Rapid appraisal of the usefulness of messenger RNA vaccines for sars-cov-2 Delta variant infections and implications for Alberta

Warren Kindzierski, PhD
Adjunct Professor, School of Public Health
University of Alberta
3-57B South Academic Building, Edmonton, AB T6G 2G7

27 September 2021

Table of Contents

Summary

1. Introduction
   1.1 Objective

2. Assumptions and limitations

3. Stated drug company objectives for mRNA vaccines in sars-cov-2 virus clinical trials

4. mRNA vaccine efficacy – relative risk reduction versus absolute risk reduction
   4.1 Relative risk reduction (RRR)
   4.2 Absolute risk reduction (ARR)
   4.3 Published RRR and ARR information for the Pfizer and Moderna vaccines

5. Government surveillance data and independent studies data on the Delta variant
   5.1 Recent government surveillance data for England
   5.2 Recent government surveillance data for Scotland
   5.3 Recent government surveillance data for Israel
   5.4 What is happening in the United States?

6. Discussion
   6.1 What do data presented here indicate about drug company objectives for mRNA vaccines?
   6.2 Are mRNA vaccines working for the Delta variant?
   6.3 Has the public been (purposely?) misinformed about vaccination benefits?
   6.4 What to do when the absolute risk reduction is small?
   6.5 Implications for Alberta

Biography

References

Summary

A rapid appraisal is presented here on the efficacy of messenger RNA (mRNA) vaccines for Delta variant infections and implications for Alberta. Government surveillance data and other data from independent studies in England, Scotland, and Israel were examined. These countries are further along in their Delta variant infection waves than Alberta.

The data presented show that fully-vaccinated people aged 60 years and over are being infected, hospitalized and dying from the Delta variant. mRNA vaccines and the mRNA-produced non-sterilizing antibodies do not appear to be working as originally intended for the Delta variant. Published absolute risk reduction – a measure of reduced risk of mild covid symptoms – from vaccination is small for a person of average health or better (≤1.1%) based on Pfizer and Moderna vaccine clinical trials.

As for people aged 60 or older who are of average health or better, or those who have been previously infected, the evidence is weak that they need to be vaccinated for covid in Alberta. Requiring proof of vaccination for people to enter certain businesses and to attend certain events is not supported by science as vaccinated people can be infected by the Delta variant and transmit it to others.

1. Introduction

A national newspaper – the Globe and Mail – reported that hospitals across Alberta are being pushed to the brink in view of the covid pandemic (1). As of September 6, 2021, greater than 97% of sars-cov-2 sequences based on RT-PCR tests were the Delta variant over the previous two weeks in Canada (2). The Delta variant is considered to cause more infections and spread faster than earlier forms of the virus that causes covid-19 (3). A majority of the Alberta population is vaccinated with mRNA – 73% of Albertans 12 years and older were fully-vaccinated as of September 22, 2021 (4).

Alberta declared a state of public health emergency with new restrictions effective September 16, 2021 (5). Using a carrot and stick analogy, their vaccination policy is quasi-voluntary with a number of carrots (incentives) (6) offered to encourage people to get vaccinated. Their stick involves mandating businesses participating in a *Restrictions Exemption Program* (7) to have patrons show proof of vaccination or a recent negative test result.

1.1 Objective of appraisal

Rapid appraisal is an approach for developing a preliminary, qualitative understanding of a situation (8). Because of the dominance of the Delta variant virus in the current covid infection wave in Alberta, a rapid appraisal is presented here on the efficacy of mRNA vaccines for Delta variant infections and implications for Alberta.

The following was examined in the appraisal:

- The objective of mRNA vaccines as identified in drug company clinical trials.
- Published measures of relative risk reduction (RRR) and absolute risk reduction (ARR) for the Pfizer and Moderna Phase III clinical trials. These measures were examined because many people misunderstand the concept of vaccine efficacy and what it means to them if they are vaccinated.
- Government surveillance data and other data on independent studies for Delta variant infections, complications requiring hospitalizations and deaths, where available. These data were from jurisdictions where Delta variant infections are well-established in their populations, more so than in Alberta (i.e., England, Scotland, and Israel). Also, data from several individual studies from United States are presented.

Where possible, the appraisal focused on data for mRNA vaccinated people aged 60 and older. This is a key demographic for covid infection-related complications. As people age, they become more susceptible to chronic and degenerative diseases (9). Also, their immune system undergoes functional and structural alterations (deterioration) that can lead to (10): decreased ability to fight infection, diminished response to vaccines, and increased susceptibility to immune system reactions against the body's own normal immune response components (autoimmunity) and chronic low-grade inflammation.

2. Assumptions and limitations

A number of assumptions and limitations are made in this appraisal:

1) RT-PCR test results presented here are assumed to be true positive cases of sars-cov-2 (covid) infection. The instability of RT-PCR testing is a known in that it can produce many false positive cases and it is not sensitive enough to detect some true positive cases (11,12). This is evidenced by the US Centers for Disease Control (CDC) stating in an earlier March 30, 2020 version of their *CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel* that a positive test result (13):

> "…*may not be indicative of the presence of an infectious virus or that sars-cov-2 is the causative agent for clinical symptoms…*" [and the test itself] "*…cannot rule out diseases caused by other bacterial or viral pathogens*".

2) Only symptomatic and asymptomatic cases of infections are discussed. These represent differences in infectivity of people carrying the covid virus. Symptomatic is being infectious, showing symptoms, and able to transmit the virus. Asymptomatic infections have the same infectivity as symptomatic infections (14). Asymptomatic is being infectious, showing no symptoms, and able to transmit the virus. Other case symptoms – pre-symptomatic (15) and post-symptomatic (16) – are not discussed.

3) Data presented for health complications – specifically complications leading to hospital admission and intensive care unit (ICU) admission – are assumed to arise from a covid infection itself and not from another complicating risk factor. For example, a patient admitted to a hospital with covid is different from a patient admitted to a hospital for a non-covid reason and, in the course of medical intervention and clinical testing after being hospitalized, tests positive for covid.

4) Adverse side effects/reactions of mRNA vaccination are known (17). How frequent might these effects/reactions be in vaccine recipients? In the United States, the Vaccine Adverse Event Reporting System (VAERS) can be used to assess the nature and frequency of negative effects of US-licensed vaccines (18). VAERS is a passive (voluntary) system that has been in place over 30 years. People can browse VAERS reports and do simple searches (19). As it is voluntary, negative vaccine effects are under reported, with one 2010 estimate indicating that fewer than 1% of vaccine adverse events are reported (20).

It is likely that other assumptions and limitations have been missed. But the approach taken here is to present the data and let the data "speak for themselves" assuming the data is true.

3. Stated drug company objectives for mRNA vaccines in sars-cov-2 virus clinical trials

mRNA vaccines are novel and they represent a potential alternative to conventional vaccine approaches (21). However, as stated elsewhere (22):

> "*The world has bet the farm on* [mRNA] *vaccines as the solution to the pandemic, but the* [clinical] *trials are not focused on answering the questions many might assume they are*."

What are the clinical trials for covid looking at? Well, it is hard to sort out a clear description of the primary endpoint(s) that drug companies want to measure in their trials. *Laboratory confirmed infections with only mild symptoms in vaccine recipients* apparently qualifies as meeting the primary endpoint definition for their clinical trials (22).

Ideally, an antiviral vaccine should accomplish two things: 1) reduce the likelihood of getting severely ill and going to the hospital, and 2) prevent infection and therefore interrupting disease transmission (22). However, the phase III trials are not set up to prove either. None of the trials are designed and being conducted to detect whether a vaccine reduces any severe outcomes from covid infections – specifically, complications leading to hospital admission, admission to an ICU, or death. Nor are the vaccines being studied to determine whether they can interrupt transmission of the covid virus.

Not even mentioned by drug companies is that their vaccines do not block infections for the covid virus or its variants. Is a vaccine that cannot block infection truly a vaccine? Drug company data collection and analysis are ongoing in the trials for up to another two years of follow-up on participants (23). Thus, the vaccine efficacy results presented here can only be considered short-term data.

4. mRNA vaccine efficacy – relative risk reduction versus absolute risk reduction

There is plenty of confusion and false understanding among health professionals, the public and media about the '*95% effective*' relative risk reduction measure initially reported for mRNA vaccines (24). Relative risk reduction (RRR) and absolute risk reduction (ARR) are measures of treatment/intervention efficacy that are both normally provided in results from randomized clinical trials. When information is presented in a relative risk format for the lay person, the risk reduction seems larger, and treatments/interventions are viewed as being more favorable than when the same information is presented using an absolute risk format (25).

4.1 Relative risk reduction (RRR)

The RRR is the difference in event rates between two groups, e.g., vaccinated and unvaccinated, expressed as a proportion of the event rate in the unvaccinated group (26). RRR is often a more impressive number than ARR. For our situation, RRR specifically tells us by how much a vaccine reduces the risk of *mild covid symptoms in vaccine recipients* (22) relative to the unvaccinated group in clinical trials.

In the case of Pfizer and Moderna mRNA vaccines, many people falsely believe that the '*95% effective*' number – a RRR number – means that 95 out of 100 people vaccinated will be protected from covid. This is not true. Drug companies did not say anything about their vaccine protecting people from covid in their clinical trials. Also, this number does not tell a person the reduced chance of exhibiting mild covid symptoms if vaccinated.

4.2 Absolute risk reduction (ARR)

The ARR is the arithmetic difference between the two event rates, and it varies with the underlying risk of an event in an individual (26). In theory, treatment/intervention benefits (presented as an ARR) will generally be greater for people at higher risk of a health effect or condition being studied in a clinical trial than for people at lower risk of the effect or condition.

In our case, ARR accounts for the unvaccinated event rate and it is a more realistic quantification of vaccination benefit than the RRR (27). ARR represents an absolute measure of reduced risk of *mild covid symptoms in vaccine recipients* (22) relative to unvaccinated people. This is the more appropriate measure to make judgments about one's reduced chance of exhibiting mild covid symptoms if vaccinated.

The US Food and Drug Administration's advice for providing efficacy information from clinical trials includes (28):

> *"Provide absolute risks, not just relative risks. Patients are unduly influenced when risk information is presented using a relative risk approach; this can result in suboptimal decisions. Thus, an absolute risk format should be used*."

4.3 Published RRR and ARR information

The following published RRR and ARR information (28) is based on reported Phase III clinical trial data for the Pfizer vaccine (29) and the Moderna vaccine (30):

- For the Pfizer vaccine – the RRR is 95.1% (95% confidence interval, CI, is 90.0% to 97.6%; *p=0.016*); the ARR is 0.7% (95% CI is 0.59% to 0.83%; *p<0.000*).
- For the Moderna vaccine – the RRR is 94.1% (95% CI is 89.1% to 96.8%; *p=0.004*); The ARR is 1.1% (95% CI is 0.97% to 1.32%; *p<0.000*).

To be clear, the absolute measure of reduced risk of exhibiting mild covid symptoms for a person of average health participating in clinical trials receiving the Pfzier (Moderna) vaccine – the ARR – is only 0.7% (1.1%). These are small risk reduction measures. It is unsurprising that people might falsely overestimate the benefit of vaccination when it is only presented in relative terms (i.e., the RRR) and absolute risk reduction measures are not provided.

The small ARR numbers are consistent with the fact that when an event rate for a health outcome in a population is low, the ARR is small. For example, event rates in the Phase III clinical trials for the Pfizer vaccine (29) and the Moderna vaccine (30) can be estimated as events/nonevents (i.e., # of infections ÷ # of no infections). Using the drug company trial data presented elsewhere (28), estimated event rates in the Pfizer clinical trial are 0.037% (vaccinated group) and 0.751% (unvaccinated group); whereas estimated event rates in the Moderna clinical trial are 0.072% (vaccinated group) and 1.23% (unvaccinated group).

5. Government surveillance data and independent studies data on the Delta variant

Health surveillance is an essential component of public health practice (31). Surveillance data along with data from independent studies are used by health agencies to guide policy, new program interventions, public communications and to help assess research needs.

5.1 Recent government surveillance data for England

Selected data from Tables 2, 3, and 4 of a recent Public Health England (PHE) report (32) are presented below to show trends in mRNA vaccine effectiveness related to new infections (cases), hospitalizations and deaths largely from the Delta variant for unvaccinated and fully-vaccinated people in England. All the released PHE reports are available for download (33).

Compare numbers in the "*Not vaccinated*" column to the "*Second dose ≥14 days before specimen date (fully-vaccinated)*" column in PHE Tables 2, 3, 4 below for the different age groups. Letting the data speak for themselves, these comparisons show that the fully-vaccinated have higher numbers than not vaccinated for people 60 years and older for cases (new infections), emergency admissions and deaths between week 33 and week 36, 2021 in England.

Others may argue that there are more people in the vaccinated column than in the not-vaccinated column (assuming vaccine uptake in England for the 60 years and older has been similar to uptake in Canada) and rates should be used here. However, the point made here is that infections, cases presenting to emergency care and deaths are occurring among the fully-vaccinated. The latter two outcomes are more severe than what drug companies are testing in their clinical trials. mRNA vaccines

are not preventing more severe covid outcomes. Are we losing our bet on the farm that mRNA vaccines are the solution to the pandemic?

PHE Table 2. Covid cases (new infections) by vaccination status between week 33 and week 36, 2021 in England (32).

Age group	Not vaccinated	Second dose ≥14 days before specimen date (fully-vaccinated)
60–69 years	2,592	39,686
70–79 years	918	23,739
80 years and older	540	10,616
total 60 years and older	4,050	74,014

PHE Table 3. Covid cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission by vaccination status between week 33 and week 36 2021 in England (32).

Age group	Not vaccinated	Second dose ≥14 days before specimen date (fully-vaccinated)
60–69 years	403	765
70–79 years	239	1,248
80 years and older	183	1,300
total 60 years and older	825	3,313

PHE Table 4. Covid deaths within 60 days of positive specimen or with covid reported on death certificate, by vaccination status between week 33 and week 36 2021 in England (32).

Age group	Not vaccinated	Second dose ≥14 days before specimen date (fully-vaccinated)
60–69 years	171	270
70–79 years	173	633
80 years and older	197	1,349
total 60 years and older	541	2,252

5.2 Recent government surveillance data for Scotland

Selected data from Table 17 from two recent Public Health Scotland (PHS) reports are presented below to show the trend in covid deaths for fully-vaccinated and unvaccinated people for a two-week period (August 5 to August 19, 2021) in Scotland. The Delta variant has been the dominant sars-cov-2 variant in Scotland since 31 May 2021 (34).

PHS Table 17(a) below is from a report published on August 18, 2021 and it shows that between December 29, 2020 and August 5, 2021 there were 2,803 covid deaths recorded for unvaccinated and 3,258 deaths recorded for fully-vaccinated people aged 60 years and over (35).

PHS Table 17(b) below is from a more recent PHS report published on September 1, 2021 and it shows that between December 29, 2020 and August 19, 2021 there were 2,816 covid deaths recorded for unvaccinated and 3,324 deaths recorded for fully-vaccinated people aged 60 years and over (34).

PHS Table 17(a). Number of confirmed covid-19 related deaths by vaccination status at time of test, 29 December 2020 to 05 August 2021 in Scotland (35).

Age group	Unvaccinated	2 Doses (fully-vaccinated)
60–69 years	425	466
70–79 years	784	894
80 years and older	1,594	1,898
total 60 years and older	2,803	3,258

PHS Table 17(b). Number of confirmed covid-19 related deaths by vaccination status at time of test, 29 December 2020 to 19 August 2021 in Scotland (34).

Age group	Unvaccinated	2 Doses (fully-vaccinated)
60–69 years	433	482
70–79 years	785	909
80 years and older	1,598	1,933
total 60 years and older	2,816	3,324

Letting the data speak for themselves, the difference in the two tables is covid deaths for the two-week period of August 5 to August 19, 2021. Here, the unvaccinated accounted for 13 deaths and the fully-vaccinated accounted for 66 deaths over the two-week period.

5.3 Recent independent data for Israel

An independent study compared covid 'natural immunity' to 'vaccine-induced immunity' in Israel (36). Specifically, the study compared breakthrough infections (fully-vaccinated people that were infected) versus reinfections (i.e., infection of unvaccinated people that were previously infected) in their data set:

- The study relied on the database of Maccabi Healthcare Services, which has about 2.5 million Israelis enrolled.
- The study found that people who were vaccinated in January and February of 2021 were – in June, July and the first half of August, 2021 – at 13-fold greater risk for breakthrough infection with the Delta variant (95% confidence interval (CI), 8.08 to 21.11) compared to those previously infected. The increased risk was significant ($p<0.001$) for symptomatic disease.
- In comparing outcomes for more than 32,000 people in the database, the study also found that: i) the risk of developing symptomatic covid was 27 times higher among vaccinated people, and ii) the risk of hospitalization from covid was eight times higher among vaccinated people.

5.4 What is happening in the United States

The CDC currently monitors hospitalizations and deaths – from any cause – among fully-vaccinated individuals with covid. However, CDC does not report breakthrough infections, which it stopped as of May 1 (37). The public is unable to track numbers of hospitalizations and deaths of infected, vaccinated people for the Delta variant infection wave moving through the US. However, examples of studies of infected, vaccinated people have been reported. Three examples are:

a) Massachusetts (38):

- During July 2021, 469 cases of covid were associated with multiple summer events and large public gatherings in a town in Barnstable County, Massachusetts.
- Vaccination coverage among eligible Massachusetts residents was 69%.
- 346 of the 469 cases (74%) occurred in fully-vaccinated people.
- 90% of the 469 cases were from the Delta variant.
- Among five covid patients hospitalized, four were fully-vaccinated; no deaths were reported.

b) Wisconsin (39):

- Researchers compared RT-PCR cycle threshold (Ct) data from 699 swab specimens collected in Wisconsin from June 29 through July 31, 2021.
- Specimens came from residents of 36 counties, most in southern and southeastern Wisconsin.
- During the study period it was estimated that prevalence of Delta variants in Wisconsin increased from 69% to over 95%.

- The researchers reported that: i) it was much more likely (82%) to contract covid from an asymptomatic, fully-vaccinated person than from an asymptomatic, unvaccinated person (29%); ii) it was equally as likely to contract covid from a symptomatic, fully-vaccinated person (69%) as from an symptomatic, unvaccinated person (68%).

c) Texas (40):
- A covid outbreak involving the Delta variant occurred in a highly vaccinated incarcerated population in Texas.
- The Delta variant was identified infecting 168 of 227 incarcerated persons in two housing units.
- Transmission rates were high among both unvaccinated and vaccinated persons.
- The attack rate for unvaccinated persons was 39 of 42 and for fully-vaccinated persons was 129 of 185.
- The attack rate was 83 of 93 among persons vaccinated 4 or more months before the outbreak and 19 of 31 among persons vaccinated 2 weeks to 2 months before the outbreak.

6. Discussion

6.1 What do data presented here indicate about drug company objectives for mRNA vaccines?

In February 2021, Pfizer CEO Albert Bourla stated in an interview on NBC (41):
"*I believe Israel has become the world's lab right now because they are using only our vaccine at this state and they have vaccinated a very big part of their population, so we can study both economy and health indices*."

He is correct. But England and Scotland are also "labs" providing valuable data about the effects of covid infections in vaccinated people. The drug company clinical trials have lost much of their relevance in view of this data showing that more severe covid outcomes are occurring among vaccinated people in these countries. The data shows that mRNA vaccines are not preventing severe covid symptoms – i.e., complications requiring hospital admission, ICU admission, and death – for people aged 60 years and older to Delta variant infections.

6.2 Are mRNA vaccines working for the Delta variant?

The answer to this is apparently no, but why? All viruses survive by replicating (creating copies of themselves). There are always a lot of imperfect copies (mutations) produced by the copying process. Among RNA respiratory viruses – including coronaviruses – these mutations occur quickly so that there is rapid genetic drift, which continually produces new strains. Mutated viruses (variants) are normal and expected.

Coronaviruses have proteins on their surface called S-spike proteins – the same one that is mimicked by an mRNA vaccine. The S-spike protein allows coronaviruses to latch onto an ACE2 (angiotensin converting enzyme-2) receptor on a cell surface of an infected host. mRNA vaccines were designed as a tool to teach our immune system to attack the S-spike protein and prime our immune system to reduce the severity of infection during an encounter with a real covid virus. However, this priming appears to be imperfect as evidenced by fully-vaccinated people becoming infected, hospitalized and dying from Delta variant infections.

The immune response to mRNA produces non-sterilizing antibodies These non-sterilizing antibodies do not appear to be working as originally intended for covid variants. Part of what may be happening is that as covid viruses mutate towards 'using' the non-sterilizing antibodies produced by mRNA, these variants can become even more infectious to fully-vaccinated people as it evolves (mutates)

to use those antibodies to infect (42). The mRNA-produced non-sterilizing antibodies might actually be helping these variants enter and damage living cells in vaccinated people.

6.3 Has the public been (purposely?) misinformed about vaccination benefits?

A problem that has persisted with the vaccination narrative is that key risk reduction information has been withheld from the public. A researcher explained the problem that has unfolded with rapid introduction and emergency authorization use of the mRNA vaccines in North America (28):

- A published critical appraisal of phase III clinical trial data for the Pfizer and Moderna vaccines shows that absolute risk reduction (ARR) measures are small and much lower than the reported relative risk reduction (RRR) measures.
- Pfizer and Moderna failed to report ARR measures in their publicly released documents.
- The US FDA Advisory Committee that recommended emergency authorization use of the mRNA vaccines did not follow their own publishing guidelines for communicating risks and benefits to the public. They failed to report ARR measures in authorizing the Pfizer & Moderna mRNA vaccines for emergency use.
- The Pfizer and Moderna failure to report ARR measures and the US FDA Advisory Committee's failure to report these measures in authorizing the Pfizer & Moderna mRNA vaccines are examples of *outcome reporting bias*. This bias serves to mislead public (and media) understanding of covid mRNA vaccine efficacy.

6.4 What to do when the absolute risk reduction is small?

The absolute measure of reduced risk of exhibiting *mild covid symptoms* for a vaccinated person of average health is ≤1.1% for the Pfizer & Moderna mRNA vaccines. In theory, when the absolute risk reduction is small, treatment/intervention of large numbers is needed to achieve a small but net benefit in a targeted population. This assumes that the targeted population all benefit from the treatment/intervention. But that is not the case. For vaccines, this also assumes that the risks of vaccination (adverse side effects/reactions from the vaccine itself) are small.

In reality, our population has large variation in health status and susceptibility to viruses – ranging from those carrying comorbid ailments, the immunocompromised, etc. at one end to those that are very healthy (e.g., Olympic and professional athletes, etc.) at the other end. Vaccination or any other type of treatment/intervention for covid should target those people carrying comorbid ailments, the immunocompromised, etc. because they would benefit the most.

Given a small absolute risk reduction for mRNA vaccines, vaccinating those with average or better health status in a population might achieve a small net benefit for the overall population (i.e., the results would look good on paper). But this achieves no benefit to those of less than average health. The same holds for vaccinating people already carrying antibodies from previous covid infection.

6.5 Implications for Alberta

Data on covid in Alberta are provided online for infections (cases), hospitalizations, ICU admissions and deaths (43). One can speculate where these metrics go in the coming weeks as the current Delta variant wave moves through the population. The data presented here for countries further along in their Delta variant infection waves than Alberta offer some insights. In particular, no speculation is needed about who can be affected by covid. The data presented tells us that the Delta variant is indiscriminate of vaccination status – i.e., it can infect both vaccinated and unvaccinated people. Of course, this was already known from the onset of the drug company clinical trials back in March 2020.

Based on two drug company clinical trials, the absolute measure of reduced risk of exhibiting "mild covid symptoms" for a person of average health receiving the Pfizer (Moderna) vaccine – the absolute risk reduction – is only 0.7% (1.1%). These are small risk reduction measures.

More importantly, the data presented here show that a vaccinated person over 60 years of age infected with the Delta variant can exhibit more severe outcomes compared to outcomes that drug companies are testing in their clinical trials – including complications requiring hospital admission, ICU admission and death. The drug company clinical trials have lost much of their relevance as a result.

As for people aged 60 or older who are of average health or better, or those who have been previously infected, overall the evidence is weak that they need to be vaccinated for covid in Alberta. Also, requiring proof of vaccination for people to enter certain businesses and to attend certain events is not supported by science as vaccinated people can be infected by the Delta variant and transmit it to others.

Biography

Warren Kindzierski is an adjunct professor of environmental health at University of Alberta School of Public Health. He has a PhD in environmental engineering (University of Alberta) and worked at the University of Alberta Faculty of Engineering and School of Public Health from 1996 to 2018 and was Head, Chemical Risk Assessment for Alberta Health from 1993 to 1996. He has authored/co-authored 60 research papers and 44 research reports at the University of Alberta and made over 70 presentations at national and international conferences in North America. He has served or acted as an academic expert and/or advisor to public and private sector organizations across Canada for over 20 years on human exposure, human health impact and environmental pollution issues.

References

1 Woo A. 2021 Alberta closer to activating triage system for critical-care patients amid rise in COVID-19 patients. *Globe and Mail*, September 22, 2021. https://www.theglobeandmail.com/canada/alberta/article-alberta-has-over-1000-covid-19-patients/

2 Coronavirus (COVID-19) Vaccinations. Statistics and Research, Our World in Data. https://ourworldindata.org/covid-vaccinations

3 US Centres for Disease Control (CDC). 2021. Covid-19. About Variants. US CDC, Atlanta, GA. https://www.cdc.gov/coronavirus/2019-ncov/variants/variant.html

4 Alberta Government. 2021. COVID-19 Alberta statistics. https://www.alberta.ca/stats/covid-19-alberta-statistics.htm

5 Alberta Government. 2021. COVID-19 public health actions. https://www.alberta.ca/covid-19-public-health-actions.aspx

6 Alberta Government. 2021. Vaccine incentives. https://www.alberta.ca/vaccine-incentives.aspx

7 Alberta Government. 2021. Restrictions exemption program. https://www.alberta.ca/covid-19-public-health-actions.aspx#REP

8 Beebe J. 1995. Basic concepts and techniques of rapid appraisal. *Human Organization*. 54(1), 42–51. https://www.jstor.org/stable/44126571

9 Maresova P, Javanmardi E, Barakovic S, Barakovic Husic J, Tomsone S, Krejcar O, Kuca K. 2019. Consequences of chronic diseases and other limitations associated with old age - a scoping review. *BMC Public Health*. 19(1), 1431. https://doi.org/10.1186/s12889-019-7762-5

10 Sadighi Akha AA. 2018. Aging and the immune system: An overview. *J Immunol Methods*. 463, 21–26. https://doi.org/10.1016/j.jim.2018.08.005

11 Li Y, Yao L, Li J, Chen L, Song Y, Cai Z, Yang C. 2020. Stability issues of RT-PCR testing of SARS-CoV-2 for hospitalized patients clinically diagnosed with COVID-19. *J Med Virol*. 92(7), 903–908. https://doi.org/10.1002/jmv.25786

12 Young BE, Ong SWX, Kalimuddin S, Low JG, Tan SY, Loh J, Ng OT, Marimuthu K, Ang LW, Mak TM, Lau SK, Anderson DE, Chan KS, Tan TY, Ng TY, Cui L, Said Z, Kurupatham L, Chen MI, Chan M, Vasoo S, Wang LF, Tan BH, Lin RTP, Lee VJM, Leo YS, Lye DC. 2020. Singapore 2019 novel coronavirus outbreak research team. Epidemiologic features and clinical course of patients infected with SARS-CoV-2 in Singapore. *JAMA*. 323(15), 1488–1494. https://doi.org/10.1001/jama.2020.3204

13 US Centres for Disease Control (CDC). 2021. Covid-19. Diagnostic testing. US CDC, Atlanta, GA. https://www.cdc.gov/coronavirus/2019-ncov/lab/testing.html

14 Gao Z, Xu Y, Sun C, Wang X, Guo Y, Qiu S, Ma K. 2021. A systematic review of asymptomatic infections with COVID-19. *J Microbiol Immunol Infect*. 54(1), 12–16. https://doi.org/10.1016/j.jmii.2020.05.001

15 Walsh KA, Jordan K, Clyne B, Rohde D, Drummond L, Byrne P, Ahern S, Carty PG, O'Brien KK, O'Murchu E, O'Neill M, Smith SM, Ryan M, Harrington P. 2020. SARS-CoV-2 detection, viral load and infectivity over the course of an infection. *J Infect*. 81(3), 357–371. https://doi.org/10.1016/j.jinf.2020.06.067

16 Ladhani SN, Chow JY, Janarthanan R, Fok J, Crawley-Boevey E, Vusirikala A, Fernandez E, Perez MS, Tang S, Dun-Campbell K, Evans EW, Bell A, Patel B, Amin-Chowdhury Z, Aiano F, Paranthaman K, Ma T, Saavedra-Campos M, Myers R, Ellis J, Lackenby A, Gopal R, Patel M, Brown C, Chand M, Brown K, Ramsay ME, Hopkins S, Shetty N, Zambon M. 2020. Investigation of SARS-CoV-2 outbreaks in six care homes in London, April 2020. *EClinicalMedicine*. 26, 100533. https://doi.org/10.1016/j.eclinm.2020.100533

17 *Whistleblower from Berlin nursing home: the terrible dying after vaccination*. 2020news.de. https://2020news.de/en/whistleblower-from-berlin-nursing-home-the-terrible-dying-after-vaccination/

18 VAERS Vaccine Adverse Event Reporting System. https://vaers.hhs.gov/index.html

19 OpenVAERS. https://openvaers.com/

20 Lazarus R, Klompas M. 2010. Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS). Agency for Healthcare Research and Quality (AHRQ), US Department of Health and Human Services Grant ID: R18 HS 017045. https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

21 Pardi N, Hogan MJ, Porter FW, Weissman D. 2018. mRNA vaccines - a new era in vaccinology. *Nat Rev Drug Discov*. 17(4), 261–279. https://doi.org/10.1038/nrd.2017.243

22 Doshi P. 2020. Will covid-19 vaccines save lives? Current trials aren't designed to tell us. *BMJ*. 371, m4037. https://doi.org/10.1136/bmj.m4037

23 Jiang HD, Li JX, Zhang P, Huo X, Zhu FC. 2021. The COVID-19 vaccine in clinical trials: Where are we now? *Infect Diseases Immunity*. 1(1), 43–51. https://doi.org/10.1097/ID9.0000000000000003

24 Doshi P. 2020. Pfizer and Moderna's "95% effective" vaccines—let's be cautious and first see the full data. November 26, 2020. thebmjopinion. https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/

25 Fischhoff B, Brewer NT, Down JS, 2011. Communicating Risks and Benefits: An Evidence-Based User's Guide. US Department of Health and Human Services, Food and Drug Administration, Silver Spring, MD. https://www.fda.gov/about-fda/reports/communicating-risks-and-benefits-evidence-based-users-guide

26 Barratt A, Wyer PC, Hatala R, McGinn T, Dans AL, Keitz S, Moyer V, For GG. 2004. Evidence-Based Medicine Teaching Tips Working Group. Tips for learners of evidence-based medicine: 1. Relative risk reduction, absolute risk reduction and number needed to treat. *CMAJ*. 171(4), 353–358. https://doi.org/10.1503/cmaj.1021197

27 Replogle WH, Johnson WD. 2007. Interpretation of absolute measures of disease risk in comparative research. *Fam Med*. 39(6), 432–435. https://fammedarchives.blob.core.windows.net/imagesandpdfs/fmhub/fm2007/June/William432.pdf

28 Brown RB. 2021. Outcome reporting bias in COVID-19 mRNA vaccine clinical trials. 2021. *Medicina* (Kaunas). 57(3), 199. https://doi.org/10.3390/medicina57030199

29 Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, Zerbini C, Bailey R, Swanson KA, Roychoudhury S, Koury K, Li P, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL, Türeci Ö, Nell H, Schaefer A, Ünal S, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC. 2020. C4591001 Clinical Trial Group. Safety and efficacy of the BNT162b2 mRNA covid-19 vaccine. *N Engl J Med*. 383(27), 2603–2615. https://doi.org/10.1056/NEJMoa2034577

30 Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, Diemert D, Spector SA, Rouphael N, Creech CB, McGettigan J, Khetan S, Segall N, Solis J, Brosz A, Fierro C, Schwartz H, Neuzil K, Corey L, Gilbert P, Janes H, Follmann D, Marovich M, Mascola J, Polakowski L, Ledgerwood J, Graham BS, Bennett H, Pajon R, Knightly C, Leav B, Deng W, Zhou H, Han S, Ivarsson M, Miller J, Zaks T. 2021. COVE Study Group. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. *N Engl J Med*. 384(5), 403-416. https://doi.org/10.1056/NEJMoa2035389

31 US Centres for Disease Control (CDC). 2021. Public Health Surveillance: Preparing for the Future. US CDC, Atlanta, GA. https://www.cdc.gov/surveillance/improving-surveillance/Public-health-surveillance.html

32 Public Health England (PHE). 2021. COVID-19 vaccine surveillance report, Week 37. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1018416/Vaccine_surveillance_report_-_week_37_v2.pdf

33 Public Health England (PHE). 2021. Research and analysis. COVID-19 vaccine surveillance reports. https://www.gov.uk/government/publications/covid-19-vaccine-surveillance-report

34 Public Health Scotland (PHS). 2021. Public Health Scotland COVID-19 Statistical Report. As at 30 August 2021. https://publichealthscotland.scot/media/8918/21-09-01-covid19-publication_report.pdf

35 Public Health Scotland (PHS). 2021. Public Health Scotland COVID-19 Statistical Report. As at 16 August 2021. https://publichealthscotland.scot/media/8760/21-08-18-covid19-publication_report.pdf

36 Gazit S, Shlezinger R, Perez G, Lotan R, Peretz A, Ben-Tov A, Cohen D, Muhsen K, PhD4; Chodick G, Patalon T. 2021. Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections. medRxiv preprint. https://doi.org/10.1101/2021.08.24.21262415

37 COVID-19 Vaccine Breakthrough Infections Team. 2021. COVID-19 vaccine breakthrough infections reported to CDC — United States, January 1–April 30, 2021. *Morb Mortal Wkly Rep*. 70(21), 792–793. http://dx.doi.org/10.15585/mmwr.mm7021e3

38 Brown CM, Vostok J, Johnson H, et al. 2021. Outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings — Barnstable County, Massachusetts, July 2021. *Morb Mortal Wkly Rep.* 70(31), 1059–1062. http://dx.doi.org/10.15585/mmwr.mm7031e2

39 Riemersma KK, Grogan BE, Kita-Yarbro A, Halfmann PJ, Segaloff HE, Kocharian A, Florek KR, Westergaard R, Bateman A, Jeppson GE, Kawaoka Y, O'Connor DH, Friedrich TC, Grande KM. 2021. Shedding of infectious SARS-CoV-2 despite vaccination. medRxiv preprint. https://doi.org/10.1101/2021.07.31.21261387

40 Hagan LM, McCormick DW, Lee C, et al. 2021. Outbreak of SARS-CoV-2 B.1.617.2 (Delta) variant infections among incarcerated persons in a federal prison — Texas, July–August 2021. *Morb Mortal Wkly Rep*, 70(38),1349–1354. http://dx.doi.org/10.15585/mmwr.mm7038e3

41 Levine C. Pfizer CEO Albert Bourla calls Israel 'world's lab' in interview to NBC. The Jerusalem Post. February 27, 2021. https://www.jpost.com/breaking-news/pfizer-ceo-albert-bourla-calls-israel-worlds-lab-in-interview-to-nbc-660349

42 Rella SA, Kulikova YA, Dermitzakis ET, Kondrashov FA. 2021. Rates of SARS-CoV-2 transmission and vaccination impact the fate of vaccine-resistant strains. *Sci Rep*. 11(1), 15729. https://doi.org/10.1038/s41598-021-95025-3

43 Alberta Government. 2021. COVID-19 Alberta statistics. Interactive aggregate data on COVID-19 cases in Alberta. https://www.alberta.ca/stats/covid-19-alberta-statistics.htm