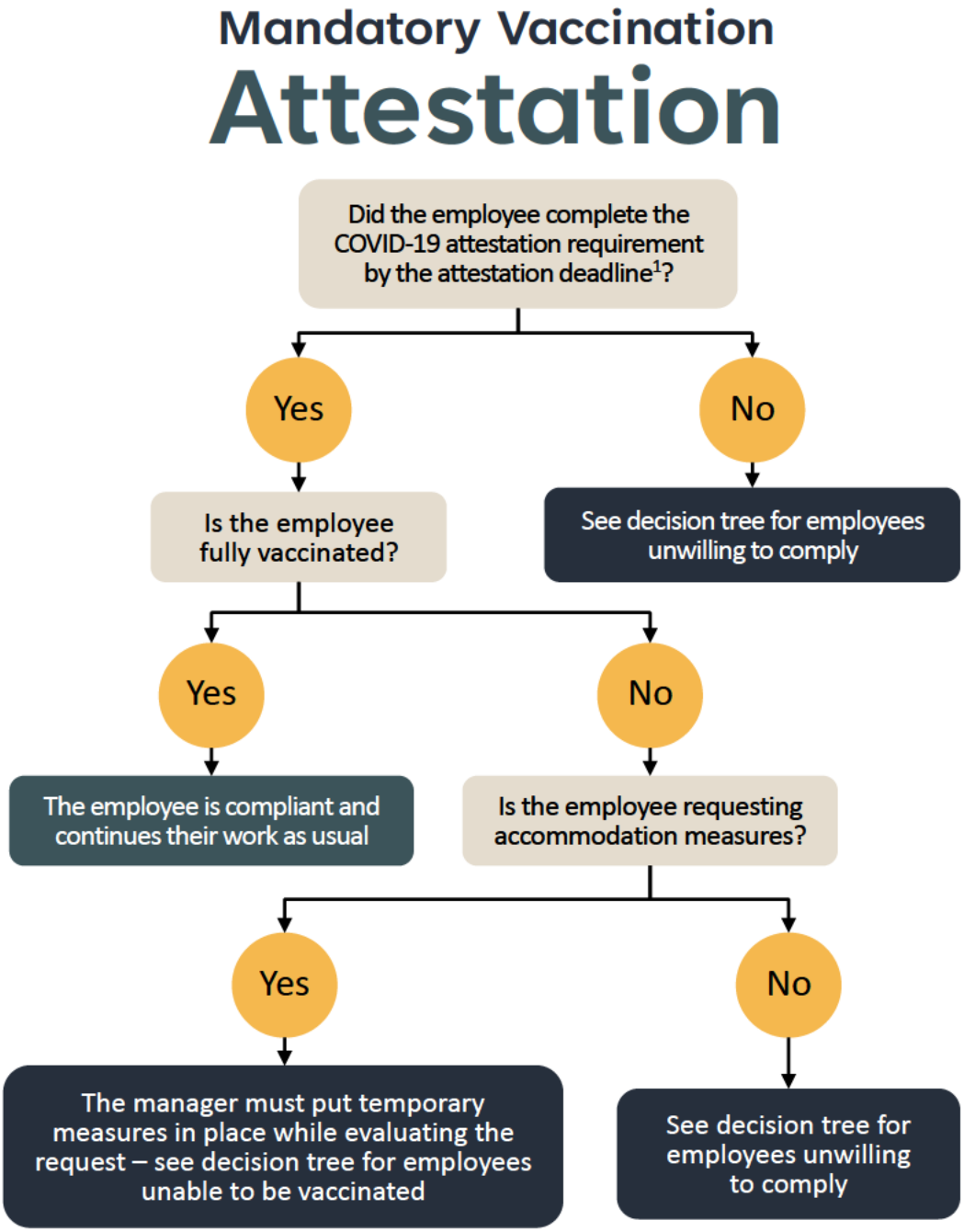
LINK TBD

3. TIMELINE INFOGRAPHIC – IMPLEMENTATION

October 6, 2021 **Effective Date**	• The Government of Canada Vaccine Attestation Tracking System (GC-VATS) is launched to departments in waves, ending October 15. The GC-VATS allows employees to enter their attestation of vaccination status, and any requests for accommodation.		
October 6-29, 2021 **Attestation Period**	• Employees enter their vaccination status into the GC-VATS, no later than October 29.	• Employees unable to be vaccinated begin making accommodation requests. Employees unable to be vaccinated are encouraged to request accommodation no later than October 29, 2021. Managers gather relevant information and render a decision as soon as possible.	• All employees are permitted to access to their workplace as per existing departmental procedures, and without testing, but with appropriate preventative measures in place.
Special Situations – Other Attestation Deadlines	• 2 weeks after return from leave if the return from leave is after October 15, 2021; or	• 2 weeks after the date on which an employee has been informed of their manager's decision that the duty to accommodate does not apply; or	• For employees who, for reasons related to their current position, are unable to attest to their vaccination status, or do not have access to vaccines for the period extending from October 15th to October 29th, the attestation deadline is 2 weeks from the date they have access to vaccines, as determined by their manager, and notwithstanding their leave status.

October 29 - November 14, 2021	• Unvaccinated employees and employees who have not attested to their vaccination status are required to attend a training session.	• Managers remind employees, in writing, of the consequences of not attesting to their vaccination status, requesting accommodation, or of being unvaccinated.
November 15, 2021 **Full Implementation Date**	• Employees who have not attested to having received their first vaccination dose or submitted a request for accommodation are considered unwilling. • Beginning of accommodation measures for employees unable to be vaccinated, including mandatory testing of employees who must report to work on-site. Please refer to the Framework on Mandatory COVID-19 Testing for implementation of the Policy on COVID-19 Vaccination for the Core Public Administration including the Royal Canadian Mounted Police.	• Employees will be placed on administrative LWOP if: o They are unwilling to be vaccinated; or o They are unwilling to attest to their vaccination status. • Employees who have attested to having received a first dose as of the attestation deadline will have a period of up to 10 weeks after the first dose to receive their second dose. If they do not receive their second dose by this time, they will be placed on LWOP.

4. DECISION TREES



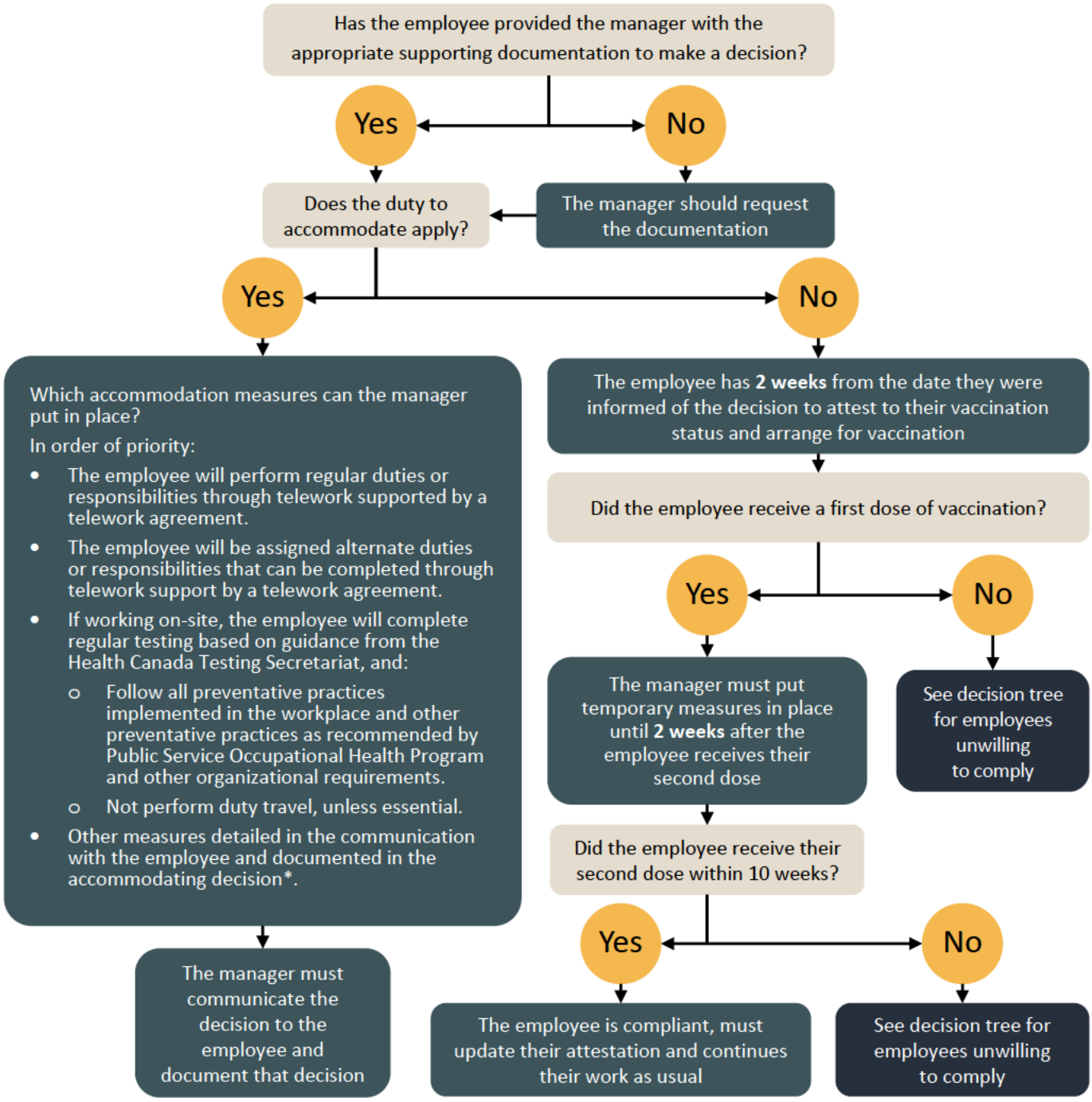
Notes

[1]Attestation deadline is the date by which an employee's attestations must be entered in the GC-VATS, or provided to managers if the employee does not have access to the GC-VATS:

- October 29, 2021, including for employees on "Other Leave With Pay (699)" for reasons related to the pandemic; or
- 2 weeks after return from leave if the return from leave is after October 15, 2021; or
- 2 weeks after the date on which an employee has been informed of their manager's decision that the duty to accommodate does not apply; or
- for employees who, for reasons related to their current position, are unable to attest to their vaccination status, or do not have access to vaccines for the period extending from October 15th to October 29th, the attestation deadline is 2 weeks from the date they have access to each, as determined by their manager, and notwithstanding their leave status.

Mandatory Vaccination

Unable

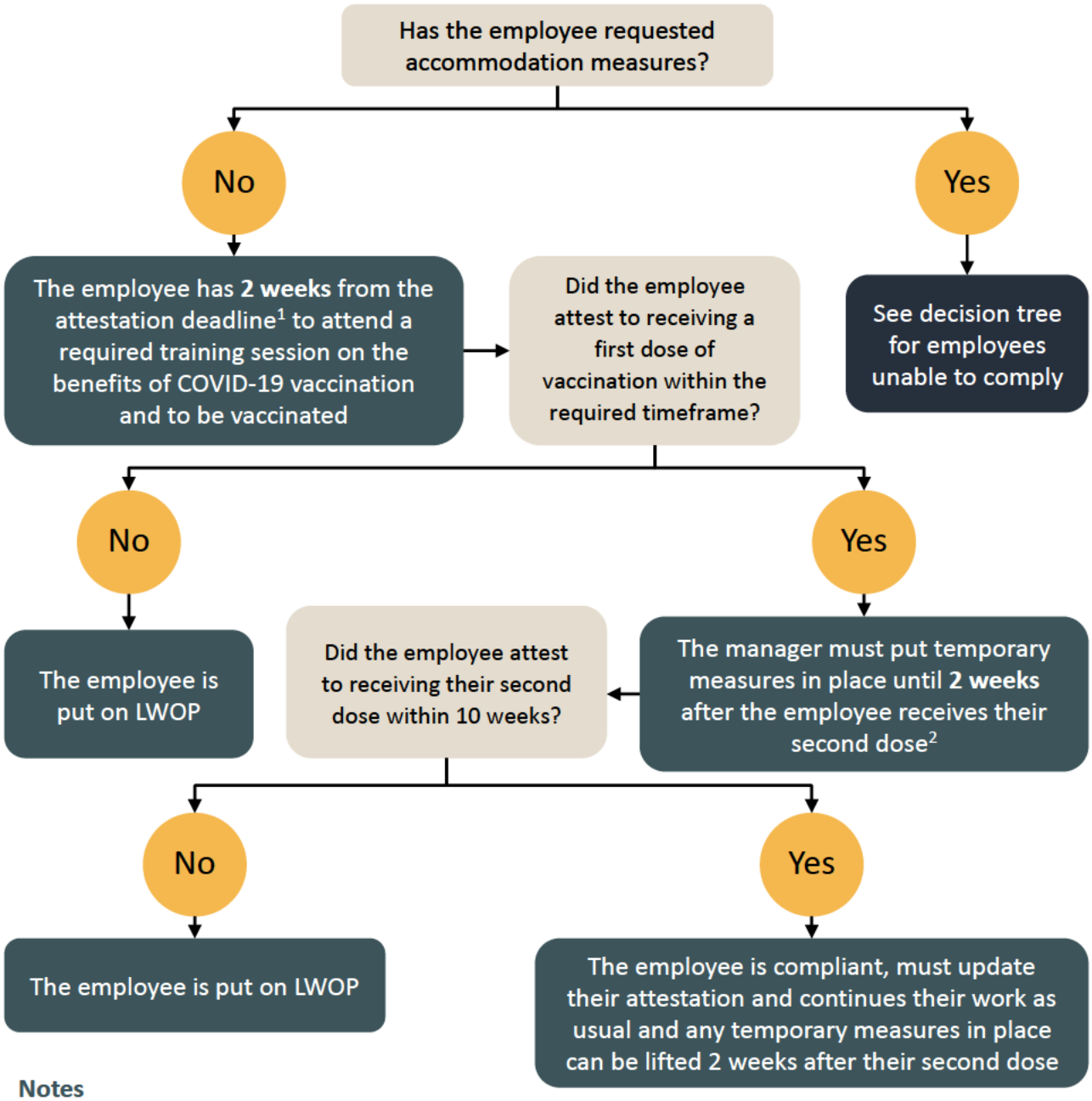


Notes

* For further guidance, managers should seek support from human resources.

Mandatory Vaccination

Unwilling Employees



Notes

[1]Attestation deadline is the date by which an employee's attestations must be entered in the GC-VATS, or provided to managers if the employee does not have access to the GC-VATS:

- October 29, 2021, including for employees on "Other Leave With Pay (699)" for reasons related to the pandemic; or
- 2 weeks after return from leave if the return from leave is after October 15, 2021; or
- 2 weeks after the date on which an employee has been informed of their manager's decision that the duty to accommodate does not apply; or
- for employees who, for reasons related to their current position, are unable to attest to their vaccination status, or do not have access to vaccines for the period extending from October 15th to October 29th, the attestation deadline is 2 weeks from the date they have access to each, as determined by their manager, and notwithstanding their leave status.

[2]The employee's second dose must be no later than 10 weeks after the first dose.

5. GOVERNMENT OF CANADA VACCINE ATTESTATION TRACKING SYSTEM (GC-VATS) – INSTRUCTIONS FOR EMPLOYEES TO COMPLETE ATTESTATION FORM IN GC-VATS

Section for Employee

Instructions that will Appear in the Application:

All employees will be required to attest to their vaccination status in order to comply with the Policy on Vaccination. To do so, they must log on to the application through the TBS Application Portal (TAP), the same portal which houses the "Public Service Performance Management (PSPM)" application. The instructions below outline the steps which employees must follow to complete the attestation form.

Step 1: Privacy Statement

- ✓ Review the Privacy statement. Click “Acknowledge and continue” to advance to Step 2: Vaccination status.
- ✓ If you do not wish to accept the Privacy statement, click “Return Home”.

Step 2: Vaccination Status

- ✓ Ensure that the name of your direct manager is correct.
  - If your manager’s name is correct, proceed to vaccination status.
  - If your manager’s name is not correct, contact your manager to request a correction before continuing.

- ✓ Select the current vaccination status that applies to you, as defined by the *Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police*

  Note: If you have not completed all required vaccine doses or are in the waiting period (14 days) after a dose, you can complete your attestation as of October 15, 2021.

  - Fully vaccinated
  - Unvaccinated
  - Unvaccinated because you are seeking accommodation:
    - You must speak with your manager directly about your request for accommodation and provide appropriate documentation at the earliest opportunity or by the attestation deadline (October 29).
    - Here are some details about the supporting materials that your manager may request:
      - Medical Contraindication: Written documentation from your

treating medical physician or nurse practitioner on grounds for not receiving or for delaying the COVID-19 vaccine (which can be provided using this form). The note must specify whether the reason is permanent or time limited. If time limited, the note should indicate how long the limitation is expected to last.

- Religion: A sworn affidavit (signed before a commissioner for taking affidavits) containing information about the sincere religious belief that prohibits full vaccination.
- Other Prohibited Grounds: Specific information on the nature of the reason a prohibited ground of discrimination under the *Canadian Human Rights Act (CHRA)* or unable to be vaccinated.

*Your manager may request additional information and supporting documentation, as may be appropriate.

*Other alternative documentation could be accepted, in consultation with departmental HR specialists

Step 3: Review

✓ Review your Attestation Before Submitting.

a. To make a correction, click “Previous” to return to Step 2: Vaccination status.

✓ Click “Submit”

b. If you have requested accommodation, follow up with your manager.

Employee Attestation Form

Note: If you have not completed all required vaccine doses or are in the waiting period (14 days) after a dose, you can complete your attestation as of October 15, 2021. You are also required at this time to provide your manager with the date of your first vaccination.

I attest that my COVID-19 vaccination status is

☐ Fully Vaccinated per the Vaccination Policy for the Core Public Administration

☐ Unvaccinated because I am requesting an accommodation

☐ Unvaccinated

I am requesting accommodation

☐ due to a medical contraindication

☐ under a prohibited ground of discrimination under s.3(1) of the *Canadian Human Rights Act*

Indicate *CHRA* ground

☐ Religion

☐ Another prohibited ground under s.3(1) of the *Canadian Human Rights Act*

By submitting this form, I certify that the statements I have made and the information I have disclosed in this form are true, complete, correct and in accordance with the Values and Ethics Code for the Public Sector. I understand that if my vaccination status changes, I must complete a new vaccination status attestation. I acknowledge that the information I submit in this form is subject to verification and audit and I specifically acknowledge that my manager reserves the right, at the manager's sole discretion, to request proof of vaccination.

Employee Accommodation Acknowledgement

☐ My manager and I have discussed my request for accommodation and the resulting decision.

Click "Submit".

Section for Managers

Instructions that will Appear in the Application:

Review employee submissions:

- If the employee is fully vaccinated, no further action is needed.
- If the employee is unvaccinated and not requesting accommodation, refer to the Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police.
- If the employee is unvaccinated and requesting accommodation:

✓ **Step 1: Review the request and make a decision as soon as possible or by the full implementation date.**

- If accommodation is requested due to a medical contraindication:
  - Written documentation from their treating medical physician or nurse practitioner on grounds for not receiving or for delaying the COVID-19 vaccine (which can be provided using this form). The note must specify whether the reason is permanent or time limited. If time limited the note should indicate how long it is expected to last.

- If accommodation is requested due to religion:
  - A sworn affidavit (signed before a commissioner for taking affidavits) containing information about the sincere religious belief that prohibits full vaccination.

- If accommodation is requested related to other prohibited grounds under the *Canadian Human Rights Act*:
  - Specific information on the nature of the reason a prohibited ground of discrimination renders them unable to be fully vaccinated against COVID-19.

Note:

- You may request any additional information and supporting documentation, as may be appropriate.
- Other alternative documentation could be accepted, in consultation with departmental HR specialists.
- All documentation received during the duty to accommodate process should be treated as Protected B (when completed).

✓ **Step 2. Record the decision:**

- If the duty to accommodate APPLIES (i.e.: you have reviewed and accepted the justification):
  - Indicate whether the accommodation is permanent or temporary:

        - If temporary, enter the end date.

    - Indicate the accommodations that will be implemented. These can include:
        - Performing regular duties and responsibilities through telework supported by a telework agreement as per the Directive on Telework.
        - Assigning alternate duties or responsibilities that can be completed through telework supported by a telework agreement as per the Directive on Telework.
        - Testing as per the Health Canada Testing framework.
        - Other measures detailed in communication with your employee and in the accommodation request.

- If the duty to accommodate does not APPLY (i.e., you have reviewed and not accepted the justification):
    - Refer to the Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police.
- Discuss the decision with your employee, acknowledge the decision in the GC-VATS, and ensure your employee acknowledges the decision in the GC-VATS.

Process request for accommodation

Documentation

Medical Contraindication

Written documentation from the employee's treating medical physician or nurse practitioner on grounds for not receiving or for delaying the COVID-19 vaccine (which can be provided using this form). The note must specify whether the reason is permanent or time limited. If time limited the note should indicate how long the limitation is expected to last.

Religion

A sworn affidavit (signed before a commissioner for taking affidavits) containing information about the sincere religious belief that prohibits full vaccination.

Other Prohibited Grounds

Specific information on the nature of the reason a prohibited ground of discrimination renders the employee unable to be fully vaccinated.

I have received and reviewed the documentation

- ☐ Necessary supporting documentation; or
- ☐ Alternative documentation in consultation with my departmental HR specialists; and,
- ☐ The supporting documentation will be retained as per information management protocols, retention guidelines and in accordance with the *Privacy Act* and its *Regulations*. (required)

Decision:

Duty to Accommodate

- ☐ Duty to accommodate DOES NOT APPLY (refer to Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police
- ☐ Duty to accommodate APPLIES (I have reviewed and accepted the justification)

Accommodation duration

- ☐ Permanent; or,
- ☐ Time limited, expiring on [Select a date]

Accommodation Measure:

- ☐ Performing regular duties/responsibilities through telework supported by a telework agreement as per the Directive on Telework;
- ☐ Assigning alternate duties/responsibilities that can be done through telework supported by a telework agreement as per the Directive on Telework;
- ☐ Testing as per Health Canada testing framework; and/or,
- ☐ Other measures _____[textbox].

  Other measures (must specify): *(For privacy reasons, only include information related to the accommodation measure being taken, not information related to the employee's personal accommodation request. Examples could include: adjusted hours, flexible schedule, etc.)*

Acknowledgement of Discussion:

☐ The employee and I have discussed this request for accommodation and the resulting decision.

Click "Submit".

6. INSTRUCTIONS FOR EMPLOYEES TO COMPLETE ATTESTATION FORM OUTSIDE OF GC-VATS (PAPER VERSION)

COVID-19 Vaccination Attestation Form

Report your vaccination status, as defined by the Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police.

**This form is only to be used when an employee does not have access to the GC-VATS Application.*

1. **Employee Name:**

   PRI/HRMIS number for RCMP/DND service number for military:

   Manager Name:

2. **Privacy Statement:**

☐ I acknowledge the below-noted privacy statement.

3. **I attest that my COVID-19 vaccination status is (required)**

Note: If you have not completed all required vaccine doses or are in the waiting period (14 days) after a dose, you can complete your attestation as of October 15, 2021. You are also required at this time to provide your manager with the date of your first vaccination.

☐ Fully Vaccinated per the Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police

☐ Unvaccinated because I am requesting accommodation

☐ Unvaccinated

I am requesting accommodation (required)

☐ Due to a medical contraindication

☐ Under a prohibited ground of discrimination under s.3(1) of the *Canadian Human Rights Act*

Indicate *CHRA* ground (required)

☐ Religion

☐ Another prohibited ground under s.3(1) of the *Canadian Human Rights Act*

By submitting this form, I certify that the statements I have made and the information I have disclosed in this form are true, complete, correct and in accordance with the Values and Ethics Code for the Public Sector. I understand that if my vaccination status changes, I must complete a new vaccination status attestation. I acknowledge that the information I submit in this form is subject to verification and audit and I specifically acknowledge that my manager reserves the right, at the manager's sole discretion, to request proof of vaccination.

4. **Employee Signature:**

Date:

---

5. **Process request for accommodation, if applicable**

Manager to complete the following:

I have received and reviewed the documentation (required)

☐ Necessary supporting documentation; or

☐ Alternative documentation in consultation with my departmental HR specialists;

☐ The supporting documentation will be retained as per information management protocols, retention guidelines and in accordance with the Privacy Act and its Regulations (required)

Decision

Duty to accommodate (required)

☐ Duty to accommodate DOES NOT APPLY (refer to Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police)

☐ Duty to accommodate APPLIES (I have reviewed and accepted the justification)

Accommodation duration (required)

☐ Permanent; or,

☐ Time limited, expiring on (enter DATE): _____ (required)

Accommodation Measure (required)

☐ Performing regular duties/responsibilities through telework supported by a telework agreement as per the Directive on Telework;

☐ Assigning alternate duties/responsibilities that can be done through telework supported by a telework agreement as per the Directive on Telework;

☐ Testing as per Health Canada testing framework; and/or,

☐ Other measures (must specify): (For privacy reasons, only include information related to the accommodation measure being taken, not information related to the employee's personal accommodation request. Examples could include: adjusted hours, flexible schedule, etc.)

Acknowledgement of Discussion:

☐ The employee and I have discussed this request for accommodation and the resulting decision.

Manager signature:

Date:

☐ My manager and I have discussed my request for accommodation and the resulting decision.

Employee signature:

Date:

Privacy Statement of Attestation Form

The Treasury Board (TB), as the employer for the Core Public Administration, has a duty to ensure the health and safety of employees in the workplace. Vaccination against COVID-19 will be a requirement for all federal public servants as part of the approach to protect federal public servants and the community from COVID-19 and ensuring safe workplaces. Vaccination will add a layer of protection that will work with other public health measures to combat the spread of the virus.

The purpose for collection and use of this information is to fulfill the responsibility of your employer to ensure the health and safety of employees. This is a requirement under section 124, Part II of the Canada Labour Code and under the Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police. Personal information is collected pursuant to section 7 and 11.1 of the *Financial Administration Act* and in accordance with the *Privacy Act*. The personal information collected will be used to confirm your vaccination status and to consider requests for accommodation for those unable to be vaccinated. The personal information will be used, in conjunction with additional COVID-19 preventative measures, including testing, to determine if you will be granted on-site access to the workplace and to determine whether you may report to work in person or remotely. Your personal information will also be used by your organization and TBS to monitor and report on the overall impact of COVID-19 and compliance with the vaccination program both within the organization and for the Core Public Administration, as described in standard personal information bank PSE 907, *Occupational Health and Safety*.

Personal information may also be used to facilitate personnel administration in the employing organization and to ensure continuity and accuracy when an employee is transferred to another organization as described in standard personal information bank PSE 901, *Employee Personnel Record*. The centralized collection, use, and disclosure of your personal information is described in TBS central personal information bank (under development).

Refusal to provide the requested information may result in employees being refused on-site access to the workplace, whether you may report to work in person or remotely and other administrative consequences such as employees being placed on leave without pay, until they are fully compliant. Under the *Privacy Act*, you have the right to access your personal information and request corrections to your information. Should you wish to exercise your rights under the *Privacy Act*, or have any questions about this statement, please contact your organization's ATIP Coordinator. You have the right to file a complaint with the Office of the Privacy Commissioner about the handling of your personal information.

Instructions to Complete the Paper Version of the Employee Attestation Form - Employee Section

Step 1: Employee Details

1. Write your name, Personal Record Identifier (PRI), HRMIS number for RCMP or DND service number for military and your direct Manager's name.

Step 2: Privacy Statement

1. Review the Privacy statement. Acknowledge the Privacy Statement on Page 4.
2. If you do not wish to accept the Privacy statement, please discuss with your manager.

Step 3: Vaccination Status

Note: If you have not completed all required vaccine doses or are in the waiting period (14 days) after a dose, you can complete your attestation as of October 15, 2021.

1. Select the current vaccination status that applies to you, as defined by the Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police.
    - Fully vaccinated
    - Unvaccinated
    - Unvaccinated because you are seeking accommodation
        - You must speak with your manager directly about your request for accommodation and provide appropriate documentation at the earliest opportunity or by the attestation deadline.
        - Here are some details about the supporting materials that your manager may request:
            - Medical Contraindication: Written documentation from your treating medical physician or nurse practitioner on grounds for not receiving or for delaying the COVID-19 vaccine. The note must specify whether the reason is permanent or time limited. If time limited the note should indicate how long it is expected to last.
            - Religion: A sworn affidavit (signed before a commissioner for taking affidavits) containing information about the sincere religious belief that prohibits full vaccination.
            - Another Prohibited Ground: Specific information on the nature of the reason a prohibited ground of discrimination under the *CHRA* that renders you unable to be vaccinated.

        *Your manager may request any additional information and supporting documentation, as may be appropriate.

        *Other alternative documentation could be accepted, in consultation with departmental HR specialists.

Step 4: Review

1. Review your attestation before signing.

Step 5: Accommodation Request

1. If you have requested accommodation, follow up with your manager.

Instructions to complete the paper version of the Employee Attestation Form - Manager Section

Review employee submissions:

- If the employee is fully vaccinated, no further action is needed.
- If the employee is unvaccinated and not requesting accommodation, refer to the Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police.
- If the employee is unvaccinated and requesting accommodation:
  1. **Review the request and make a decision as soon as possible or by the full implementation date.**
     - If accommodation is requested due to a medical contraindication:
       - Written documentation from your treating medical physician or nurse practitioner on grounds for not receiving or for delaying the COVID-19 vaccine (which can be provided using this form). The note must specify whether the reason is permanent or time limited. If time limited the note should indicate how long it is expected to last.
     - If accommodation is requested due to religion:
       - A sworn affidavit (signed before a commissioner for taking affidavits) containing information about the sincere religious belief that prohibits full vaccination.
     - If accommodation is requested related to other prohibited grounds under the *Canadian Human Rights Act:*
       - Specific information on the nature of the reason a prohibited ground of discrimination renders them unable to be fully vaccinated against COVID-19.

Note:

- You may request any additional information and supporting documentation, as may be appropriate.
- Other alternative documentation could be accepted, in consultation with departmental HR specialists.
- All documentation received during the duty to accommodate process must be treated as Protected B (when completed).

2. **Record the decision:**
   - If the duty to accommodate APPLIES (i.e.: the manager has reviewed and accepted the justification):

    - Indicate whether the accommodation is permanent or temporary:
        - If temporary, enter the end date.
    - Indicate the accommodations that will be implemented. These can include:
        - Performing regular duties or responsibilities through telework supported by a telework agreement as per the Directive on Telework.
        - Assigning alternate duties or responsibilities that can be completed through telework supported by a telework agreement as per the Directive on Telework.
        - Testing as per the Health Canada Testing framework.
        - Other measures detailed in communication with your employee and in the accommodation request.
- If the duty to <u>accommodate does not APPLY</u> (i.e., the manager has reviewed and not accepted the justification):
    - Refer to the Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police.
- Discuss the decision with your employee, acknowledge the decision by signing at the end of the Attestation pages, and ensure your employee acknowledges the decision as well.

7. GOVERNMENT OF CANADA VACCINE ATTESTATION TRACKING SYSTEM (GC-VATS)-myEmployees

Establishing your Team with myEmployees

Managers use myEmployees to claim and release employees. This new application serves both GC-VATS and the Public Service Performance Management (PSPM) application. Therefore, those managers already using PSPM will see their team as it has been established there reflected in GC-VATS. The manager's ability to track their employees' vaccination status depends on properly establishing their team in myEmployees.

Note: any change made in myEmployees is reflected in **both** GC-VATS and PSPM applications.

Select one of the Fact Sheets below for easy, step-by-step instructions.

1. Factsheet for NEW USERS
2. Factsheet for SENIOR MANAGEMENT, MANAGERS AND SUPERVISORS
3. Factsheet For EMPLOYEES

HOW TO USE THE myEMPLOYEES APPLICATION
FACTSHEET FOR NEW USERS

Managers must now use the myEmployees application to update their reporting structure. This application allows managers to claim employees as their direct report and release them when they no longer report to them directly. They can also update key information in their direct reports' profile. Any changes made will be reflected in both the Public Service Performance Management (PSPM) app and the Government of Canada Vaccine Attestation Tracking System (GC-VATS) app.

INSTRUCTIONS

IMPORTANT NOTES

a)New users: employees at all levels who were not PSPM app users as of October 1, 2021.

b)Employees on interchange: you will meet the requirement of being an "active employee" for the registration to the TAP once your name has been included in the data feed sent to TBS by your organization.

c)Employees on secondment: your current manager will be able to claim you but your profile will remain attached to your home organization.

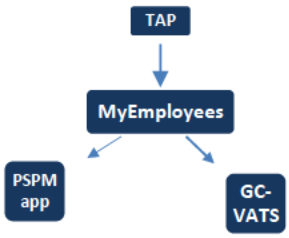
❶: Register in the TBS Applications Portal (TAP)

The myEmployees app is accessed through the TAP.

Prior to registering into the TAP, a user will need to:

- Have a PRI or a HRMIS (RCMP & DND members)
- Obtain a valid MyKey
- Log into Entrust at least once with their MyKey on their current device
- Be an active employee, which means that your user's account has been activated in Phoenix or, if you are not paid by Phoenix, your information was included in the latest data feed sent to TBS by your organization.
- ***NOTE: If you do not have any of the above, you may have to be registered manually. Please contact your HR department.***

Workflow



When logging in, the TAP verifies additional information such as the user's name and the date of birth.

❷: Logging in the myEmployees app

At this point you'll be able to see your profile, review your manager or accept your new manager.

❸: Review your profile information

Review your profile information to ensure it is up to date. If there are errors, contact your manager. Your manager can change the following: the place of work, the location of work, the group and level, and the position number. All other information is system-generated.

❹: Request to be claimed by your manager

Contact your current manager and ask that they claim you as their direct report. When they do, you will see their claim request in the Current manager table.

HOW TO USE THE myEMPLOYEES APPLICATION
FACTSHEET FOR SENIOR MANAGEMENT, MANAGERS AND SUPERVISORS

Whether you are a deputy minister, executive, manager or supervisor, you must now use the myEmployees application to update your reporting structure. This change will reduce the burden on you to have to claim and release employees in multiple TBS applications, including the Public Service Performance Management (PSPM) app and the new Government of Canada Vaccine Attestation Tracking System (GC-VATS) app.

INSTRUCTIONS ON HOW TO CREATE YOUR TEAM IN THE myEMPLOYEES APP

1 How to register

Users of the PSPM app as of October 1, 2021

- Your profile will automatically show in the myEmployees app
- Log in to myEmployees app and review your reporting structure - refer to steps 2-3-4

Non-Users of the PSPM app as of October 1, 2021

- You must register to the TBS Applications Portal (TAP) - refer to the factsheet for new users
- Log in to myEmployees app and start creating your reporting structure - refer to steps 2-3-4

2 How to claim employees

a. Click Add employee

- With My department selected, enter at least 1 character of the employee's first or last name.
- To search across all departments, select All departments, and enter the PRI and at least 1 character of the employee's name you want to find.

b. Click Search to display the results

- Locate the employee you want to add in the Employee details filter table.
- If the employee's registration is shown as "No", the employee is not registered in TAP and cannot be claimed. Ask the employee to register in TAP. (refer your employee to the factsheet for new users)

c. If the employee has already been released by their previous manager

- Click Add employee to send a claim request to the employee.
- Once the employee accepts your request, they will appear in your reporting structure.

d. If the employee has not been released by their previous manager:

- Contact the manager (or ask the employee to do so) to request that they proceed with the release.
- Once the release is complete, you will be able to claim the employee.

3 How to update employees' profile

a. **Click Table view** to display the list of all employees in your reporting structure.
b. **Select the employee** whose profile you want to update. The employee's profile page displays.
c. **Click update.** You can only update the employee's: place of work, location of work, group & level and position number.

4 How to release employees

1. **Click Table view** to display the list of all employees in your reporting structure.

- Select the employee you want to release and click Release.
- The employee will be removed from your reporting structure and can now be claimed by another manager.

Important notes

- Entries that can't be modified in the employee's profile are system-generated. Contact HR to request updates.
- If you or the employee can't reach a manager to request they be released, contact HR.

HOW TO USE THE myEMPLOYEES APPLICATION
FACTSHEET FOR EMPLOYEES

Managers must now use the myEmployees application to update their reporting structure. This application allows managers to claim employees as their direct report and release them when they no longer report to them directly. They can also update key information in their direct reports' profile. Any changes made will be reflected in both the Public Service Performance Management (PSPM) app and the new Government of Canada Vaccine Attestation Tracking System (GC-VATS) app.

INSTRUCTIONS

1 How to register

Users of the PSPM app as of October 1, 2021

- Your profile will automatically show in the myEmployees app
- Log in to myEmployees app and review your profile information - refer to steps 2-3-4

Non-Users of the PSPM app as of October 1, 2021

- You must register to the TBS Applications Portal (TAP) - refer to the factsheet for new users
- Log in to myEmployees app and start reviewing your profile information - refer to steps 2-3-4

2 View or change your profile

Review your profile information:

Make sure your profile information is up to date.

If there are errors, contact your manager.

3 Request a change in manager

If the manager listed in your profile is no longer your current manager:

a) Contact them to ask that they release you as a direct report.

b) Once your previous manager has released you, your current manager will be able to claim you as their direct report.

c) Contact your current manager and ask that they claim you as their direct report. When they do, you will see their claim request in the Current manager table. If others have claimed you as their employee, you will also see their claim requests.

4 Accept a manager's claim request

Review the Current manager table:

To accept a manager as your current manager, select that manager's claim request and click Accept.

Any remaining manager claim requests will be cleared.

Important notes

- If you cannot reach a manager (i.e., they are on leave, or have left the public service) to request to be released or to be claimed, contact the acting manager or the next manager in line to make the request.
- Your manager can only change the following: the place of work, the location of work, the group and level, and the position number. All other information is system-generated.

8. VACCINATION STATUS – PERSONAS

 **Anna** Returning from leave	 **Mohamed** Not vaccinated	 **Jane** Unwilling to disclose vaccination status	 **Taylor** Requests accommodation
Upon return from leave* Anna is required to familiarize herself with the new Framework and Policy. **Within 2 weeks:** Anna must enter her attestation of vaccination status, or accommodation request, via the GC-VATS or other mechanism. Since Anna is not yet vaccinated, she has **2 weeks** to attend a training session on COVID-19 Vaccination on GCcampus and receive her first dose. During this time, Anna can still access the worksite if needed, If Anna does not receive her first dose within **4 weeks** of her return from leave, she will be placed on LWOP. **After 5 days** on LWOP, Anna will receive a Record of Employment. *Includes, for example, maternity, parental, sick and vacation leave.	**October 6, 2021:** Mohamed is required to familiarize himself with the new Framework and Policy. **By October 29, 2021**: Mohamed is required to enter his attestation of vaccination status, or accommodation request, via the GC-VATS or other mechanism, but Mohamed is not vaccinated. During this time, Mohamed can still access the worksite if needed. Mohamed must attend a training session on COVID-19 Vaccination available on GCcampus. If Mohamed has not received his first dose by **November 15, 2021**, he will be placed on LWOP. **After 5 days** on LWOP, Mohamed will receive a Record of Employment. If, at a later date, Mohamed decides to be vaccinated, his pay will be reinstated as of the date of his revised attestation. Mohamed will have a period of **10 weeks** to receive a second dose or he will be put back on LWOP.	**October 6, 2021:** Jane is required to familiarize herself with the new Framework and Policy. **By October 29, 2021**: Jane is required to enter her attestation of vaccination status, or accommodation request, via the GC-VATS or other mechanism. During this time, Jane can still access the worksite if needed. Jane decides not to disclose her vaccination status on GC-VATS or other mechanism. Jane must attend a training session on COVID-19 Vaccination available on GCcampus. If Jane does not disclose her vaccination status by **November 15, 2021,** she will be placed on LWOP. **After 5 days** on LWOP, Jane will receive a Record of Employment. If, at a later date, Jane decides to attest that she has been fully vaccinated, her pay will be reinstated as of the date of her revised attestation. Jane will have a period of **10 weeks** to receive a second dose or she will be put back on LWOP.	**October 6, 2021:** Taylor is required to familiarize themselves with the new Framework and Policy. **By October 29, 2021:** Taylor enters an accommodation request into GC-VATS or other mechanism. Taylor provides their manager with supporting documentation for their request at the earliest opportunity or **before November 15, 2021:** • Medical contraindication or • Affidavit for religious grounds; or • Attestation regarding other prohibited grounds of discrimination under the *CHRA* that renders the employee unable to be fully vaccinated. Manager discusses request with HR or LR advisors as needed. HR/LR can contact OCHRO as needed. Manager makes an informed decision as soon as possible or by **November 15, 2021.** Accommodation, if approved, is implemented and Taylor keeps manager informed of any changes in accommodation needs. If the accommodation is not approved, Taylor would be required to attend a training session on COVID-19 Vaccination available on GCcampus within 2 weeks of being informed of the decision. Taylor would then be placed on LWOP if Taylor does not receive their first dose within the same 2-week period.

9. QUESTIONS AND ANSWERS

Note: This is not an exhaustive list of questions and answers. More will be added as they arise.

Non-compliance and Leave Without Pay

1. What happens to employees' access to the workplace when they are placed on LWOP?

- Employees' access to the workplace is restricted (managers would notify security to suspend access).
- Off-site visits, business travel and conferences would also be restricted.

2. How long will an employee be on LWOP?

- As is outlined in the Policy on Vaccination, an employee will be on LWOP until the employee's vaccination status changes, until the Policy is rescinded or until the Policy is changed in this regard. The Policy will be reviewed every six months.

3. Is an employee on LWOP for non-compliance with the Policy on Vaccination able to return to work after their first dose?

- Yes, an employee can return to work with temporary measures in place if necessary.
- An employee's pay will be reinstated after they complete their revised attestation. At that time, the employee will have a period of 10 weeks within which they must receive their second dose. If an employee does not attest to having received their second dose of a 2-dose series, during that period, they are considered unwilling and will return to LWOP.

4. Will an employee on LWOP eventually have their employment terminated if they continue to be unwilling to be vaccinated?

- The current Policy on Vaccination does not consider termination of employment or a specific end date to LWOP. The Policy will be reviewed every six months.

5. Will progressive discipline be used for employees who are unwilling to be vaccinated?

- If employees do not comply with the Policy on Vaccination, they will be placed on LWOP until after they receive their first dose. This is an administrative measure, not a disciplinary one.

6. What leave code should managers use when placing employees on LWOP for non-compliance with the Policy on Vaccination?

- Managers are to use leave code 999 LWOP-Other.

7. What is the impact to contributions and benefits under the public sector pension plans (public service, the Royal Canadian Mountain Police and Canadian Forces pension plans) for those placed on LWOP?

- The public sector pension plans have existing provisions for members on LWOP. In general, employer approved LWOP can be pensionable, meaning that the period of service may count in the calculation of the employee's public service pension,

though some exceptions apply.

- In most situations, contributions for the first 3 months of LWOP continue at a normal single rate. After 3 months, a double rate is applied to those placed on **LWOP** to cover both the employer and employee contributions.
- For more complete information regarding LWOP, consult the following links:
  - Members of the Public Service pension plan**:** LWOP information package;
  - Services and information - Canadian Armed Forces Pension and
  - LWOP information package: Royal Canadian Mounted Police pension.

8. Are there limits on how much LWOP may be counted for pension purposes?

- Yes. The *Income Tax Act* places restrictions on the total periods of LWOP that can be treated as pensionable during an employee's career. The maximum permitted is 5 years, excluding sick LWOP. However, an employee may also be credited with an additional three years of LWOP for parenting purposes. The 5-year maximum may also be exceeded for "on-loan" situations where the services of a public service employee are loaned out to another employer.
- More information on the tax implications of taking a period of LWOP is available in the LWOP Information Package.

9. What happens to coverage under the Supplementary Death Benefit (SDB) plan while on LWOP?

- Members of the Public Service or Canadian Forces Supplementary Death Benefit (SDB) plan remain covered. Their required contributions under the plan are owed upon their return to work.

10. What Group Insurance Benefits do members of the core public administration, and the Royal Canadian Mountain Police retain while on any authorized LWOP?

- The group insurance benefit plans have existing provisions for members of the core public administration on LWOP. If a benefit plan member goes on authorized LWOP, they may retain their employer-paid coverage for themselves and their eligible dependants for the first 3 months of any authorize LWOP, meaning the employer continues to pay the employer share as follows:
  - For employees enrolled in the voluntary Public Service Health Care Plan (PSHCP), coverage continues and missed employee contributions, if any, are collected upon employee's return to work or termination of employment.
  - The Public Service Dental Care Plan (PSDCP) coverage continues at 100% employer paid.
  - Disability Insurance (DI) or Public Service Management Insurance Plan (PSMIP) Long-Term Disability (LTD) insurance plan coverage continues. Missed employee premiums are recovered upon a return to work or termination of employment.
  - The Public Service Management Insurance Plan (PSMIP) Life insurance plan coverage may continue provided the employee remits the employee share of the premiums to Industrial Alliance directly. The Public Service Pay Centre

or relevant Departmental Compensation Office will provide the requisite information to the employee.

11. What Group Insurance Benefits do members of the core public administration and Royal Canadian Mountain Police continue to retain after the first 3 months of authorized LWOP?

- In the event an employee remains on an authorized LWOP for more than 3 months, they are responsible both the employee and the employer share of contributions for themselves, and their eligible dependents as follows:
  - For employees enrolled in the voluntary Public Service Health Care Plan (PSHCP), coverage continues with missed employee and employer contributions collected upon the employee's return to work or termination of employment.
  - Disability Insurance (DI) or Long-Term Disability (LTD) insurance plan coverage continues with the employee being responsible for both the employee and employer share of premiums for the period in excess of 3 months of authorized LWOP. Missed premiums are recovered upon the employee's return to work or termination of employment.
  - The Public Service Dental Care Plan (PSDCP) coverage can continue if requested in advance with both the employee and employer share of contributions collected quarterly and in advance.
  - The Public Service Management Insurance Plan (PSMIP) Life insurance plan coverage may continue provided the employee remits both the employee and employer share of the premiums to Industrial Alliance directly for the period in excess of 3 months of authorized LWOP. The Public Service Pay Centre or relevant Departmental Compensation Office will provide the requisite information to the employee.

12. How long would it take to reintegrate employees into the various benefits plans following time off on LWOP once they receive the vaccine?

- If employees want to retain health and dental coverage during the period of LWOP and pay all necessary contributions, there would be no disruption in coverage.
- If an employee on LWOP wants to terminate health and dental coverage for the LWOP period, plan-specific waiting periods will apply when reintegrating into the group insurance benefit plans as follows:
  - Employees who cancel their **PSHCP** coverage at any time while on LWOP will not be allowed to reinstate their coverage until they return to work at which time a three-month waiting period will apply.
  - **Disability insurance (DI) and Long-term disability (LTD) benefits** are a term and condition of employment and coverage continues during a LWOP. Premiums are collected upon a return to work.
  - Employees who cancel their **PSDCP** coverage at any time while on LWOP can reinstate it when they return to duty. A three-month waiting period

will apply.

- **PSMIP** - **Employer paid coverage**
  - An employee who is entitled to employer paid PSMIP coverage, i.e. Basic Life, AD&D, and Dependants' Life Insurance(s), will continue to be covered during a period of LWOP with premiums paid by the employer. A member insured under the optional insurance provision, Supplementary Life, must arrange to pay premiums directly to the Insurer to maintain coverage while on LWOP.
- **PSMIP** - **Employee paid coverage**
  - An employee not entitled to employer paid PSMIP coverage, Basic Life, Supplementary, AD&D, and Dependants' Life Insurance(s), will not continue to be covered during a period of LWOP unless the employee pays the premiums directly to the insurer while on LWOP.
  - Note: If an employee fails to remit their life insurance(s) premiums during a period of LWOP, premiums will not be reinstated upon a return to work. To reacquire PSMIP life insurance coverage an application together with suitable medical evidence of insurability to the satisfaction of the insurer is necessary, provided the employee is both actively at work and occupies a PSMIP eligible position.

Policy Application

13. Does the Policy on Vaccination apply to members of the Canadian Armed Forces?

- No, the Policy on Vaccination does not apply to members of the Canadian Armed Forces or their cadets attending the Canadian Defence Academy.

Vaccination and Testing

14. What if employees experience a side effect that prevents them from working after their vaccination?

- In cases where employees are incapacitated by such symptoms, the sick leave with pay provision provided in the collective agreements is available to cover employees' absences. Where employees do not have any sick leave credits available, collective agreements provide for an advance of credits at the employer's discretion. Such needs and requests would be discussed on a case-by-case basis between the employee and their manager.

15. Will departments and agencies set up workplace COVID-19 testing sites?

- This option is available for departments to consider depending on their operational needs.

16. Will testing be considered for those who are unwilling to be vaccinated?
- No, testing is not an alternative to vaccination.
- It could be offered as an accommodation to employees who are unable to be vaccinated or as a temporary measure for those who are partially vaccinated.

17. Is the time necessary for taking the testing and waiting for these results considered work time?
- Yes, it is expected that testing will be provided on or near the employer's premises and will be considered part of the workday.
- At-home tests may also be available.

18. What happens when an employee receives a negative on-site testing result?
- They will enter the workplace as they would normally, provided that they have no COVID-19-related symptoms and will follow the workplace's COVID-19 procedures.

19. What happens when an asymptomatic employee receives a positive on-site testing result?
- The employee must immediately return home safely following the Public Service Occupational Health Program guidance and local public health guidance.
- If the employee can work remotely, they may be accommodated through remote work.
- The result will be reported to the local public health authority, either by the employee or the health care professional, depending on the site-specific procedure, and the employee will schedule and take a confirmatory test as directed by the public health authority as soon as possible.
- The department must follow existing guidance on completing a Hazardous Occurrence Investigation Report.

20. What leave code is to be used when an employee has obtained a positive test result and is awaiting the results from the confirmatory test as directed by the public health authority?
- The employee is expected to schedule the confirmatory test as rapidly as possible.
- If the employee is well enough to continue working and can do so remotely, and the employer can provide remote work no leave code is required.
- Otherwise, the employee may be eligible for "Other Leave with Pay (699)" for the time it takes to get confirmatory testing. Please refer to the "Other Leave with Pay (699)" leave guidance on the Employee illness and leave webpage.

- If the confirmatory test is positive, the employee would use sick leave in accordance with the clarified guidance that came into effect on November 9, 2020.

21. If the confirmatory test is negative, can an employee return to work?

- The employee must follow the local public health authorities' guidelines.
- Health authorities may impose a period of self-isolation depending on the individual's circumstances (for example, if an individual was a close contact of a known case), even if the person has a negative confirmatory test result for COVID-19.
- If a self-isolation period is prescribed by public health authorities, employees may be eligible for "Other Leave With Pay (699)" for that period of time. Please refer to the "Other Leave with Pay (699)" leave guidance on the Employee illness and leave page.

22. What consequences will result if an employee refuses to take an on-site test?

- Testing is only mandatory if put in place as an accommodation measure for those unable to be vaccinated or those partially vaccinated and required to be on-site.
- Testing is not an alternative to those who are able to be vaccinated.
- A fully vaccinated employee will not require on-site testing unless they are directed otherwise by the local public health authority.
- An employee refusing to be tested in those circumstances will not be granted access to the workplace; the employee will be considered non-compliant.

23. Do employees on leave, including LWOP when the vaccination requirement comes into force need to attest to their status?

- Upon returning from leave, including LWOP, the employee will have 2 weeks to complete their attestation. If they attest that they are not vaccinated, they will be given a 2-week period to attend the training session after which they will be placed on LWOP unless they receive a first dose (i.e.: 4 weeks after their return).

24. Who pays for the regular testing for employees who require accommodation? Is the employee expected to complete the testing on their own time, outside of working hours?

- Where regular testing is a part of the accommodation measures and on-site testing is not available, costs for regular tests would be paid by the department. It is expected that time for testing will be considered part of the employee's workday.

Attestation, Tracking and GC-VATS

25. What is GC-VATS?

- GC-VATS is the Government of Canada Vaccine Attestation Tracking System.

- GC-VATS is a user-friendly web platform within the TBS Application Portal. It allows employees to attest to the status of their COVID-19 vaccinations and stores the attestations securely and privately.
- GC-VATS provides access to aggregated data to TBS, in compliance with the Privacy Act, security requirements and the associated policy instruments. Deputy Heads and departmental Heads of Human Resources will have access to department-level aggregated data.

26. In the reporting system, what categories of employees will be identified?
Four categories of employees are identified as defined in the policy:

- Fully vaccinated.
- Unvaccinated because the employee is requesting an accommodation.
- Unvaccinated
- Note: Partially vaccinated will be added as an option as of October 15, 2021.

27. What will employees need to do "to attest to their vaccination status"?

- Employees will follow procedures in place to report their vaccination and testing status truthfully and accurately. The employer may require a proof of immunization in a format that is recognized federally, provincially, or territorially (to be defined by the employer) at any time.

Duty to Accommodate

28. What if an employee is unable to be fully vaccinated?

- Managers will address accommodation needs on a case-by-case basis for employees who are unable to be fully vaccinated based on a medical contraindication, religion, or another prohibited ground of discrimination as defined under the Canadian Human Rights Act.

29. What if a candidate informs a potential hiring manager that they are unable to be fully vaccinated?

- The duty to accommodate applies to candidates and persons employed; therefore, managers will need to follow the accommodation process to address their request.

Medical Contraindications

30. What are medical contraindications?

- Certified medical contraindications to full vaccination against COVID-19 with an mRNA vaccine are based on recommendation of the National Advisory Committee on Immunization. The following are medical contraindications as of September 10, 2021:
    - A history of anaphylaxis after previous administration of an mRNA COVID-19 vaccine

    - A confirmed allergy to polyethylene glycol (PEG) which is found in the Pfizer-BioNTech and Moderna COVID-19 vaccines (Note that if a person is allergic to tromethamine which is found in Moderna, they can receive the Pfizer-BioNTech product)

- Medical reasons for delay of full vaccination against COVID-19 as described by the National Advisory Committee on Immunization as of September 10, 2021 include:
    - A history of myocarditis/pericarditis following the first dose of an mRNA vaccine
    - An immunocompromising condition or medication, waiting to vaccinate when immune response can be maximized (i.e., waiting to vaccinate when immunocompromised state / medication is lower)
- A medical reason precluding full vaccination against COVID-19 (not covered above) as described. For privacy reasons, the physician or nurse practitioner should only include information related to why the medical reason precludes full vaccination.

31. Who can sign a form for a medical contraindication?

- The employee's treating medical physician (e.g., family doctor, allergist, immunologist) or nurse practitioner can sign the medical form on the grounds for not receiving or for delaying the COVID-19 vaccine. The note must specify whether the reason is permanent or time limited. If time limited, the note should indicate how long the limitation is expected to last.

32. What happens if an employee submits a form not signed by a licensed medical physician or nurse practitioner?

- Managers should consult their HR specialists if they receive a form that is not signed by a licensed physician or nurse practitioner, or if there is any other concern about the information provided on the form.

33. Is the employee required to use the medical form provided on the GC-VATS app or is another type of medical note acceptable?

Alternative documentation is acceptable if it includes information related to the medical contraindication or other medical reason why vaccination is precluded, and whether the medical contraindication or reason is permanent or time limited. If time limited, the note should indicate how long the limitation is expected to last.

34. An employee is part of a Health Canada COVID-19 vaccination study. How will a manager address this situation?

- An employee who is participating, or has participated, in a Health Canada authorized COVID-19 vaccination study is considered to be not fully vaccinated. An employee should use the accommodation process until such time that either:
    - The study is completed, Health Canada authorizes the COVID-19 vaccine, and the employee can disclose that they are fully vaccinated as per the Vaccination Policy; **or**

- The employee withdraws from the study or is informed they received a placebo, or Health Canada declines authorization of the study vaccine. At that time, the employee is expected to be vaccinated against COVID-19 with a Health Canada authorized vaccine as per PHAC or NACI recommendations. The employee will be given 4 weeks from any of the preceding events occurring to begin their COVID-19 vaccine series, failing which they would no longer be eligible for accommodation. When they complete their primary vaccination, they should disclose this information as per the policy and will then be considered fully vaccinated and will no longer require accommodation.
- There may be additional exceptions that would need to be addressed on an individual basis (e.g., participants in clinical trials outside of Canada, employees who received non-HC approved vaccines outside of work-related postings).

35. Why do the contraindications listed on the medical statement form refer only to mRNA vaccines?

- The form includes only references to mRNA vaccines because if an individual has a contraindication to a viral vector vaccine (e.g., Astra Zeneca), they are likely still able to be vaccinated with an mRNA vaccine, and therefore would not have a medical contraindication to being fully vaccinated.

36. If an employee has already submitted a medical note to request an exemption to provincial or territorial authorities (e.g. to obtain a vaccine passport), do they need to provide a new form for this process?

- Employees will always need to provide a medical note to support their request for accommodation to their manager.
- If they already have a medical note which provides the necessary information (i.e. why the medical contraindication or reason prevents them from being vaccinated, whether this is permanent or temporary, and if temporary how long the limitation is expected to last), this information could be provided to the manager rather than a new form.

Religion

37. How does a manager decide whether to approve accommodation for religion?

- The manager must be satisfied that the employee holds a sincere religious belief that prevents them from being fully vaccinated.
- The requirement is to focus on the sincerity of the individual belief rooted in religion, not whether it is recognized by other members of the same religion.
    - The belief must be religious in nature (not a personal, moral belief), and the employee must explain the nature of the belief and why it prevents vaccination.

- The manager can request more information if the explanation provided is not sufficient.
- The validity of the belief itself must not be challenged by the manager;
- They must determine only if the belief is sincerely held by the employee.

38. What is a commissioner for taking affidavits?

- A commissioner for taking affidavits is a person who is entitled in accordance with the provincial or territorial law where the person is located to take affidavits and administer oaths and affirmations. This will vary depending on the province or territory but will usually include lawyers, notary publics, judges, along with other persons specifically authorized by law.

39. What happens if an employee is unwilling or unable to obtain a sworn affidavit?

- It is recommended that employees use the religious affidavit provided.
  - That said, managers may accept alternative documents which provide the necessary information, in consultation with departmental HR specialists.

40. Does an employee need to go in person to get their affidavit sworn?

- For the purpose of obtaining the signature from a commissioner for taking affidavits, the employee will need to act in accordance with applicable laws in the province or territory in which they are located. Some may allow for signatures via videoconference, and some may not.

Other Prohibited Grounds

41. What are the other prohibited grounds under the *Canadian Human Rights Act*?

- The other prohibited grounds of discrimination are race, national or ethnic origin, colour, age, sex, sexual orientation, gender identity or expression, marital status, family status, genetic characteristics, disability, and conviction for an offence for which a pardon has been granted or in respect of which a record suspension has been ordered.

42. How should it be decided whether another prohibited ground prevents a person from being vaccinated?

- The employee would need to provide an attestation as to how their request for accommodation relates to the relevant prohibited ground. Managers may request additional information and supporting documentation, as may be appropriate, to assess the accommodation request. Other documentation could be accepted, in consultation with departmental HR specialists. Managers are advised to work with

their human resources/labour relations advisors when deciding whether the duty to accommodate applies.

43. Where can the manager go for guidance and advice on addressing their employee's accommodation request?

- Managers can contact their departmental human resources/labour relations advisors. Corporate HR/LR can contact OCHRO if they need further support.

General

44. Who pays for the costs related to obtaining documents necessary to support an accommodation request?

- As with most accommodation requests, the employee provides and pays for the information to support the request. Since each request is considered on a case-by-case basis, on rare occasions, a manager could decide to pay for the medical form or sworn affidavit if they felt it would cause economic hardship to the employee.

45. What is the deadline for making an accommodation request?

- Employees are asked to make their accommodation request as soon as possible, or by the attestation deadline; however, under the Directive on the Duty to Accommodate, employees can request accommodation any time there is a need.

46. What are some recommended accommodation measures?

The following are recommended accommodation measures, in order of priority:

- Performing regular duties or responsibilities through telework supported by a telework agreement as per the Directive on Telework;
- Assigning alternate duties or responsibilities that can be completed through telework supported by a telework agreement as per the Directive on Telework;
- Testing as per the Health Canada Testing protocol;
- Other measures detailed in communication with the employee and documented in the accommodation request.

47. Should a manager notify its employees of their colleague's accommodation?

- Generally, other co-workers should not be notified about an employee's accommodation measure. Since operational requirements are unique to the team being managed, in situations where the measure could affect other employees, the manager should contact their departmental human resources/labour relations

advisors for advice on how to proceed. Corporate HR/LR can contact OCHRO if they need further support.

48. While assessing an employee's accommodation request or if the accommodation measures take time to implement, does a manager need to provide temporary measures?

- Yes, as with any accommodation situation, temporary measures should be provided until a decision is made or the accommodation measures are implemented.

49. What recourse does an employee have if they disagree with their manager's decision on accommodation?

- The employee should first discuss with their manager the reasons for the decision. If they are not satisfied with the response, they can begin the normal recourse processes e.g., informal conflict resolution and/or the grievance process as per the applicable collective agreement and in consultation with their bargaining agent.
- An employee may also file a human rights complaint with the Canadian Human Rights Commission (CHRC).

Interchange Canada

50. Does the requirement for mandatory vaccination apply to Interchange Canada outgoing participants (i.e., public servants on Interchange OUTSIDE the public service, for instance another level of government or private sector)?

- Yes, outgoing participants are still public servants while they are on Interchange assignments, therefore, they are expected to comply with the requirement for vaccination. They are required to be vaccinated and to attest to their vaccination status and may seek accommodation if they are unable to be vaccinated for medical contraindications, religion or other grounds protected under the *Canadian Human Rights Act*.

51. Does the requirement for mandatory vaccination apply to Interchange Canada incoming participants (i.e., individuals on Interchange assignments INTO the public service)?

- Yes, incoming participants are required to be vaccinated and to attest to their vaccination status. They may seek accommodation for medical contraindications, religion or other grounds protected under the *Canadian Human Rights Act*.

52. What happens if an Interchange participant does not comply with the requirement to be vaccinated and attest to their vaccination status?

- Their Interchange Canada agreement will be terminated, and they will return to

their sponsoring organization. Those returning to the public service, will be subject to the same measures as other public servants.

Staffing

53. Can a manager hire a candidate from the public (not a public servant) who is unwilling to be vaccinated, i.e. Is vaccination a condition of employment?

- All new hires on or after the effective date of the Policy on Vaccination are required to be fully vaccinated as a condition of employment and to attest that they are fully vaccinated prior to their starting date unless accommodation measures are granted.

Leave

54. What is the appropriate leave code if an employee or family member must attend an appointment to be vaccinated during the regularly scheduled workday?

- Vaccination clinics usually have convenient hours, and an employee who wishes to be vaccinated is encouraged to do so outside of work hours. In accordance with the Directive on Leave and Special Working Arrangements an employee who requires time away from work to get their vaccine may request up to 3.75 hours as paid time off for "medical and dental appointment" (Code 698) for an employee who works 7.5 hours/day.
- If accompanying a family member to receive a vaccine, paid family-related responsibilities leave would apply, in accordance with the relevant collective agreement or terms and conditions of employment.

55. Some vaccines require two appointments, i.e. two doses of the COVID-19 vaccine, and perhaps boosters. Can a manager still approve time off for "medical and dental appointments" (Code 698) or is the second appointment considered sick leave?

- COVID-19 vaccinations are preventative, and two doses are generally required through two separate appointments. Additional appointments may also be required. Leave code 698 should be approved for all doses as they are preventative measures.

56. If employees require more than half a day off (3.75 hours for an employee who works 7.5 hours/day) to obtain the COVID-19 vaccine, will that still be coded 698?

- If time away from work is required to be vaccinated, organizations should consider such time as a "medical and dental appointment" (Code 698). If more than 3.75 hours is required for the appointment, the excess is to be charged against the appropriate leave.

57. What is the appropriate leave code when an employee experiences a side effect that prevents them from working following vaccination?

- The employee must use the sick leave provision of collective agreements or terms and conditions of employment to cover such absences.
- When the employee does not have sick leave credits available, sick leave credits can be advanced at the employer's discretion, in accordance with the relevant collective agreement or terms and conditions of employment.

Employee Safety and Wellness

58. What COVID-19 preventative measures does the employer have in place in addition to the required vaccination and how long will they remain?

- The employer has implemented, and regularly reviews, preventative measures to mitigate COVID-19 workplace transmission.
- Vaccination is not a substitute for following the recommended and widely known preventative practices related to COVID-19, such as wearing a mask, maintaining physical distance, and frequent handwashing. Vaccination will add a layer of protection that will work with other preventative practices to combat the pandemic.
- Consistent with current advice from Health Canada's Public Service Occupational Health Program, federal departments and agencies will maintain infection prevention and control measures such as remote working, staggered working hours, engineering controls, and other preventative practices. Rigorous adherence to these measures can reduce the risk of transmission of COVID-19.

59. Can an employee refuse to work because other employees in the workplace are not fully vaccinated?

- Refusal to undertake a dangerous work is to be distinguished from vaccination refusal or refusal to disclose vaccination status.
- The right to refuse dangerous work is defined under Canada Labour Code, Part II.
- Should a refusal to undertake dangerous work be exercised based on vaccination-related issues, it will be assessed on its merits and organizations will follow the work refusal process under Canada Labour Code, Part II to resolve the issues. Please refer to Labour Program's information on the right to refuse dangerous work.

60. What is the employer doing to protect employees when contractors, visitors and other individuals enter the workplace?

- Departments and organizations are working with contractors either through PSPC or their own contracting authority to ensure that the vaccination requirement is

reflected. All departments and organizations have to keep their COVID-19 Hazard Prevention Program up to date and consult their occupational health and safety team, Health Canada's PSOHP (or their organization's own medical advisors), along with the appropriate Health and Safety Committee. Members of the public entering the workplace must follow public health guidelines and site-specific rules when required.

61. How can a manager help address stress some employees may experience around the mandatory vaccination policy?

- Whether an employee is worried about vaccines or worried about working with someone who is not fully vaccinated, as a manager, it is important to recognize and acknowledge the negative stress they may be experiencing. Approaching employees with empathy and engaging in non-judgmental active listening are key to navigating these sensitive conversations.
- Resources, support and training are available to help managers prepare for challenging conversations with confidence:

    - Mental Health Commission of Canada: Tips on talking to someone in crisis during COVID-19
    - Centre of Expertise on Mental Health in the Workplace: Supporting employees and teams
    - Canada School of Public Service: How to manage difficult conversations (W009)

- Inform and remind employees of the mental health supports available to them, such as the Employee Assistance Program.

Privacy

62. Does an employee have the right to know the vaccination status of colleagues with whom they share physical space?

- Vaccination status is private medical information.
- The employer, through the Policy on Vaccination, is aware of the vaccination status of their workforce and will manage the safety of their workplaces and its employees accordingly. This will be achieved without individual employees knowing about the vaccination status of their colleagues.

10. TEMPLATE LETTERS

LETTER TO UNWILLING EMPLOYEE STATING CONSEQUENCES (REMINDER LETTER PRIOR TO LEAVE WITHOUT PAY)

[insert date]

[insert employee's name]
[insert employee's title]
[insert employee's address]

Dear [insert name],

On [insert date] you were notified that the Government of Canada was implementing the *Policy on COVID-19 Vaccination for the Core Public Administration including the RCMP* (the *Policy*) which came into effect on October 6, 2021. As per this *Policy*, you were required to attest to your vaccination status by October 29, 2021 **[if the employee is returning from leave, adjust date to reflect the date to which they were required to complete an attestation form]**.

To date, you have not yet complied with the *Policy*; therefore, you are required to attend a training session on the benefits of COVID-19 vaccination and receive your first dose prior to November 15, 2021 **[if the employee is returning from leave, adjust date to 2 weeks after they were required to complete an attestation form].** Should you not comply with the *Policy* by November 15, 2021, **[if the employee is returning from leave, adjust date to 2 weeks after they were required to complete an attestation form]**, you will be placed on administrative leave without pay until such time as you comply with the *Policy*.

As the country's largest employer, the Government of Canada is leading by example on vaccination to protect the health and safety of employees and the communities where they live and work. Vaccines are the best way to bring this pandemic to an end. I encourage you to do everything you can to protect yourself, your family and colleagues, and to protect the community you live in by reducing the risk of COVID-19.

Should you have any questions regarding the process, please feel free to contact me [insert coordinates].

Please note that the Employee Assistance Program is available to assist you at any time and can be reached at [phone number].

Sincerely,

[insert name]

[insert title of delegated official]
c.c. [insert name]

LETTER PLACING EMPLOYEE ON LEAVE WITHOUT PAY

[insert date]

[insert employee's name]
[insert employee's title]
[insert employee's address]

Dear [insert name],

On [insert date] you were notified that the Government of Canada was implementing the *Policy on COVID-19 Vaccination for the Core Public Administration Including the RCMP* (the *Policy*) which came into effect on October 6, 2021. As you [insert reason: have not attested to your vaccination status / are not fully vaccinated], you are not compliant with the *Policy* and will be placed on administrative leave without pay effective on the date of this letter until such time as you comply with the *Policy*.

I will review this decision should your situation change.

Please note that the Employee Assistance Program is available to assist you at any time and can be reached at [phone number].

Should you have any questions regarding the process, please feel free to contact me [insert coordinates].

Sincerely,

[insert name]
[insert title of delegated official]

c.c. [insert name]
Pay Centre or Name of Internal Compensation Team

LETTER FOR REMOVING EMPLOYEE FROM LEAVE WITHOUT PAY (TEMPORARILY – FIRST DOSE)

[insert date]

[insert employee's name]
[insert employee's title]
[insert employee's address]

Dear [insert name],

As directed by the *Policy on COVID-19 Vaccination for the Core Public Administration including the RCMP* (the *Policy*), on [insert date] you were notified that you would be placed on Leave Without Pay. As you have attested that you have now received your first dose of vaccination against COVID-19, you will no longer be on leave without pay as of [insert date that they received their first dose] and as of that date, you will be able to resume working with the following temporary measures in place until two weeks after you receive your second dose:

******* [Choose applicable temporary measures for the employee's specific situation and delete the other measures]**

[Regular duties while teleworking]
You will perform your regular duties or responsibilities through telework supported by a telework agreement as per the *Directive on Telework*.

[Alternate duties while teleworking]
You will be assigned alternate duties or responsibilities that can be completed through telework supported by a telework agreement as per the *Directive on Telework*.

[Critical employee who must work onsite]
You will complete regular mandatory tests as per the *Framework on Mandatory COVID-19 Testing for Implementation of the Policy on COVID-19 Vaccination for the Core Public Administration Including the Royal Canadian Mounted Police*, and:

- Follow all preventative practices implemented in the workplace and other preventative practices as recommended by the Public Service Occupational Health Program and other organizational requirements such as wearing a mask, maintaining physical distance, and frequent handwashing; and,

- Not perform duty travel, unless essential.

It is important to note that you must attest to receiving your second dose by [insert date which is 10 weeks after the first dose]. Should you not attest to receiving your second dose by this date, you will again be placed on leave without pay until you comply with the *Policy*.

Please note that the Employee Assistance Program is available to assist you at any time and can be reached at [phone number].

Should you have any questions regarding the process, please feel free to contact me [insert coordinates].

Sincerely,

[insert name]
[insert title of delegated official]

c.c. [insert name]
Pay Centre or Name of Internal Compensation Team

LETTER TO EMPLOYEE RETURNING FROM LEAVE AFTER THE EFFECTIVE DATE OF THE POLICY

[insert date]

[insert employee's name]
[insert employee's title]
[insert employee's address]

Dear [insert name],

On [insert date] the Government of Canada announced the *Policy on COVID-19 Vaccination for the Core Public Administration including the RCMP* (the *Policy*) which came into effect on October 6, 2021.

As you are now returning from leave, you have until [insert date which is 2 weeks after the date of the employee's return from leave] to attest to your vaccination status against COVID-19 and/or ask for accommodation measures, if applicable.

As the country's largest employer, the Government of Canada is leading by example on vaccination to protect the health and safety of employees and the communities where they live and work. Vaccines are the best way to bring this pandemic to an end. I encourage you to do everything you can to protect yourself, your family and colleagues, and to protect the community you live in by reducing the risk of COVID-19.

Please note that if you do not attest to your vaccination status or ask for accommodation measures by [insert date], you will have a two-week period during which you will be required to attend a training session on the benefits of COVID-19 vaccination and receive a first dose. Should you not comply with the *Policy* by the end of this two-week period, you will be placed on administrative leave without pay on [insert date].

Please note that the Employee Assistance Program is available to assist you at any time and can be reached at [phone number].

Should you have any questions regarding the process, please feel free to contact me [insert coordinates].

Sincerely,

[insert name]
[insert title of delegated official]

c.c. [insert name]

11. RESOURCES AND LINKS

Legislation

- *Canadian Human Rights Act* (*CHRA*)
- *Canada Labour Code* (*Part II – Occupational Health and Safety*)
- *Canada Occupational Health and Safety Regulations* (*COHSR*)
- *Government Employees Compensation Act* (*GECA*)
- *Privacy Act*
- *Privacy Regulations*
- *Work Place Harassment and Violence Prevention Regulations* (*WHVP*)

Related Policy Instruments

- Directive on Leave and Special Working Arrangements
- Directive on Privacy Practices
- Directive on Telework
- Directive on the Duty to Accommodate
- National Joint Council Occupational Health and Safety Directive
- Policy on People Management
- Policy on Privacy Protection
- Values and Ethics Code for the Public Sector

Additional Information

- About COVID-19 vaccines and vaccination
- Employee Assistance Program (EAP)
- Government of Canada Announcement to Require Vaccination of Federal Workforce
- Information for Government of Canada Employees: Coronavirus disease (COVID-19) - Canada.ca
- Mental health and COVID-19 for public servants resource hub
- Provincial and Territorial Restrictions
- Public Service Occupational Health Program COVID-19 Guidance
- World Health Organization (WHO) – COVID-19

Tab 23

Epidemiology of myocarditis and pericarditis following mRNA vaccines in Ontario, Canada: by vaccine product, schedule and interval

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Abstract

Importance: Increased rates of myocarditis/pericarditis following COVID-19 mRNA vaccines have been observed. However, little data are available related to product-specific differences, which have important programmatic impacts.

Objective: The objective of this study was to estimate reporting rates of myocarditis/pericarditis following COVID-19 mRNA vaccine by product, age, sex, and dose number, as well inter-dose interval.

Design: We conducted a population-based cohort study using passive vaccine safety surveillance data. All individuals in Ontario, Canada who received at least one dose of COVID-19 mRNA vaccine between December 14, 2020 and September 4, 2021 were included.

Setting: This study was conducted in Ontario, Canada (population: 14.7 million) using the provincial COVID-19 vaccine registry and provincial adverse events following immunization database.

Participants: We included all individuals with a reported episode of myocarditis/pericarditis following COVID-19 vaccine in the study period. We obtained information on all doses administered in the province to calculate reporting rates.

Exposure: Receipt of COVID-19 mRNA vaccine (mRNA-1273 [Moderna Spikevax] or BNT162b2 [Pfizer-BioNTech Comirnaty]).

Main Outcome(s) and Measure(s): Reported rate of myocarditis/pericarditis meeting level 1-3 of the Brighton Collaboration case definitions.

Results: There were 19,740,741 doses of mRNA vaccines administered and 297 reports of myocarditis/pericarditis meeting our inclusion criteria. Among these, 69.7% occurred following the second dose of COVID-19 mRNA vaccine and 76.8% occurred in males. The median age of individuals with a reported event was 24 years. The highest reporting rate of myocarditis/pericarditis was observed in males aged 18-24 years following mRNA-1273 as the second dose; the rate in this age group was 5.1 (95% CI 1.9-15.5) times higher than the rate following BNT162b2 as the second dose. Overall reporting rates were higher when the inter-dose interval was shorter (i.e., $\leq$30 days) for both vaccine products. Among individuals who received mRNA-1273 for the second dose, rates were higher for those who had a heterologous as opposed to homologous vaccine schedule.

Conclusions and Relevance: Our results suggest that vaccine product, inter-dose interval and vaccine schedule combinations may play a role in the risk of myocarditis/pericarditis, in addition to age and sex. Certain programmatic strategies could reduce the risk of myocarditis/pericarditis following mRNA vaccines.

Introduction

Post-marketing vaccine safety surveillance systems in multiple countries have identified a likely association between myocarditis and pericarditis following BNT162b2 (Pfizer-BioNTech Comirnaty) and mRNA-1273 (Moderna Spikevax) COVID-19 mRNA vaccines.[1-5] In Ontario, Canada, (population approximately 14.7 million), enhanced surveillance for myocarditis/pericarditis following mRNA vaccines began in early June 2021. This consisted of healthcare provider communication from the Ontario Ministry of Health and Public Health Ontario, and hospital-led algorithms for clinical investigations and management that also included instructions on reporting events to Ontario's existing passive vaccine safety surveillance system. This enhanced surveillance directive (ESD) coincided with a number of changes to Ontario's COVID-19 vaccine program including: expanded vaccine eligibility to young adults and adolescents (Health Canada authorization of BNT162b2 for individuals aged 12-15 years occurred on May 5, 2021), a large acceleration in vaccine supply and administration of second doses to the population, permissive language from Canada's National Advisory Committee on Immunization on the use of heterologous mRNA vaccine schedules,[6] and over the course of the summer of 2021, a gradual return to the scheduling of second doses in accordance with the product monograph (PM) interval following a period of extended intervals between dose 1 and 2 (hereafter referred to as inter-dose interval) to maximize the number of individuals protected with a first dose of vaccine.[6] These programmatic changes provided an opportunity to examine the risk of myocarditis/pericarditis in relation to a number of factors.

Our objectives were to examine reporting rates of myocarditis/pericarditis following mRNA vaccines by age, sex, vaccine product, dose number, inter-dose interval and homologous/heterologous vaccine schedule, using passive vaccine safety surveillance data.

Methods

We used the Public Health Case and Contact Management Solution (CCM), Ontario's electronic reporting system for COVID-19 adverse events following immunization (AEFI), to identify reports of myocarditis and pericarditis following a COVID-19 vaccine reported between December 14, 2020 (the start of Ontario's immunization program) and September 4, 2021. In Ontario, reporting of AEFI by healthcare providers is mandated by provincial public health legislation; voluntary reporting by vaccine recipients or their caregivers also occurs.[7] Reports are submitted to local Public Health Units (PHUs) where additional investigation of the event occurs to obtain supporting information (e.g., laboratory findings, diagnostic imaging).

Events were identified through both a keyword search (i.e., 'myocarditis' or 'pericarditis') and where cardiovascular injury or myocarditis/pericarditis was selected from a list of pre-defined adverse events. Case level review of all reports was completed by a group of specialized nurses and physicians on the PHO vaccine safety team to assign a level of diagnostic certainty using Brighton Collaboration (BC) case definitions for myocarditis or pericarditis, as appropriate.[8] We restricted our analyses to events meeting BC levels 1-3 of diagnostic certainty. In sensitivity analyses that examined only myocarditis, AEFI reports with physician diagnoses of myopericarditis and perimyocarditis were included only if the BC case definition (levels 1-2) for myocarditis was met. We included all reports following vaccination, regardless

of time since vaccination, in crude reporting rates. We used a 7-day risk interval in analyses of observed versus expected number of events.

To calculate reporting rates, we extracted information from the Ontario Ministry of Health's COVaxON database, the provincial COVID-19 vaccine registry. We calculated reporting rates of myocarditis/pericarditis combined per million doses of COVID-19 mRNA vaccine by age, sex, dose number and vaccine product. Confidence intervals were calculated using the Poisson exact method. Our primary analysis was restricted to individuals who initiated their vaccine series on or after June 1, 2021, in order to account for any increase in AEFI reporting following the increased awareness resulting from media reports and the provincial ESD for myocarditis/pericarditis that began in early June 2021. This timing also coincided with other changes to the vaccine program, including implementation of heterologous mRNA schedules (Supplementary Figure 1). We also examined reporting rates of heterologous or homologous vaccine schedules, and by inter-dose interval, for the total population and in males aged 18-24 years, restricted to individuals who received dose 2 (regardless of dose 1 date) on or after June 1, 2021 in order to maximize our sample of dose 2 recipients during the period of enhanced surveillance. We selected the interval groupings by examining the distribution of intervals among individuals receiving a second dose and to align with the product monograph(s) and programmatic decisions (i.e., extended inter-dose intervals). In order to estimate an overall rate following dose 2 by product, we used Poisson regression and adjusted for dose 1 product and interval.

We also performed the analysis for myocarditis/pericarditis outcomes for the entire reporting period (i.e., any dose received December 14, 2020 – September 4, 2021).

Finally, we compared our observed events of myocarditis/pericarditis to those expected based on historical data, following the methodology outlined by Mahaux et al.[9] Historical background rates from the Ontario population were obtained from linked health administrative databases. These rates reflected episodes of myocarditis/pericarditis (see Supplementary Table 1 for ICD-10-CA definitions) obtained from the Canadian Institute for Health Information's Discharge Abstract Database and National Ambulatory Care Reporting System, reflecting hospitalizations and emergency department visits, respectively. These databases were linked using unique encoded identifiers and analyzed at ICES (formerly the Institute for Clinical Evaluative Sciences). We used the mean rate from 2015-2019 to calculate expected events by age and sex based on the number of vaccines that were administered in each group, using a 7-day risk interval, chosen because the majority of events occurred within this time frame. We estimated a range in expected events by using the confidence limits of the background rates. We focused this part of the analysis on events occurring in individuals who received their second dose on or after June 1, 2021.

The Public Health Ontario Ethics Review Board determined that this project did not require research ethics committee approval as the activities described in this manuscript were conducted in fulfillment of Public Health Ontario's legislated mandate "to provide scientific and technical advice and support to the health care system and the Government of Ontario in order to protect and promote the health of Ontarians" (Ontario Agency for Health Protection and Promotion Act, SO 2007, c 10) and are therefore considered public health practice, not research.

Results

Between December 14, 2020 and September 4, 2021, there were 19,740,741 doses of mRNA vaccines administered in Ontario and 417 reports of myocarditis or pericarditis reported to the provincial AEFI system. Of these, 297 met the inclusion criteria based on the BC case definitions (level 1-3); among these, 69.7% occurred following the second dose of COVID-19 mRNA vaccine, 76.8% occurred in males, and the median age of individuals with a reported event was 24 years (Table 1). Events were classified as myopericarditis (36.0%), followed by myocarditis (35.4%), and pericariditis (28.6%). Nearly all (97.6%) events involved an emergency department visit, with 70.7% of events also leading to a hospital admission. The proportion of individuals hospitalized was 82.9%, 38.8%, and 84.1% for myocarditis, pericarditis, and myopericarditis, respectively (Supplementary Table 2). The median time to onset was three days after vaccine administration (interquartile range: 2-8; range: 0-73). Most events (73.9%) with a known onset date occurred within 7 days of vaccine administration. For events following dose 2, 86.9% occurred within 7 days of vaccine with 97.1% occurring within 30 days (Supplementary Figure 2).

In our primary analysis focusing on those who initiated their vaccination series on or after June 1, 2021, the reporting rate of myocarditis or pericarditis was higher following the second dose of mRNA vaccine than after the first dose, particularly for those individuals receiving mRNA-1273 as the second dose of the series (Table 2). The highest reporting rate of myocarditis or pericarditis was observed in males aged 18-24 years following mRNA-1273 as the second dose, which (in our primary analysis) was 5.1 (95% CI 1.9-15.5) times higher than the rate following BNT162b2 as the second dose (299.5 vs. 59.2 per million doses, respectively). The second highest reporting rate was observed among males 12-17 following their second dose of BNT162b2 (97.3 per million [95% CI 60.3-148.8]). However, confidence intervals were wide. In a sensitivity analysis restricting the analysis to those meeting level 1 or 2 of the BC case definition for myocarditis only, our observed patterns remained unchanged (Supplementary Table 3). When we performed the analysis for myocarditis/pericarditis outcomes for the entire reporting period, the results were similar (Supplementary Table 4; rates following dose 2 by age in years and product in Supplementary Figure 3).

To explore differences in the rate of myocarditis/pericarditis following the second dose of mRNA-1273 vs. BNT162b2, we also examined rates by mixed schedule and inter-dose interval (Figure 1a; further data in Supplementary Table 5). Among all ages and sexes combined, rates of myocarditis/pericarditis were higher for individuals with shorter inter-dose intervals ($\leq$30 days vs. $\geq$56 days) and the unadjusted rate ratios comparing these intervals were similar for mRNA-1273 (RR= 5.2, 95% CI 2.6-10.0) and BNT162b2 (RR=5.5, 95% CI 3.1-9.6). We also examined overall rates by inter-dose interval within homologous or heterologous schedules (Figure 1b); the highest rate reported was in those who received BNT162b2 followed by mRNA-1273 with an inter-dose interval of $\leq$30 days. Among males aged 18-24, rates in those who received a second dose of mRNA-1273 (regardless of first dose product) were significantly higher than in those who received two doses of BNT162b2 (Table 3). The rate among males aged 18-24 receiving two doses of mRNA-1273 were lower than those who received BNT162b2 followed by mRNA-1273 (288.4 per million [95% CI 190.1-419.6] vs. 337.6 per million [95% CI 226.1-484.9], respectively). There were no reported events in males aged 18-24 years who received a first dose of mRNA-1273 followed by a second dose of BNT162b2; however fewer than 9,000 males in this age group received this schedule. Within each of these schedules (i.e., BNT162b2-BNT162b2, mRNA-1273-mRNA-1273, BNT162b2-mRNA-1273) rates were lower with a longer interval between dose 1 and 2 ($\geq$31 days). After adjusting for dose 1 product and interval, the rate ratio for dose 2 mRNA-1273 compared to dose 2 BNT162b2 was 6.6 (95% CI 3.3-13.2) in males 18-24 who received their second dose on or after June 1, 2021.

The number of observed events of myocarditis/pericarditis following vaccination exceeded that of the expected events based on a 7 day risk window for several age groups following dose 2, when restricted to dose 2 administration on/after June 1, 2021 (Table 4; analyses of the full period including dose 1 are provided in Supplementary Table 6). The ratio of observed to expected events was highest for males aged 18-24 following dose 2 of mRNA-1273 and for males aged 12-17 following dose 2 of BNT162b2.

Discussion

Using passive vaccine safety surveillance data, we identified 297 reports of myocarditis/pericarditis following receipt of an mRNA vaccine that met the BC case definition since the start of the COVID-19 vaccine program in Ontario, Canada. Consistent with other surveillance systems and studies,[10,11] we found that rates of myocarditis/pericarditis were highest among young males following dose 2, where they were tightly clustered within the first week after vaccination. Although rates were higher following a second dose of either mRNA vaccine as compared to a first dose, we observed a strong suggestion of a product-specific association; the rates following a second dose of mRNA-1273 were higher than those following a second dose of BNT162b2, in particular for young males. In addition to product specific insights for age/sex groups at highest risk, our analyses suggest that inter-dose interval and vaccine schedule combinations may also play a role in the risk of myocarditis/pericarditis. These observations suggest that there may be programmatic strategies relating to product, interval, and schedule that could play a role in reducing the risk of myocarditis/pericarditis following mRNA vaccines.

The crude reporting rates for myocarditis/pericarditis from Ontario are in line with estimates from other passive surveillance systems and other data sources,[2-5,12] although there is variability in age-specific rates across systems and countries. In Israel, where only BNT162b2 vaccines were used following the product monograph with a 21 day inter-dose interval, the rate of myocarditis (using the BC definition) following dose two among males 16-19 was 150 per 1,000,000 between December 2020 and May 2021, although this time period encompassed both active and passive surveillance periods.[2] The rate of myocarditis/pericarditis among males aged 12-17 who received two doses of BNT162b2 at an interval of 30 days or less in Ontario was similar at 159.7 per million doses. In the United Kingdom (UK), the reporting rate for myocarditis after both first and second doses across all ages was estimated at 10 per million doses of BNT162b2 and 36 per million doses of mRNA-1273 based on events submitted as of November 17, 2021.[4] For those aged 19-29, rates of myocarditis following dose two were 22 and 69 per million for BNT162b2 and mRNA-1273, respectively. This trend of increased rate for mRNA-1273 is consistent with our findings, although the overall rate is lower. The UK employed an extended inter-dose interval and their overall results may be more comparable to our subgroup analyses reflecting the rates among individuals who had 8 or more weeks in between doses. Rates across data sources in the United States (US) vary. Using data from four FDA Biologics Effectiveness and SafeTy (BEST) administrative data claims databases, among males 18-25, the rate of myocarditis/pericarditis within 7 days following second dose mRNA-1273 ranged from 72.4 (95%CI 23.2-228.1) per million to 283.7 (95% CI 145.2-573.5) per million.[13] In Ontario, we estimated a similar rate of myocarditis/pericarditis at 299.5 per million following a second dose of mRNA-1273 in males 18-24 years. Using data from the Vaccine Adverse Event Reporting System (VAERS), a passive reporting system, the reported rate of myocarditis per million doses in males within seven days of a second dose of mRNA-1273 was much lower than estimated in the BEST databases, with a rate of 38.5 per million.[14] The rate per million following a second dose of BNT162b2 was 36.8 in males aged 18-24 years, 69.1 in those aged 16-17 years and 39.9 in those aged 12-15 years.[14] Data from the US also include those from the active surveillance system,

Vaccine Safety Datalink (VSD), with reporting rates higher than in VAERS.[15] In a head-to-head analysis of BNT162b2 and mRNA-1273 among those aged 18-39 years, the VSD reported the adjusted rate of myocarditis/pericarditis within 7 days of dose two was 2.72 times greater (95% CI 1.25-6.05) for those who received mRNA-1273 as compared to BNT162b2, with an excess of 13.3 cases per million second doses of mRNA-1273 vs. BNT162b2.[16] There are several possible explanations for differences in reporting rates across systems, including outcomes studied (i.e., myocarditis only versus myocarditis/pericarditis), different case definitions used to classify outcomes, completeness in reporting, and health system context (i.e., access to publicly-funded health services). Finally, our analyses suggest that country-specific differences in the inter-dose interval and heterologous schedules may be an additional influence on variability in reporting rates across jurisdictions.

Following extensive review and discussion of the product-specific differences identified from passive vaccine safety surveillance, Ontario modified its COVID-19 vaccine program on September 29, 2021 to preferentially offer the BNT162b2 vaccine to individuals 12-24 years of age.[7] Although authorized by Health Canada for adolescents 12-17 years of age in late August 2021, the mRNA-1273 vaccine has yet to be incorporated into Ontario's adolescent vaccine program. As of mid-November 2021, several countries, including Norway, Sweden, Finland, France, and Germany, have issued similar guidance limiting the use of mRNA-1273 in those adolescents and young adults.[17-20]

Although data on the possible relative risks between products for myocarditis/pericarditis are emerging, these findings need to be considered within the context of absolute risk, as myocarditis/pericarditis is still a rare or very rare event, based on standard pharmacovigilance definitions.[21] Importantly, the risk of myocarditis/pericarditis following mRNA vaccines also needs to be considered in relation to risks of myocarditis following SARS-CoV-2 infection (i.e., higher rates of myocarditis following infection than vaccination)[22-24] and the high effectiveness of mRNA vaccine products, including some suggestion of a more durable response following mRNA-1273 vaccine.[25]

These analyses include data on all AEFI entered into a single passive vaccine safety surveillance system in a large jurisdiction with high vaccine coverage (77.6% two-dose coverage among the vaccine eligible population [i.e., ≥12 years of age] as of September 4, 2021). All AEFI reports were individually reviewed by a team of specialized nurses and physicians to limit analyses to those events meeting BC case definitions for myocarditis or pericarditis (levels 1-3). We utilized data on the entire vaccine program through the provincial COVID-19 vaccine registry, which allowed us to examine reporting rates in the context of detailed denominator data relating to various product schedules and intervals. Lastly, we used historical data from the same population giving rise to these outcomes, in a jurisdiction with universal access to publicly-funded health services, which allowed for the comparison of observed versus expected events in the context of the vaccination program. Despite these strengths, there are several limitations in this analysis worth noting, including those inherent to passive vaccine safety surveillance systems such as stimulated reporting during the period of enhanced reporting. However, these limitations were minimized by a restriction of events only to those meeting BC levels 1-3, and thorough sensitivity analyses; when we analyzed our rates in different time periods, as well as restricted our analysis to myocarditis only (BC levels 1-2), our conclusions were unchanged. Lastly, several of our reporting rates for product and schedule combinations were based on small numbers, leading to very wide confidence intervals; as such, rates for individual strata should be interpreted with caution.

Conclusions

Although myocarditis/pericarditis following mRNA vaccines is rare, our analyses suggest that modifications to mRNA COVID-19 vaccine programs relating to age-based product considerations and the use of longer inter-dose intervals may reduce the risk of these events. Confirmation of these findings, and further exploration of the influence of heterologous mRNA vaccine schedules on the risk of myocarditis/pericarditis, are needed.

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Conflict of interest

The authors declare no conflicts of interest.

Ethics approval

The Public Health Ontario Ethics Review Board has determined that this project did not require research ethics committee approval as the activities described in this manuscript were conducted in fulfillment of Public Health Ontario's legislated mandate "to provide scientific and technical advice and support to the health care system and the Government of Ontario in order to protect and promote the health of Ontarians" (Ontario Agency for Health Protection and Promotion Act, SO 2007, c 10) and are therefore considered public health practice, not research.

Table 1. Characteristics of myocarditis/pericarditis reports following COVID-19 mRNA vaccines

	After dose 1 (N=90)		After dose 2 (N=207)		Total (N=297)
	Dose administered before June 1	Dose administered on or After June 1	Dose administered before June 1	Dose administered on or After June 1	
Total number of reports	50	40	5	202	297
Median age, years (range)	32 (12 – 81)	23 (13 – 76)	50 (34 – 61)	23 (12 – 81)	24 (12 – 81)
Age group (years)					
12-17	5 (10.0%)	14 (35.0%)	0 (0.0%)	36 (17.8%)	55 (18.5%)
18-24	12 (24.0%)	7 (17.5%)	0 (0.0%)	77 (38.1%)	96 (32.3%)
25-39	11 (22.0%)	10 (25.0%)	2 (40.0%)	49 (24.3%)	72 (24.2%)
≥40	22 (44.0%)	9 (22.5%)	3 (60.0%)	40 (19.8%)	74 (24.9%)
Sex					
Male	32 (64.0%)	30 (75.0%)	2 (40.0%)	164 (81.2%)	228 (76.8%)
Female	18 (36.0%)	10 (25.0%)	3 (60.0%)	38 (18.8%)	69 (23.2%)
Median time to onset, days (interquartile range)*	14.5 (7-29)	4 (2-14)	2 (2 – 73)	2 (1-3)	3 (2-8)
Vaccine product					
BNT162b2	39 (78.0%)	29 (72.5%)	4 (80.0%)	87 (43.1%)	159 (53.5%)
mRNA-1273	11 (22.0%)	11 (27.5%)	1 (20.0%)	115 (56.9%)	138 (46.5%)
Clinical diagnosis					
Myocarditis	18 (36.0%)	13 (32.5%)	2 (40.0%)	72 (35.6%)	105 (35.4%)
Pericarditis	23 (46.0%)	15 (37.5%)	2 (40.0%)	45 (22.3%)	85 (28.6%)
Myopericarditis**	9 (18.0%)	12 (30.0%)	1 (20.0%)	85 (42.1%)	107 (36.0%)
Healthcare utilization/outcome					
Emergency department visit	49 (98.0%)	37 (92.5%)	5 (100.0%)	199 (98.5%)	290 (97.6%)
In-patient hospitalization	32 (64.0%)	24 (60.0%)	4 (80.0%)	150 (74.3%)	210 (70.7%)
Intensive care unit admission	1 (2.0%)	3 (7.5%)	0 (0.0%)	10 (5.0%)	14 (4.7%)
Death	0	0	0	0	0

*2 reports with unknown time to onset were excluded from this calculation.

**Includes "myocarditis/pericarditis" (n=2), myopericarditis (n=81), and perimyocarditis (n=24).

Table 2. Crude reporting rate of myocarditis/pericarditis per million doses administered by vaccine product, dose number, age, and sex: series initiation on or after June 1, 2021

BNT162b2						
	All		Female		Male	
Age group (years)	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
12-17*	27.3 (14.9 - 45.8)	54.4 (34.5 - 81.7)	20.1 (6.5 – 47.0)	9.7 (1.2 - 35.1)	34.2 (15.6 - 64.9)	97.3 (60.3 - 148.8)
18-24	17.9 (5.8 - 41.7)	44.3 (17.8 - 91.3)	7.9 (0.2 - 44.1)	27.4 (3.3 – 99.0)	26.2 (7.1 – 67.0)	59.2 (19.2 - 138.1)
25-39	13.0 (5.2 - 26.8)	16.0 (5.2 - 37.4)	3.9 (0.1 - 21.6)	19.7 (4.1 - 57.6)	21.5 (7.9 - 46.7)	12.6 (1.5 - 45.4)
≥40	5.9 (1.2 - 17.3)	0.0 (0.0 - 11.7)	4.0 (0.1 - 22.3)	0.0 (0.0 - 23.5)	7.8 (0.9 - 28.3)	0.0 (0.0 - 23.3)
Total	15.6 (10.4 - 22.4)	29.0 (20.2 - 40.3)	8.9 (3.9 - 17.6)	11.9 (4.8 - 24.5)	21.8 (13.5 - 33.3)	45.3 (30.1 - 65.5)
mRNA-1273						
	All		Female		Male	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
12-17*	-	-	-	-	-	-
18-24	21.6 (2.6 - 77.9)	195.5 (117.7 - 305.3)	0.0 (0.0 - 95.1)	69.1 (14.2 - 201.9)	37.2 (4.5 - 134.6)	299.5 (171.2 - 486.4)
25-39	16.2 (3.3 - 47.3)	58.7 (30.3 - 102.6)	0.0 (0.0 - 45.4)	21.5 (2.6 - 77.7)	28.8 (5.9 - 84.3)	90.1 (43.2 - 165.7)
≥40	30.0 (11.0 - 65.2)	0.0 (0.0 – 19.0)	22.0 (2.7 - 79.4)	0.0 (0.0 - 40.9)	36.7 (10.0 - 93.9)	0.0 (0.0 - 35.6)
Total	23.0 (11.5 - 41.1)	62.5 (42.4 - 88.6)	9.5 (1.1 - 34.2)	22.0 (7.1 - 51.4)	33.7 (15.4 – 64.0)	96.8 (63.2 - 141.9)

*Estimates were not provided for individuals aged 12-17 for mRNA-1273 because this product was not used for this age group in Ontario.

Figure 1. Overall reporting rate of myocarditis/pericarditis among people who have completed their two-dose series with dose 2 on or after June 1, 2021 by A) homologous/heterologous schedule and inter-dose interval and B) homologous/heterologous schedule by inter-dose interval

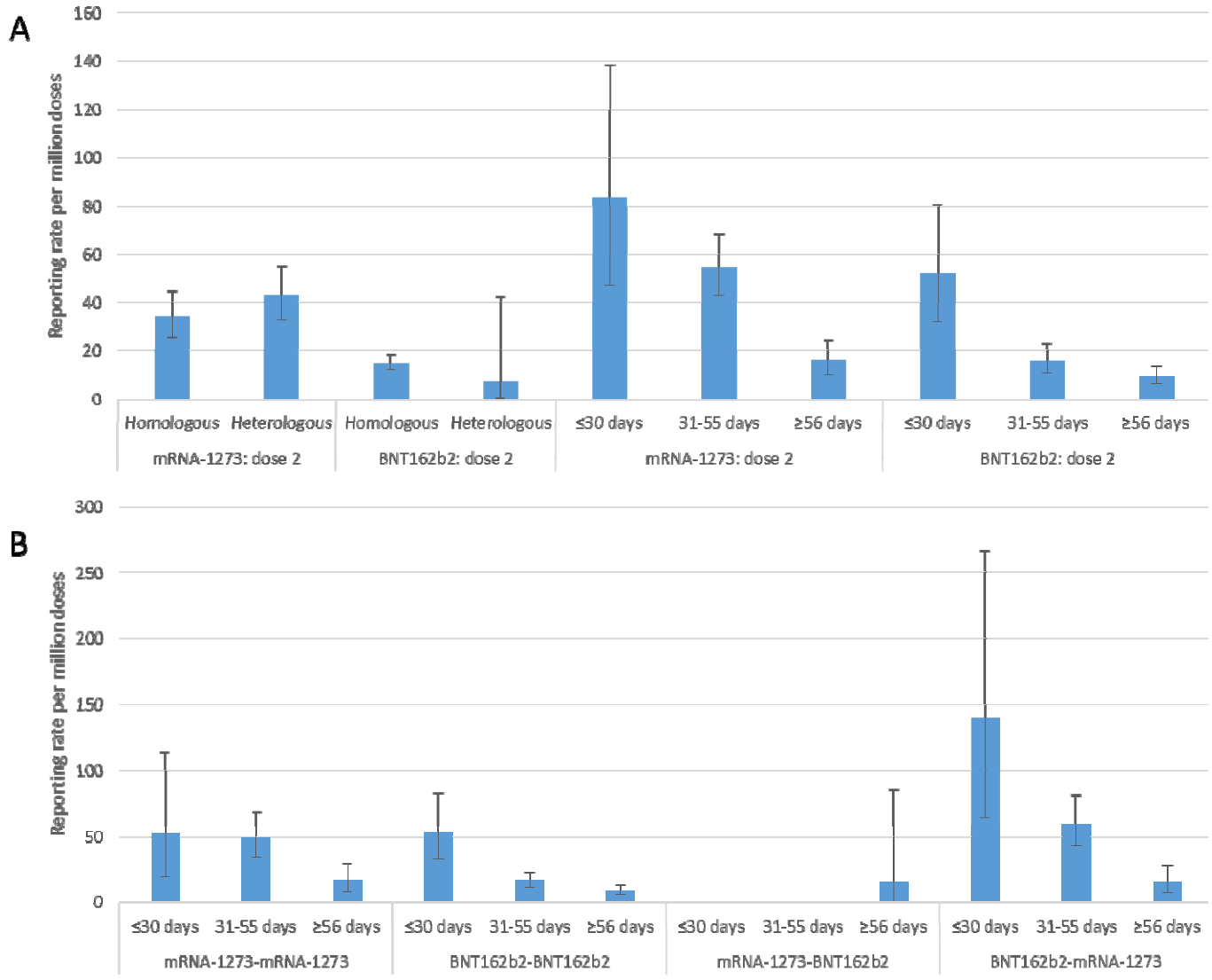

Table 3. Reporting rate of myocarditis/pericarditis among males aged 18-24 years by vaccine products and inter-dose interval with dose 2 on or after June 1, 2021

Vaccine schedule	Reports (N)	Doses administered (N)	**Rate (95% CI) per million doses**
People with two doses			
BNT162b2-BNT162b2	11	235,819	46.6 (23.3 - 83.5)
Interval ≤30 days	2	21,160	94.5 (11.4 - 341.4)
Interval 31-55 days	8	124,235	64.4 (27.8 - 126.9)
Interval ≥56 days	1	90,424	11.1 (0.3 - 61.6)
mRNA-1273-mRNA-1273	27	93,616	288.4 (190.1 - 419.6)
Interval ≤30 days	4	10,623	376.5 (102.6 - 964.1)
Interval 31-55 days	20	60,352	331.4 (202.4 - 511.8)
Interval ≥56 days	3	22,641	132.5 (27.3 - 387.2)
mRNA-1273-BNT162b2	0	8,853	0 (0.0 – 416.7)
Interval ≤30 days	0	1,058	0.0 (0.0 - 3486.7)
Interval 31-55 days	0	5,402	0.0 (0.0 - 682.9)
Interval ≥56 days	0	2,393	0.0 (0.0 – 1541.5)
BNT162b2-mRNA-1273	29	85,893	337.6 (226.1 - 484.9)
Interval ≤30 days	6	7,720	777.2 (285.2 - 1691.6)
Interval 31-55 days	20	62,717	318.9 (194.8 - 492.5)
Interval ≥56 days	3	15,456	194.1 (40.0 - 567.2)

Table 4. Observed vs. expected episodes of myocarditis/pericarditis using a 7-day risk window following dose 2 of COVID-19 mRNA vaccines among individuals receiving dose 2 on or after June 1, 2021, by age group, sex, and vaccine product

Age group (years)	Females			Males		
	Individuals with 2 doses	Expected*	Observed	Individuals with 2 doses	Expected*	Observed
BNT162b2 – Dose 2						
12-17	331,016	0.1-0.1	**4**	338,234	0.4-0.5	**31**
18-24	255,580	0.3-0.3	**2**	245,430	0.9-1.0	**10**
25-29	196,378	0.2-0.3	**3**	190,586	0.5-0.6	**2**
30-39	404,704	0.5-0.6	**2**	369,721	1.1-1.3	**6**
40-49	404,785	0.5-0.7	0	350,902	1.0-1.1	1
50-59	460,742	0.8-1.0	0	420,927	1.2-1.4	1
60-69	441,965	1.0-1.2	0	392,472	1.3-1.5	**3**
70-79	368,666	1.0-1.3	1	319,305	1.2-1.5	**3**
≥80	193,578	0.5-0.6	0	148,837	0.5-0.7	0
mRNA-1273 – Dose 2						
12-17**	-	-	-	-	-	-
18-24	170,317	0.2-0.2	**7**	179,866	0.6-0.7	**55**
25-29	133,420	0.1-0.2	0	151,079	0.4-0.5	**12**
30-39	266,347	0.3-0.4	**5**	292,548	0.9-1.0	**15**
40-49	261,699	0.4-0.4	**2**	274,340	0.8-0.9	**5**
50-59	292,890	0.5-0.6	**1**	311,910	0.9-1.0	**2**
60-69	247,723	0.6-0.7	0	249,489	0.8-0.9	**2**
70-79	139,124	0.4-0.5	0	128,971	0.5-0.6	**1**
≥80	66,729	0.2-0.2	0	47,684	0.2-0.2	0

*The expected range is estimated from the confidence intervals around the mean background rate from 2015-2019.

**Estimates were not provided for individuals aged 12-17 for mRNA-1273 because this product was not used for this age group in Ontario.

Bold results indicate where the observed number was greater than the upper confidence limit of the expected number.

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Tab 24

Risk of myocarditis following sequential COVID-19 vaccinations by age and sex

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ABSTRACT

In an updated self-controlled case series analysis of 42,200,614 people aged 13 years or more, we evaluate the association between COVID-19 vaccination and myocarditis, stratified by age and sex, including 10,978,507 people receiving a third vaccine dose. Myocarditis risk was increased during 1-28 days following a third dose of BNT162b2 (IRR 2.02, 95%CI 1.40, 2.91). Associations were strongest in males younger than 40 years for all vaccine types with an additional 3 (95%CI 1, 5) and 12 (95% CI 1,17) events per million estimated in the 1-28 days following a first dose of BNT162b2 and mRNA-1273, respectively; 14 (95%CI 8, 17), 12 (95%CI 1, 7) and 101 (95%CI 95, 104) additional events following a second dose of ChAdOx1, BNT162b2 and mRNA-1273, respectively; and 13 (95%CI 7, 15) additional events following a third dose of BNT162b2, compared with 7 (95%CI 2, 11) additional events following COVID-19 infection. An association between COVID-19 infection and myocarditis was observed in all ages for both sexes but was substantially higher in those older than 40 years. These findings have important implications for public health and vaccination policy.

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MAIN

Our recent article on the association between COVID-19 vaccination and myocarditis generated considerable scientific, policy and public interest [1]. It added to evidence emerging from multiple countries that have linked exposure to BNT162b2 messenger RNA vaccine with acute myocarditis [2-8] .In the largest and most comprehensive analysis to date, we confirmed prior findings and reported an increase in hospital admission or death from myocarditis following three different types of vaccine including both mRNA and adenoviral vaccines.

Importantly, we also demonstrated that across the entire vaccinated population in England, the risk of myocarditis following vaccination was small compared to the risk following a positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) test [1]. However, myocarditis is more common in younger persons and in males in particular [9, 10]. Additional analyses stratified by both age and sex and following a third vaccine dose were requested as vaccine campaigns are rapidly being extended to include children and young adults. Furthermore, given the consistent observation that the risk of myocarditis is higher following the second dose of vaccine compared to the first dose [1, 11], there is an urgent need to evaluate the risk associated with a third dose as booster programmes are accelerated internationally to combat the omicron variant [12].

We therefore extended our analysis to include persons aged 13 years or more and those receiving a third dose to further evaluate the association between COVID-19 vaccination or infection and myocarditis, stratified by age and sex.

In brief, we used the NHS Immunisation Management Service (NIMS) database, which includes data for all people receiving a COVID-19 vaccine in England. We linked individual patient data to national data for hospital admission, mortality and SARS-CoV-2 testing to examine associations between exposures to the first, second or third dose of ChAdOx1, BNT162b2 or mRNA-1273 vaccine, or a positive SARS-CoV-2 test before or after vaccination, and hospital admission or death from myocarditis. The self-controlled case series (SCCS) method [13, 14] compares the incidence rate of myocarditis in exposed and unexposed periods within individuals implicitly controlling for within person covariates. The incidence rate ratio (IRR) is calculated for hospital admission or death in a 1-28 day risk period after vaccination or a positive test, compared to baseline periods. The IRR was calculated following stratification by sex and age in those younger or older than 40 years.

Between December 1, 2020, to November 15, 2021 a total of 42,200,614 people were vaccinated with at least one dose of ChAdOx1 (n=20,646,456), BNT162b2 (n=20,391,600) or mRNA-1273 (n=1,162,558) in England (Supplementary Table 1). Of these, 38,347,981 received two doses of either ChAdOx1 (n=20,059,058), BNT162b2 (n=17,294,004) or mRNA-1273 (n=1,039,919) and 10,978,507 people received a third dose of ChAdOx1 (n=35,608), BNT162b2 (n=10,599,183) or mRNA-1273 (n=343,716). Amongst people receiving at least one vaccine dose, 5,185,772 (12.3%) tested positive for SARS-CoV-2; 2,834,579 (54.7%) prior to vaccination, 698,993 (13.5%) after a first vaccine dose, 1,604,087 (30.9%) after a second vaccine dose and 48,113 (0.9%) after a third vaccine dose. Of the 42,200,614 persons included in the study population, 2,539 (0.006%) were hospitalised or died from myocarditis during the study period; 552 (0.001%) of these events occurred during 1-28 days following any dose of vaccine (Supplementary Table 2).

Over the 1-28 days post vaccination, we observed an association with the first dose of ChAdOx1 (IRR 1.27, 95%CI 1.05, 1.55) and BNT162b2 (IRR 1.37, 95%CI 1.12, 1.67), but not mRNA-1273 (IRR 1.80, 95%CI 0.91, 3.58; Table 1 and Extended Figure 1). Following a second dose, the risk was higher with mRNA-1273 (IRR 13.71, 95%CI 8.46, 22.20) compared to BNT162b2 (IRR 1.60, 95%CI 1.31, 1.97). No association with a second dose of ChAdOx1 was found. An association after a third dose was only observed for BNT162b2 (IRR 2.02, 95%CI 1.40, 2.91). No myocarditis events occurred 1-28 days after a third dose in the small number of persons receiving ChAdOx1 or mRNA-1273 vaccine. The risk of myocarditis was increased in the 1-28 days following a SARS-CoV-2 positive test (IRR 8.40, 95%CI 6.89, 10.25).

In males aged less than 40 years, we observed an increased risk of myocarditis in the 1-28 days following a first dose of BNT162b2 (IRR 1.66, 95%CI 1.14, 2.41) and mRNA-1273 (IRR 2.34, 95%CI 1.03, 5.34); after a second dose of ChAdOx1 (2.57, 95%CI 1.52, 4.35), BNT162b2 (IRR 3.41, 95% CI 2.44, 4.78) and mRNA-1273 (IRR 16.52, 95%CI 9.10, 30.00); after a third dose of BNT162b2 (IRR 7.60, 95%CI 2.44, 4.78); and following a SARS-CoV-2 positive test (IRR 2.02, 95%CI 1.13, 3.61; Extended Figure 1 and Table 1). In older males, the risk of myocarditis was increased 1-28 days following a third dose of BNT162b2 vaccine (IRR 2.48, 95%CI 1.46, 4.19) and following a positive test (IRR 5.98, 95%CI 2.83, 12.63).

In females aged less than 40 years, we only observed an increased risk of myocarditis in the 1-28 days following a second dose of mRNA-1273 vaccine (IRR 7.55, 95%CI 1.67, 34.12; Figure 1). However, the numbers of events were small. In older females, we found no association between myocarditis and vaccination. Supplementary Table 4 shows IRRs per week following exposure.

We estimated the number of excess myocarditis events per million persons in the 1-28 days following each exposure for the main analysis and by age and sex (Supplemental Table 5 and Figure 1). Following the first dose of the ChAdOx1 and BNT162b2 vaccines an additional 1 (95%CI 0, 2) and 2 (95%CI 1, 2) myocarditis events per million persons exposed would be anticipated, respectively. Following the second dose of BNT162b2 and mRNA-1273 an additional 2 (95%CI 2, 3) and 36 (95%CI 34, 37) myocarditis events would be anticipated, respectively. Following a third dose of BNT162b2 an additional 2 (95%CI 1, 2) myocarditis events per million persons would be anticipated. These estimates compare to an additional 30 (95%CI 29, 31) myocarditis events per million in the 1-28 days following a SARS-CoV-2 positive test.

In males aged less than 40 years, we estimated an additional 3 (95%CI 1, 5) and 12 (95%CI 1, 13) myocarditis events per million in the 1-28 days following a first dose of BNT162b2 and mRNA-1273, respectively; an additional 14 (95%CI 8, 17), 12 (95%CI 1, 7) and 101 (95%CI 95, 104) myocarditis events following a second dose of ChAdOx1, BNT162b2 and mRNA-1273, respectively; and an additional 13 (95%CI 7, 15) myocarditis events following a third dose of BNT162b2 vaccine. This compares with 7 (95%CI 2, 11) additional myocarditis events in the 1-28 days following a positive SARS-CoV-2 test. In older males, we estimated 3 (95% CI 2, 4) and 73 (95% 71, 75) additional myocarditis events per million following a third dose of BNT162b2 and a positive SARS-CoV-2 test, respectively.

In females aged less than 40 years, we estimated an additional 8 (95% CI 4, 9) and 7 (95% CI 6, 8) events per million following a second dose of mRNA-1273 and a positive SARS-CoV-2 test, respectively. In older females, we estimated no additional myocarditis events following

vaccination, but an additional 39 (95% CI 37, 40) events per million following a positive SARS-CoV-2 test.

We report several observations that may have implications for policy makers and the public. First, we confirm and extend our previous findings in more than 42 million persons that the risk of hospitalization or death from myocarditis following COVID-19 infection is higher than the risk associated with vaccination in the overall population. Second, the risk of myocarditis is greater following sequential doses of mRNA vaccine than sequential doses of the adenovirus vaccine. For the first time, we observe an increase in myocarditis events following a third dose of BNT162b vaccine. Whilst the incidence rate ratios are higher sequentially following each dose of mRNA vaccine, the risk remains small in the overall population with an estimated 2 additional cases of myocarditis per million following a booster dose of BNT162b. Third, we report the risk associated with vaccination and infection in younger persons stratified by sex. Despite more myocarditis events occurring in older persons, the risk following COVID-19 vaccination was largely restricted to younger males aged less than 40 years, where the risks of myocarditis following vaccination and infection were similar. However, the notable exception was that in younger males receiving a second dose of mRNA-1273 vaccine, the risk of myocarditis was higher following vaccination than infection, with an additional 101 events estimated following a second dose of mRNA-1273 vaccine compared to 7 events following a positive SARS-CoV-2 test.

There are some limitations we should acknowledge. First, the number of people receiving a third dose of ChAdOx1, or mRNA-1273 vaccine was too small to evaluate the risk of myocarditis. Second, we relied on hospital admission codes and death certification to define myocarditis, and it is possible that we have over or underestimated risk, due to misclassification. Third, although we were able to include 2,136,189 children aged 13 to 17 years old in this analysis, the number of myocarditis events was too small (n=43 in all periods and n=15 in the 1-28 days post vaccination) in this population and precluded an evaluate of risk. Given our observation that risk is largely confined to males under the age of 40 years further research is needed pooling data from international studies to evaluate further the risks in children.

In summary, the risk of hospital admission or death from myocarditis is greater following COVID-19 infection than following vaccination and remains modest following sequential doses of mRNA vaccine including a third booster dose of BNT162b in the overall population. However, the risk of myocarditis following vaccination is consistently higher in younger males, particularly following a second dose of RNA mRNA-1273 vaccine.

Figure Labels

Figure 1: (Left panel) Incidence rate ratios (IRRs) with 95% confidence intervals (CI) and (Right panel) number of excess myocarditis events for million people with 95% confidence intervals (CI) in the 1-28 day risk periods after the first, second and third dose of ChAdOx1, BNT162b2 and mRNA-1273 vaccine or a positive SARS-CoV-2 test in (top) a population of 42,200,614 vaccinated individuals and (bottom) younger males (n=5,893,724), older males (n=11,694,015), younger females (n=6,905,830) and older females (n=13,708,352).

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AUTHOR CONTRIBUTIONS

MP, JHC, CC led the study conceptualisation, development of the research question and analysis plan. JHC obtained funding, designed the analysis, obtained data approvals, contributed to interpretation of the analysis. MP undertook the data specification, curation, analysis. MP and NLM wrote the first draft of the paper. SD undertook and reported on the PPIE engagement. LH, KMC, FZ, XWM, NLM, KK, MSH, PW, AH, FZ, SD, AS contributed to the discussion on protocol development and provided critical feedback on drafts of the manuscript. All authors approved the protocol, contributed to the critical revision of the manuscript, and approved the final version of the manuscript.

DECLARATION OF INTERESTS

AS is a member of the Scottish Government Chief Medical Officer's COVID-19 Advisory Group, the Scottish Government's Standing Committee on Pandemics. and AstraZeneca's Thrombotic Thrombocytopenic Advisory Group. All roles are unremunerated.

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AH is a member of the Joint Committee on Vaccination and Immunisation (JCVI).

KK is a member of the Governments Scientific Advisory Group for Emergencies.

All other authors declare no competing interests related to this paper.

TABLES

Table 1: Incidence rate ratios (IRR 95% CI) for main analysis and by age group (aged 40 or younger, older than 40) and sex (female and male) for the outcomes in pre-defined risk periods immediately before and after exposure to vaccination and before and after a positive SARS-CoV-2 test result, adjusted for calendar time from December 1 2020 to November 15 2021 (cells with * are suppressed as counts < 5). Day 0 of each exposure has been removed due to small numbers.

	ChAdOx1nCoV-19 vaccine		BNT162b2 mRNA vaccine		mRNA-1273 vaccine		Positive SARS-CoV-2 test	
Time period	**events**	**IRR (95% CI)**	**events**	**IRR (95% CI)**	**events**	**IRR (95% CI)**	**events**	**IRR (95% CI)**
Main analysis								
Baseline*	1696	1.00	1696	1.00	1696	1.00	2268	1.00
Pre-risk**	283	0.70 (0.61, 0.80)	283	0.70 (0.61, 0.80)	283	0.70 (0.61, 0.80)	43	2.18 (1.57, 3.04)
1-28 days: 1st dose/positive test	**139**	**1.27 (1.05, 1.55)**	**120**	**1.37 (1.12, 1.67)**	11	1.80 (0.91, 3.58)	**177**	**8.40 (6.89, 10.25)**
1-28 days: 2nd dose	89	0.94 (0.75, 1.18)	**114**	**1.60 (1.31, 1.97)**	**40**	**13.71 (8.46, 22.20)**		
1-28 days: 3rd dose	*	n/a	**39**	**2.02 (1.40, 2.91)**	*	n/a		
Age <40 & Male								
Baseline*	304	1.00	304	1.00	304	1.00	484	1.00
Pre-risk**	34	0.59 (0.41, 0.85)	34	0.59 (0.41, 0.85)	34	0.59 (0.41, 0.85)	9	1.38 (0.68, 2.79)
1-28 days: 1st dose/positive test	13	1.33 (0.72, 2.47)	**39**	**1.66 (1.14, 2.41)**	**8**	**2.34 (1.03, 5.34)**	**14**	**2.02 (1.13, 3.61)**
1-28 days: 2nd dose	**21**	**2.57 (1.52, 4.35)**	**56**	**3.41 (2.44, 4.78)**	**36**	**16.52 (9.10, 30.00)**		
1-28 days: 3rd dose	*	n/a	*	**7.60 (1.92, 30.15)**	*	n/a		
Age >= 40 & Male								
Baseline*	691	1.00	691	1.00	691	1.00	897	1.00
Pre-risk**	148	0.80 (0.66, 0.98)	148	0.80 (0.66, 0.98)	148	0.80 (0.66, 0.98)	**16**	**2.57 (1.49, 4.44)**
1-28 days: 1st dose/positive test	68	1.16 (0.87, 1.54)	29	0.97 (0.65, 1.47)	*	n/a	**91**	**12.86 (9.45, 17.50)**
1-28 days: 2nd dose	44	0.91 (0.65, 1.26)	24	0.79 (0.51, 1.23)	*	n/a		
1-28 days: 3rd dose	*	n/a	**20**	**2.48 (1.46, 4.19)**	*	n/a		

Age <40 & **Female**								
Baseline*	140	1.00	140	1.00	140	1.00	176	1.00
Pre-risk**	13	0.42 (0.24, 0.76)	13	0.42 (0.24, 0.76)	13	0.42 (0.24, 0.76)	*	n/a
1-28 days: 1st dose/positive test	7	0.99 (0.42, 2.31)	13	1.44 (0.78, 2.66)	*	2.88 (0.56, 14.74)	**11**	**5.98 (2.83, 12.63)**
1-28 days: 2nd dose	*	0.29 (0.07, 1.22)	9	1.37 (0.67, 2.80)	*	**7.55 (1.67, 34.12)**		
1-28 days: 3rd dose	*	n/a	*	n/a	*	n/a		
Age >= 40 & Female								
Baseline*	557	1.00	557	1.00	557	1.00	706	1.00
Pre-risk**	88	0.62 (0.49, 0.80)	88	0.62 (0.49, 0.80)	88	0.62 (0.49, 0.80)	**17**	**3.82 (2.19, 6.66)**
1-28 days: 1st dose/positive test	51	1.32 (0.94, 1.85)	38	1.42 (0.96, 2.09)	*	n/a	**61**	**12.37 (8.53, 17.94)**
1-28 days: 2nd dose	22	0.58 (0.37, 0.91)	25	1.00 (0.64, 1.55)	*	n/a		
1-28 days: 3rd dose	*	n/a	16	1.64 (0.91, 2.96)	*	n/a		

*Same for each exposure.

**-28 to 1 days prior to each vaccine dose or positive test. Same for each exposure.

ONLINE METHODS

Data

We used the National Immunisation (NIMS) Database of COVID-19 vaccination to identify vaccine exposure. This includes vaccine type, date and doses for all people vaccinated in England. We linked NIMS vaccination data, at individual level, to national data for mortality (ONS), hospital admissions (HES) and SARS-CoV-2 infection data (SGSS).

Study design

The self-controlled case series (SCCS) design was used, this design was originally developed to examine vaccine safety [13, 14]. The analyses are conditional on each case, so any fixed characteristics during the study period, such as sex, age, ethnicity or chronic conditions, are inherently controlled for. Any time-varying factors, like seasonal variation, need to be adjusted for in the analyses.

Study period and population

People were considered eligible for inclusion if they were at least 13 years old and had received at least one dose of ChAdOx1 (AstraZeneca), BNT162b2 (Pfizer) and mRNA-1273 (Moderna) and were admitted to hospital with or died from myocarditis between December 1 2020 and November 15 2021 (last data update). Patients were followed up from the study start (December 1 2020) to the earliest of the end of the study period (November 15 2021) or when they died. People were excluded if they had a hospital admission for myocarditis in the two years prior to the start of the study period or if they received Ad26.COV2.S (Janssen) vaccine as there were too few doses delivered to permit a meaningful analysis.

Outcomes

The outcomes of interest in this study were hospital admission or death from myocarditis. Myocarditis was defined as the first hospital admission in the study period or death using International Classification of Diseases (ICD)-10 codes (Supplementary Table 6).

Exposures

The exposure variable included the first, second and third dose of the ChAdOx1, BNT162b2 and mRNA-1273 vaccines. Infection with SARS-CoV-2 defined as a COVID-19 reverse transcription–polymerase chain reaction (RT-PCR) positive test was included as a separated exposure variable. Only the first positive test within the study period was used. We defined the exposure risk intervals as the following pre-specified time-periods: 0, 1-7, 8-14, 15-21 and 22-28 days after each exposure date, under the assumption that the adverse events under consideration are unlikely to be related to exposure from 28 days post-exposure. People who experience the outcome are likely to delay vaccination until symptoms have improved, and therefore a pre-risk period of 1-28 days before each exposure was removed from the baseline period to account for

this potential bias. Hospital admission for myocarditis often results in testing for SARS-CoV-2. Whilst these outcomes may well be caused by SARS-CoV-2 infection, reverse causality involved in their detection could over- or under-estimate the effect of infection on myocarditis. To interrogate this potential source of bias, we allocated day 0 to a risk period of its own.

Statistical analysis

We described characteristics of the whole vaccinated cohort in terms of age, sex, ethnicity, SARS-CoV-2 positive test status, number of doses received, homologous and heterologous vaccination by vaccine doses and type.

We described demographic characteristics of vaccinated people with admission or death from myocarditis during and outwith the risk period (1-28 days post each vaccine dose).

The SCCS models were fitted using a conditional Poisson regression model. Incidence rate ratios (IRR), the relative rate ratio of hospital admissions or deaths due to each outcome of interest in risk periods relative to baseline periods, were estimated by the SCCS model adjusted for two-week calendar periods as time-varying covariates (to account for seasonal effects).

Absolute risk differences cannot be obtained using SCCS. We supplemented our estimates of IRRs with measures of effect of each exposure in absolute terms using a method developed to estimate the number of exposures needed to produce one excess adverse outcome and the excess number of events per 1,000,000 exposed for each outcome [15].

Stata version 17 was used for these analyses.

Data availability

The data that support the findings of this study - National Immunisation (NIMS) Database of COVID-19, mortality (ONS), hospital admissions (HES) and SARS-CoV-2 infection data (PHE) -are not publicly available because they are based on de-identified national clinical records. Due to national and organizational data privacy regulations, individual-level data such as those used for this study cannot be shared openly.

Code availability

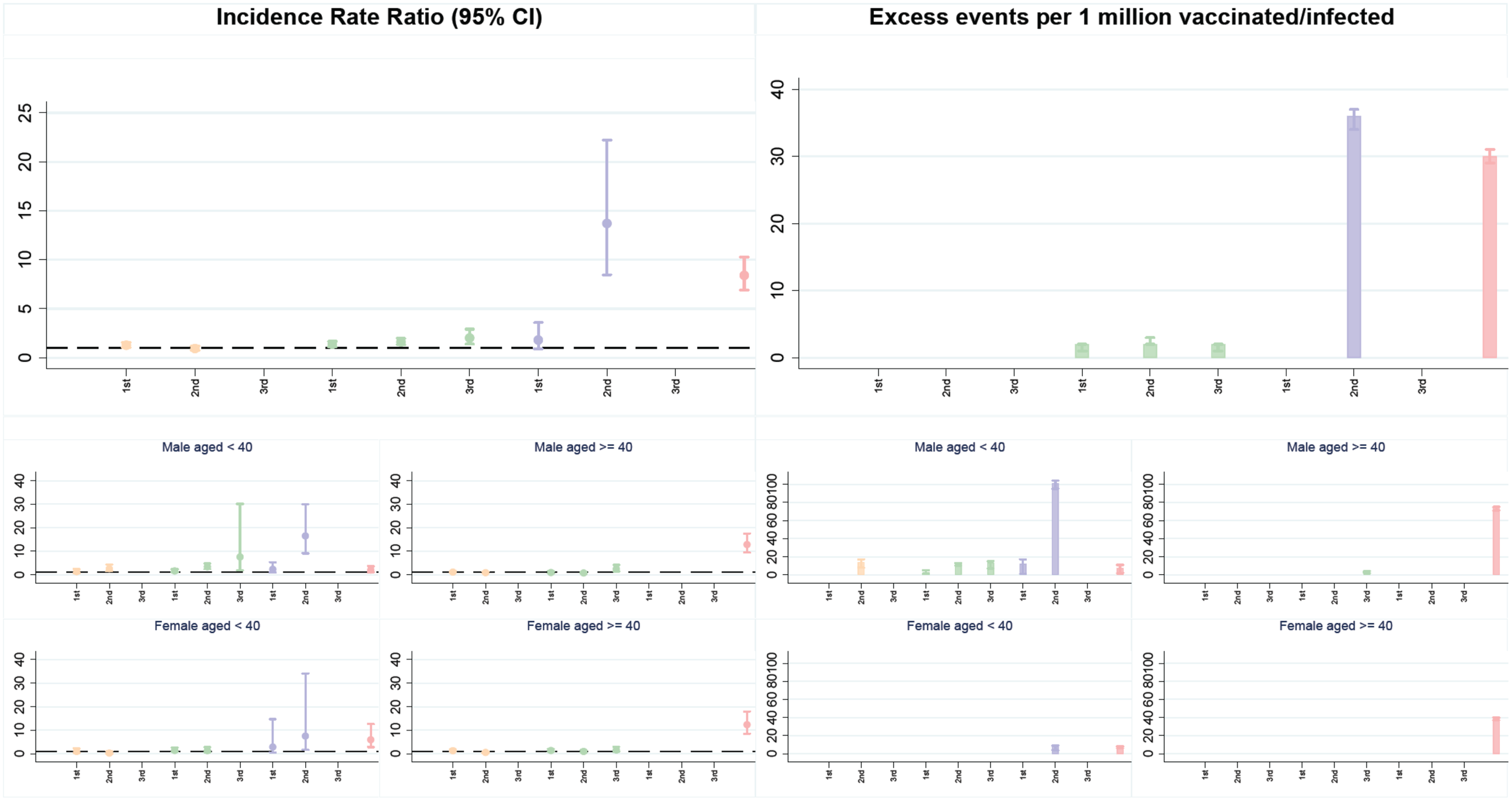
The code used for this study has been deposited in the git repository of the research group, which is protected by privacy. Access to the code is available from the authors on request for non-commercial, academic and research use only. Stata version 17 was used for these analyses.

Additional References

15. Wilson, K. and S. Hawken, *Drug safety studies and measures of effect using the self-controlled case series design.* Pharmacoepidemiol Drug Saf, 2013. **22**(1): p. 108-10.

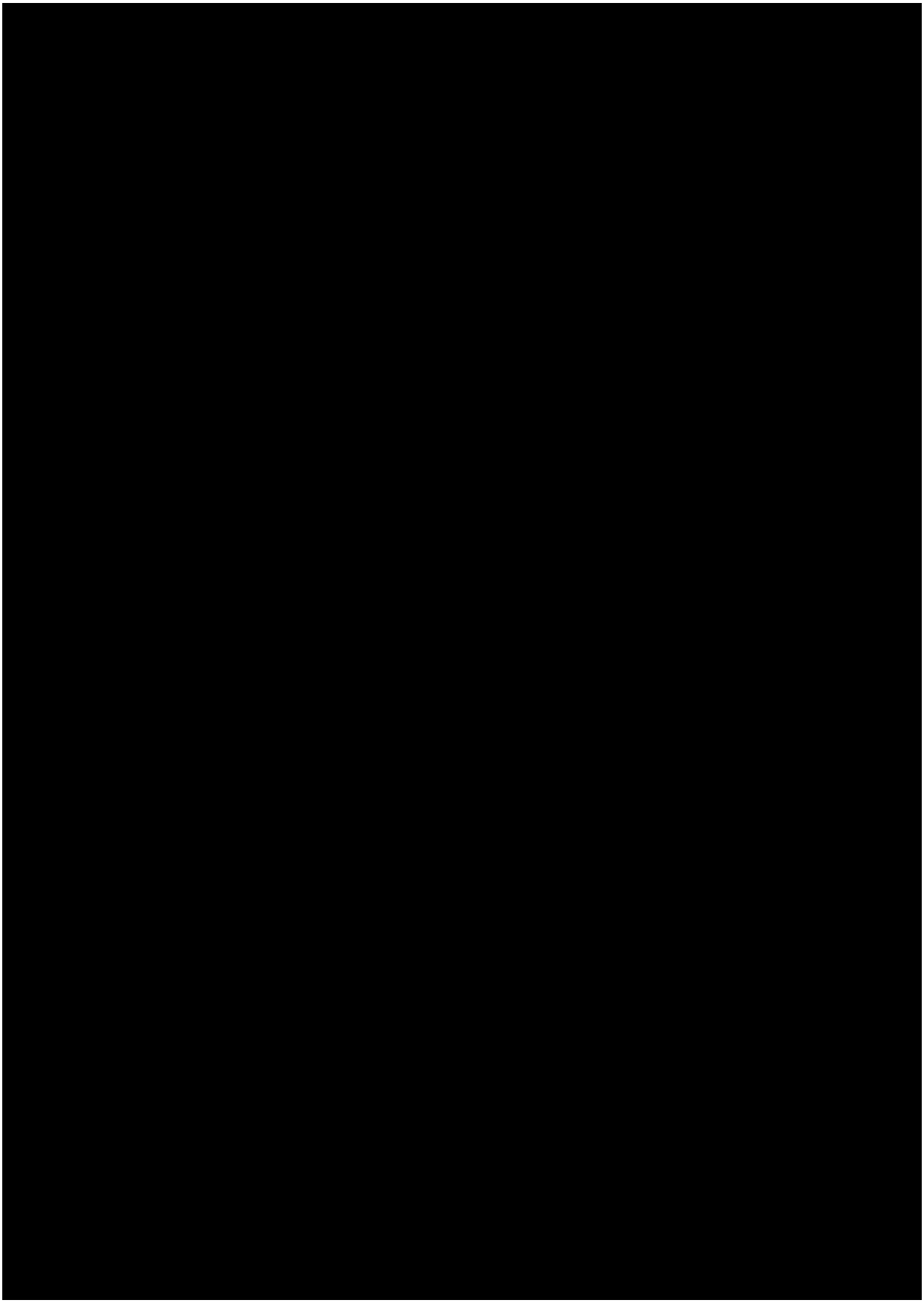
Risks of myocarditis in the 1-28 days after COVID-19 vaccines or SARS-CoV-2 [718]

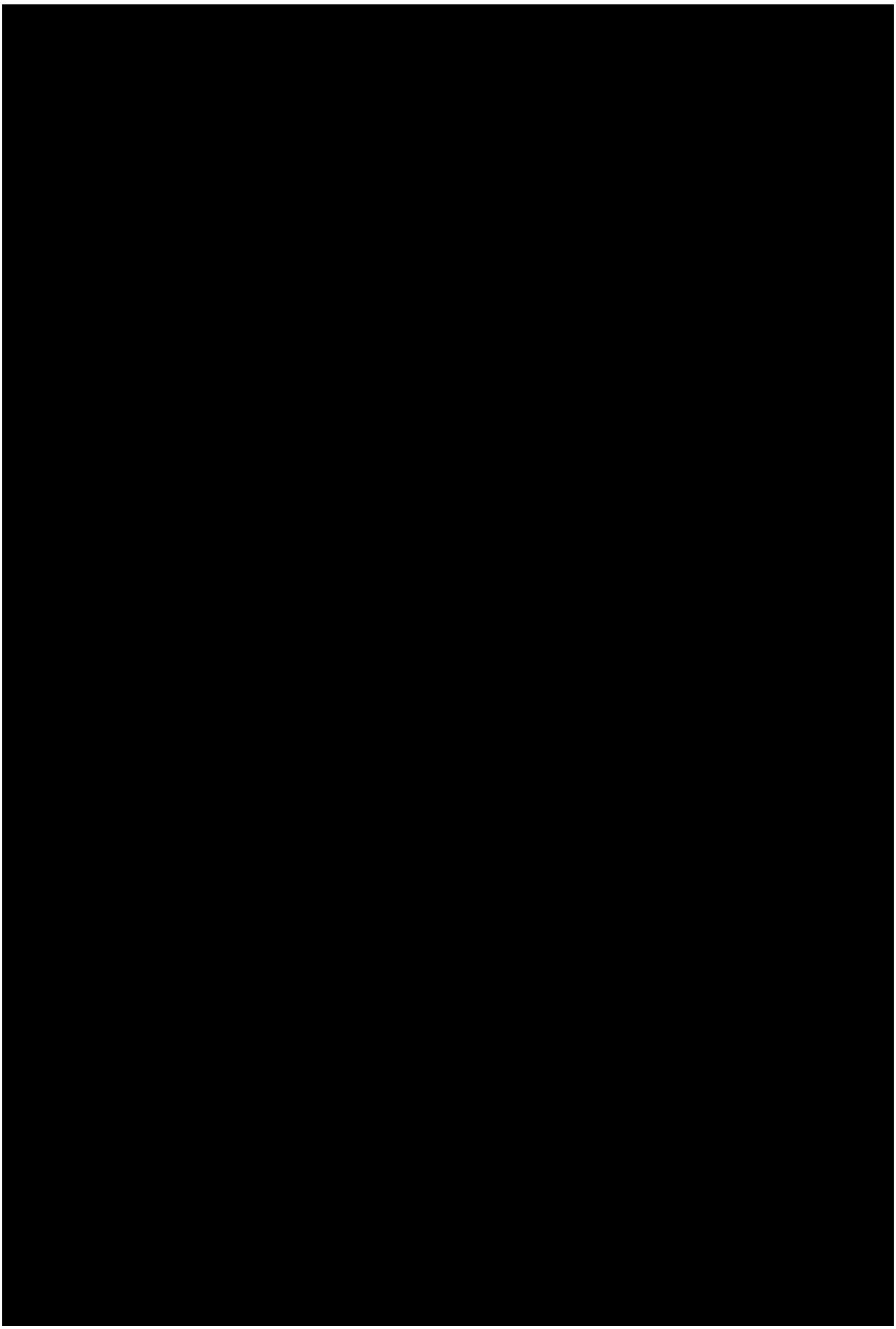
Study period: December 1, 2020 to November 15, 2021

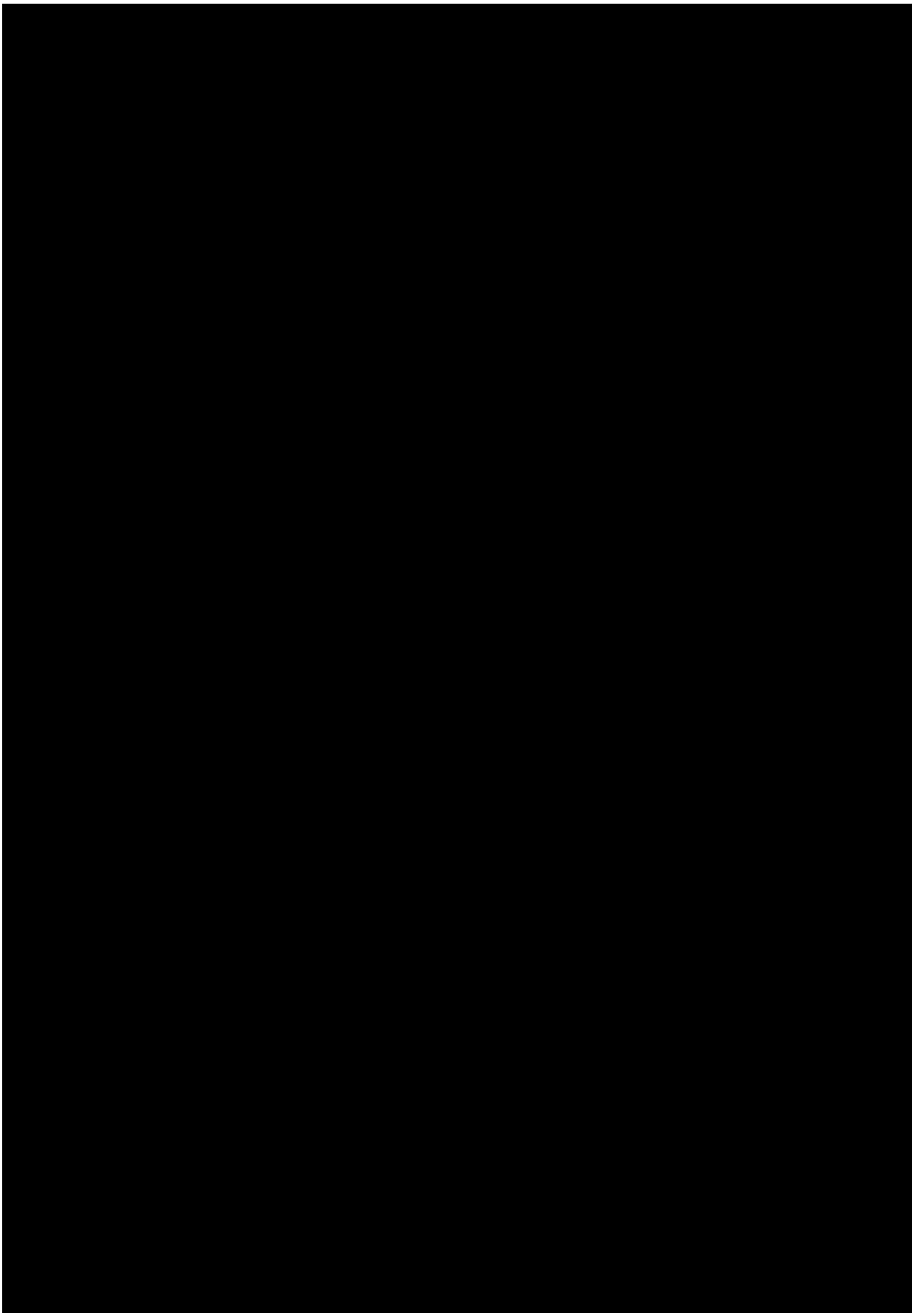


Patone et al., University of Oxford, 2021. Funding source: HDRUK.

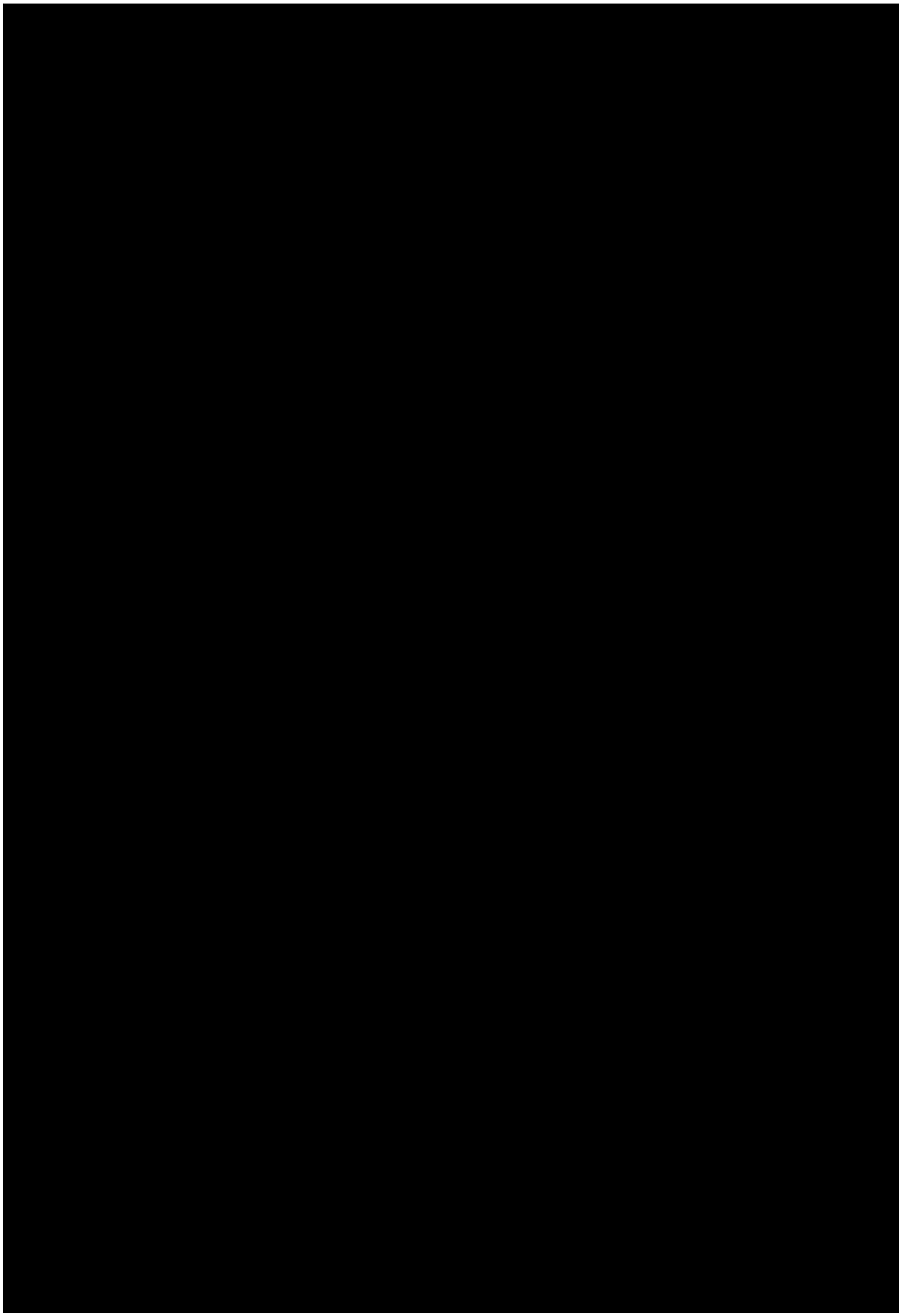
Tab 25

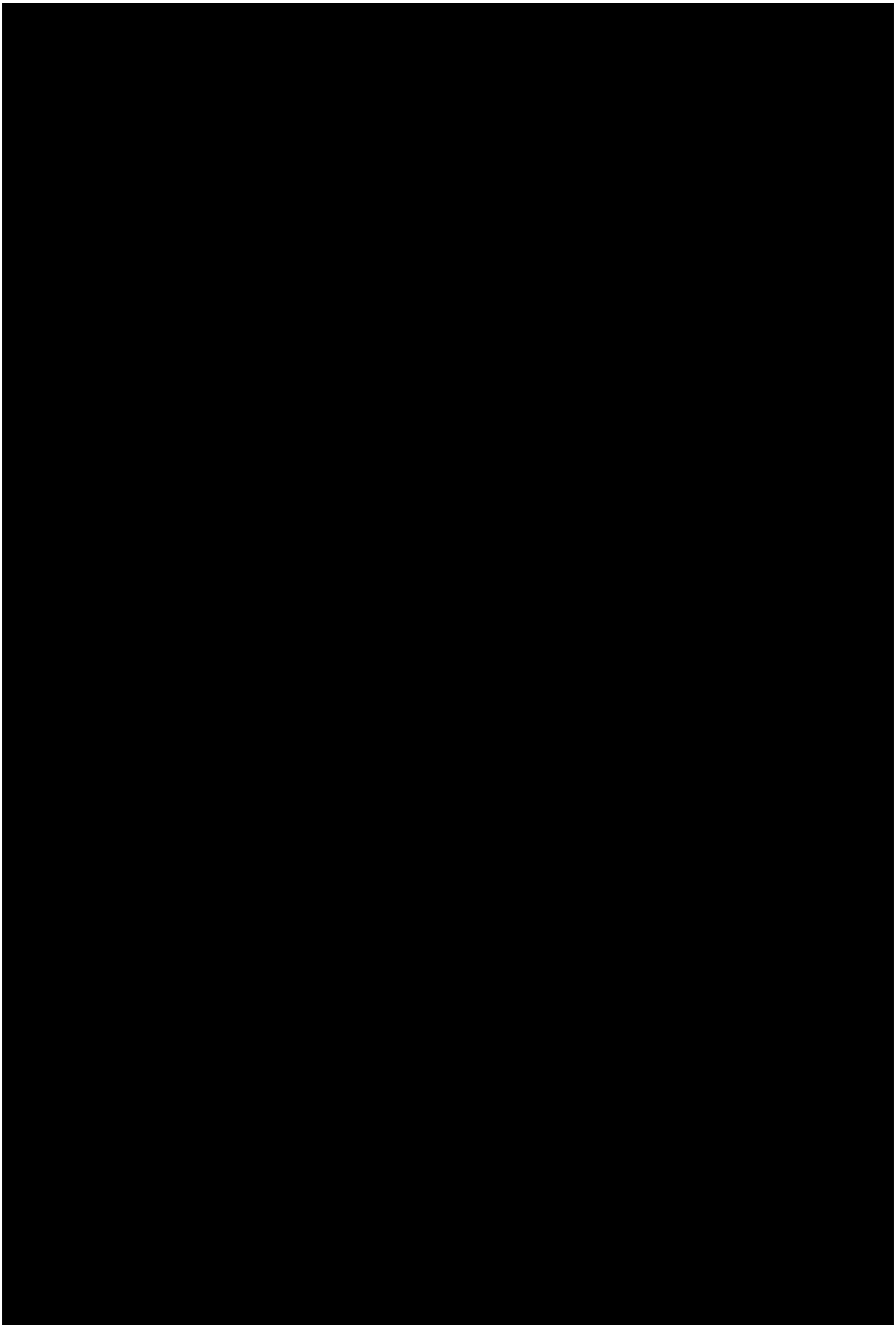


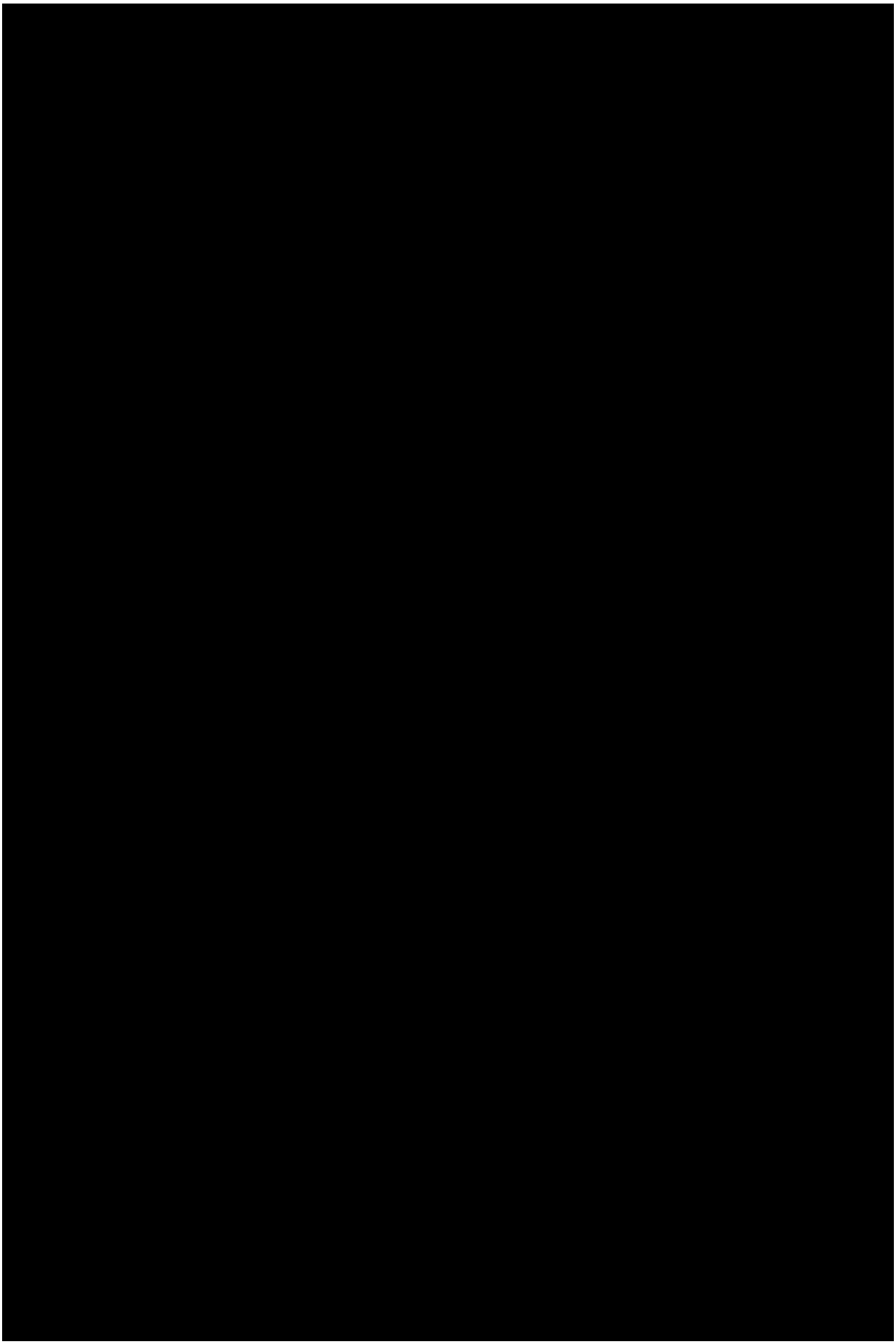




Tab 26







Tab 27

BANK OF CANADA
BANQUE DU CANADA

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Requisition Number: 7390
Position Type: Term
Position Length: 3 years (extension / permanent possible)
Location: Ottawa (Downtown), ON, CA
Remote Work: Hybrid Model (up to 50% telework)
Closing Date: March 8, 2022 23:59 EST

Diversity and Inclusion
We strive to make our policies, programs and workplace more inclusive, respectful and barrier-free. We encourage applications from women, Indigenous peoples, veterans, persons with disabilities, members of visible minorities and persons of all races, ethnic origins, religions, abilities, sexual orientations, and gender identities and expressions.

We make career growth and professional development a priority. We are committed to developing inclusive, barrier-free recruitment and selection processes, and a work environment that supports our diverse workforce.

Let our team know if you need accommodation or support during the recruitment process due to a disability or other reason. We can provide support in multiple ways, from using this site and submitting your application, right through to the interview process. If you are the successful candidate, you can also

discuss accommodation needs when you receive your offer.

Contact accessiblecareers@bankofcanada.ca to discuss how.

Senior Data Management Specialist

Take a central role

The Bank of Canada has a vision to be “a leading central bank—dynamic, engaged and trusted—committed to a better Canada.” No other employer in the country offers you the unique opportunity to work at the very center of Canada’s economy, in a diverse and inclusive organization with significant impact on the economic and financial well-being of all Canadians. You will be challenged, energized and motivated to excel in an environment where we are reinventing central banking, renewing ways of doing business and reinforcing a culture of innovation.

Find out more about the next steps in our Recruitment process.

What’s new

In the next Strategic Plan, the Information, Data and Analytics Services (IDAS) is leading the replacement of FAME and transitioning from the DACS, AE’s critical data platform, to the Data Lake. The Senior Data Management Specialist will be participating in those initiatives, gathering technical requirements, designing solutions, leading the implementation, and providing recommendations.

What you will do

As the Senior Data Management Specialist, you will be responsible for the the design, development, testing, deployment and operationalization of new data pipelines and enhancements to existing pipelines. You will provide direction and guidance to IDAS-Data Management (IDAS-DM) team on pipeline development and all technical and coding aspects. You will also gather, determine, and identify high-level functional and technical requirements by collaborating with the user community and stakeholders, and possessing knowledge of enterprise architecture.

In addition, you will:

- design solutions to support the requirements, as well as provide for present and future cross-functional requirements while following technology and data lifecycle
- interact with project management and/or stakeholders to plan project schedules and technical direction
- provide quality assurance review by reviewing all code work for accuracy and functionality, as well as ensuring data pipelines follow coding standards and best practices
- build re-usable framework, libraries, and recipes to facilitate data onboarding, pipeline development and data quality checks
- identify opportunities to improve the functioning of the business and the delivery of business services
- document and demonstrate solutions by developing documentation, flowcharts, layouts, diagrams, charts, code comments and clear code, which will also be used for testing and debugging purposes

What you need to succeed

- solid knowledge of on-premise and cloud technologies, databases, and systems with strong aptitude for technology
- advanced knowledge of programming languages such as Python, SQL, R, Matlab, Stata
- good understanding of Web Services protocols such as REST, SOAP and API design for extensibility and portability
- experience writing SQL queries for SQL Server or another Relational Database
- ability to use version control software such as GIT
- knowledge of data management principles and best practices
- ability to manage multiple projects and meet deadlines.

Nice-to-have

- Knowledge of macro-economic concepts and the role of central banking

Your education and experience

The position requires a Bachelor's degree in a related field (computer science, computer engineering, information technology, etc.) and a minimum of five years of relevant work experience or an equivalent combination of education and experience may be considered, and:

- Operating in an Agile Scrum environment
- Working in a continuous improvement environment where changes are encouraged, and priorities shift often.

What you need to know

- Language requirement: English and French essential (bilingual) with a minimum starting level of functional (level 4) in second official language. Training may be provided to help reach the required level of fully functional (level 5) in second official language.
- Priority will be given to Canadian citizens and permanent residents
- Security level required: Reliability
- Please save a copy of the job poster. Once the closing date has passed, it will no longer be available.
- In response to the COVID-19 pandemic and further to public health guidelines, preventative measures are being taken to ensure health and safety during the recruitment process. All interviews are conducted virtually.

Hybrid Work Model

The Bank is moving towards a hybrid working model which allows employees to telework up to 50 percent of the time, balanced over a two-week period. Relocation assistance may be offered by the Bank for terms greater than 2 years.

Vaccination Policy

In response to the COVID-19 pandemic that was declared by the World Health Organization, the mandates issued by the federal government, and the direction provided by public health authorities, the Bank of Canada requires all new employees to be fully vaccinated prior to their start date.

Selected candidates will be asked to provide proof of vaccination status at the reference stage. Candidates who are unable to be vaccinated against COVID-19 and require an accommodation for a legitimate medical, religious or other human rights-based grounds will follow a sperate process.

Covid-19 Authorized Vaccines in Canada

We wish to thank all applicants for their interest and effort in applying for this position. Only candidates selected for interviews will be contacted.

What you can expect from us

This is a great opportunity to join a leading organization and be part of a high-performing team. We offer a competitive compensation and benefits package designed to meet your needs at every stage of your life and career. For more information on key benefits please visit A great deal to consider.

- Salaries are based on qualifications and experience and typically range from $81,865 to $96,310 (job grade 16)
- Depending on performance, you may be eligible for performance pay for successfully meeting (5 to 7% of your base salary) or for exceeding expectations (10% of your base salary). Exceptional performers who far exceed expectations may be eligible for higher performance pay.
- Flexible and comprehensive benefits so you can choose the level of health and dental coverage that meets your needs
- Extra vacation days (up to five each year) that you can purchase to add to your vacation entitlement
- Option to join the indexed, defined-benefit pension plan after 24 consecutive months of service #LI-POST

Apply now »

Gmail

Tab 28

[redacted]

Recap of Nov. 18 meeting re: request for accommodation, COVID-19 vaccination policy

Joseph Hickey [redacted] Mon, Nov 22, 2021 at 3:38 PM
To: [redacted]@bank-banque-canada.ca

Dear [redacted]

I'm following up on our meeting of Nov. 18 that took place on Microsoft Teams, regarding the Bank's decision on my request for an accommodation with respect to the Bank's COVID-19 vaccination policy. I will respond to your email of Nov. 19 separately. You have asked for my personal email address – please use [redacted] to contact me going forward.

I would like to recap a few of the points from our meeting of Nov. 18, as follows:

- In our meeting, you informed me that my request for an accommodation for medical, religious, and human rights (age and sex) reasons was reviewed by third party experts (individuals external to the Bank) and that based on their recommendations, the Bank has decided not to grant me an accommodation.

- You informed me that medical aspects of my request for accommodation were reviewed by individuals working for the firm Raymond Chabot Grant Thornton, and that the religious and human rights (age and sex) aspects of my request were reviewed by an internal committee at the Bank as well as by individuals external to the Bank.

- You informed me that I may request additional information from all the third party individuals and the Bank's internal committee about their reviews of my request for accommodation.

- You informed me that there is an internal process to appeal the Bank's decision to deny my request for accommodation. You informed me that this internal process requires me to make a submission to Raymond Chabot Grant Thornton by way of a dedicated email address and to the Bank's internal committee by way of an email to you.

- You informed me that the Bank was mandated by the Federal Government to create a vaccination policy requiring all employees to be vaccinated, except for cases in which specific employees cannot be vaccinated, in which cases those employees must be accommodated under human rights legislation. You told me that even though Crown corporations have their own regulations and laws, the Bank is bound by the Federal Government's mandate to create and apply this (the Bank's) vaccination policy.

- You informed me that the Bank will follow further direction from the Federal Government (expected in 4-6 months) regarding what to do about the status of employees on unpaid leave under the vaccination policy, such as terminating these employees, returning them to work, or prolonging their period of leave.

- You informed me that the Bank's vaccination policy makes no distinction based on where the employee works, whether on-site at a Bank workplace, from the employee's home, or elsewhere. For employees that are on 100% telework (i.e. working from home 100% of the time and not required to be physically on-site at a Bank workplace), you told me that the reason the policy requires these employees to be vaccinated is that the policy includes the objective of protecting the Canadian population as a whole, not only Bank employees and others who are physically present in the Bank's workplaces. You told me that the Bank's policy has this objective because protecting the health of all Canadians is part of the mandate given to the Bank (and other Crown corporations) by the Federal Government.

- You told me that the Bank constructed its vaccination policy to align with the policies of other Crown corporations, and that, in developing its policy, the Bank followed guidelines provided by the Federal Government that are similar to the guidelines the Treasury Board used to construct its vaccination policy.

Please let me know if any of the above is incorrect.

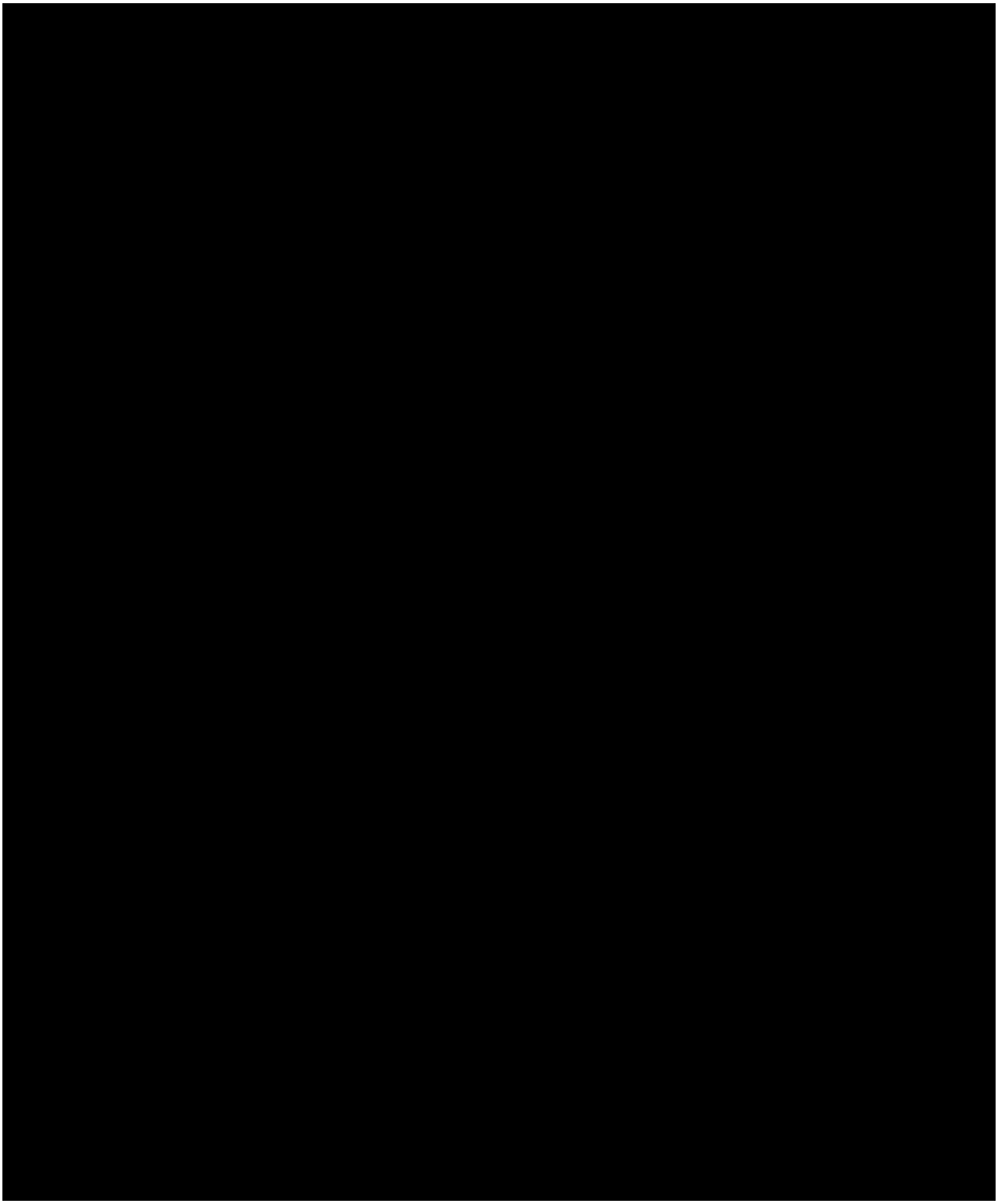
I also note that it has been announced (via an "Info Bytes" memo to employees dated Nov. 2, 2021) that many employees at the Bank, including my departmental colleagues, will not be required to physically come on-site to a Bank workplace until Feb. 7, 2022, at the earliest. I assume that the reason I am not being permitted to continue working from home until at least that date (Feb. 7, 2022) is because the Bank's policy has the objective of protecting the health of all Canadians,

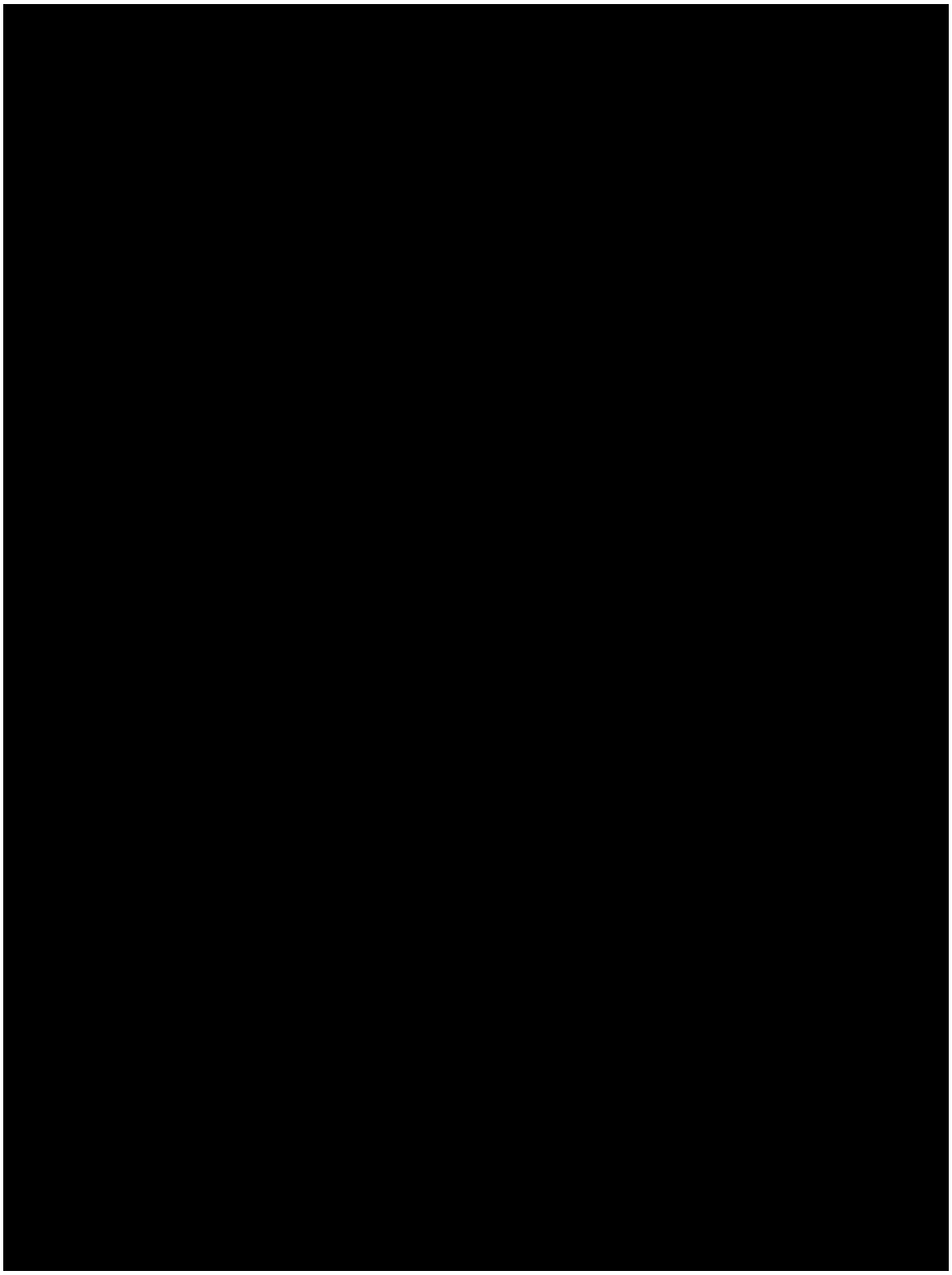
not only individuals physically present in Bank workplaces. Please let me know if this is incorrect.

Sincerely,
Joseph

--
Joseph Hickey, PhD
[redacted]

Tab 29





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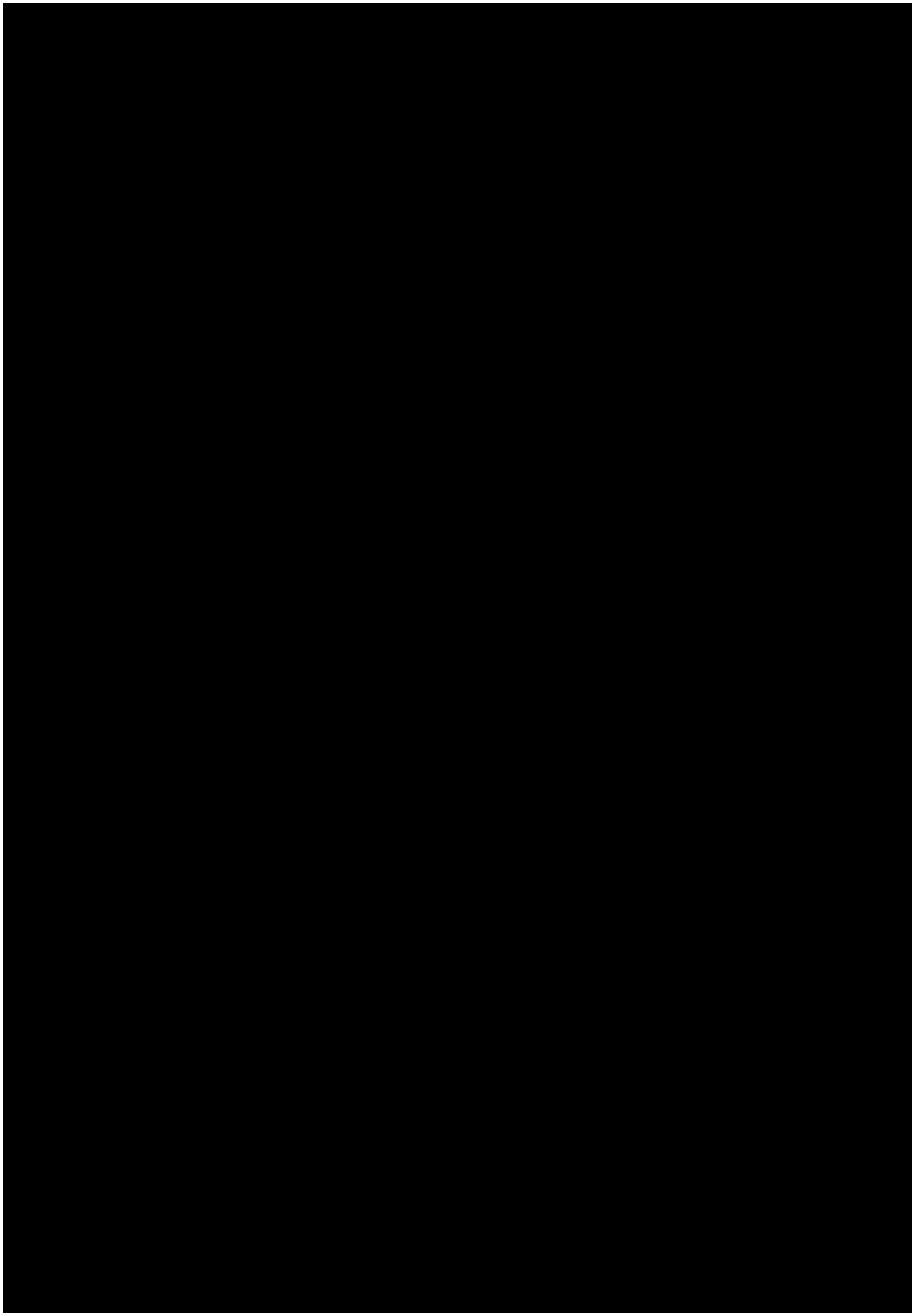

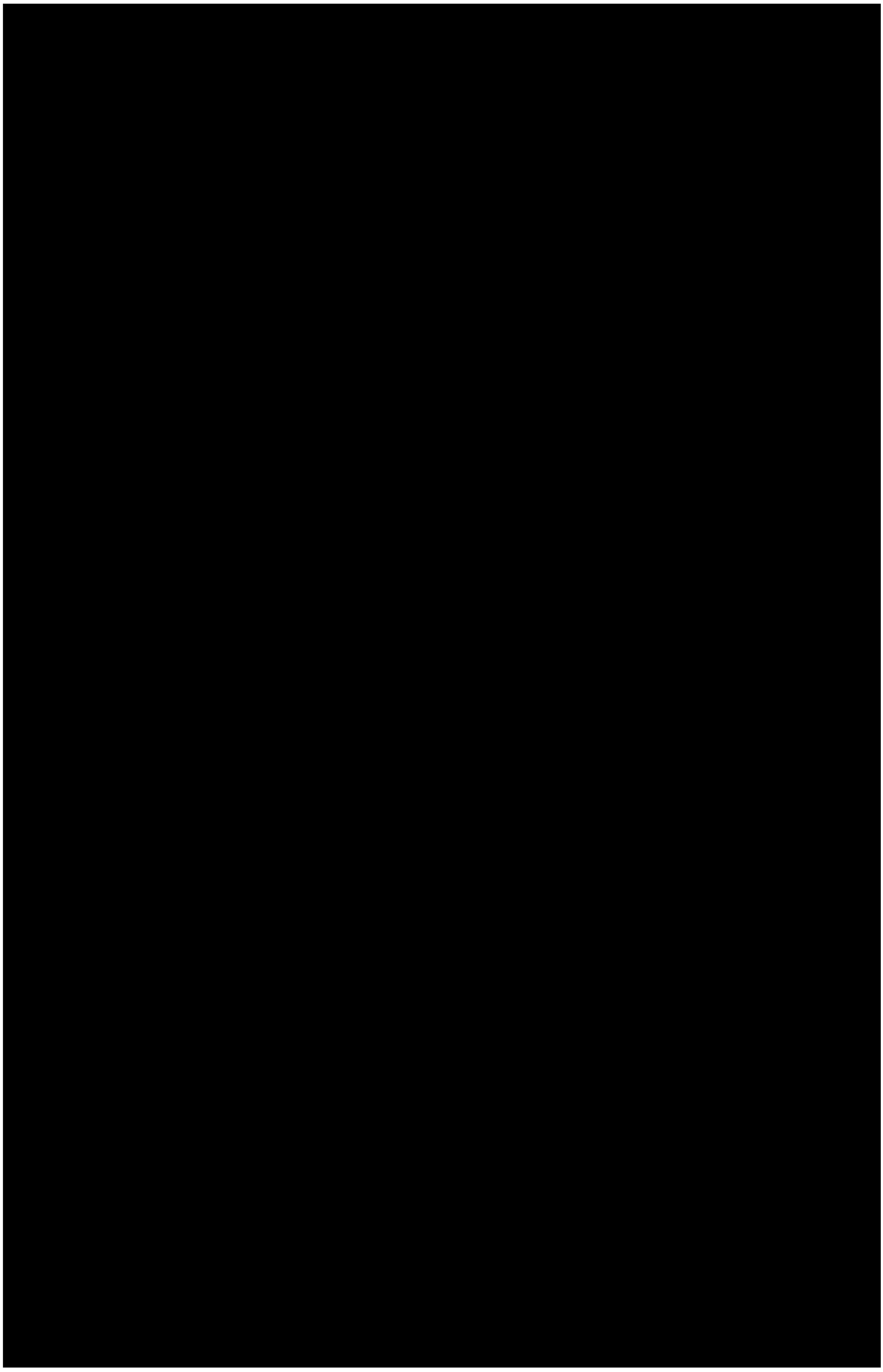

Tab 31

From: Shannon Worek
Sent: Wed, 22 Dec 2021 14:52:15 +0000
To: Shelby Croghan
Subject: FW: Letter for your action // Lettre pour votre action
Attachments: BOC - Letter to Crown Corp.pdf

Category/Catégorie: Non-Sensitive/Non-Délicat

From: Gillian Brouse <gbrouse@bank-banque-canada.ca>
Sent: October 29, 2021 12:12 PM
To: Shannon Worek <sworek@bank-banque-canada.ca>
Subject: FW: Letter for your action // Lettre pour votre action

Category/Catégorie: Non-Sensitive/Non-Délicat

See attached and let's make sure we have some placeholding text in AR for vaccination status/implementation of the policy.

From: Alexis Corbett <alexiscorbett@bank-banque-canada.ca>
Sent: October 29, 2021 10:09 AM
To: Gillian Brouse <gbrouse@bank-banque-canada.ca>; Sylvie Latulippe <SLatulippe@bank-banque-canada.ca>; Katherine Murray <katherinemurray@bank-banque-canada.ca>; Matthew Meagher <mmeagher@bank-banque-canada.ca>
Subject: FW: Letter for your action // Lettre pour votre action

Category/Catégorie: Non-Sensitive/Non-Délicat

FYI we will be asked to feed into this response to demonstrate how we are complying.

Alexis Corbett
Managing Director and Chief Human Resources Officer | Directrice générale et chef des ressources humaines
Human Resources| Ressources humaines
☎ 613.782.8690

From: Tiff Macklem <TMacklem@bank-banque-canada.ca>
Sent: October 29, 2021 9:31 AM
To: Jeremy Farr <jfarr@bank-banque-canada.ca>; Alexis Corbett <alexiscorbett@bank-banque-canada.ca>

Cc: Filipe Dinis <fdinis@bank-banque-canada.ca>; Jill Vardy <JVardy@bank-banque-canada.ca>
Subject: Fwd: Letter for your action // Lettre pour votre action

Category/Catégorie: Non-Sensitive/Non-Délicat

Jeremy

Please draft a letter in response to this one from DPM with input from Alexis and her team.

Thanks. Tiff.

From: Lamarche, Mackenzie <Mackenzie.Lamarche@fin.gc.ca> on behalf of Wright, Janelle <Janelle.Wright@fin.gc.ca>
Sent: Friday, October 29, 2021 9:13:23 AM
To: Tiff Macklem <TMacklem@bank-banque-canada.ca>
Subject: {External} Letter for your action // Lettre pour votre action

(la version française suit)

Good morning,

On behalf of the Honourable Chrystia Freeland, Deputy Prime Minister and Minister of Finance Canada, please find attached a letter for your action.

Should you have any questions, do not hesitate to reach out.

Thank you,

Bonjour,

Au nom de l'honorable Chrystia Freeland, vice-première ministre et ministre des Finances Canada, veuillez trouver ci-joint une lettre pour votre action.

Si vous avez des questions, n'hésitez pas à nous contacter.

Merci,

Janelle Wright
Assistant Deputy Minister | Sous-ministre adjoint

Corporate Services Branch | Direction des services ministériels
Department of Finance Canada | Ministère des Finances Canada
Ottawa, Canada K1A 0G5

Deputy Prime Minister
and Minister of Finance

Vice-première ministre
et ministre des Finances

Ottawa, Canada K1A 0A2

2021FIN508389

Tiff Macklem
Bank of Canada
234 Wellington Street
Ottawa (Ontario) K1A 0G9

Dear Mr. Macklem,

Public health authorities continue to advise that combined with the existing safety measures, vaccination is the most effective tool to reduce the risk of COVID-19 for Canadians.

The new *Policy on COVID-19 Vaccination for the Core Public Administration, Including the Royal Canadian Mounted Police* stipulates that all employees must be vaccinated. As announced on October 6, 2021, the Government of Canada expects all other federal institutions outside the core public administration, including Crown corporations, to align with the policy.

The Bank of Canada (BOC) is expected to ensure that its vaccination requirements (and those of any wholly-owned subsidiaries) are fully aligned with the requirements of the policy by November 30, 2021. Specifically, this includes, but is not limited to, ensuring that employees attest to their vaccination status no later than November 30, 2021. Compliance measures, including leave without pay, should be underway by as early as December 15, 2021. It is further expected that you parallel the policy by developing monitoring, verification, and assurance frameworks, within the governance appropriate to your organization. To ensure this deadline is met, I encourage you to engage with relevant bargaining agents where collective agreements should be considered. Where the policy refers to processes that do not apply to your organization, you may wish to adopt public service guidance and processes, or to adapt existing ones in keeping with your obligations under the *Privacy Act*.

Vaccination requirements should apply to all employees, officers, and directors. Crown corporations are also expected to implement the vaccination requirements that apply to Governor in Council (GIC) appointees affiliated with their corporation, including members and chairs of their governing boards and Chief Executive Officers. The *Terms and conditions applying to Governor in Council appointees* will require GIC appointees to be fully vaccinated subject to applicable exceptions and to comply with all oversight, information requirements, compliance, and reporting measures put in place by Crown corporations. More information for GIC appointees is available from the Senior Personnel Secretariat at the Privy Council Office (PCO-SPS).

The BOC is asked to report to Janelle Wright, Assistant Deputy Minister of the Corporate Services Branch at the Department of Finance Canada, on the implementation of your

vaccination strategy in a format to be determined in consultation with my officials. The BOC will also be asked to report to PCO-SPS with respect to the GiC appointee population, specifically. The format and scope of this reporting will be communicated by PCO-SPS. The BOC is also expected to report on implementation status through the usual reporting instruments, including your annual report and corporate plan (where relevant).

Thank you in advance for paying close personal attention to the material attached and for taking the necessary measures for the BOC to align with the policy.

Should you have any questions, my officials would be pleased to assist you. Please contact Janelle Wright (janelle.wright@fin.gc.ca).

I am confident that, with your support, we will reach the overall levels of vaccination Canada needs to sustain a resilient economic recovery, and to protect the health and safety of employees working in the federal sphere and the communities where they live and work.

Yours sincerely,

The Honourable Chrystia Freeland, P.C., M.P.

Deputy Prime Minister
and Minister of Finance

Vice-première ministre
et ministre des Finances

Ottawa, Canada K1A 0A2

2021FIN508389

Tiff Macklem
Banque du Canada
234, rue Wellington
Ottawa (Ontario) K1A 0G9

Cher Monsieur,

Les autorités de la santé publique continuent d'indiquer que, combiné aux mesures de sécurité existantes, la vaccination est l'outil le plus efficace pour réduire le risque de COVID-19 pour les Canadiens.

La nouvelle *Politique sur la vaccination contre la COVID-19 applicable à l'administration publique centrale, y compris à la Gendarmerie royale du Canada* stipule que tous les employés doivent être vaccinés. Comme il a été annoncé le 6 octobre 2021, le gouvernement du Canada s'attend à ce que toutes les autres institutions fédérales à l'extérieur de l'administration publique centrale, y compris les sociétés d'État, respectent la politique.

La Banque du Canada, devrait s'assurer que ses exigences en matière de vaccination (et celles de toute filiale en propriété exclusive) s'harmonisent entièrement avec les exigences de la politique d'ici le 30 novembre 2021. Plus précisément, il s'agit notamment de s'assurer que les employés attestent de leur statut vaccinal au plus tard le 30 novembre 2021. Les mesures de conformité, dont les congés sans solde, devraient être en cours dès le 15 décembre 2021. On s'attend également à ce que vous mettiez en place, parallèlement à la politique, des cadres de surveillance, de vérification et d'assurance dans le respect de la structure de gouvernance adaptée à votre organisation. Pour vous assurer que ce délai est respecté, je vous invite à communiquer avec les agents négociateurs compétents dans les cas où il faut tenir compte des conventions collectives. Lorsque la politique fait référence à des processus qui ne s'appliquent pas à votre organisation, vous pouvez choisir d'adopter des lignes directrices et des processus de la fonction publique ou d'adapter ceux qui existent déjà dans le respect de vos obligations en vertu de la *Loi sur la protection des renseignements personnels*.

Les exigences de vaccination devraient s'appliquer à tous les employés, dirigeants et administrateurs. Les sociétés d'État doivent également mettre en oeuvre les exigences de vaccination applicables aux personnes nommées par le gouverneur en conseil qui relèvent de leur société, notamment les membres et les présidents des conseils d'administration ainsi que leurs premiers dirigeants. Les *modalités applicables aux personnes nommées par le gouverneur en conseil* exigeront de celles-ci qu'elles soient entièrement vaccinées, sous réserve des exceptions applicables, et qu'elles se conforment à toutes les mesures de surveillance, d'information, de conformité et de déclaration mises en place par les sociétés d'État auxquelles elles sont

nommées. De plus amples renseignements sur les personnes nommées par le gouverneur en conseil sont disponibles auprès du Secrétariat du personnel supérieur du Bureau du Conseil privé (SPS-BCP).

La Banque du Canada est invité à faire rapport à Janelle Wright, Sous-ministre adjointe de la Direction des services ministériels au ministère des Finances Canada, sur la mise en oeuvre de sa stratégie de vaccination dans un format à déterminer en consultation avec mes fonctionnaires. La Banque du Canada sera également invité à faire rapport au SPS-BCP en ce qui a trait particulièrement aux personnes nommées par le gouverneur en conseil. Le format et la portée de ce rapport seront communiqués par le SPS-BCP. La Banque du Canada doit également faire rapport de l'état d'avancement de la mise en oeuvre au moyen des instruments de déclaration habituels, y compris son rapport annuel et son plan intégré (le cas échéant).

Je vous remercie à l'avance d'avoir prêté une attention particulière aux documents ci-joints et de prendre les mesures nécessaires pour que la Banque du Canada, respecte la politique.

Si vous avez des questions, mes fonctionnaires seraient heureux de vous venir en aide. Veuillez communiquer avec Janelle Wright (janelle.wright@fin.gc.ca).

Je suis convaincu qu'avec votre appui, nous atteindrons les niveaux globaux de vaccination dont le Canada a besoin pour soutenir une reprise économique résiliente et protéger la santé et la sécurité des employés travaillant dans la sphère fédérale et dans les collectivités où ils vivent et travaillent.

Je vous prie d'accepter l'expression de mes sentiments distingués.

L'honorable Chrystia Freeland, P.C., députée

From: Wright, Janelle
Sent: Wed, 3 Nov 2021 21:27:25 +0000
To: Matthew Meagher
Cc: Katherine Murray;Ievers, Erin
Subject: {External} RE: Bank of Canada Reporting on Vaccination Policies

Hi Matt.

Many thanks for the initial update. To date, I have not been provided with any additional information on reporting, nor a template. This said, you are not the first organization to make this request, so will circle back to see if I can find additional information.

In the interim, I have taken note of the Bank's policy and your status update. I will ensure this information is relayed back to the Minister's Office.

Janelle

From: Matthew Meagher <mmeagher@bank-banque-canada.ca>
Sent: Tuesday, November 2, 2021 5:29 PM
To: Wright, Janelle <Janelle.Wright@fin.gc.ca>
Cc: Katherine Murray <katherinemurray@bank-banque-canada.ca>
Subject: Bank of Canada Reporting on Vaccination Policies

Category/Catégorie: Protected A/Protégé A

Dear Ms. Wright,

I am writing with respect to the October 29 letter to the Bank of Canada from Deputy Prime Minister Freeland, which indicated that Crown corporations will be required to report to you on the implementation of their Covid-19 vaccination policies.

The Bank has already implemented its mandatory vaccination policy for employees, directors and officers. Attestations of vaccination status were required to be submitted prior to November 1, and those individuals who are not fully vaccinated and who do not qualify for an exemption under human rights legislation will be placed on leave without pay effective November 22. The Bank has engaged a third party service provider to conduct audits of all attestations that were submitted.

If you are ready to do so, I would appreciate it if you would be able to provide us with guidance in terms of the format and content of the reports that you are looking to receive. We'd also be interested in any

guidance that you might be able to provide on the reports for directors, if you have that available. Whatever information you can provide would be much appreciated.

Thank you very much.

Matt

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Government of Canada | Gouvernement du Canada

Tab 32

Government of Canada will require employees in all federally regulated workplaces to be vaccinated against COVID-19

From: Employment and Social Development Canada

News release

December 7, 2021 Gatineau, Quebec Employment and Social Development Canada

Vaccination is the best line of defense against COVID-19. It not only protects those who are vaccinated, but it protects vulnerable populations like young children who aren't yet able to get vaccinated. To finish the fight against COVID-19, protect workers and their families, and ensure businesses can get back up to speed, we need to do everything we can to keep public spaces safe, particularly as we continue to face new variants.

Today the Minister of Labour, Seamus O'Regan Jr., announced that the Government of Canada will propose regulations under Part II of the *Canada Labour Code* to make vaccination mandatory in federally regulated workplaces. These regulations would complement existing occupational health and safety measures, such as masking, handwashing, and physical distancing, and provide further protection against the risk of COVID-19 transmission in the

workplace. The Government will consult with key stakeholders, including representatives of small and medium-sized employers, as it works expeditiously to finalize the new regulations, which would come into force in early 2022.

The Government will also develop resources to help federally regulated workplaces implement the COVID 19 vaccination requirements in consultation with their workplace health and safety committees or representatives.

Mandatory vaccination requirements are already in place for the public sector, employees working in the federally regulated air, rail, and marine transportation sectors, and travelers on these modes of transportation. The new regulations would ensure that employees in all other federally regulated industries, such as road transportation, telecommunications, and banking, are also vaccinated. Many employers in these and other industries have already made vaccination mandatory for their employees. By doing so, employers and employees are helping to limit the spread of COVID-19 in their workplaces and their communities.

Quotes

> “Canada has led the world on vaccination rates, thanks to Canadians, their belief in science, and their willingness to roll up their sleeves. Making vaccination mandatory across all federally regulated workplaces will protect workers, their families, and their communities. It will help us finish the fight against COVID-19 and help us sustain a strong and stable economic recovery.”
>
> – Minister of Labour, Seamus O’Regan Jr.

> "Vaccinations are one of the strongest tools we have in the fight against COVID-19 and in keeping Canadians safe and healthy. Through these requirements we help add an extra layer of protection in federally regulated workplaces. I encourage Canadians who have not yet received a vaccine to book their shot today."
>
> – Minister of Health, Jean-Yves Duclos

Quick facts

- The federally regulated sector is comprised of workplaces from a broad range of industries, including interprovincial air, rail, road, and marine transportation, pipelines, banks, postal and courier services, among others.
- There are approximately 18,500 employers in federally regulated industries, including federal Crown corporations, which together employ 955,000 people (about 6% of all employees in Canada). The vast majority (87%) of these people work in companies with 100 or more employees. These figures exclude the federal public service. Including the federal public service, there are approximately 19,000 employers and 1,300,000 employees (about 8.5% of all employees in Canada).
- All federal public servants in the Core Public Administration (CPA), including members and reservists of the Royal Canadian Mounted Police (RCMP) must be vaccinated against COVID-19. This requirement applies whether employees are teleworking, working remotely or working on site. More than 95% of employees have attested to being fully vaccinated and approximately 98% have had at least one dose.

- Employers who do not comply with their obligations under the *Canada Labour Code* may be subject to compliance and enforcement measures, including administrative monetary penalties.
- In recognition of Indigenous peoples' right to self-determination and self-government, Indigenous Governing Bodies and First Nation Band Councils will be exempted from the new requirements. The Government of Canada will work with Indigenous partners to provide information on the new measures should they wish to follow the same approach, however, doing so will be at their discretion. This is also in line with the Government's commitment to implement the United Nations Declaration on the Rights of Indigenous Peoples.
- A copy of the consultation paper may be requested from the Labour Program by email at EDSC.LAB.SST.POLITIQUES-LAB.OHS.POLICY.ESDC@hrsdc-rhdcc.gc.ca.

Associated links

- Prime Minister announces mandatory vaccination for the federal workforce and federally regulated transportation sectors
- Mandatory COVID-19 vaccination requirements for federally regulated transportation employees and travellers
- List of federally regulated industries and workplaces

Contacts

For media enquiries, please contact:

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Date modified:
2021-12-07

Gmail

Tab 33

[redacted]

Your Bank of Canada ATIP Request [redacted] - Final release

[redacted]r@bank-banque-canada.ca> Wed, Mar 9, 2022 at 5:56 PM
To: Joseph Hickey [redacted]

Category/Catégorie: Protected A/Protégé A

Good evening Mr. Hickey,

Please find attached the final release of records related to your request [redacted]. With the partial release of records provided to you on Feb. 23, 2022, this represents all of the remaining records relevant to this request.

With regards to your inquiry below, we have performed a thorough search for records and you are being provided with everything that is relevant based on the text of your request. Please be advised, should you wish to submit another Access to Information request using different parameters, we would be happy to assist you again.

Regards,

[redacted]

[redacted]

Analyst | Analyste

Access to Information and Privacy Office |

Bureau d'access a l'information et protection des renseignments personnels

BANK OF CANADA
BANQUE DU CANADA

From: Joseph Hickey [redacted]
Sent: March 8, 2022 1:37 PM
To: [redacted]@bank-banque-canada.ca>
Subject: {External} Re: Your Bank of Canada ATIP Request [redacted] - Partial Release

Dear [redacted]

I have reviewed the documents you sent me in the partial response with cover letter dated Feb. 22, 2022.

I note that none of the documents in the partial response are dated prior to Oct. 29, 2021. However, the Bank announced and communicated its mandatory vaccination policy to staff on Oct. 6, 2021.

I would like to emphasize that, since the goal of my access request is to find the communications that would specify the nature of the government's directive or request to the Bank of Canada to develop a vaccination policy and what the government expects the Bank's policy to establish, my access request should definitely turn up records dated prior to Oct. 6, 2021.

Could you let me know if any of the remaining records that I have not yet received are dated prior to Oct. 6, 2021?

Sincerely,
Joseph

--

Joseph Hickey, PhD

[redacted]

[redacted]

On Wed, Feb 23, 2022 at 10:05 AM [redacted]@bank-banque-canada.ca> wrote:

> Category/Catégorie: Protected A/Protégé A
>
> Good morning Mr. Hickey,
>
> As promised, please find attached the partial release of records related to your request [redacted]. We will continuing processing the remaining records and will get back to you as soon as possible.
>
> [redacted]
>
> [redacted]
>
> Analyst | Analyste
>
> **Access to Information and Privacy Office |**
>
> **Bureau d'access a l'information et protection des renseignments personnels**
>
> BANK OF CANADA
> BANQUE DU CANADA

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La version française suit le texte anglais.

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La version française suit le texte anglais.

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2 attachments

Final Response Letter - [redacted] - final release.pdf
179K

[redacted] Records.pdf
14796K

Government of Canada Gouvernement du Canada

Tab 34

Government of Canada to require vaccination of federal workforce and federally regulated transportation sector

From: Treasury Board of Canada Secretariat

News release

August 13, 2021 – Ottawa, Ontario – Treasury Board of Canada Secretariat

Vaccination is the most effective tool to reduce the risk of COVID-19 for Canadians and to protect broader public health. It is our most important instrument and so we continue to take action to get as many Canadians vaccinated as possible.

The Government of Canada today announced its intent to require vaccination as early as the end of September across the federal public service. Vaccinations are our best line of defence and for those few who are unable to be vaccinated, accommodation or alternative measures, such as testing and screening, may be determined in each situation, to protect broader public health by reducing the risk of COVID-19.

As the country's largest employer, the Government of Canada is committed to playing a leadership role by further protecting the health and safety of public servants and the communities where they live and work across Canada and around the world.

In addition, as soon as possible in the fall and no later than the end of October, the Government of Canada will require employees in the federally regulated air, rail, and marine transportation sectors to be vaccinated. The vaccination requirement will also extend to certain travellers. This includes all commercial air travellers, passengers on interprovincial trains, and passengers on large marine vessels with overnight accommodations, such as cruise ships.

The government will engage with key stakeholders, including bargaining agents and transportation sector operators, as we plan for the implementation of these initiatives. Details will be communicated as the work unfolds. The process will include determining how this requirement will be implemented, through confirmation of COVID-19 vaccination and other means of protection, such as testing when necessary.

Further, the Government of Canada expects that Crown corporations and other employers in the federally regulated sector will also require vaccination for their employees. The government will work with these employers to ensure this result.

Today’s announcement comes in recognition of the dynamic public health situation in Canada. Since the start of the vaccination campaign in mid-December, less than 1% of COVID 19 cases have been among those who were fully protected by the vaccine. These measures will contribute to reaching the overall levels of vaccination Canada needs to sustain a resilient economic recovery in the face of more transmissible and dangerous COVID-19 variants of concern. More than 71% of eligible people in Canada are fully vaccinated, and more than 82% have had their first shot. However, more than 6 million eligible people in Canada are still unvaccinated. We are urging all of you to get out there and get vaccinated now. Doing so will help keep our communities safe.

The Government of Canada is also calling on all organizations beyond the federally regulated sector to put in place their own vaccination strategies, drawing on the advice and guidance available from public health authorities and the Canadian Centre for Occupational Health and Safety.

Quotes

"We know vaccinations are the best way to help protect our fellow Canadians from COVID 19 variants of concern. We are encouraged by the many federal employees who have already been vaccinated and hope that vaccination rates will continue to climb as the Government of Canada moves ahead on its vaccination strategy."

The Honourable Dominic LeBlanc, President of the Queen's Privy Council for Canada and Minister of Intergovernmental Affairs

"Driving vaccine uptake in Canada to as high a level as possible is one of the most effective, and least disruptive, means at our disposal to sustain the gains we have made in recent months, and ensure that we continue on our path to economic recovery, and a healthier and more equitable future. With this announcement, we are doing more to protect the health and safety of Canadians and reduce the risk of COVID 19."

The Honourable Jean Yves Duclos, President of the Treasury Board

"There are enough doses in Canada for every person to be fully vaccinated across the country. By getting vaccinated, you are protecting yourself, your family and your community. By being fully vaccinated, you are also protecting the safety of your workplaces. If you haven't been vaccinated yet, please make a plan to do so."

– *The Honourable Patty Hajdu, Minister of Health*

The Government of Canada is leading by example in requiring vaccinations for public service employees, and we are asking all federally regulated employers to develop vaccine plans to ensure their employees and workplaces are safe. This is the right thing to do and will ensure Canada continues to build back better from the global COVID-19 pandemic."

– *The Honourable Omar Alghabra, Minister of Transport*

Quick facts

- The majority of public servants (173,358 [57.7%])* are located outside the National Capital Region. This includes the core public administration and separate agencies.

  **As of March 2020. The most recent numbers on the population of the public service by province can be found here: Population of the federal public service by province - Canada.ca.*

- There are approximately 18,500 employers in federally regulated industries, including federal Crown corporations, that together employ 955,000 employees (or 6.2% of the Canadian workforce), the vast majority (87%) of whom work in medium-size to large firms (in other

words those with 100 or more employees). These numbers exclude the federal public service. With the federal public service, there are approximately 19,000 employers and 1,235,000 employees (8% of all workers in Canada).

- The Treasury Board Secretariat is collecting data from federal departments and separate agencies regarding the number of confirmed COVID 19 cases among employees working remotely and on-site. As of July 29, 2021, 5,311 cases of COVID-19 have been reported in the federal public service. These figures represent cumulative and not active cases.

Associated links

- President of the Treasury Board urges all eligible federal public servants to get vaccinated against COVID-19
- COVID-19 vaccination coverage in Canada
- List of federally regulated industries and workplaces

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