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Re: The risks of COVID-19 and the acquisition of natural immunity verses the efficacy and safety of COVID-19 vaccines

1. For the upcoming National Citizen's Inquiry into the COVID-19 pandemic, I have been asked to provide my expert opinion related to the risks of COVID-19-related infections and the public health recommended guidelines for COVID-19 vaccination to mitigate these risks, and whether these measures have their own inherent risks. This required a comprehensive assessment of the dangers of COVID-19, and the effectiveness of the various strategies to protect against the SARS-CoV-2 virus, which is the identified viral agent that causes COVID-19. The major approach taken by public health authorities has been to recommend and in many cases, mandate COVID-19 vaccination. However, the scientific literature is building that these genetic vaccines are actually not particularly efficacious and pose significant health concerns to those that are vaccinated. The federal public health and provincial health officers in Canada, in my opinion, have not provided a proper accounting of the benefits and risks of the available COVID-19 vaccines to allow informed consent and have promoted these vaccines in an unbalanced manner.

2. I have been actively involved in COVID-19 research for the past 3.3 years, especially with respect to the replication of the SARS-CoV-2 virus, and the production of antibodies against this virus in people who have been infected by this virus and/or have been vaccinated against this virus. At the end of this report, I have described my background that qualifies me as an expert to comment on these matters.

3. Throughout this report, I have identified many of the key publications in the scientific literature and government websites as well as my own research that informed my opinions about COVID-19 and the effectiveness of the counter strategies put forth by public health authorities. In view of the position

taken by the public health authorities in Canada with respect to the natural immunity and the need for, the efficacy and safety of COVID-19 vaccines, I think it is necessary to provide some basic background information in my report. Initially, I offer a brief introduction to COVID-19, SARS-CoV-2, COVID-19 vaccines and immunity. I then discuss COVID-19 vaccine efficacy and safety, taking into account the influence of age in terms of the benefits and risks of vaccination. I highlight some of the known and potential harms of COVID-19 vaccines, with an emphasis on myocarditis in males under 40 years of age and reproductive risks for women. I then summarize my knowledge about the wide extent of natural immunity to SARS-CoV-2 in Canada and its superiority to vaccine-induced immunity. I also mention some of the promising treatments that are available to those that get COVID-19.

Section A. COVID-19 and SARS-CoV-2 Introduction

4. COronaVIrus Disease 2019 (COVID-19) is a symptomatic respiratory illness cause by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This ribonucleic acid (RNA) containing virus has a single, positive stranded genome that is around 29,903 nucleotides long. Its genome encodes the information for construction of at least 28 different viral proteins that compose the viral particle. Each protein has an amino acid composition and sequence that is dictated by the sequences of the nucleotides in the SARS-CoV-2 virus genes. The virus is in the coronavirus family that are all characterized by their crown-like appearance under an electron microscope, which arises from the location of copies of a large Spike protein on their surfaces.

5. The Spike protein, which is made initially as a 1273 to 1278 amino acid long precursor protein is clipped into S1 and S2 subunits that remain tightly associated. When expressed on the surface of a virus or cell, the Spike protein is located in trimeric complexes of three S1 subunits and three S2 subunits. The recently introduced bivalent vaccines with mixed versions of the Spike protein gene from both original Wuhan strain and Omicron BA.4/5 strains, allows for the formation of four possible combinations of triplets, two of which are not found naturally in these virus strains. In fact, x-ray crystallographic structures of the spike protein complexes isolated from cells that have been exposed to these bivalent vaccines have not been described in the scientific literature from my searches. The effects of the mixed, heterogeneous versions of the Spike protein complexes that result from the new bivalent vaccines are unclear.

6. The S1 subunit features a region called the receptor binding domain (RBD) by which the virus is able to attach to receptors on host cells, including the angiotensin converting enzyme – II (ACE-2) protein, to gain access into these cells, where it can replicate. Apart from copies of the Membrane and Envelope proteins that are also exposed on the outside of the virus, all of the other viral proteins are buried in the interior of the virus particle. These internal viral proteins, including the Nucleocapsid protein, are less useful for immune cell recognition of the intact virus for its removal.

7. In view of the virus surface accessibility and large size of the Spike protein, it has been specifically targeted for the production of vaccines that can evoke the adaptive immune system in people to produce two main classes of lymphocytes, *i.e*., T-cells and B-cells.

8. T-cells feature antigen-receptors that can allow for these lymphocytes to specifically seek out and kill pathogens that feature a tiny and specific part that may be present in the pathogen known as an epitope. Most epitopes are typically portions of only 3 to 7 amino acids long within the structure of a protein, but they can be longer and also encompass other molecular structures such as found in complex sugars and lipids. T-cell typically attack infected host cells that are exposing the pathogen's proteins on their surfaces.

9. The B-cells produce antibodies that can recognize similar epitopes, and which bind to proteins on the surfaces of pathogens to act effectively serve as beacons for attraction of innate immune cells, such as macrophages, neutrophils and dendritic cells, to directly attack and destroy the pathogen. The bound antibodies to a pathogen such as a virus or bacteria, act as receptors for immune cells and for proteolytic enzymes in the complement system, which can kill infected cells, bacteria and large viruses

Section B. Introduction to COVID-19 Vaccines

10. Early on, SARS-CoV-2 was considered by many to be a very deadly virus, and this spurred the development of very novel drugs and vaccines that have their own concerning issues, and the imposition of other measures to control of the spread of this virus, such as lockdowns, social distancing and masking. After careful monitoring of the scientific literature, in my opinion, for most adults and certainly children, the potential harms of COVID-19 vaccination far outweigh the benefits that they provide against infection with SARS-CoV-2 and development of COVID-19, especially since the

emergence of the Omicron variants of this virus that have predominated in the last year and a half. A long treatise can be generated with extensive references to the scientific publications that have helped to formulate my conclusions. In this report, I will provide only some of the reasons for my conclusions. I recognize that much of what I have written is very technical in nature in my attempt to be as accurate as possible to assist those experts that may come with contrary opinions to my views. However, I have made a concerted effort to permit readers not skilled in biochemistry, immunology and virology to comprehend the complexities of the COVID-19 problem, and the deficiencies in federal and provincial health agency recommendations and actions to deal with this matter.

11. After over three and a half years into the COVID-19 pandemic, and more than two years of wide spread dissemination of COVID-19 vaccines, there is a vast literature on this disease, the virus that causes it, and the effects of experimental COVID-19 genetic vaccines in terms of efficacy and injury. At this stage of the COVID-19 pandemic, it is evident that the Omicron variants are more infectious than previous variants of SARS-CoV-2, but fortunately, these variants are much more mild in their COVID-19 symptoms in the general population. For example, there appears to be at least a 4-fold reduced risk of hospitalizations, and about half the time needed for recovery from illness for those that get COVID-19 from Omicron BA.1 as compare to the Delta variant. At the same time, there are increasing concerns about the efficacy and safety associated with the currently available COVID-19 vaccines. Healthy children and adolescents have always been a low risk for serious injury from COVID-19 ever since the start of the COVID-19 pandemic. By contrast, the elderly over 70 years of age, the very obese and those with multiple existing co-morbidities are particularly vulnerable to severe COVID-19, and reasonable arguments might have been offered in support of vaccination in these instances in the past, but much less so now.

12. For clarification, there were only four COVID-19 genetic vaccines approved for use in Canada in 2021: Pfizer-BioNTech BNT162b2 (later named Comirnaty) and Moderna (later named Spikevax), which are both vaccines that deliver RNA for production of the Spike protein that is located on the outside of the virus; AstraZeneca Vaxzevria and Janssen (Johnson & Johnson), which are both adenovirus preparations that contain DNA that provide for RNA production to then permit biosynthesis of the Spike protein. In 2022, Novavax Nuvaxovid and Medicago Corifenz were also approved by Health Canada, and these are exosomes (lipid encapsulated portions of cells) derived from genetically

engineered caterpillar cells and tobacco leaf cells, respectively, that present the Spike protein on their surfaces along with other cellular host proteins.

13. The first two doses for those over 12 years of age of the Moderna vaccine have 100 micrograms of the RNA for the Spike protein, compared to 30 μg of the RNA for the same protein in the first two adult doses of the Pfizer-BioNTech vaccine. After 6 months, booster shots have been recommended for those 12 years of age or older with the Pfizer-BioNTech vaccine (30 μg/dose) and for those over 18 years of age with the Moderna vaccine (50 μg/dose).[1]

14. For the COVID-19 vaccination of babies 6 months and older, only the Pfizer-BioNTech and Moderna RNA vaccines have been approved by Health Canada.[1] The Moderna product was approved for 6 month to 5 year olds on July 14, 2022 with a 2 dose regimen (25 μg/dose one month apart), whereas the Pfizer product was approved on September 9, 2022 with a 3 dose regiment) (3 μg/dose at an interval of three weeks between the first and second doses, with eight weeks between the second and third dose). The Pfizer-BioNTech vaccine is used at a dosage that is a third of the teen and adult dose (10 μg/dose) in 5 to 11 year olds,[1] whereas the Moderna vaccine is used at half the adult dose (50 μg/dose) for 5 to 11 year olds. [2], and a quarter of the adult dose for 6 month to 4 years old children (25 μg/dose). Therefore, a five-year old child will receive 5-times higher levels of the Spike protein mRNA with the pediatric dose of the Moderna vaccine when compared to the Pfizer-BioNTech product. A 6 months old child will receive an 8-times higher levels of the Spike protein mRNA with the pediatric dose of the Moderna vaccine when compared to the Pfizer-BioNTech product. Normally, a dose of a vaccine would be related to body size, but it is quite evident that this has been largely ignored with the COVID-19 vaccines.

15. Based on the doses of Spike protein mRNA that have been used in these vaccines, it can be estimated that a single 100 μg inoculation may contain over 50 trillion lipid nanoparticles that typically feature around 5 to 10 copies of the Spike protein gene. The whole SARS-CoV-2 RNA is close to 30,000 nucleotides long and is singe-stranded, but the spike gene is only around 4,000 nucleotides. It is calculated that the human genome, with 2,900,000,000 nucleotides per strand weighs about 0.855

[1] https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines.html

[2] https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/moderna.html

picogram per strand. Therefore 4000 nucleotides would weigh around 0.00000118 picograms or 0.00000000000118 µg per 4,000 nucleotide RNA molecule. With 100 µg of RNA in one vaccine injection, this works out to 85 trillion RNA molecules by this calculation. From each RNA molecule, which has been genetically engineered with non-natural nucleosides to be more stable to degradation, it is feasible that hundreds of copies of the Spike protein can be produced.

16. Traditional vaccines with attenuated, weakened strains of a pathogenic virus typically range from a low as 50 to a few thousand virus particles in an inoculation, with each virus having only one copy of each viral gene. Consequently, the COVID-19 genetic vaccines permit the generation of Spike proteins in vaccine recipients that are at levels that could never be achieved with previous vaccines or a natural infection without causing severe disease or death. This incredible capacity of these RNA and adenovirus vaccines to produce such high levels of Spike proteins accounts for their ability to elicit strong immune responses, but also their higher capacity for vaccine injury.

Section C. SARS-CoV-2 Infection and Protection Testing

17. To establish whether a person actively has an ongoing infection with SARS-CoV-2 and not another pathogen that produces similar symptoms to COVID-19, specific tests are necessary. Likewise, other tests are required to determine whether an individual has immunity from future infections with SARS-CoV-2 and is protected from getting COVID-19 again. These specific tests have been feasible ever since the release of the genome sequence of the original Wuhan strain of SARS-CoV-2 in January of 2020.

18. There are three major types of testing that are performed for determination if a person is actively infected with SARS-CoV-2 or has been infected in the past. For active infections, a Nucleic Acid Test (NAT), most commonly the Reverse Transcription - Polymerase Chain Reaction (RT-PCR)-based test, has been use for detection of the RNA component of the virus. It relies on amplification of this nucleic acid material through repeated cycles of separation and annealing (rejoining) of the nucleic acid strands by oscillations in temperature, with a doubling of the genetic material with each thermal cycle.

19. To also determine the presence of virus, antigen tests can be performed to detect target proteins in the SARS-CoV-2 virus particle, and this relies on the availability of pre-made antibodies that are specific for binding to one or more of its viral proteins, most commonly the Spike or Nucleocapsid proteins. Such antibodies may be generated in animals inoculated with whole or portions of the target viral

proteins that are artificially manufactured in cells and which are described as recombinant versions of the proteins in view of their unnatural production. These recombinant proteins are essentially identical to the original viral proteins, although they may be subjected to minor modifications by genetic engineering. A major difference between the genetic tests and the viral protein antigen tests is that there are no available means to amplify the number of viral protein molecules as can be done with viral RNA molecules using the RT-PCR method.

20. Once the SARS-CoV-2 virus is cleared by the immune system of recovered COVID-19 survivors, one can look for evidence of immunity in the form of antibodies present in their serum and other body fluids such as saliva, or less commonly, for the presence of specific T lymphocytes in their blood. It is important to understand that a positive PCR or rapid antigen test indicates the presence of active virus (or a very recent infection), but provides no measure of a person's subsequent state of immunity against that virus.

21. The main issue with the RT-PCR test is that it is often used in a manner with a high number of thermal cycles, which can generate a large percentage of high-false positive results (*e.g.*, a 90% false-positive rate is typical with more than 35 cycles. Individuals can still test positive with the RT-PCR test even two week after they have fully recovered from COVID-19 and are non-infectious. Studies have shown that if more than 30 cycles of PCR amplification are required to detect the presence of SARS-CoV-2 RNA in a specimen sample, this is insufficient to actually propagate the virus in optimal cell culture conditions in a lab.[33] A major issue with much of the results reported in the scientific literature for the presence of SARS-CoV-2 virus in clinical specimens is that 35 cycles or greater is commonly used. This is also true for the clinical phase III trials that have been used to test the efficacy of the COVID-19 vaccines. For example, a substack of Dr. Byram Bridle lists 48 of the most influential publications that have been cited by public health officials to mislabel asymptomatic people as sources of SARS-CoV-2 causing COVID-19 spread.[44] This problem undermines much of the public health data with respect to how many people were infected with SARS-CoV-2, as well as many clinical studies that seek to determine the

[33] Bullard, J., Dust, K., Funk, D., Strong, J.E., Alexaner, D. *et al.*, (2020) Predicting infectious SARS-CoV-2 from diagnostic samples. *Clin. Infect. Dis*. Ciaa638. doi: 10.1093/cid/ciaa638

[44] Bridle, B.W. (2022) Fundamentally flawed COVID-19 'Science': The misinformation that crushed constitutional freedoms of healthy/asymptomatic people. *COVID Chronicals*. https://viralimmunologist.substack.com/p/fundamentally-flawed-covid-19-science

effectiveness of a vaccine to prevent COVID-19.

22. With the antigen test, it is not possible to amplify up the viral protein material as can be done with the RT-PCR test, so it suffers from a lack of sensitivity and can often generate false-negatives. Depending on the specificity of the antibody detection reagent used, it may also cross-react with similar proteins that are found in other common cold coronaviruses related to SARS-CoV-2, and produce false-positives. However, such cross-reactive antibodies may still offer some degree of protection against severe infection with SARS-CoV-2.

23. The serological tests for antibody detection have the advantage that they can be highly sensitive and may provide a measure of the immunity present in a previously infected individual, even years after the initial exposure to the virus. However, it is also possible to pick up immunoreactivities with antibodies that were also produced against related viral proteins found in other coronaviruses. Historically, the RT-PCR test was most commonly used due to its accuracy and sensitivity, but antigen testing is more convenient and can even be performed in one's home or workplace for rapid analyses of SARS-CoV-2 infection status. By contrast, relatively little serological antibody testing is still performed presently in Canada and is primarily offered commercially by just a few companies.

24. While I could easily expand as to the 'pros' and 'cons' of these SARS-CoV-2 tests, for the purposes of this report, I have not delved into these details, except to highlight some of my own research observations and those from the scientific literature with respect to the extent of natural immunity.

Antibody Tests and Natural Immunity

25. Testing for SARS-CoV-2 antibodies in serum or saliva samples has actually been discouraged by many public health agencies, including the British Columbia Centre for Disease Control (BCDCD).[55] Whereas over 40 million dollars has been allocated for just the genome sequencing of the SARS-CoV-2 isolates from the Federal government, for example, with the CanCOGeN Project,[66] little funding has been provided in Canada for the development and application of antibody tests to determine the extent of

[55] http://www.bccdc.ca/health-professionals/clinical-resources/covid-19-care/covid-19-testing/antibody-testing-(serology)

[66] https://www.genomecanada.ca/en/cancogen

natural immunity and the immunity provided by the COVID-19 vaccines.

26. One project to evaluate antibody based immunity was primarily funded through the Angus Reid Group and conducted with the University of Toronto, and is called Ab-C for Action to Beat Corona Virus.[77] Using over 22,000 dried blood spot samples provided by over 11,000 Canadians, the antibodies that detected the Spike and Nucleocapsid proteins were used to ascertain vaccine-induced and natural-induced levels of immunity, respectively, against the virus. Ab-C study originally reported that by March 2021, only around 6.5% of tested Canadians had natural immunity.[88] Later, the Ab-C study indicated that only 5.25% of tested Canadians had Nucleocapsid protein antibodies, apparently through seroreversion.[7] These findings indicate that their SARS-CoV-2 antibody screening program has markedly underestimated the degree of natural immunity in the Canadian population, since a much larger percentage of Canadians have tested positive for SARS-CoV-2 infection by PCR-based tests. Moreover, the RT-PCR testing is believed to underestimate actual SARS-CoV-2 infection rates by at least 4-fold.[99] In the Ab-C study recombinant versions of the Spike and Nucleocapsid proteins were exclusively used as antigens for the testing of endogenous antibodies in the dried blood samples that bind to these antigens. This affords low sensitivity, and since antibody levels normally begin to subside in the months following the elimination of a viral infection, and they may decline to below the threshold of detection with standard tests. As to be discussed later, antibodies against the Nucleocapsid protein are often not always detectable in the serum of convalescent, recovered COVID-19 patients. The ramification of this is that the degree of natural immunity in populations is markedly underestimated, since they often rely on the presence of Nucleocapsid proteins exclusively as a biomarker. Consequently, public health officials in 2020 and 2021 almost completely discounted the prevalence and impact of natural immunity in their modelling of the COVID-19 pandemic and public policies.

27. The use of fresh serum samples can provide much better yields of active antibody, and studies performed by Ichor Blood Services in Alberta have shown that about 51% of the serum samples from unvaccinated people that they had tested by August of 2021 had detectable Spike and Nucleocapsid

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[77] https://www.abcstudy.ca/

[88] Tang, X., Sharma, A., Pasic, M., *et al.* (2022) Assessment of SARS-CoV-2 seropositivity during the first and second viral waves in 2020 and 2021 among Canadian adults. JAMA Netw. Open. 2002;5(2):e2146798. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789086

[9] [9] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

antibodies that were comparable in levels to those that are found in PCR-confirmed COVID-19.[1010] Subsequently, Ichor Blood Services recorded around 89% positive SARS-CoV-2 Spike protein antibody results in unvaccinated people even in rural areas in northern Alberta with lower population densities.[1111] With such high rates of natural immunity in remote rural settings, it is reasonable to expect comparable or even higher rates in urban, higher density settings.

28. The Canadian Blood Services, using highly sensitive Roche Elecsys Anti-SARS-CoV-2 Spike protein antibody and Nucleocapsid antibody tests determined that 99.65% of 13,189 unique donors had Spike antibodies, and 22.65% had Nucleocapsid antibodies by mid-February 2022.[1212] The seroprevalence level of the Nucleocapsid antibodies, which could only arise from natural infection, was evident in 36.6% of blood donors between 17-24 years of age across Canada. Despite nearly all donors having vaccine-related antibodies as of December 2021, with the emergence of the Omicron variants, by mid-February 2022 the infection related antibody rate was more than 4-times the monthly seroprevalence rate for the Nucleocapsid antibodies observed for the year of 2021. Consequently, the COVID-19 vaccination of the donors was not very protective against infection by SARS-CoV-2.

29. In the United States, a seroprevalence study observed that about 75% of US children that were tested had infection-induced antibodies following Omicron infection, meaning that there was clearly widespread naturally-acquired immunity in this population by early 2022.[1313,1414]

30. Likewise, in England, SARS-CoV-2 antibody testing of unvaccinated school pupils from January to February 2022, showed that 62.4% and 97% of primary and secondary students, respectively, were

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[1010] Personal communication: Mr. Michael Kuzmickas, Chief Executive Officer, Ichor Blood Services

[1111] https://www.cbc.ca/news/canada/edmonton/private-covid-19-antibody-tests-la-crete-alberta-1.6307357

[1212] Canadian Blood Services COVID-19 Seroprevalence Brief Report #19A: February 1-15, 2022 Survey. https://www.covid19immunitytaskforce.ca/wp-content/uploads/2022/04/covid-19-report-feb-2022-march-2022.pdf

[1313] Mallapaty, S. (2022) Most US kids have caught the coronavirus, antibody survey finds. *Nature* 605(7909):207-207. doi:10.1038/d41586-022-01231-y

[1414] Clarke, K.E.N., Jones, J.M., Deng, Y., *et al.* (2022) Seroprevalence of infection-induced SARS-CoV-2 antibodies - United States, September 2021-February 2022. *MMWR Morb Mortal Wkly Rep*. 2022;71(17):606-608. doi:10.15585/mmwr.mm7117e3

serologically positive for previous infection with the virus.[1515] It is reasonable to expect that the actual prevalence of SARS-CoV-2-directed antibodies in children in Canada is comparable to that seen in the US and UK.

31. In British Columbia, using a serological test for antibodies against the Spike and Nucleocapsid proteins of SARS-CoV-2, the BC Centre for Disease Control (BCCDC) reported that by August 2022, at least 70-80% of children ≤19 years, 60-70% of adults 20-59 years, but only ~40% of adults ≥60 years had been infected.[1616]

32. All of these serological tests track antibodies against the Nucleocapsid protein as a marker of natural immunity. These tests utilize recombinant version of the protein that is expensive to manufacture in bacteria or insect cells, and it is used at dilute concentrations in order to minimize costs, but at the sacrifice of sensitivity. As will be further explained, antibodies against the Nucleocapsid protein alone are insufficient to establish prior infection and recovery from SARS-CoV-2.

33. In my capacity of the president and chief scientific officer at Kinexus Bioinformatics Corporation in February 2020, I initiated a research program to determine if our company could identify the parts of the various proteins encoded by the genome of the SARS-CoV-22 that elicited strong immunoreactivities with antibodies in people who had recovered from COVID-19. I am the principal investigator of this clinical study that had originally received Independent Review Board (IRB) approval from Veritas IRB in Quebec, Canada (IRB Tracking Number: 16567-09:39:354-06-2020).

34. The ~30,000 nucleotide long RNA genome of this virus specifies 28 different proteins, but the Spike, Membrane and Envelope proteins are located on the surface of the virus, with the Nucleocapsid protein in its interior. With the knowledge of the nucleotide sequences of the genes that encode these viral proteins, it was feasible to predict the amino acids sequences of all 28 of these proteins.

35. Using an automated SPOT peptide synthesis technique, Kinexus was able to create cellulose

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1515 https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/datasets/covid19schoolsinfectionsurveyantibodydataengland (release date April 1, 2022)

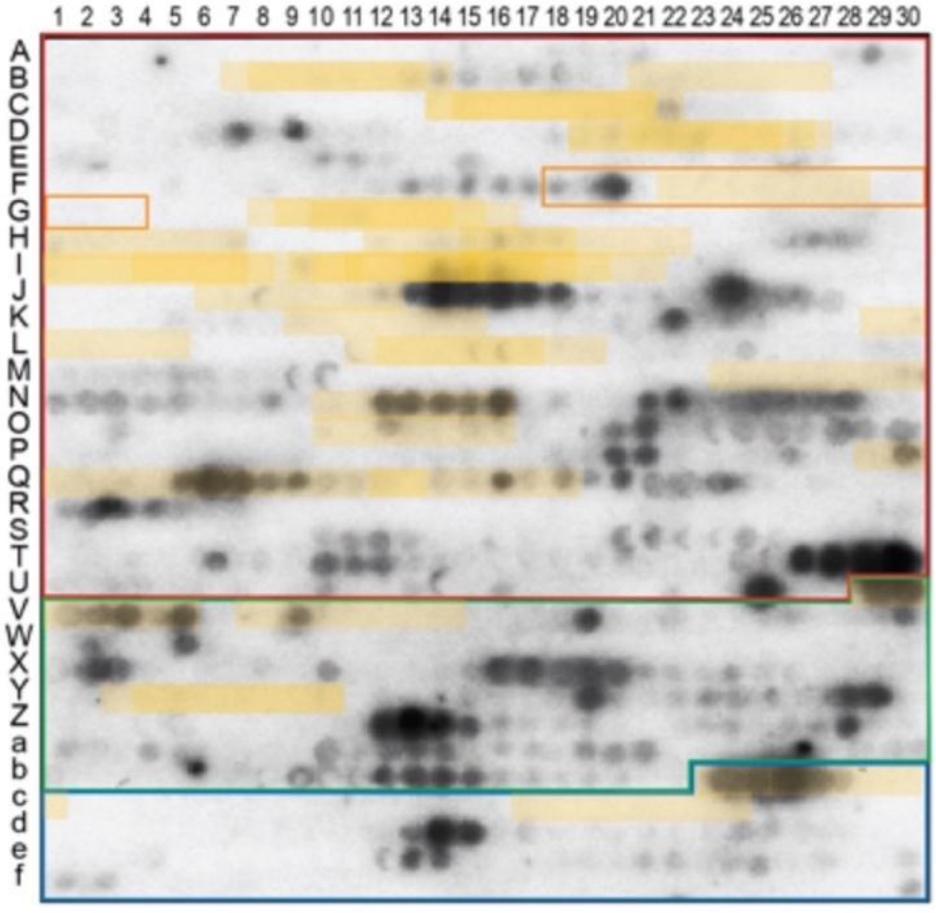
1616 Skowronski, D., Kaweski, S. E., Irvine, M.A., Kim, S., Chuang, E.S.Y., *et al.* (2022) Serial cross-sectional estimate of vaccine and infection-induced SARS-CoV-2 serolprevalence in children and adults, British Columbia, Canada: March 2020 to August 2022. medRxiv preprint doi: https://doi.org/10.1101/2022.09.09.22279751

membranes on which overlapping 15 amino acid-long pieces of all of these viral proteins were tiled out as arrays of distinct peptide spots of defined composition. This permitted the detection of epitopes as small as two amino acids long. Essentially, over 6000 distinct, but overlapping parts of all 28 viral proteins were robotically synthesized over a series of cellulose membranes with replicate copies of each membrane. Note that the concentrations of these peptides were at least 50-times higher than what could be achieved if we used recombinant versions of these peptides, which allows for very high sensitivity detection of antibodies that might specifically bind to these peptides at much lower concentrations than other serological tests. By testing serum samples from recovered COVID-19 patients separately with replicate copies of these SARS-CoV-2 peptide arrays, we identified over 400 viral peptides that generated strong immune responses with respect to antibody production following infection of these people with the virus. From studies with serum samples from over 20 COVID-19 convalescent patients with protein spot membranes with 257 to 1768 separately arrayed peptides, we further narrowed down the number of best markers to 120 peptides. Figure 1 provides an image of the overlaid results from 9 separate analyses with large 960 SARS-CoV-2 peptide SPOT membranes. With 120 peptide spot arrays, we further tested serum samples from another 450 recovered COVID-19 patients as well as healthy adults to identify 41 peptides that served as the most commonly targeted parts of 10 of the SARS-CoV-2 proteins for the creation of a 41-marker screen. With these 41-marker peptide spot arrays, we have since screened more serum or dried blood spot samples from over 3500 additional individuals that were COVID-19 confirmed or suspected as well as samples from healthy individuals with no prior history of COVID-19-like symptoms to explore the degree of natural and COVID-19-vaccine induced immunity in people primarily located in B.C. and Ontario.

36. The Kinexus SARS-CoV-2 antibody clinical study with the various SARS-CoV-2 peptide spot arrays has revealed that almost everyone tested has very unique antibody responses shown with their blood samples, as exemplified by the very diverse spot patterns of immunoreactivities with selected SARS-CoV-2-based peptides between people. However, when the same individuals were retested nearly a year later, from when they were initially screened following a recent SARS-CoV-2 infection, we have found that the patterns are very similar and reproducible for each person**. In fact, we have now been able to show that the presence of multiple antibodies against the SARS-CoV-2 protein is clearly evident in people even 3 years after their initial infection with SARS-CoV-2, which demonstrates the establishment of lasting immune memory from natural infection.** This is shown in Figure 2, which

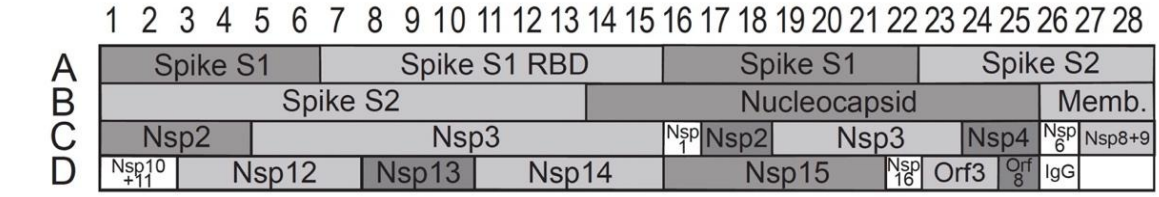
provides typical representative immunoblot images of 12 from over a hundred individuals that were initially tested for SARS-CoV-2 antibodies in the first COVID-19 wave of COVID-19 cases and then again about 10-12 months later. Several of these individuals had COVID-19 typically around 4 months before their initial testing.

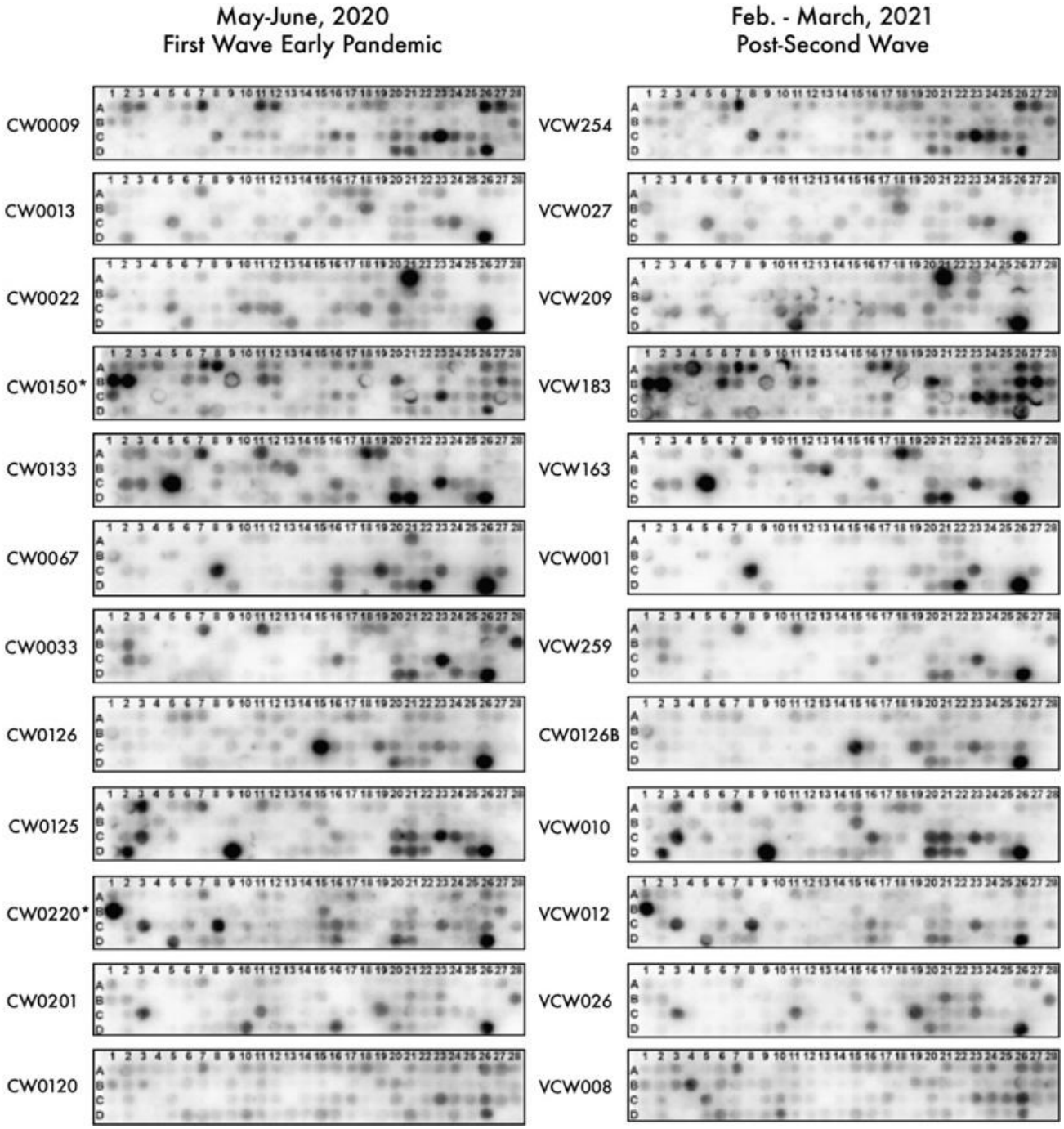
Figure 1. Kinexus CDH/CDR SARS-CoV-2 SPOT array overlay of 9 images of serum sample results from different participants that recovered from COVID-19. Short overlapping peptides that cover the entire structures of the Spike (upper, red outline), Nucleocapsid (middle, green outlined) and Membrane (lower, blue outlined) proteins of the Wuhan strain, where produced on arrays that were probed with serum samples that contained antibodies from confirmed COVID-19 cases. A dark spot indicated that this region of the targeted protein were immunogenic and elicited antibodies against this part of the virus proteins. Peptides that are expected to feature Omicron BA.1 mutations are highlighted in yellow shading. Apart from the D796Y and N969K mutations in the Omicron Spike protein, none of the other 32 mutations are in parts of this viral protein that elicited strong antibody responses.



Omicron Mutations	SPOT Array Locations
Spike	
A67V	B7-B13
Δ69-70	B8-B14
T95I	B21-B27
G142D	C14-C21
Δ143-145	C15-C22
Δ211	D19-D25
L212I	D19-D26
ins214EPE	D21-D27
G339D	F22-F28
S371L	G8-G14
S373P	G9-G15
S375F	G10-G16
K417N	H1-H7
N440K	H12-H18
G446S	H15-H22
S477N	I1-I7
T478K	I1-I8
E484A	I4-I11
Q493R	I9-I15
G496S	I10-I17
Q498R	I11-I18
N501Y	I13-I19
Y505H	I15-I21
T547K	J6-J12
D614G	K9-K15
H655Y	K29-L5
N679K	L11-L17
P681H	L12-L19
N764K	M24-M30
D796Y	N10-N16
N856K	O10-O16
Q954H	P29-Q5
N969K	Q6-Q13,
L981F	Q12-Q18
Nucleocapsid	
P13L	U29-V5
Δ31-33	V7-V14
R203K	Y3-Y10
G204R	Y4-Y10
Membrane	
D3G	b23-b24
Q19E	b25-c1
A63T	c17-c24

Figure 2. Stability of SARS-CoV-2 antibody patterns in serum samples of COVID-19 recovered individuals tested with the Kinexus 110 marker SARS-CoV-2 antibody screen. The locations of peptides within the various SARS-CoV-2 proteins are indicated in the map shown immediately below. Spot D26 corresponds to a positive control to ensure that the test was working properly.





37. The Kinexus SARS-CoV-2 antibody clinical study with the various SARS-CoV-2 peptide spot arrays has revealed that almost everyone tested has very unique antibody responses shown with their blood samples, as exemplified by the very diverse spot patterns of immunoreactivities with selected SARS-CoV-2-based peptides between people. However, when the same individuals were retested nearly a year later, from when they were initially screened following a recent SARS-CoV-2 infection, we have found that the patterns are very similar and reproducible for each person**. In fact, we have now been able to show that the presence of multiple antibodies against the SARS-CoV-2 protein is clearly evident in people even 30 months after their initial infection with SARS-CoV-2, which demonstrates the establishment of lasting immune memory from natural infection.** This is shown in Figure 2, which provides typical representative immunoblot images of 12 from over a hundred individuals that were initially tested for SARS-CoV-2 antibodies in the first COVID-19 wave of COVID-19 cases and then again about 10-12 months later. Several of these individuals had COVID-19 typically around 4 months before their initial testing.

38. Another important insight from the Kinexus clinical study was that with infection with the SARS-CoV-2 virus, for each person, their antibodies can actually recognize hundreds of very different parts of the virus proteins. This is known as a polyclonal antibody response, and underlies the effectiveness of the immune system to take on mutated versions of the virus. Scores of different antibodies may be detected against different parts of the Spike protein alone with the serum from a recovered COVID-19 patient. Another striking finding is that when the locations of the amino acids mutations in the Alpha, Beta, Delta and Omicron variants of SARS-CoV-2 are mapped, it turns out that these mutations rarely occur in the parts of the SARS-CoV-2 proteins that people usually make antibodies against (Figure 1). Therefore, most of the antibodies made against the original Wuhan strain of the virus should and do work effectively as well as against any of the variants, and *vice versa*. This is why the COVID-19 vaccines that were produced with the original Wuhan strain of the Spike protein could still produce effective protection from even the Omicron BA.4 and BA.5 strains of SARS-CoV-2, and are still offered today for this purpose even against the more recent BQ1 and BQ1.1 strains. In fact, the bivalent vaccines with the Wuhan/Omicron BA.4/5 Spike RNA combination are proving to be no better for eliciting antibody responses than the original Wuhan Spike RNA vaccines.

39. Yet another key finding from the Kinexus clinical study is that with over 4500 people subjected to testing, over 90% of these individuals clearly possessed antibodies that can recognize the SARS-CoV-2 virus, with numbers and intensities of visible immunoreactive spots that are similar to that seen with RT-PCR-test confirmed, recovered COVID-19 patients. Some of this work has already been published in the peer-reviewed, flagship journal of the American Society for Clinical Investigation (JCI).[1717] In this JCI Insight study, which included serum samples collected in Spring 2020 from 276 healthy, adult participants, half of which were healthcare workers, about 90% of those tested had detectable antibodies that immunoreacted with our smaller SARS-CoV-2 peptide spot arrays and also worked with recombinant preparations of the Spike and Nucleocapsid proteins. The Kinexus SARS-CoV-2 antibody test results were cross-validated with another SARS-CoV-2 antibody test developed and marketed by the U.S. company MesoScale Devices.[1818] The Kinexus SARS-CoV-2 antibody tests are likely among the most sensitive and accurate serological antibody tests developed. No other reported tests permit the detection of antibodies against so many different SARS-CoV-2 proteins. However, Kinexus does not plan to offer these serological tests as a commercial service.

40. In the Kinexus clinical study for SARS-CoV-2 antibody levels in PCR test confirmed and those with COVID-19 symptoms, despite clear detection of antibodies against the Spike and other proteins from this virus, we have observed that many have little or no detectable antibodies against the Nucleocapsid protein of the SARS-CoV-2 virus. This is evident in Figure 1, and in Figure 3, which shows the testing results from 56 PCR confirmed COVID-19 cases and 16 healthy negative controls using a smaller 41-marker version of our antibody test.

41. Since most commercial serological tests, and the one used in the Ab-C study are based on detection of antibodies against the Nucleocapsid protein of SARS-CoV-2 to evaluate natural immunity, this may explain why the degree of natural immunity in the Canadian population has been dramatically underestimated. This lack of appreciation of the extent of natural immunity in the Canadian population by health authorities in this country accounts for why natural immunity was not factored

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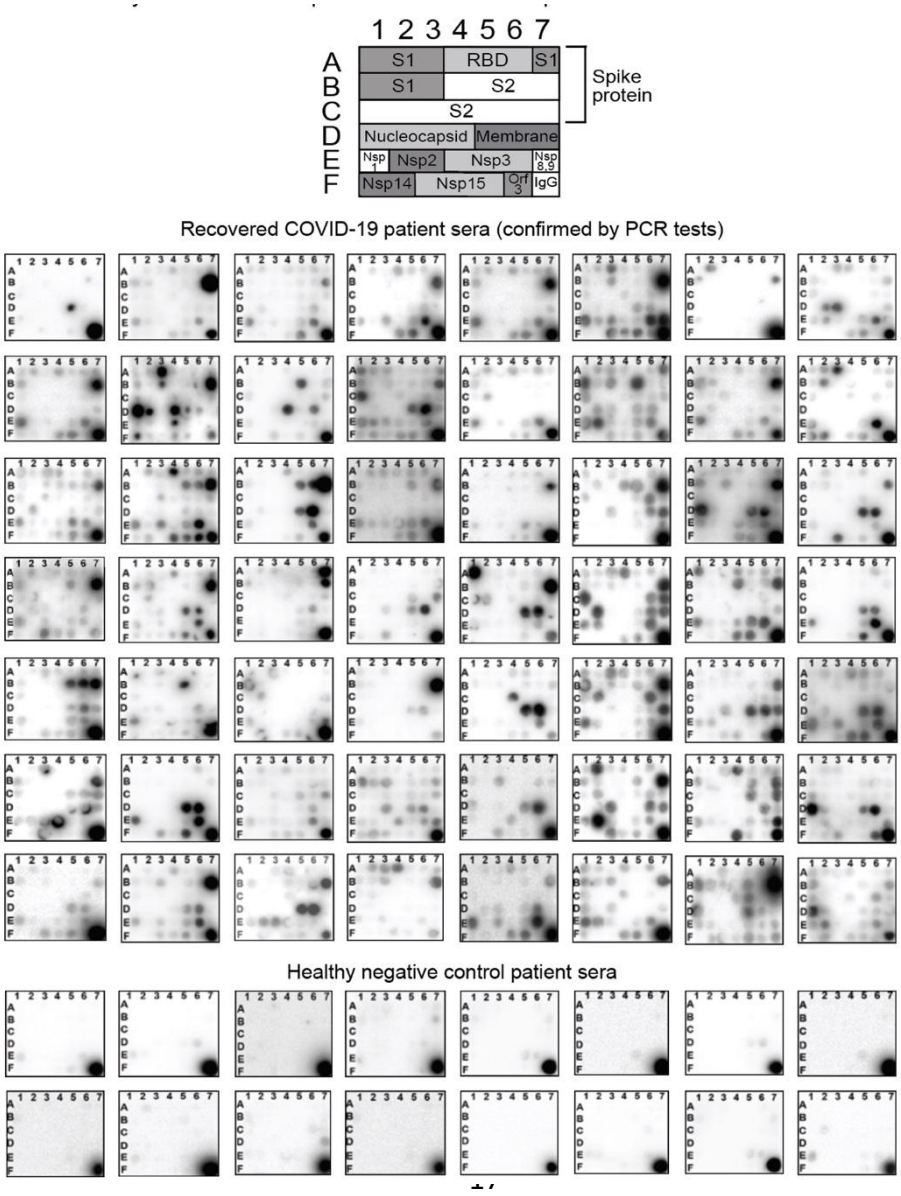
[1717] Majdoubi, A., Michalski, C., O'Connell, S.E., Dada, S., Narpala, S. *et al*. (2021) A majority of uninfected adults show pre-existing antibody reactivity against SARS-CoV-2. *JCI Insight* 6(8): e14631. https://doi.org/10.1172/jci.insight.146316

[1818] https://www.mesoscale.com/en/products_and_services/assay_kits/covid-19

into projected models of the COVID-19 pandemic and the policies such as implementation of vaccine passports that discounted natural immunity. By contrast, natural immunity was recognized in the issuing of vaccine passports in many European countries. More recently, serological tests based on Nucleocapid-directed antibodies are showing rates of natural immunity approaching 90%. This is likely due to production of much more robust antibody responses from repeated exposures to the SARS-CoV-2 virus, which acts as a natural booster.

Figure 3. Poor detection of Nucleocapsid antibody patterns in serum samples of COVID-19 recovered individuals tested with the Kinexus 41 marker SARS-CoV-2 antibody screen. The locations of peptides within the various SARS-CoV-2 proteins are indicated in the map shown immediately below. Nucleocapsid antibody detection is evident in D1 – D4 spots. Spot F7 corresponds to a positive control to ensure that the test was working properly.



42. The recent scientific literature and our own SARS-CoV-2 antibody testing with over 4500 people to date, clearly demonstrate that most people in Canada already have antibodies against SARS-CoV-2 regardless of whether they have been vaccinated or not. This is not surprising, considering that we are now well into the fourth year of the COVID-19 pandemic. Even the 1918 influenza pandemic only lasted a year (in the absence of vaccines and anti-viral drugs), and the more recent SARS-CoV-1 pandemic in 2003 only lasted for less than a year. This is likely due to the acquisition of natural immunity in the population, and the evolution of the virus into a more infectious but less virulent strain, similar to what has transpired with SARS-CoV-2.

43. When individuals are infected and mount an immune response, it is not surprising that antibody levels will begin to naturally wane, but there should still be a high degree of residual immune protection. Antibody levels typically decline in blood once a pathogen is eradicated by the immune system over a period of weeks or months. This is because maintenance of high antibody titres can affect the viscosity of blood flow and increases the chances of autoimmunity due to antibody cross-reactivity with off-targets that include normal cellular proteins. A sensitive test will still be able to detect residual levels of antibodies that reveal previous exposure to a pathogenic virus or bacteria. Importantly, despite the low antibody levels, the B-cells that produced these antibodies still remain alive in a dormant state as plasma or memory B-cells. Upon re-infection with the pathogen, these hibernating B-cells are individually stimulated to grow and divide to generate identical cells that pump out more of the exactly same antibody with a defined specificity for a small portion of the pathogen that we refer to as an epitope. Plasma and memory B-cells are known to survive for decades and are able to produce more antibodies upon reinfection with the same pathogen.[1919] Symptomatic disease occurs when the virus with an infection or reinfection can propagate faster than the immune systems can mount an effective response against it. However, the immune system usually overcomes the virus in a few days and full recovery is achieved.

[1919] Xiaocong, Y., Tsibane, T., McGraw, P. *et al*. (2008 Sept. 25) Neutralizing antibodies derived from the B-cells of 1918 influenza pandemic survivors. *Nature*. 455(7212) 532–536.

Section D. The Experimental Nature of COVID-19 Vaccines

44. Four of the currently available COVID-19 vaccines in Canada are RNA-based using lipid nanoparticle carriers (*i.e*., Pfizer/BioNTech and Moderna) or DNA-based using adenovirus carriers (*i.e*., Johnson&Johnson (J&J) and AstraZeneca). In each case, these particular vaccines deliver genetic instructions for the production of the Spike protein of the SARS-CoV-2 virus inside of the host cells that take up these vaccines (usually in deltoid muscle region of the arm at the site of injection). The Spike protein is then presented on the surface of these cells to elicit an inflammatory immune response that culminates in the stimulation and proliferation of T-cells and B-cells, the latter of which will produce antibodies that specifically target epitopes on the Spike protein. **To produce the activation of T- and B-cells, this necessitates the damage and likely destruction of the Spike-presenting host cells**.

45. Lipid nanoparticles and adenoviruses have been used to deliver drugs and toxins into animals for therapeutic purposes, and even to elicit immune responses.[2020] The lipid nanoparticles or genetically engineered adenoviruses normally present the antigen of the pathogen on their own surfaces. However, the combination of the lipid nanoparticles to get production of a target pathogenic protein on the surface of the body's own cells to elicit an immune response against that target remains experimental as we are still learning more about the consequences of this novel method of antibody production. In a sense, the genetic vaccines are pro-drugs, which require further processing to produce the active ingredients. Unfortunately, the production of the Spike protein is very host cell-dependent, and this processing is influenced by many different factors, including vaccine dose to body size ratio, cell type taking up the vaccine, health, nutritional, hormonal and pharmacological status.[2121] Consequently, the levels of Spike protein could potentially vary by up to two orders of magnitude. This can lead to marked variations in vaccine efficacy and injury.

[2020] Dolgin, E. (2021) The tangled history of mRNA vaccines. *Nature*. 597:318-324. https://www.nature.com/articles/d41586-021-02483-w

[2121] Gutchi, L., Speicher, D. J., Natsheh, S., Oldfield, P., Britz-McKibbn, P. *et al.* (2022) An independent analysis of the manufacturing and quality issues of the BNT162b BioNtech/Pfizer quasi-vaccine based on the European Medicines Agency's Public Assessment Report (EPAR). Canadian Covid Care Alliance. https://www.canadiancovidcarealliance.org/wp-content/uploads/2022/11/22OC29_EMA-Analysis-of-BNT162b-Manufacture.pdf

46. To counteract the crisis of the COVID-19 pandemic, these four COVID-19 vaccines were first released for general use in the Canadian population starting in mid-December 2020 under an Interim Order. In the US, only three of these vaccines (AstraZeneca's adenovirus vaccine was not approved) were authorized for general use through Emergency Use Authorization (EUA). In Canada, the US and elsewhere, all of these vaccines are actually technically still in Phase III clinical trials. For example, the Pfizer/BioNTech COVID-19 vaccine, which is the most widely used, is still in Phase III trials that are not scheduled to be completed until July 30, 2023.[2222] The approvals provided by the FDA and Health Canada remain contingent on active and passive monitoring of the efficacy and safety of these non-traditional vaccines. Consequently, these COVID-19 vaccines are still regarded by many as highly experimental in nature.

47. Normally, the testing of drugs and vaccines by manufacturers requires pre-clinical trials in at least two different animal models to ensure efficacy and safety. Phase I trials are performed on healthy volunteers to evaluate initial safety concerns. Phase II trials are then undertaken with the main targeted participants with different concentrations of the vaccine to establish an optimum dose, in this case, to elicit antibody production. Phase III trials are subsequently conducted on a large number of targeted participants in multiple centers to investigate the longer-term efficacy and safety of the tested vaccine at the optimal dose.

48. The current continuation of the phase III studies with COVID-19 vaccines has been prompted by several factors, including an unprecedented shortening of the typical testing period of a vaccine from five to ten years before approval for general release to under a single year with "Operation Warp Speed" in the US. This was achieved by skipping many cell and animal preclinical trials with the vaccines from 1 to 3 years normally down to a couple of months and running them in parallel with phase I and II human trials. Of particular concern, many of the safety studies were performed in rats or mice, which is problematic, because these rodents do not feature ACE2 receptors that can bind to the SARS-CoV-2 spike protein. Phase II and III trials, which instead of being conducted over 3 to 5 years normally, were combined, and in less than 6 months, given to the general population with an

[2222] Pfizer-BioNTech COVID-19 BNT162b2 Vaccine effectiveness study - Kaiser Permanente Southern California. https://clinicaltrials.gov/ct2/show/NCT04848584

Interim Order in Canada and EUA in the US. For example, the phase III clinical studies with the Pfizer/BioNTech vaccine commenced in July 27th, 2020, and the vaccine was approved for general use for those over 18 years of age by early December of 2020. Ultimately, these novel genetic vaccines were approved in about a tenth of the time as traditional vaccines for wide spread use.

49. It should be appreciated that the RNA- and adenovirus-based genetic vaccine did not even originally meet the original definition of a "vaccine," which was previously described as "*a product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease*" by the US CDC.[2323] Later, on September 1, 2021, the definition of vaccine was broadened to "*a preparation that is used to stimulate the body's immune response against diseases*." The new definition of "*immunity*" was also problematic with "*protection from an infectious disease*." The CDC states that "*If you are immune to a disease, you can be exposed to it without becoming infected*."[2424] It is now clear that one can still become infected, but the claims have been made that protection is provided to reduce the severity of the illness, but not necessarily to prevent infection. One can still become infected, but be asymptomatic and still transmit the pathogen. These genetic vaccines are more like genetic therapy, because they do not contain the actual immunogen to elicit an antibody response, but rather can provide genetic instructions for the body to produce the immunogen. Normally, the use of genetic therapy products commands a much higher level of testing than traditional drugs or vaccines. It is also noteworthy that vaccines do not carry the same degree of liability to manufacturers in the US as do drugs for injury from these products.[2525]

Section E. COVID-19 Vaccine Efficacy

50. In any discussion of efficacy of a vaccine, it is important to understand the concept of relative risk reduction (RRR) and absolute risk reduction (ARR). The ARR represents the difference in rates of an event (*e.g.*, infection) between the experimental group and the control group. It is calculated by subtracting the experimental group event rate from the control group event rate and is usually

[2323] http://web.archive.org/web/20200317214611/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm
[2424] https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm? Sourced September 10, 2022.
[2525] https://www.law.cornell.edu/uscode/text/42/300aa-22

expressed as a percentage. In contrast, the relative risk reduction (RRR) represents the relative decrease in the risk of an adverse event in the experimental group compared to the control group. It is calculated by dividing the rate of the experimental group by the rate of the control group, and, as with the ARR, usually expressed as a percentage.

51. In a hypothetical example, in a study trial with 100 vaccinated participants, only 1 of them may have become ill, and was not protected by the tested vaccine from getting sick. In the unvaccinated arm of the trial with 100 more participants, only 2 of them become ill. In this study, the RRR of the vaccine is 50% (= 0.01 / 0.02 x 100%), a potentially attractive reduction likely to persuade users to accept the treatment. In contrast, the ARR is merely 1% (= (0.02 – 0.01) x 100%), which means that individuals who did not take the 'vaccine' are still likely to remain free from the "disease" 98% of the time, as opposed to 99% of the time if they took the vaccine. This may give pause to patients and health professionals when considering the desirability of accepting a new treatment, especially considering the scant safety data.[2626] Of note, while the RRR of the first Pfizer/BioNTech trial was 95%, the ARR was only 0.8%, which was calculated by independent investigators but not reported in the original peer-reviewed publication (although the raw data was available in Supplemental section to permit such calculations).[2727]

52. Because communicating relative risk can be so misleading, not only to the public but also to health professionals, the US FDA, in a 2011 report entitled "Communicating Risks and Benefits: A User's Guide", instructed investigators to "*provide absolute risks, not just relative risks,*" noting (on page 60) that "*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.*"[2828] To put this all into perspective, with respect to COVID-19, if everyone was vaccinated, we would expect a reduction in the total number of people in the population that get COVID-19 to be reduced by less

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[2626] Brown, R.B. (2021) Outcome reporting bias in COVID-19 mRNA vaccine clinical trials. *Medicina (Mex)*. 57(3):199. doi:10.3390/medicina57030199

[2727] Thomas, S.J., Moreira, E.D., Kitchin, N. *et al.* (2021) Safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine through 6 months. *N Engl J Med*. 385:1761-1773

[2828] Brewer, N.T., Downs, J.S., Fischhoff, B, eds. (2011) Communicating risks and benefits: An evidence-based user's guide.:242.

than 1% with a RRR value of 95% based on the COVID-19 RNA vaccine phase III trials in a 6 months period, which is the duration of the clinical study used to generate this data.

53. It should be appreciated that efficacy estimates in this regard with RRR values are limited in the phase III clinical trials to ascertaining whether the COVID-19 vaccines reduce the actual occurrence of SARS-CoV-2 infection and COVID-19 symptoms within the duration period of these studies. **These clinical trials did not access whether the vaccines reduced transmission, severity, hospitalizations, and deaths. Moreover, they poorly evaluated whether COVID-19 vaccines reduced occurrence of the disease in those segments of populations that are at greatest risk, namely the very elderly, obese or those with comorbidities.** The preclinical, phase I, phase II and phase III trials were all accelerated for these vaccines, and the formal phase III clinical trials never tested end points such as protection from COVID-19-induced death or transmissibility of the virus. Nor were biochemical studies performed such as D-dimer analyses to detect for potential blood clotting, C-reactive protein for inflammation, and troponin for heart damage. In the absence of properly matched placebo controls, this will not be clear from the post-marketing safety studies of the COVID-19 vaccines following their release to the general public. It is also problematic that over 85% of the population has been at least double vaccinated, so it is harder to identify vaccine-related injury above the background levels of morbidity. The post-marketing, phase IV studies are being relied upon instead to learn more about the benefits, limitations and risks of the COVID-19 vaccines, for example, on pregnancy outcomes. For all intents and purposes, these novel RNA and adenovirus vaccines remain “experimental” and regulations about their use are being constantly refined as more data accumulates about them. As highlighted in the next paragraph, the definition of “unvaccinated” itself is very problematic and it can cause significant misrepresentation of the COVID-19 data on public health websites.

54. In consideration of all the epidemiology studies that bench mark the risk reduction of acquisition of COVID-19 with the vaccines relative to “unvaccinated” individuals, irrespective of whether such comparisons are made in the clinical trials or the post-approval release of these vaccines, the following are significant issues that must be appreciated:

a. A higher testing bias by PCR or rapid antigen testing of unvaccinated people occurs, especially since the adoption of vaccine passports, where workplace testing is usually focused, or even restricted to those that are unvaccinated;

b. Very frail and elderly people, who are also at greatest risk of requiring hospitalization due to their fragile condition, are often not vaccinated for fear of vaccine-induced injury from mounting overly strong immune responses;

c. The definition of unvaccinated includes those that are actually vaccinated and develop COVID-19 within 2- to 3-weeks after their first vaccination (depending on the province in Canada). Consistently, it has been a practice by public health authorities to include such COVID-19 cases as those associated with the unvaccinated for statistical purposes. This is particularly problematic, because vaccination appears to initially increase one's risk of getting COVID-19;

d. The over-reporting of hospital cases, ICU admissions and deaths of individuals with COVID-19 as having the disease under circumstances where the original hospitalizations were due to other reasons independent of having a SARS-CoV-2 infection, *i.e.,* the individuals had an existing comorbidity or death from other causes, but happened to test positive for SARS-CoV-2 at the time of admission or during their stay in hospital. This number appears to be around 46% of all COVID-19 hospital cases in Ontario as of January 1, 2022;[2929] and

e. Many of the "vaccinated" and "unvaccinated" cases already have immunity from natural infection with SARS-CoV-2, and this is especially evident in children, many of whom were asymptomatic for COVID-19.

55. With respect to Paragraph 54b, recent data from Scotland revealed that at the time of triple vaccination of the elderly, there were increased COVID-19 case numbers in the elderly as shown in the original Figure 16 from a report provide by Public Health Scotland.[3030] This was attributed to

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[2929] https:/covid-19.ontario.ca/data/hospitalizations

[3030] https://www.publichealthscotland.scot/publications/covid-19-statistical-report/covid-19-statistical-report-16-february-2022/) https://www.publichealthscotland.scot/media/11916/22-02-16-covid19-winter_publication_report.pdf

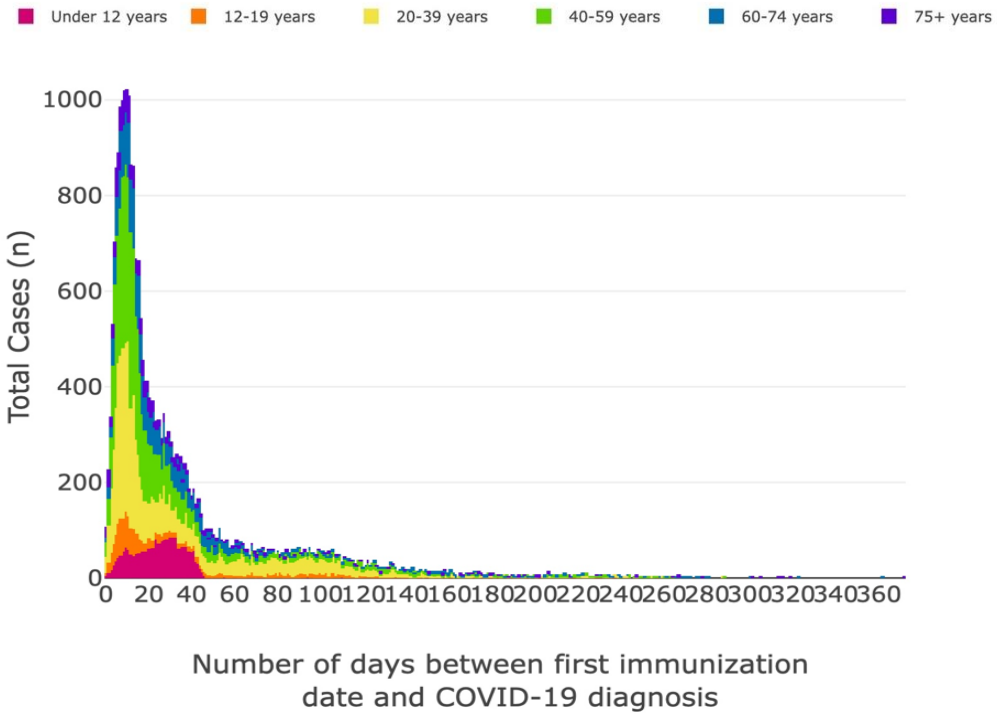
vaccination "*and the prioritisation of the booster/third dose to the clinically extremely vulnerable at the beginning of the booster programme*."[30] However, as further explained below, due to the extremely high production of Spike protein with each vaccination, the capacity of immune system may be overwhelmed initially with appearance of Spike protein on body cells and is insufficient to deal with SARS-CoV-2 virus particles that enter into the respiratory system. These viruses are able to propagate sufficiently to then produce illness.

56. With respect to Paragraph 54c, one of the reasons why the aggregation of COVID-19 cases in people that were vaccinated within 2 weeks with the unvaccinated is very problematic is apparent from the analyses of epidemiology data that was provided by Alberta Health at their website.[3131] Data in tabular and graphic forms were provided between the occurrence of COVID-19 in vaccinated individuals as a function of time following vaccination was available between August 11, 2021 and January 11, 2022 on-line. Figure 4 is a captured screen shot taken on January 11, 2022 of one of these figures that shows the timing of COVID-19 infections in people that were vaccinated only once. Note that this image needed to be recovered using the Way Back Machine website as this has since been removed after January 11, 2022.[3232] It is evident that there was a dramatic rise in COVID-19 cases in the first seven days post-inoculation. After about 9 days, the number of COVID-19 cases declined as antibodies were produced by immune B cells and immune T cells became activated. It appears that vaccination actually increases the chances of getting COVID-19. If it did not, then the rate of COVID-19 should have been the highest on the first day and stayed that way for about a week, and then it should have then declined with the building of immunity. In view of this vaccine-induced increase in COVID-19 cases within the first two weeks of vaccination for the first time, it is highly inappropriate to include these cases with the unvaccinated cases as has been routinely done by public health authorities. **It renders case counts, hospital admissions and deaths higher than they should be for the unvaccinated, and makes the single vaccinated data look more favourable for protection from SARS-CoV-2 infection and COVID-19 disease with vaccines**. Again, the extremely highly levels of Spike production during this initial period places a burden on the immune system that may divert it from an effective response to an actual SARS-CoV-2 infection. Antibodies and T-cells that could

[3131] https://www.alberta.ca/stats/covid-19-alberta-statistics.htm
[3232] https://archive.org/web/

recognize the Spike protein, rather than targeted incoming SARS-CoV-2 virus particles, are instead preoccupied with attacking the vaccinated cells that are actively producing the Spike protein on their surfaces throughout the body.

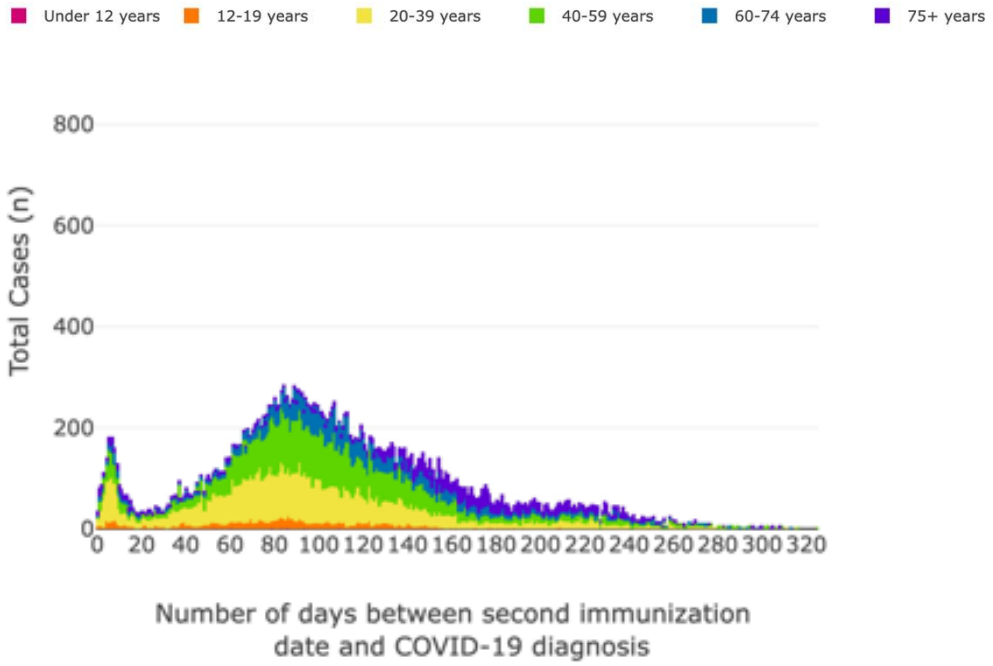
Figure 4. Timing of COVID-19 cases in Alberta following first vaccination – January 11, 2022.[31]



57. Another captured screen shot from the Alberta Health website that was taken on November 29, 2021, shown in Figure 5, displays the timing of COVID-19 infections in people that were vaccinated once, and then were also vaccinated a second time. There was also a rise in COVID-19 cases in the first seven days as well.[31] Considering that these individuals would have been vaccinated typically about 4 weeks to 6 weeks before, and should have peak immunity, it surprising to see an increase in COVID-19 case counts immediately following the second shot. This likely explains why, for some people, the vaccine appears to increase susceptibility to infection with SARS-CoV-2, which is a phenomenon also consistent with antibody-dependent enhancement. The data shown here indicates that the peak number of the COVID-19 vaccine breakthrough cases up to November 29, 2021 occurs at around 3 months after the second shot. This data reveals that most breakthrough COVID-19 cases, when the Delta variant of SARS-CoV-2 was predominating, happened within 3 months post-second vaccination.

This shows that the protection offered from COVID-19 by the COVID-19 vaccines for the Delta variant for many people was only about 3 months rather than the 6 months that was commonly stated by public health authorities.

Figure 5. Timing of COVID-19 cases in Alberta following second vaccination – November 29, 2021.[31] These breakthrough infections correspond to primarily Delta cases and precedes Omicron cases.



58. While it is clear that the new variants of SARS-CoV-2 are less deadly than the original Wuhan strain, the overall chances of surviving COVID-19 during the entire course of the 3-year pandemic in Canada to December 23, 2022 can be estimated to about 98.91%, based on 1.09% of Canadians reported as infected that have died with COVID-19. This estimate is based simply on taking the total reported deaths with COVID-19 (46,948) and total PCR-confirmed COVID-19 cases (4,475,268).[3333] This includes those at higher risk of COVID-19 based on old age, obesity, pulmonary disease, smoking, diabetes, immune compromised and those with other predisposing factors. Likewise, a similar calculation performed with US statistics obtained from a Google search indicates 930,000 deaths associated with 7,820,000 COVID-19 cases and indicates a similar death risk of 1.19% if infected.

[3333] https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html

However, the reported number of people that get COVID-19 is estimated by the US CDC to be at least 4-fold higher than recorded numbers for those that are tested and confirmed by RT-PCR testing, and this is likely to be true in Canada as well.[3434] Therefore, actual rate of death across the entire population based on cumulative data is probably closer to 0.27% for SARS-CoV-2 variants before Omicron predominated. Looking at the numbers of 31,367 PCR- confirmed cases of COVID-19 and only 108 COVID-19 deaths for one day on December 14th, 2021, this indicates a COVID-19 case mortality rate of 0.34%, which again is likely closer to less than 0.1% in reality in view of the undercounting of COVID-19 cases. By comparison, influenza even with an existing strong vaccination program for those at greatest risk has a case fatality rate in the Spring of 2020 in the US that was not that much different from COVID-19 before its vaccines were available.[3535]

59. When one considers the risks of severe COVID-19 leading to hospitalizations, ICU admissions and deaths in Canada in terms of age based on data available up to December 14th, 2021, there are huge differences. Over the course of 2 years into the pandemic, 2.5% of the hospitalization cases with COVID-19 were in the 0-19 year-olds, 4.7% in 20-29 year-olds, 17% in 30-49 year-olds, 31.9% in 50-69 year-olds and 43.8 % in 70 years and older people.[33] With respect to COVID-19 ICU admissions, 1.5% of these cases were in the 0-19 year-olds, 3.1% in 20-29 year-olds, 17.4% in 30-49 year-olds, 46.2% in 50-69 year-olds and 31.8% in 70 years and older people.[33] With respect with COVID-19 deaths, 0.08% of these cases were in the 0-19 year-olds, 0.3% in 20-29 year-olds, 2.4% in 30-49 year-olds, 15.1% in 50-69 year-olds and 82.2% in 70 years and older people.[33] Only 41 children from 0 to 11 years of age, and 25 adolescents from 12 to 19 years of age, and 144 adults from 20 to 29 years of age died with and most likely not from COVID-19 in Canada up to December 15, 2022 during the entire COVID-19 pandemic in Canada.

60. Canada-wide, since the second wave of COVID-19 cases that peaked around January 10, 2021 (7 day daily average = 8,261), there has been five additional waves that peaked around April 15 (7 day daily average = 8,670) and September 19 (7 day daily average = 4,411) in 2021, January 7, 2022 (7 day daily

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[3434] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

[3535] Faust, J.S., del Rio C. (2020) Assessment of deaths from COVID-19 and from seasonal influenza. *JAMA Intern Med.* 180(8):1045-1046. doi:10.1001/jamainternmed.2020.2306

average = 41,972), around April 13, 2022 (7 day average = 28,465, and around July 20, 2022 (7 day daily average =5,808).[3636] By January 7, 2022, 84.2% of Canadians had been vaccinated at least once, 77.9% at least twice and 31% three times. Despite almost an 850% increase in COVID-19 cases between the peaks of the fourth and fifth waves, there was only a 221% increase in hospitalizations, a 29% increase in ICU admissions and a 53% increase in deaths. These data clearly demonstrate that Omicron BA.1 and BA.2 variants were much less severe than the Delta variant. The duration of the illness for those with COVID-19 was also about half the length of time. The same relatively low rates of hospitalization, ICU admissions and deaths with the latest Omicron strains were also evident with the sixth wave of COVID-19 cases around April, 2022. Since then the incidence of COVID-19, hospitalization and deaths have remained low in Canada for the past 10 months through to the date of this report even with the predominance now of the BQ1 and BQ1.1 variants of SARS-CoV-2. The substantially reduced progression to severe COVID-19 outcomes seen with the early Omicron variants as compared to the Delta variant was also described in a meta-analysis of the large, integrated healthcare system in Southern California.[3737]

61. A failure of triple vaccination to sustain immunity is why Israel and other countries started boosting their populations with a fourth inoculation of the Pfizer/BioNTech vaccine, since it only provided protection for less than 4 months. Both the Pfizer/BioNTech and Moderna vaccines are available in Canada with a fourth shot for those 18 years and older.[3838] A fifth inoculation was initially available for those 12 years and older if they were immune compromised,[38] and now the elderly also are receiving a fifth shot.

62. Further studies from Israel have shown that while protection against infection and severe COVID-19 increased after a fourth dose in those over 60 years of age, the effectiveness of the vaccine against

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[3636] Google analytics searched for “Canada” and “COVID-19” – Our World in Data (retrieved July 20, 2022)

[3737] Lewnard, J.A., Hong, V.X., Patel, M.M., Kahn, R., Lipsitch, M. Tartof, S.Y. (2022) Clinical outcomes associated with SARS-CoV-2 Omicron (B.1.1.529) variant and BA.1/BA.1.1 or BA.2 subvariant infection in southern California. Nature Medicine 28, 1933-1943. https://doi.org/10.1038/s41591-022-01887-z

[3838] https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_third_dose_recommendations.pdf

infection began to wane after just several weeks.[3939,4040] While some elderly people and those that are immune compromised might derive a temporary benefit from a fourth vaccination, the evidence of a clear benefit for those under 60 years is lacking.[4141]

63. A recent study from Iceland further also showed that repeated vaccination actually increases the chances of an Omicron re-infection.[4242] ***"The probability of reinfection*** *increased with time from the initial infection (odds ratio of 18 months vs 3 months, 1.56; 95% CI, 1.18-2.08) (Figure)* ***and was higher among persons who had received 2 or more doses compared with 1 dose or less of vaccine*** *(odds ratio, 1.42; 95% CI, 1.13-1.78)."*

64. There does not appear to be any unequivocal evidence that vaccination reduces the risk of acquiring COVID-19 in the long term. Early on, a Harvard study published in the *International Journal of Epidemiology* that analyzed 68 countries found "*no discernable relationship*" between the percentage of population fully vaccinated and the total number of cases of COVID-19. The authors even found a marginally positive association between the latter and the percentage of vaccinated population - *i.e*., the higher the percentage of population vaccinated, the higher the number of cases of COVID-19 appeared to be.[4343] This trend is even more evident with the dramatic up surge in cases of COVID-19 in Canada and other countries with Omicron, particularly in those with the highest rates of COVID-19 vaccinations.

65. The evidence to date indicates that the RNA and adenovirus COVID-19 vaccines are clearly effective in adults initially at inducing a strong immune response and protection from infection by SARS-CoV-2 within the first few months following an initial inoculation and a booster shot a month later. However,

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[3939] Bar-On, Y.M., Goldberg, Y., Mandel, M., Bodenheimer, O., Amir, O., *et al.* (2022) Protection by a fourth dose of BNT162b2 against Omicron in Israel. *N Engl J Med.* 386:1712-1720. doi: 10.1056/NEJMoa2201570

[4040] Gazit, S., Saciuk, Y., Perez, G., Peretz, A., Pitzer, V. Patalon, T. (2022) Short term, relative effectiveness of four doses versus three doses of BNT162b2 vaccine in people aged 60 years and older in Israel: retrospective, test negative, case-control study. *BMJ.* 377 doi: https://doi.org/10.1136/bmj-2022-071113

[4141] https://www.cbc.ca/news/health/fourth-dose-covid-vaccine-canada-omicron-ba5-1.6521937

[4242] Eythorsson, E., Runolfsdottir, H.L., Ingvarsson, F., Sigurdsson, M.I., Palsson, R. (2022) Rate of SARS-CoV-2 reinfection during an Omicron wave in Iceland. *JAMA Netw Open.* 5(8):e2225320. doi:10.1001/jamanetworkopen.2022.25320

[4343] Subramanian, S.V., Kumar, A. (2021 Sept. 30) Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States. *Eur J Epidemiol*. Published online. doi:10.1007/s10654-021-00808-7

they have waning efficacy to lower than 50% relative risk reduction by 6 months after double vaccination. For example, one of the largest studies indicating that the effectiveness of COVID-19-injections wanes over time was conducted on more than 780,225 of the US Veteran Health Administration (VA) patients.[4444] The study indicated that in a time span of around 9 months from February 1 to October 1, 2021, the ability of COVID-19 vaccines to protect from infection declined - from 86.9% to 43.3% for the Pfizer/BioNTech product, from 89.2% to 58% for the Moderna product, and from 86.4% to 13.1% for the Janssen product. For ages 65 years and older, the ability of COVID-19 vaccines to protect from death was 70.1% for the Pfizer/BioNTech product, 75.5% for the Moderna product, and 52.2% for the Janssen product.[44] It should be appreciated that these are passive reporting studies, and with an elderly population there is already a high risk of death, and US veterans that have had combat duty may have a higher rate of lifetime injury and co-morbidities than the general population. The poorer performance of these vaccines in the elderly is not surprising. In the original Pfizer/BioNTec 6-month phase III trial with the BNT162b2 mRNA COVID-19 vaccine, although 58% of the people at risk from death from COVID-19 are over 75 years of age, only 4% of the trial participants were in this age group.[27]

66. With respect to the ability of the COVID-19 vaccines to reduce the acquisition and spread of COVID-19, it also appears that these vaccines have failed. One study in Dane County, Wisconsin, USA, with among the highest vaccination rates in that country at the time, indicated equally high viral loads among the vaccinated (84%) as among the unvaccinated (83%) – in other words, an equal capacity of both to spread infection.[4545] **It is now widely accepted that COVID-19 double vaccinated individuals can still become infected with SARS-CoV-2, develop sickness and can transmit the virus with equal**

[4444] Cohn, B.A., Cirillo, P.M., Murphy, C.C., Krigbaum, N., Wallace, A.W. (2021) SARS-CoV-2 vaccine protection and deaths among US veterans during 2021. *Science* doi: 10.1126/science.abm0620

[4545] Riemersma, K.K., Grogan, B.E., Kita-Yarbro, A. *et al.* (2021 July 31) Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant. *medRxiv*. Published online. doi:10.1101/2021.07.31.21261387

viral loads as unvaccinated individuals.[4646,4747] This has been clearly expressed by Dr. Anthony Fauci of the US National Institutes of Health (NIH).[4848]

67. It is also becoming apparent that COVID-19 vaccine boosted individuals may even be more transmissible for SARS-CoV-2 according to at least one report.[4949] In this study, one-third of boosted people still carried live, culturable virus at 10 days after the beginning of the infection. This is contrasted with unvaccinated people with COVID-19, who had only 6% of persons still contagious at Day 10.

68. British Columbia is one of the provinces in Canada that provided more recent breakdowns for the incidence of COVID-19 hospitalization, ICU admissions and deaths, which was posted on the BCCDC website. From April 17 to May 14, 2022, it is evident that hospitalizations and critical care cases per 100,000 were at best 2-fold higher for unvaccinated as compared to double or triple vaccinated individuals as shown in Figure 6.[5050] Moreover, during this period, the rates of COVID-19-related deaths were fairly comparable in the vaccinated compared to the unvaccinated group. This is despite the fact that deaths included any COVID-19 lab positive cases that died from any cause (COVID-19 or non-COVID-19, as recorded in Vital Statistic, BC Ministry of Health, within 30 days of their first lab positive result date). In considering such data, it is important to also recognize the caveats presented in Paragraph 54. Such comparative data is no longer provided beyond June 23, 2022 on the BCCDC website.

[4646] Franco-Paredes, C. (2022) Transmissibility of SARS-CoV-2 among fully vaccinated individuals. *The Lancet Infectious Diseases* 22(1) 16. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00768-4/fulltext

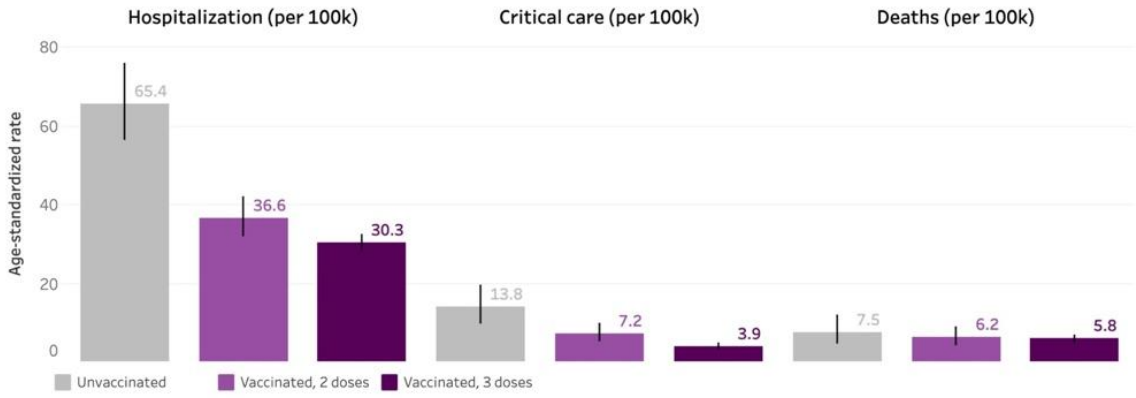
[4747] https://www.ucdavis.edu/health/covid-19/news/viral-loads-similar-between-vaccinated-and-unvaccinated-people

[4848] https://www.youtube.com/watch?v=mP9iHyj1uiU

[4949] Boucau, J., Marino, C., Regan, J., Uddin, R., Choudhary, M.C., *et al.* (2022) Duration of shedding of culturable virus in SARS-CoV-2 Omicron (BA.1) infection. New Engl. J. Med. doi: 10.1056/NEJMc2202092

[5050] http://www.bccdc.ca/health-professionals/data-reports/covid-19-surveillance-dashboard (Retrieved May 22, 2022)

Figure 6. Age-standardized hospitalization, critical care and death rates in BC from April 17 to May 14, 2022.[50]



69. To offset the relative loss of efficacy of the original COVID-19 vaccines with the Omicron variants, new bivalent COVID-19 vaccines were tested in clinical studies that use a combination of mRNA for the original Wuhan Spike protein and the Omicron BA.1 variant Spike protein.[5151] This is despite the fact that the Wuhan SARS-CoV-2 virus and even the Omicron BA.1 variant were supplanted by the BA.4 and BA.5 variants. On August 31, 2022, bivalent COVID-19 vaccines from Moderna and Pfizer/BioNTech that include mRNA for the Wuhan Spike protein and a variant that is in common between the BA.4 and BA.5 lineages of Omicron were approved by the FDA based on pre-clinical studies in mice.[5252] At the same time, monovalent vaccines based on the original Wuhan Spike protein were no longer authorized as booster doses for individuals 12 years or age and older. It is noteworthy that the Pfizer bivalent COVID-19 vaccine was approved based on studies with only 8 mice for their efficacy in producing "neutralizing" antibodies that blocked Omicron BA.4 and BA.5 spike protein binding to ACE2.[5353] From a safety standpoint, SARS-CoV-2 spike protein is not capable of binding to mouse or rat ACE2, so evaluation of spike protein toxicity was highly compromised in these animal

[5151] Chalkias, S., Harper, C., Vrbicky, K., Walsh, S.R., Essink, B., Brosz, A., *et al.* (2022) A bivalent omicron-containing booster vaccine against Covid-19. *New Eng. J. Med*. Doi: 10.1056/NEJMoa2208343

[5252] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use

[5353] https://www.science.org/content/article/omicron-booster-shots-are-coming-lots-questions

models.[5454] Data from no other animal model or humans was presented to the FDA by these manufactures for these particular bivalent vaccines prior to the approval.[53]

70. It has been commonly suggested that inoculation with COVID-19 vaccines based on the structure of the original Wuhan strain of SARS-CoV-2 renders the antibodies that are produced much less effective against the Omicron variants. This appears to be incorrect based on several points:

    a. The overall difference in amino acid structure between the Spike proteins of the Wuhan and Omicron strains is only 3% (*i.e.,* ~34 mutated amino acids out of 1273 amino acids in the whole protein). As shown in Figure 1, recovered COVID-19 survivors each generate antibodies against scores of different parts of the Spike protein;

    b. The actual regions that most people tend to make antibodies against the Spike protein are largely distinct from where the Omicron mutations occur as shown in Figure 1;

    c. The vaccines that are produced with the Wuhan Spike protein RNA are still effective, at least initially for reducing Omicron infections in vaccinated people, so the antibodies that are produced must still recognize the Omicron variants;

    d. RNA vaccines that are based on the Omicron Spike protein, when tested in monkeys and other animals, gave no better immune protection against COVID-19 than RNA vaccines based on the

[5454] Rawle, D.J., Le, T.T., Dumenil, T., Yan, K., Tang, B., *et al.* (2022) ACE2-lentiviral transduction enables mouse SARS-CoV-2 infection and mapping of receptor interactions. PLoS Pathog. 17(7): e1009723. https://doi.org/10.1371/journal.ppat.1009723

Wuhan Spike protein amino acid sequence.[5555,5656,5757,5858] Note that some studies observed a decline in "neutralizing" antibodies that specifically target the ACE2 receptor binding domain of the Spike protein.[57,58] However, most protective antibodies can still permit the tagging of virus and bacteria for their efficient recognition by immune cells and the complement system, which leads to their destruction; and

e. The fact that infected people get milder symptoms with Omicron variants and are able to more quickly more recover from these variants clearly shows the clear capacity of the immune system of these individuals to recognize and neutralize the Omicron variants.

71. In my opinion, collectively all of these findings seriously calls into question the wisdom of vaccination of youth and most working adults considering that are already at such low risk of hospitalization and death from COVID-19, especially in view of the poor efficacy of these COVID-19 genetic vaccines, and their potential for vaccine injury in the short and long term as presented in the next section.

Section F. COVID-19 Vaccine Safety

72. No vaccine is 100% safe. A risk/benefit analysis must be carried out individually and at a population level. Safety is influenced by a whole host of factors, including the toxicity of components of the COVID-19 vaccines, the consistency and quality of vaccine production, the injection procedures and protocols, and individual variations in the immune response, which is determined by health status,

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[5555] Gagne, M., Moliva, J.I., Foulds, K.E., Andrew, S.F., Flynn, B.J., *et al.* (2022) mRNA-1273 or mRNA-Omicron boost in vaccinated macaques elicits comparable B cell expansion, neutralizing antibodies and protection against Omicron. *bioRxiv* doi: https://doi.org/10.1101/2022.02.03.479037

[5656] Ying, B., Scheaffer, S.M., Whitener, B., Liang, C-Y., Dymtrenko, O., *et al*. (2022) Boosting with Omicron-matched or historical mRNA vaccines increases neutralizing antibody responses and protection against B.1.1.529 infection in mice. *bioRxiv* doi: https://doi.org/10.1101/2022.02.07.479419

[5757] Hawman, D.W., Meade-White, K., Clancy, C., Archer, J., Hinkley, T., *et al.* (2022) Replicating RNA platform enables rapid response to the SARS-CoV-2 Omicron variant and elicits enhanced protection in naïve hamsters compared to ancestral vaccine. *bioRxiv* doi: https://doi.org/10.1101/2022.01.31.478520

[5858] Lee, I.-J., Sun, C.-P., Wu, P.-Y., Lan, Y.-H., Wang, I.-H. *et al.,* (2022) Omicron-specific mRNA vaccine induced potent neutralizing antibody against Omicron but not other SARS-CoV-2 variants. *bioRxiv* doi: https://doi.org/10.1101/2022.01.31.478406)

environmental influences and genetic background. With respect to COVID-19 vaccine production with the RNA lipid nanoparticles, this is particularly problematic, because the RNA is enzymatically generated, it is unstable, and the encapsulation of the RNA inside of the lipid nanoparticles is difficult. Quality control from batch to batch is also very difficult to ascertain. For example, DNA accounts for up to 20-35% of the nucleic acids contained in each of the tested batches of Pfizer/BioNTech and Moderna vaccines.[5959] This is the DNA used to produce spike RNA that is packaged within the lipid nanoparticles, and might produce additional spike RNA inside of transfected cells.

73. Many of the issues related to the production of the Moderna/Pfizer vaccine as identified by the European Medicines Agency (EMA) have been recently reviewed by my colleagues and I at the Canadian Covid Care Alliance.[21] In particular, the uracil nucleosides of the Spike RNA has been replaced with pseudo-uracil analogues, which do not exist in human mRNA, and using the genetic code, the triplets of nucleosides that specify each amino acid in the Spike protein have been altered to increase the guanosine and cytosine and content. This results in more stable RNA structures to produce more copies of the Spike protein product, but the final structure of that product has not been demonstrated. This is problematic, because the size of the Spike protein produced with the lipid nanoparticles in cells is much larger than what was predicted. This has been attributed, but not proven, to be due to changes in the glycosylation of the protein, which could be expected to alter its immunogenicity (*i.e.,* result in the production of ineffective antibodies against the Spike protein on the virus).

74. In addition, the Spike RNA undergoes abnormal processing, due in part to the damage of the RNA, and this may result in the generation of truncated versions of the Spike protein that are missing the front (N-terminus) or back (C-terminus) portions of the protein.[21] When the backend of the Spike protein is missing, the protein cannot be anchored onto the surface of the cell after its synthesis, if it is missing its transmembrane domain that provides for cell attachment. Without this tethering to the

[5959] Palmer, M., Gilthorpe, J. (2023) COVID-19 mRNA vaccines contain excessive quantities of bacterial DNA: evidence and implications. https://home.solari.com/covid-19-mrna-vaccines-contain-excessive-quantities-of-bacterial-dna-evidence-and-implications/

cell surface membrane, the shorter Spike protein may be released into the circulation, where it may encounter and bind to other cells that express receptors for the Spike protein. While the engineering of a double proline residue motif into the vaccine version of the Spike protein locks the protein into a prefusion state, this will still not prevent the engagement of the Spike protein with ACE2 receptors on other cells, and interference with ACE2 function. ACE2 is important for reducing blood pressure through its ability to degrade the hormone angiotensin 2. This potential release of Spike protein from cells was not described by the vaccine manufacturers, and there remains little information about the actual structures of the Spike protein made from the COVID-19 genetic vaccines.

75. At the time of the original conditional approval of the Moderna/Pfizer vaccine, the EMA had allowable limits of up to 50% purity of the Spike RNA in its final product.[6060] A pure preparation of the Spike RNA would feature 100% of the Spike RNA with the precise expected size of full length RNA as originally designed. The appearance of shorter fragments of the Spike RNA (*e.g.*, missing the Spike transmembrane domain encoding portion) would be the likely source of such impurities. In its rolling review in November 2020, the EMA noted that there was a decrease in the purity of the mRNA. In the clinical trial batches, the intact mRNA was 78-83% pure, which was much higher than in the bulk commercial batches at 60%, which was what was released to the general public.

76. It is also notable that the lipids used in the lipid nanoparticles have not undergone rigorous safety assessments. They contain PEGylated lipid (ALC0159) and the cationic lipid (ALC-0315), neither of which have been used in humans before. Normally, approval for such novel components would require a full independent review for pharmacology and toxicity. PEGylated lipids can cause significant allergic reactions.[6161] Some of the other components in the lipid nanoparticles are proprietary, and their toxicities have not been disclosed.

[6060] Rappaport Rolling Review Report overview LoQ-COVID-19 mRNA vaccine BioNTech. https://www.covidtruths.co.uk/2021/04/ema-leaked-papers/ Accessed August 24, 2022

[6161] Moghimi, S.M. (2021). Allergic reactions and anaphylaxis to LNP-based COVID-19 vaccines. Mol Ther 29(3), 898-900. https://doi.org/10.1016/j.ymthe.2021.01.030

77. A significant portion of the vaccine may enter the blood stream during injection and afterwards, and become widely distributed throughout the body as originally revealed in the Pfizer/BioNTech pre-clinical studies performed with rats that were subjected to the same lipid nanoparticles used in their vaccine.[6262,6363] Moreover, the uptake of the lipid nanoparticles into the recipient's host cells following injection varies. There are metabolic differences and fluctuations in the cells that take in the RNA and process it to make the Spike protein. It is unknown how much Spike protein is actually presented on the surfaces of these cells and for how long. Immunohistochemistry studies with deceased individuals even 10 months after vaccination have revealed the presence of Spike protein, along with immune cell infiltration and tissue destruction in the endothelium (*i.e.,* lining of blood vessel walls) and organs throughout the body.[6464] The actual differences in Spike protein levels on the surfaces of these cells may vary by a hundred-fold when one knowledgeable about these matters considers all of the variables at play. All of this contributes to variations in the strength of immune responses and the risks of an adverse event from person to person.

78. No one knows the potency, the quantity, or the duration of the spike protein produced in different organs and the endothelium given widespread biodistribution. There is no control of the amount of or length of time spike protein is produced by our cells. Tens of trillions of lipid nanoparticles are injected with each vaccination. It is not known if age, sex, weight or other characteristics affect the potency of the vaccine. We do not know how much spike protein is made in each organ in humans that takes up the synthetic mRNA. Evidence appears to indicate that small amounts of LNPs may result in large amounts of spike protein being produced in a particular organ.[63] Basic pharmacological data of the optimal dose, its ranges, and its upper toxicity thresholds are lacking.

79. The Spike protein on its own appears to be toxic. It is a potent inflammagen and allergen, that is strongly immunogenic with biotoxin-like properties. The Spike protein also shares amino acid

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[6262] "SARS-CoV-2 mRNA Vaccine (BNT162, PF-07302048) 2.6.4 薬物動態試験の概要文 (translation: "Summary of pharmacokinetic study")" https://pandemictimeline.com/wp-content/uploads/2021/07/Pfizer-report_Japanese-government.pdf

[6363] Di, J., Du, Z., Wu, K., Jin, S., *et al.* (2022). Biodistribution and non-linear gene expression of mRNA LNPs affected by delivery route and particle size. Pharm Res 39(1): 105-114

[6464] https://worldcouncilforhealth.org/multimedia/uvc-arne-burkhardt/

sequence homology to numerous human proteins, including tumour-associated proteins, raising the possibility that molecular mimicry could lead to increased risk of autoimmune disease[6565] and cancer.[6666] One of the chief concerns with the Spike protein is that it may engage the ACE2,[6767] TMEM16F,[6868] and CD42b receptors on platelets and stimulate their activation and aggregation,[6969] and contribute to thrombosis (blood clotting) and thrombocytopenia (reduction of production of platelets), which are known risks associated with COVID-19 vaccines.[7070]

80. With COVID-19 mRNA or DNA vaccinations, the genetic information to manufacture the Spike protein of SARS-CoV-2 is injected into the muscle, which then disseminates to, and may be produced by various tissues throughout the body as shown in animal studies with vaccine lipid nanoparticles.[7171] Biodistribution studies performed in rats with lipid nanoparticles with a similar formulation to those used in the Pfizer/BioNTech vaccine demonstrated that they travel through practically the entire body, with accumulation in many tissues, systems and organs, including especially the liver, spleen, adrenals and ovaries, over the 48-hour study window.[62] They also traverse the blood brain barrier.[62]

81. Pfizer/BioNTech vaccine Spike mRNA in plasma and circulating lipid nanoparticles in 16 healthy individuals was shown to persist in the systemic circulation for at least 2 weeks (last time point was 15 days) post-vaccination.[7272] Spike protein has also recently been reported to be expressed on

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[6565] Dotan, A. *et al.* (2021 Aug. 18) Molecular mimicry between SARS-CoV-2 and the female reproductive system. Am J Reprod Immunol. 10.1111/aji.13494. doi: 10.1111/aji.13494

[6666] Kanduc, D. (2021) From anti-Severe Acute Respiratory Syndrome Coronavirus 2 immune response to cancer onset viamolecular mimicry and cross-reactivity. Global Med Genet. doi: 10.1055/s-0041-1735590

[6767] Zhang, S., Liu, Y., Wang, X. *et al.* (2020) SARS-CoV-2 binds platelet ACE2 to enhance thrombosis in COVID-19. *J Hematol Oncol* 13, 120. https://doi.org/10.1186/s13045-020-00954-7

[6868] Cappelletto, A., Allan, H.E., Cresente, M., Schneider, E., Bussani, R. *et al.* SARS-CoV-2 Spike protein activates TMEM16F-mediated platelet pro-coagulant activity. *biorxiv* doi: https://doi.org/10.1101/2021.12.14.472668

[6969] Li, T., Y.Y., Li, Y., Wang, Z., Ma, F. *et al.* (2020) Platelets mediate inflammatory monocyte activation by SARS-CoV-2 spike protein. *J Clin Invest.* 2022;132(4):e150101. https://doi.org/10.1172/JCI150101

[7070] Cox, D. (2021) Targeting SARS-CoV-2-platelet interactions in COVID-19 and vaccine-related thrombosis. *Front. Pharmacol*. https://doi.org/10.3389/fphar.2021.708665

[7171] Schädlich, A., Hoffmann, S., Mueller, T., Caysa, H., Rose, C., Göpferich, A. *et al.* (2012 May 30) Accumulation of nanocarriers in the ovary: a neglected toxicity risk? *J Control Release* 160(1):105–12

[7272] Fowlkes, A.L., Yoon, S.K., Lutrick K., *et al.* (2022) Effectiveness of 2-Dose BNT162b2 (Pfizer BioNTech) mRNA vaccine in preventing SARS-CoV-2 infection among children aged 5–11 years and adolescents

exosomes for up to 4 months post injection.[7373] Exosomes are small fragments of cells that migrate throughout the body in the circulation and are secreted in bodily fluids such as colostrum, urine, sweat, semen, and breath exudate. It is possible that exosomes coated with the Spike protein may underlie the unexplained, but commonly described phenomena of "shedding" where unvaccinated people complain of symptoms of allergic-type reactions to people who have been recently vaccinated. The vaccine RNA and resultant Spike protein have recently been reported to persist for weeks in lymph nodes germinal centres.[7474] This might be achieved from conversion of the Spike RNA back to a DNA copy by reverse transcriptase enzymes in host cells such as LINE-1.[7575] Such a conversion of Spike RNA into stable DNA in the nucleus of a liver cell line by LINE-1 was independently confirmed.[7676] Liver is one of the major organs that accumulates the Pfizer/BioNTech vaccine lipid nanoparticles,[7777] and it is feasible that the DNA copy may permit more sustained production of more Spike RNA molecules, and more Spike protein copies.[76] In another study of a patient with persistent varicella zostervirus infection, even 3 months after COVID-19 RNA vaccination, Spike protein was still detectable by immunohistochemistry in the vesicular keratinocytes and endothelial cells in the dermis.[7878]

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aged 12–15 years — PROTECT Cohort, July 2021–February 2022. *MMWR Morb Mortal Wkly Rep* 71:422–428. doi: http://dx.doi.org/10.15585/mmwr.mm7111e1

[7373] Bansal S J. (2021, Nov. 15) Cutting edge: Circulating exosomes with COVID spike protein are induced by BNT162b2 (Pfizer–BioNTech) vaccination prior to development of antibodies: A novel mechanism for immune activation by mRNA vaccines. *Immunol.* 207(10):2405-2410

[7474] Roltgen, K., Nielsen, S.C.A., Silva, O., Pinsky, B.A., Nadeau, K.C., Boyd, S.D. (2022, Jan. 24) Immune imprinting, breadth of variant recognition and germinal center response in human SARS-CoV-2 infection and vaccination. *Cell.* https://doi.org/10.1016/j.cell.2022.01.018)

[7575] Zhang, L., Richards, A., Barrasa, M.I., Hughes, S.H., Young, R.A., Jaenisch, R. (2022) Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues. *Proc. Natl. Acad. Sci. USA* 2021, 118, e2105968118. https://pubmed.ncbi.nlm.nih.gov/33958444/

[7676] Aldén, M., Olofsson Falla, F., Yang, D., Barghouth, M., Luan, C., Rasmussen, M., De Marinis, Y. (2022) Intracellular reverse transcription of Pfizer BioNTech COVID-19 mRNA vaccine BNT162b2 *in vitro* in human liver cell line. *Curr. Issues Mol. Biol. 44*, 1115-1126. https://doi.org/10.3390/cimb44030073

[7777] https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf

[7878] Yamamoto, M., Kase, M., Sano, H., Kamijima, R., Sano S. (2022) Persistent varicella zoster virus infection following mRNA COVID-19 vaccination was associated with the presence of encoded spike protein in the lesion. *J Cutan Immunol Allergy* 00:1–6. doi: 10.1002/cia2.12278

82. Surprisingly, there has actually been very few reported studies in the scientific literature on the location of expressed spike protein post vaccination in autopsied people following death associated with COVID-19 vaccines. However, a German pathologist recently described the detection of the spike protein in a Parkinson's male patient who died within 3 weeks of receiving his third COVID-19 vaccination.[7979] Only the spike protein was detected within the foci of inflammation in both the brain and the heart, particularly in the endothelial cells of small blood vessels. No Nucleocapsid protein could be detected at these sites, which ruled out an actual SARS-CoV-2 infection to account for the Spike protein detection. From inspection of the foci of Spike protein detected in the brain and heart slices, it was evident that the Spike protein has been locally produced, almost certainly from the spread of the lipid nanoparticles in the COVID-19 vaccines. Similar expression of spike protein in the brain, liver, heart, ovaries and many other tissues of cadavers of individuals that were previously COVID-19 vaccinated even 9 months before has also been observed by other pathologists by immunohistochemistry.[64]

83. The original 6-months phase III efficacy and safety clinical studies in adults reported by Pfizer/BioNTech with their COVID-19 vaccine demonstrated around 5% of vaccinated recipients experienced severe adverse events from the inoculations.[28] The vaccinated participants had 300% more total adverse events and 75% more severe adverse events than observed with the placebo injected, control participants (considered unvaccinated).[28] Moreover, there were slightly more deaths in the vaccinated group than with the unvaccinated, control group (20 versus 15 deaths). Consequently, this phase III clinical study clearly failed to demonstrate any reductions in COVID-19 deaths with double vaccination.

84. Unfortunately, in the ongoing Pfizer/BioNTech vaccine clinical trial, after 2 months into the trial, it was unblinded to the participants, and 89% of the unvaccinated, matching control cohort elected to take the COVID-19 vaccine too within the 6 months period of the clinical study. This undermined the ability of the trial to detect longer term vaccine adverse events, which is normally performed to obtain a more accurate assessment of longer term benefits and risks of a treatment.[28] Furthermore, the high

[7979] Mörz, M. (2022) Case report: Multifocal necrotizing encephalitis and myocarditis after BNT162b2 mRNA vaccination against COVID-19. *Vaccines* 10, 1651. https://doi.org/10.3390/vaccines10101651

degree of vaccination that has now occurred in the general population post release of this vaccine makes it extremely difficult to statistically correlate vaccine injury above background rates of these same morbidities with the data collected in passive vaccine injury reporting systems.

85. Recently, a secondary analysis of the 6 month, placebo-controlled, phase III randomized clinical trials of the Pfizer/BioNTech and Moderna mRNA COVID-19 vaccines in adults (NCT04368728 and NCT04470427) were performed, and shown to be associated with an excess risk of serious adverse events of 1 in 990, and 1 in 662 over placebo baselines, respectively.[8080] These events were defined as an adverse event that results in any of the following conditions: death; life-threatening at the time of the event; inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; a congenital anomaly/birth defect; medically important event, based on medical judgment.

86. Further concerns in the safety of the Pfizer/BioNTech vaccine have been raised by the first release of the Pfizer's post marketing pharmacovigilance report. On November 17, 2021, the FDA released the first batch of what is predicted to be at least 451,000 pages that 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/BioNTech's COVID-19 inoculations. The FDA originally asked in court to have 55 years to release the documents, and then calculated it would take 75 years. With the first release that covered the period of up to February 28, 2021, there were 42,086 cases, of which 11,361 (27%) had not recovered and 1,223 deaths recorded (Table 1).[8181] In the 9 pages of the appendix of this report, there were over 1,236 different disease indications that were associated with the Pfizer/BioNTech COVID-19 vaccine.

Table 1. General overview: Selected characteristics of all cases received during the reporting interval. (From Table 1 of original Pfizer report.[81])

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

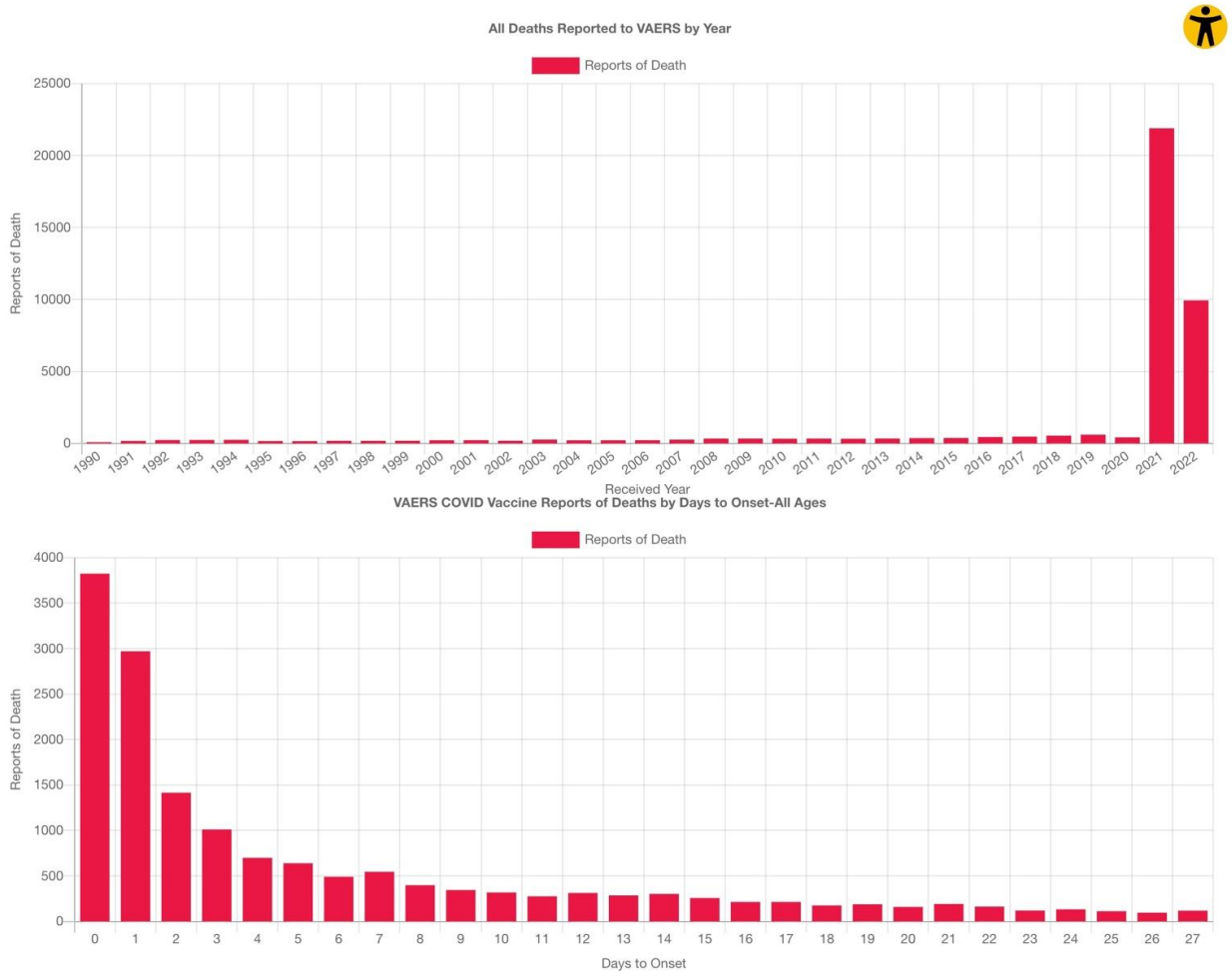
87. Reports of adverse events and especially death from COVID-19 vaccines are typically described '*as very rare, and when such deaths are reported, they do not necessarily mean that the vaccine caused the death*.' However, it is notable that are more reports of severe injury and deaths from the three COVID-19 vaccines in the US FDA Vaccine Adverse Effects Reporting System (VAERS) than in the previous 30 years combined since VAERS was first established in 1990. It should be appreciated that most VAERS reports are made by doctors and other health professionals, and the system is closely monitored for the quality of the reports. More than 55% of all serious adverse effects and deaths ever reported in VAERS were associated with the COVID-19 vaccines. As of April 14, 2023, in the VAERS, there have been over 1,547,355 adverse events linked with the COVID-19 vaccines, 197,564 hospitalizations, of which 149,580 required urgent care and 35,152 ended in death.[8282] Figure 7 summarizes the total number of annual reports of death in VAERS.[82] Moreover, these numbers underreport the true extent of adverse events after injection of the COVID-19 vaccines by a factor between 10-times[8383] to 41-times.[8484]

[8282] https://www.openvaers.com/covid-data (retrieved April 25, 2023)

[8383] Lazarus, R., Klompas, M. (2011) Harvard Pilgrim Study - Lazarus Final Report 2011 | PDF | Electronic Health Record | Adverse Effect. Grant Final Report ID R18 HS 017045. Accessed September 24, 2021. https://www.scribd.com/document/434088983/Lazarus-Final-Report-2011

[8484] Kirsch, S., Rose, J., Crawford, M. (2021 October 26) Estimating the number of COVID vaccine deaths in America. *Trialsite News* 57

Figure 7. Annual reported deaths in US VAERS from all vaccines (Top panel) and days to onset for COVID-19 vaccine reports.[82]



88. Several other post-hoc passive surveillance systems for COVID-19 vaccine injury have also been established, including the Canada Adverse Events Following Immunization System (CAEFIS), the UK Yellow Card Scheme, the WHO VigiAccess website, and the European Medicines Agency EudraVigilance website. The data in these systems can be difficult to interpret, and adverse events are widely underreported and those that are filed are vetted with strict criteria.[8585] Nevertheless, numerous adverse events have been attributed to the current COVID-19 vaccines. As of December 17, 2022, reported adverse events worldwide with COVID-19 vaccines had surpassed 4.77 million in the WHO reporting system VigiAccess.[8686] Table 2 shows how vaccine injury reports with the COVID-19 genetic vaccines compare with the other most commonly applied vaccines. It is evident that the COVID-19 vaccines have 148-times more reports of vaccine adverse events in the last year than seen for influenza vaccines, which are also widely used.

Table 2. VigiAccess listing of vaccine adverse events (AE) associated with the most commonly used vaccines. (Sourced on July 15, 2022.[86])

Disease Targeted	**# Total AE**	**Since Year**	**# AE since 2021**	**Rate***
COVID-19	4,002,925	2021	4,002,925	78,489X
Influenza	286,069	1968	27,051	530X
Polio	125,888	1882	11,608	228X
Hepatitis B	107,196	1985	4242	83X
BCG for TB	37,574	1973	2046	40X
Tetanus	15,478	1968	804	16X
Measles	6,250	1968	553	11X
Diphtheria	1,915	1979	51	1X

*Rate verses Diphtheria vaccine adverse events since 2021

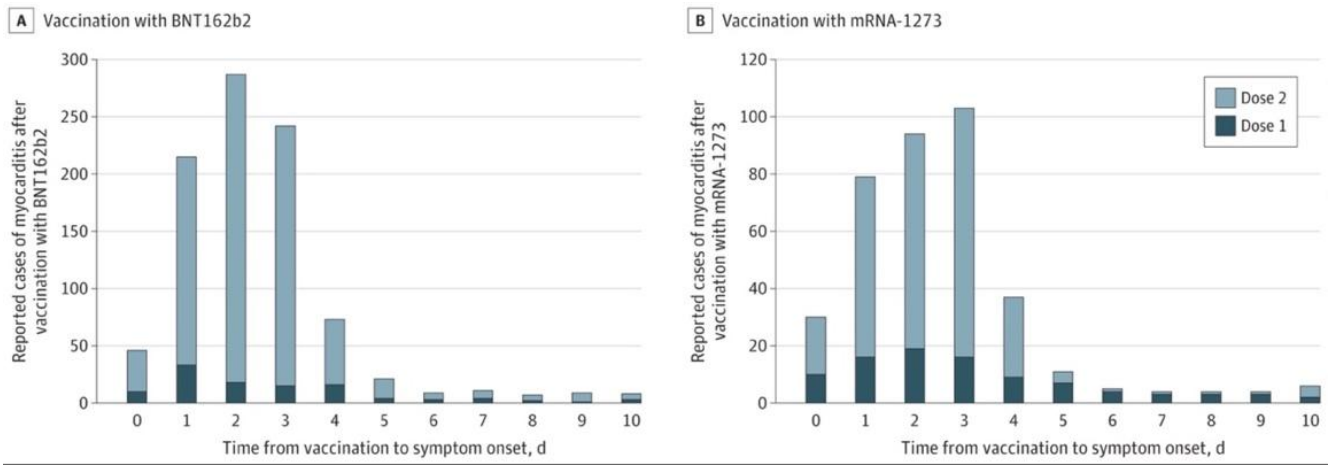
[8585] Di Pasquale, A. *et al.* (2016) Vaccine safety evaluation: Practical aspects in assessing benefits and risks. *Vaccine* 20;34(52):6672-6680

[8686] World Health Organization. (2022, December 17) VigiAccess - WHO collaborating center for international drug monitoring. http://vigiaccess.org/ Accessed December 17, 2022. Searched with "Comirnaty"

Section G. Myocarditis and Myopericarditis Risk

89. Myocarditis and Myopericarditis are amongst the best recognized risk of COVID-19 RNA vaccine injury, especially in males aged 12 to 29 years of age following the second inoculation. A study in the US based on analysis of the VAERS, the occurrence of myocarditis in males from 12 to 24 years after the second dose of the Pfizer/BioNTech vaccine ranged down to about 1 in 9446 in 16-17 year-olds.[8787] As shown in Figure 8, most reports in VAERS of Pfizer/BioNTech and Moderna COVID-19 vaccine injury related to myocarditis were evident in Days 1, 2 and 3 after vaccination with either the Pfizer/BioNTech or Moderna vaccines, which demonstrates a high temporal correlation and a more likely causal relationship.

Figure 8. Daily US VAERS myocarditis cases reported for COVID-19 vaccines. From Figure 2 of Oster *et al.*[87]



90. A recommendation was made based on the advice of Ontario's Children COVID-19 Vaccine Table, Ontario Vaccine Clinical Advisory Group, and Public Health Ontario for those aged 18 to 24 years to receive the Pfizer/BioNTech COVID-19 vaccine over Moderna's product, due to higher incidence of pericarditis/myocarditis following injection.[8888] This adverse event following the Moderna injection

[8787] Oster, E.O., Shay, D.K., Su, J.R. *et al.,* (2022) Myocarditis cases reported after mRNA-based COVID-19 vaccination in the US from December 2020 to August 2021. *JAMA* 327(4):331-340. https://jamanetwork.com/journals/jama/fullarticle/2788346)

[8888] https://www.cbc.ca/news/canada/toronto/covid-19-ontario-september-29-moore-briefing-update-1.6193455

was easily picked up in younger people, because myocarditis and pericarditis are quite rare normally in those under 24 years of age.

91. The risk of COVID-19 vaccine-induced myocarditis in people under 24 years old varies with the vaccine, dose and gender. The Moderna vaccine appears to have the worst risk for myocarditis, which is why in France and Scandinavian countries, the Moderna vaccine was not recommended in people under 30 years of age.[8989,9090] From many studies, the Pfizer/BioNTech vaccine risk of myocarditis appears to be closer to 1 in 6,700 in males after double dose, which is still high for a vaccine. For males aged 18-24 years of age following the second dose of one of the two RNA COVID-19 vaccines, Public Health Ontario reported a rate of 1 in 5,181 (19.34 events per 100,000 vaccine doses).[9191] In another study, the risk of symptomatic myocarditis for US males 16 to 17 years of age within 7 days of administration of a second dose with the Pfizer/BioNTech vaccine was estimated as 1 in 9,434 (10.59 events per 100,000 vaccine doses) and 96% of these vaccine victims were hospitalized.[9292]

92. In British Columbia, the BCCDC recently reported the results of their careful analysis of the risks of symptomatic myocarditis and myopericarditis for those 12 years and older with the Pfizer Pfizer/BioNTech vaccine, and 18 years and older with the Moderna vaccine.[9393] Some of the key observations in this study, which evaluated the risks with a third shot of a COVID-19 RNA vaccines, included:

    a. The rate of symptomatic myocarditis within 7 days in males 18-29 years of age with second shot of the Moderna vaccine was around 1 in 4,535. Remarkably, no data was available for those 12 to 17 years of age with the Moderna product.

[8989] https://www.france24.com/en/live-news/20211109-france-advises-against-moderna-for-under-30s-over-rare-heart-risk

[9090] Lehto, E. (2021) Finland joins Sweden and Denmark in limiting Moderna COVID-19 vaccine. https://www.reuters.com/world/europe/finland-pauses-use-moderna-covid-19-vaccine-young-men2021-10-07/

[9191] https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-aefi-report.pdf?sc_lang=en

[9292] https://jamanetwork.com/journals/jama/fullarticle/2788346

[9393] Naveed, Z. Li, J., Spencer, M., Wilton, J., Naus, M., García, H.A.V., Otterstatter, M., Janjua, N.Z. (2022) Observed versus expected rates of myocarditis after SARS-CoV-2 vaccination: a population-based cohort study. CMAJ 194:E1529-36. doi: 10.1503/cmaj.220676

b. The rate of symptomatic myocarditis within 7 days in males 18-29 years of age with second shot of the Pfizer/BioNTech vaccine was around 1 in 19,762 and for 12 to 17 year olds was 1 in 14,858.
c. For the Pfizer/BioNTech vaccine, the risk of symptomatic myocarditis from vaccination was about the same in the first 7 days post inoculation compared to 8 to 21 days. However, the risk continued to grow after 7 to 21 days for getting symptomatic myopericarditis.
d. With the Pfizer/BioNTech vaccine, the risk of symptomatic myocarditis for males under 29 years remains high with the third shot compared to the second, but increases over 3-fold in males from 30 to 49 years of age. This was evident within 7 days of vaccination, but by 21 days post-vaccination, the risk of symptomatic myocarditis also increased in the 50 to 69 year olds too.
e. With the Moderna vaccine, the risk of symptomatic myocarditis for males 18 to 29 years dropped 5-fold with the third shot compared to the second shot. It is likely that those at the highest risk for symptomatic myocarditis with the Moderna vaccine got it after the second shot, and so were unlikely to subject themselves to a third shot. However, with the Moderna vaccine, by 21 days post-inoculation with the third dose, the risks of symptomatic myocarditis increased in the 60 to 79 year olds.
f. The rate of symptomatic myopericarditis within 7 days in males 18-29 years of age with second shot of the Moderna vaccine was around 1 in 3,300, compared to 1 in 12,820 with the Pfizer/BioNTech vaccine. Like seen for the risk of symptomatic myocarditis with males in this age group, the risk declined with the third shot compared to the second inoculation for both vaccines.
g. For males 12 to 17 years old, the risk of symptomatic myopericarditis slightly increased from the second (1 in 11,111) to the third shot (1 in 8,547) of the Pfizer/BioNTech vaccine.
h. Assuming no overlap in myopericarditis and myocarditis cases, **the overall risks of the Moderna vaccine for males 18 to 29 years old for acquiring either heart issue and hospitalization within 7 days of the second inoculation can be calculated as 1 in 1,910, and 1 in 12,578 for the third shot**. Presumably, anyone who had problems with the second shot, did not get the third shot. There was no data for the symptomatic myocarditis and myopericarditis rates for males 12 to 17 years old following any shots of the Moderna vaccine, but it is likely to be greater than 1 in 1910 based on the Pfizer/BioNTech vaccine trend. Note that the Moderna and Pfizer/BioNTech vaccines are approved in Canada for those that are 6 months of age and older.

i. Assuming no overlap in myopericarditis and myocarditis cases, the overall risks of the Pfizer/BioNTech vaccine for males 18 to 29 years old for acquiring either heart issue and hospitalization within 7 days of the second shot can be calculated as **1 in 7,776**, and 1 in 14,326 for the third shot. For males 12 to 17 years old for acquiring either heart issue and hospitalization within 7 days of the second Pfizer/BioNTech shot can be calculated as **1 in 6,357**, and **1 in 5,345** for the third shot.

93. These risk numbers in British Columbia are generally in line with many of the studies of symptomatic myocarditis and myopericarditis risks from studies in Israel and elsewhere. Stats Canada (indicates that by December 4, 2022, 81% of males aged 18-29 years have been vaccinated twice for a total number of 2,055,723 males.[9494] Statistics Canada also indicates that by December 4, 2022, 80.4% of males aged 12-17 years have been vaccinated twice for a total number of 1,034,269 males. The Pfizer vaccines were used more than 3-times as often as the Moderna. It can therefore be roughly calculated that for males 12-17 years of age, there were at least [(25% of 1,034,269 x 1 / 1910[95*])+(75% of 1,034,269 x 1 / 6357) =] **257** that required hospitalization for symptomatic myocarditis and myopericarditis in Canada (Assumed rate for 18-29 year olds with Moderna COVID-19 vaccine). Likewise, it can be roughly calculated that for males 18-29 years of age, there were at least [(25% of 2,055,723 x 1 / 1910*)+(75% of 2,055,723 x 1 / 7776) =] **467** that required hospitalization for symptomatic myocarditis and myopericarditis in Canada. This means that there are at least **724** hospitalized cases of symptomatic myocarditis and myopericarditis in 12 to 29 years old males from the COVID-19 vaccines, and the number is likely **at least 4-times** higher if asymptomatic cases are included. There does not seem to be a difference in damage to the heart whether the myocarditis is diagnosed as symptomatic or not.

94. It should be appreciated that these previous studies are passive, and did not try to investigate the damage to hearts of all COVID-19 vaccine recipients in any formal study. Recently, a study performed in Thailand did examined the rates of myocarditis and pericarditis in all of 301 13 to 18 year-olds who

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[9494] https://health-infobase.canada.ca/covid-19/vaccination-coverage/

[95]

received the second dose of the BNT162b2 mRNA COVID-19 vaccine.[9695] Cardiovascular effects were found in 29.24% of patients, ranging from tachycardia, palpitation, and myopericarditis. Seven of the 201 males had evidence of asymptomatic myocarditis (four), myopericarditis (one) or pericarditis (two) for a rate of **1 in 29**. This involved active monitoring of heart abnormalities, including presence of heart proteins such as troponin in the blood, magnetic resonance imaging (MRI) of the heart, which is enlarged after myocarditis, EKG, electrocardiogram measurements and physical examinations.[95] Earlier measures of myocarditis with vaccination depended on having symptoms and passive reporting, and these findings indicate that the risk of heart damage following vaccination is far worse than previously believed. Such safety studies should have been performed much earlier by the manufacturers of the COVID-19 RNA vaccines.

95. In another study that examined the general population of 12-19 years-old who were pre-screened to have had COVID-19, there were 6 out of 6,846 cases (0.09%) that had symptomatic myocarditis associated with COVID-19, which is about a 1 in 1,141 rate.[9796] However, note that these are based on hospital records, and about 99.5% of people with symptomatic myocarditis typically end up admitted to a hospital. Therefore, this is actually not representative of the general risk of SARS-CoV-2-induced myocarditis. However, public health authorities have repeatedly argued that the risk of acquiring myocarditis from COVID-19 is much higher than associated with COVID-19 vaccination using such estimates of myocarditis occurrence in hospitalized COVID-19 patients.

96. Based on US data, the chances of hospitalization of people under 24 years of age with COVID-19 is around 2.5% (and much lower yet with the Omicron variant), and after a year into the pandemic only 2.8% of all of the 0-24 years olds in the U.S. were recorded as having COVID-19 based on PCR tests.[9897] The actual number of people that got COVID-19 has been estimated by the US CDC to be at least 4-fold higher than recorded PCR test numbers,[8] so the rates of hospitalization from COVID-19 is really

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[9695] Mansanguan, S., Charunwatthana, P., Piyaphanee, W., Dechkhajorn, W., Poolcharoen, A., Mansanguan, C. (2022) Cardiovascular manifestation of the BNT162b2 mRNA COVID-19 vaccine in adolescents. *Trop. Med. Infect. Dis.* 7, 196. Trop. Med. Infect. Dis. 2022, 7, 196. doi: 10.3390/tropicalmed7080196

[9796] Singer, M.E., Taub, I.B., Kaelber, D.C. (2021) Risk of myocarditis from COVID-19 infection in people under age 20: A population-based analysis. Medrxiv. https://www.medrxiv.org/content/10.1101/2021.07.23.21260998v1

[9897] https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e1.htm

closer to 4-times lower in this age group and about 0.7%. Furthermore, it is likely, based on serological testing for SARS-CoV-2 antibodies, that an even much greater proportion of Americans have been infected with SARS-CoV-2 and fully recovered. Consequently, in 12-19 year-olds, the risk of myocarditis from COVID-19 is like in the order of 1 in (40 x 1,141=) 45,640, which is a magnitude less likely than from COVID-19 vaccination in this age group.

97. The above calculations focus on youth and young adults, because it is easier to attribute myocarditis and pericarditis in this age group due to COVID-19 or COVID-19 vaccination due to the rarity of the diseases in younger people. However, it is reasonable to expect that the same underlying mechanisms may promote or exacerbate these conditions in older adults.

98. In one retrospective study of 42,842,345 COVID-19 vaccinated and 5,934,153 SARS-CoV-2-infected people in the UK between December 1, 2020 and December 15, 2021, the risk of myocarditis from COVID-19 in the entire group of those with diagnosed COVID-19 within 28 days was estimated as 1 in 9,618.[9998] It was observed that in males between 13 and 40 years of age, the risk of myocarditis was higher 1 to 28 days after a second dose of the Moderna's mRNA-1273 vaccine (11.76 [95% Confidence Interval, 7.25–19.08]) and persisted after a booster dose (2.64 [95% Confidence Interval, 1.25–5.58]). The risk of excess myocarditis events in this group was calculated as 6-times higher with the vaccine than from SARS-CoV-2 infection, whereas in females under 40 years of age the risks were similar.[98]

99. Another recent retrospective cohort study of 196,992 adults after COVID-19 infection in Clalit Health Services members in Israel between March 2020 and January 2021 failed to observe any increased incidence of either pericarditis or myocarditis in adult patients recovering from COVID-19 infection.[10099] They were compared to a control cohort of 590,976 adults with at least one negative PCR and no positive PCR tests for COVID-19 and were age- and sex-matched. Nine post-COVID-19 patients developed myocarditis (0.0046%), and eleven patients were diagnosed with pericarditis

[9998] Patone, M., Mei, X.W., Handunnetthi, L., Dixon, S., Zaccardi, F., *et al.* (2022) Risk of myocarditis after sequential doses of COVID-19 vaccine and SARS-CoV-2 infection by age and sex. Circulation 146, 743-754. https://doi.org/10.1161/CIRCULATIONAHA.122.059970

[10099] Tuvali, O., Tshori, S., Derazne, E., Hannuna, R.R., Afek, A., *et al.* (2022) The incidence of myocarditis and pericarditis in post COVID-19 unvaccinated patients—A large population-based study. *J. Clin. Med.* 11(8), 2219; https://doi.org/10.3390/jcm11082219

(0.0056%). In the control cohort, 27 patients had myocarditis (0.0046%) and 52 had pericarditis (0.0088%).

100. Another Israeli study that utilized a unique dataset from Israel National Emergency Medical Services (EMS) from 2019 to 2021, aimed to evaluate the association between the volume of cardiac arrest and acute coronary syndrome EMS calls in the 16–39-year-old population with potential factors including COVID-19 infection and vaccination rates.[101][100] "*An increase of over 25% was detected in both call types during January–May 2021, compared with the years 2019–2020. Using Negative Binomial regression models, the weekly emergency call counts were significantly associated with the rates of 1st and 2nd vaccine doses administered to this age group but were not with COVID-19 infection rates. While not establishing causal relationships, the findings raise concerns regarding vaccine-induced undetected severe cardiovascular side-effects and underscore the already established causal relationship between vaccines and myocarditis, a frequent cause of unexpected cardiac arrest in young individuals*."

101. It should be appreciated that myocarditis results in the destruction of cardiomyocytes from inflammation with immune cells. It is noted in a recent study of 14 patients with confirmed myocardial inflammation, ranging from inflammatory cardiomyopathy to active myocarditis and severe giant cell myocarditis following vaccination against SARS-CoV-2: "*Although a causal relationship between vaccination and the occurrence of myocardial inflammation cannot be established based on the findings, the cardiac detection of spike protein, the CD4+ T-cell-dominated inflammation and the close temporal relationship argue for a vaccine-triggered autoimmune reaction."*[102][101]

102. The lost cardiomyocytes are replaced by non-contractile scar tissue and the remaining cardiomyocytes increase in size to permit maintenance of blood pressure and circulation, which results in enlargement of the heart. This damage is irreversible and eventually leads to cardiovascular

[101][100] Sun, C.L.F., Jaffe, E., Levi, R. (2022) Increased emergency cardiovascular events among under-40 population in Israel during vaccine rollout and third COVID-19 wave. *Nature Scientific Reports*. https://www.nature.com/articles/s41598-022-10928-z.pdf

[102][101] Baumeier, C., Aleshcheva, G., Harms, D., Gross, U., Hamm, C*., et al. (*2022) Intramyocardial Inflammation after COVID-19 vaccination: An endomyocardial biopsy-proven case series. *International Journal of Molecular Sciences*. 23(13):6940. https://doi.org/10.3390/ijms23136940

disease. Since the damage from myocarditis is irreversible and may be cumulative, it is inappropriate to suggest that a person may have a mild case of myocarditis. The acute observable effects may be experienced as mild, and apparently asymptomatic in most cases, but it may induce more serious consequences in the longer term.

103. While the long term outcomes of COVID-19 vaccine-induced myocarditis are yet unknown, viral induced myocarditis causes death in about 20% of those afflicted within 6 years.[103][102] The lethality of myocarditis is also highlighted in the 12th October 2021 *The Journal of Clinical Medicine* article: "*Occurrence, Trends, Management and Outcomes of Patients Hospitalized with Clinically Suspected Myocarditis—Ten-Year Perspectives from the MYO-PL Nationwide Database,"*[104][103] which concluded that: *"Myocarditis has been shown in post-mortem studies to be a major cause (up to 42% of cases) of sudden and unexpected death in children and young adults. In contrast, a recently published study on autopsies reported that 6% of 14,294 sudden deaths were assigned as being caused by myocarditis. In patients with biopsy-proven myocarditis in long-term observation (the median follow up of 4.7 years), all-cause mortality was 19.2%, while sudden death occurred in 9.9% of cases."* Another older report notes: *"The Myocarditis Treatment Trial reported mortality rates for biopsy-verified myocarditis of 20% and 56% at 1 year and 4.3 years, respectively. These outcomes are similar to the Mayo Clinic's observational data of 5-year survival rates that approximate 50%. Survival with giant cell myocarditis is substantially lower, with <20% of patients surviving 5 years."*[105][104]

Section H. Other Vaccine Injury

104. In addition to myocarditis and myopericarditis, there are many serious recognized potential harms that arise from COVID-19 mRNA vaccines, such as cardiovascular events, including heart attacks,

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[103][102] Kang, M. (2022) Viral myocarditis. An J. Viral Myocarditis. [Updated 2022 January 5]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; Available from: https://www.ncbi.nlm.nih.gov/books/NBK459259/

[104][103] Ozierański, K., Tymińska, A., Kruk, M., *et al.* (2021) Occurrence, trends, management and outcomes of patients hospitalized with clinically suspected myocarditis-Ten-year perspectives from the MYO-PL nationwide database. *J Clin Med*. 10(20):4672. doi:10.3390/jcm10204672

[105][104] Magnani, J., Dec, G. (2006). Myocarditis: Current trends in diagnosis and treatment. Circulation. 113. 876-90. 10.1161/CIRCULATIONAHA.105.584532.

strokes, neurological problems such as paralysis, dermatological, reproductive issues such as prolonged and heavy menstruation and reduced male fertility, hematological such as blood clots, autoimmune, hepatic, renal, respiratory, and more than 1200 disorders listed in the six pages submitted by Pfizer,[106105] as well as those in Table 7 of the 5.3.6 Cumulative Analysis of Post-immunization Adverse Event Reports.[107106] These Adverse Events of Special Interest (AESIs) included:

- Anaphylactic Reactions
- Cardiovascular AESIs
- COVID-19 AESIs
- Dermatological AESIs
- Haematological AESIs
- Hepatic AESIs
- Facial Paralysis
- Immune-Mediated/Autoimmune AESIs
- Musculoskeletal AESIs
- Neurological AESIs (including demyelination)
- Pregnancy Related AESIs
- Renal AESIs
- Respiratory AESIs
- Thromboembolic Events
- Stroke
- Vasculitic Events
- as well as other AESIs

105. After the Emergency Use Authorization of COVID-19 vaccines in the U.S. and wide-spread vaccination in the general population, there has been increasing reports of other vaccine adverse events, and that has caused concern and placement of restrictions. In Canada, the National Advisory Committee on Immunization (NACI), for example, recommended a pause for using the AstraZeneca COVID-19

[106105] Pfizer-BioNTech COVID-19 vaccine (BNT162, PF-07302048) Vaccine and Related Biological Products Advisory Committee briefing document (10 December 2020). https://www.fda.gov/media/144246/download#page=87

[107106] World-wide Safety Pfizer. 5.3.6 Cumulative analysis of post-authorization adverse event reports of PF-07302048 (BNT162N2) received through 28-Feb-2021. https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf

vaccine in people under 55, due to issues of blood clotting and vaccine-induced immune thrombotic thrombocytopenia (VIIT) following injection with this adenovirus vector product.[108][107] Ontario Public Health finally decided to suspend offering the AstraZeneca vaccine on May 11, 2021 out of caution due to the increased risk of blood clots,[109][108] whereas in British Columbia, this vaccine continued to be offered. At this time, Health Canada does not approve AstraZeneca's vaccine for those under 18 years of age, based on continuing increased safety concerns for this age group.[110][109]

106. A concern that has been expressed by researchers in Denmark who recently found that the mRNA inoculations were associated with a significant increase in all-cause and cardiac-related mortality compared to the adenovirus-vector vaccines.[111][110,112][111] The Denmark findings indicate the potential for inoculation-induced adverse effects, including inoculation-enhanced COVID-19 disease[113][112,114][113] or development of T-cell exhaustion[115][114] and immune fatigue especially in the context of multiple and frequent boosters.[116][115,117][116,118][117] These studies underline the lack of quality evidence

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[108][107] https://www.cbc.ca/news/politics/astrazeneca-under-55-1.5968128

[109][108] https://www.cbc.ca/news/canada/toronto/ontario-update-astrazeneca-vaccine-1.6022545

[110][109] https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html

[111][110] Benn, C.S., Schaltz-Buchholzer, F., Nielsen, S, Netea MG, Aaby P. (2022) Randomised clinical trials of COVID-19 vaccines: Do adenovirus-vector vaccines have beneficial non-specific effects? *Social Science Research Network*; doi:10.2139/ssrn.4072489

[112][111] UnHerd. Danish professor: mRNA vaccine study sends "danger signals."; 2022. Accessed May 12, 2022. https://www.youtube.com/watch?v=o_nKoybyMGg

[113][112] Xu, L., Ma, Z., Li, Y., Pang, Z., Xiao, S. (2021) Antibody dependent enhancement: Unavoidable problems in vaccine development. *Adv Immunol.* 151:99-133. doi:10.1016/bs.ai.2021.08.003

[114][113] Gartlan, C., Tipton, T., Salguero, F.J., Sattentau, Q., Gorringe, A., Carroll, M.W. (2022) Vaccine-associated enhanced disease and pathogenic human coronaviruses. *Front Immunol*. 13. Accessed May 13, 2022. https://www.frontiersin.org/article/10.3389/fimmu.2022.882972

[115][114] Wherry, E.J. (2011) T cell exhaustion. *Nat Immunol.* 12(6):492-499. doi:10.1038/ni.2035

[116][115] Boston 677 Huntington Avenue, Ma 02115 +1495-1000. Science unclear around fourth COVID-19 shot. *News*. Published January 19, 2022. Accessed May 17, 2022. https://www.hsph.harvard.edu/news/hsph-in-the-news/science-unclear-fourth-covid-shot/

[117][116] Welle (2022) (www.dw.com) D. COVID: Do multiple boosters "exhaust" our immune response? | DW | 18.01.2022. DW.COM. Accessed May 17, 2022. https://www.dw.com/en/covid-do-multiple-boosters-exhaust-our-immune-response/a-60447735

[118][117] Kershner, I. (2021) Israel considers 4th vaccine dose, but some experts say it's premature. *The New York Times*. https://www.nytimes.com/2021/12/23/world/middleeast/israel-vaccine-4th-dose.html. Published December 23, 2021. Accessed May 17, 2022.

supporting COVID-19 inoculation efficacy in the post-Omicron era and from these signals potential harm.

107. Since many other adverse events have been associated with the COVID-19 injections, and appear to be more common in younger age groups, benefit versus injection risk and safety needs to be determined by age and gender demographics, and uncertainties should be taken into consideration. For the elderly and those with risk-related comorbidities (*e.g.,* obesity, diabetes, smoking, cardiovascular disease), the risk of COVID-19 damage may exceed the risk of vaccine adverse events, and boosters will be required for those with waning immunity.

108. A real-world study conducted by the US Center for Disease Control showed that 25.8% of the 3,168 adolescent inoculation recipients aged 12 to 17 years were unable to perform daily activities; 20.0% were unable to attend school or work; and ~0.9% received medical care.[119][118] The inoculations were associated with dramatic increases in dose-dependent short term all-cause morbidity with a low likelihood of acquiring long-term safety. While the aforementioned studies focus on the health risks of COVID-19 vaccines on the younger people despite their very low risk of serious COVID-19, it is important to recognize that these people are being encouraged to become vaccinated by public health officials with the idea that their vaccination will help prevent the transmission of COVID-19 to older populations, which is actually not supported by the available data.

109. In my opinion, there is significant potential danger in my opinion that repeated inoculations with the RNA- or adenovirus-based COVID-19 vaccines along with the inflammatory responses that they induced against the injected tissues and elsewhere may cause irreversible cellular destruction and development of immune recognition of one's own tissues, *i.e*., autoimmune disease. The incidence of myocarditis associated with COVID-19 vaccination is such an example of immune attack against cardiac tissues.

[119][118] Hause, A.M., Baggs, J., Marquez, P., *et al.* (2022) Safety Monitoring of COVID-19 vaccine booster doses among persons aged 12–17 years — United States, December 9, 2021–February 20, 2022. *MMWR Morb Mortal Wkly Rep*. 71(9):347-351. doi:10.15585/mmwr.mm7109e2

110. The observation of new-onset Type 1 diabetes in a 1-year old COVID-19 vaccinated girl is another example of a long-term consequence of what is likely to be an immune attack against the beta-islet cells of the pancreas, which is a well known cause of child diabetes.[120119] It is feasible that the pancreatic cell took up the lipid nanoparticles and expressed the Spike protein, which triggered an immune attack. This finding was reported on page 62 in the 68-page appendix of the supplemental data of the results from the Moderna Phase III trials with children with their vaccine.[119] The footnotes to the Table S26 stated, "*the other SAE [serious adverse event] considered related was new-onset Type 1 diabetes mellitus and diabetic ketoacidosis in a 1-year-old female reported 37 days post dose 2."* The investigator in the study claimed that the event is "*more likely caused by a genetic predisposition to pre-diabetes and viral upper respiratory tract infection that occurred prior to second dose of study vaccine*." However, this was not verified by gene sequencing studies, and in view of the relatively small number of vaccinated study participants (*i.e*., 1,911) in the 6 to 23 months old group in this study, this is still alarming.

111. There may also be fertility issues related to the COVID-19 vaccines as well. Since the Pfizer COVID-19 vaccine lipid nanoparticles have been show to accumulate in the ovaries, it is possible that this might contribute to the abnormal menstrual cycles in 40% or more of fertile women following vaccination.[121120,122121] The pituitary glands and the ovaries hormonally control the menstrual cycle, so damage to the ovaries from an inflammatory attack might contribute to this effect, as well as platelet depletion following blood clotting induced by the COVID-19 vaccines. In addition, with men, inoculation with two doses of the Pfizer/BioNTech COVID-19 vaccine was associated with a 15.4% temporary decline in total spermatozoa concentration in semen and their motility, which was largely

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[120119] Anderson, E. J., Creech, C.B., Berthaud, V., Piramzadian, A., Johnson, K.A., *et al*. (2022) Evaluation of mRNA-1273 in children 6 months to 5 years of age. *N Engl J Med.* 387:1673-1687. doi: 10.1056/NEJMoa2209367

[121120] Lessans, N., Rottenstreich, A., Stern, S., *et al.* (2022) The effect of BNT162b2 SARS-CoV-2 mRNA vaccine on menstrual cycle symptoms in healthy women. *Int J Gynecol Obstet*. 00: 1- 6. https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.14356

[122121] Lee, K.M.N., Eleanor J., Junkins, E.J., Luo, C., Fatima, U.A., Cox, M.L., Clancy, K.B.H. (2022) Investigating trends in those who experience menstrual bleeding changes after SARS-CoV-2 vaccination. *Science Advances* 8(28), 1-15. doi: 10.1126/sciadv.abm7201

recovered by 3 months later.[123][122] These studies demonstrate that the gonads of COVID-19 genetic vaccine recipients may also be subjected to damage by inflammation.

112. It is important to appreciate that a female is born with all of the oocytes that she will have, and once she is fertile after puberty, she will have approximately 400 periods in which one (and sometimes more) oocyte is converted to a fertilizable egg by the process of meiosis. The vast majority of oocytes start to die off without undergoing this meiosis. Menopause occurs in women when they deplete their supply of oocytes. Inflammatory damage to the ovaries can endanger the overall supply of oocytes, and could possibly lead to an earlier onset of menopause. In working women, there is a trend to delay having children, so if the ovaries are damaged by COVID-19 vaccine injury, there may be a much shorter window in which they will be able to procreate. While this is a hypothetical risk at this time in the absence of hard data, it is serious enough to warrant caution when weighing the risks and the benefits of the COVID-19 vaccines.

113. It is also feasible that repeated COVID-19 vaccinations may actually reduce immune recognition of the SARS-CoV-2 Spike protein by antibody-dependent enhancement,[124][123] original antigenic sin or tolerance, and this could increase susceptibility to future infections with SARS-CoV-2. Antibody-dependent enhancement is a mechanism by which the coating of the pathogen such as a virus with antibodies actually increases the affinity of pathogen for the immune cells to allow it to enter inside of an immune cell and destroy it, rather than the other way around. The more targeted the antibody response, the greater the risk of antibody-dependent enhancement. This phenomenon was evident in preclinical animal trials with vaccines developed against the SARS-CoV-1 virus.[125][124]

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[123][122] Gat, I., Kedem, A., Dviri, M., Umanski, A., Levi, M., Hourvitz, A., Baum, M. (2022) Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count among semen donors. *Andrology*. 10:1016–1022. doi: 10.1111/andr.13209

[124][123] Lee, W.S., Wheatley, A.K., Kent, S.J., DeKosky, B.J. (2020) Antibody-dependent enhancement and SARS-CoV-2 vaccines and therapies. *Nature Microbiology* 5, 1185-1191. https://doi.org/10.1038/s41564-020-00789-5

[125][124] Tseng, C-T., Sbrana, E., Iwata-Yoshikawa, N.I., Newman, P.C., Garron, T, Atmar, R.L., Clarwnce, J.P., Couch, R.B. (2012) Immunization with SARS Coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus. *PLOS One*. https://doi.org/10.1371/journal.pone.0035421

114. Original antigenic sin refers to a phenomenon whereby the antibody response to an earlier strain of a pathogen predominates upon a subsequent exposure to a new mutated version of the original strain. Essentially, the B cells that produced the original antibodies get re-stimulated to generate identical antibodies against the original strain, such that other B cells are less likely to produce more antibodies that better recognize the new mutated strain.

115. Tolerance refers to the ability of the immune system to recognize an agent in the environment as non-threatening, *e.g.*, typically the proteins that are normally found in the body. Such self-recognition is achieved by selective destruction of the B cells that would produce antibodies against one's own proteins and other immunogens that are common in the environment such as in food or in the air. Repeated exposure of an environmental allergen is one way to induced tolerance, and reduce the immune recognition of the allergen. In the case of COVID-19 vaccines, there is the risk that with high levels of the spike protein produced along with regular booster injections, this could induce the suicide of the very B cells that produce the highest affinity antibodies against the spike protein, and reduce immune protection from future infections with the SARS-CoV-2 virus. Any of these mechanisms may contribute to the negative efficacy that has been observed COVID-19 vaccines.

116. In a recent German study,[126][125] the long-term effect of repeated immune stimulations with SARS-CoV-2 mRNA vaccines was associated with a switching from IgG1 and IgG3 from T helper (Th) 1 cells to non-inflammatory IgG2 and especially IgG4 isotypes, which was further boosted with a third mRNA vaccination and/or SARS-CoV-2 variant breakthrough infections. This may contribute to the recent upsurge in COVID-19 cases, despite heavy vaccination to prevent this from happening in the first place. The repeated vaccine inoculations may be inducing tolerance against the Spike protein of the SARS-CoV-2, much like repeated allergen administration can mitigate allergies.

117. Very recently, a secondary meta-analysis of serious adverse events reported in the placebo-controlled, phase III randomized clinical trials of Pfizer and Moderna mRNA COVID-19 vaccines in adults was undertaken that focused on analysis of Brighton Collaboration adverse events of special

[126][125] Irrgang, P., Gerling, J., Kocher, K., Lapuente, D., Steininger, P. *et al.* (2022) Class switch towards non-inflammatory IgG isotypes after repeated SARS-CoV-2 mRNA vaccination. medRxiv. doi: https://doi.org/10.1101/2022.07.05.22277189

interest.[127126] Pfizer and Moderna mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events of special interest of 1 in 990, and 1 in 662 vaccinated over placebo baselines, respectively. Such increased risks of COVID-19 vaccine-induced injuries are unacceptably high, especially when compared to precedents of other vaccines that were removed from the market,[128127] including for example the occurrence of intussusception (telescoping action in the intestines leading to blocking of food and liquids) in 1 in 10,000 children inoculated with a vaccine for rotavirus.[129128,130129]

118. Since the introduction of the COVID-19 genetic vaccines, there has been at least an 8-fold surge in news reports of collapses and unexpected deaths in otherwise young healthy people, pilots, musicians and athletes.[131130,132131] Sudden Adult Death Syndrome of "unknown" cause is now amongst the top causes of death in Alberta since the rollout of the COVID-19 vaccines.[133132] It is hard to ignore the rise of these unusual deaths with the timing of the launch of the COVID-19 genetic vaccines. While such a temporal link in these increased deaths with COVID-19 vaccination exists, it does not necessarily have to be a causal. However, in considering the mechanisms of action of the COVID-19 genetic vaccines and their inadequate testing prior to wide-spread dissemination, it is not actually that surprising.

[127126] Fraiman, J., Erviti, J., Jones, M., Greenland, S., Whelan, P. *et al.,* (2022) Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. Vaccine 40, 5798-5805. https://doi.org/10.1016/j.vaccine.2022.08.036

[128127] Hampton, L.M., Aggarwal, R., Evans, S.J.W., Law, B**.** (2021) General determination of causation between Covid-19 vaccines and possible adverse events. Vaccine, 39 (10),1478-1480. https://doi.org/10.1016/j.vaccine.2021.01.057

[129128] Centers for Disease Control and Prevention (CDC). (2004) Suspension of rotavirus vaccine after reports of intussusception--United States, 1999. *MMWR Morb Mortal Wkly Rep.* 53(34):786-9. Erratum in: MMWR Morb Mortal Wkly Rep. 2004 Sep 24;53(37):879.

[130129] Murphy, T.V., Gargiullo, P.M., Massoudi, M.S., *et al.* (2001) Intussusception among infants given an oral rotavirus vaccine. *N Engl J Med.* 344(8):564-72. doi: 10.1056/NEJM200102223440804. Erratum in: N Engl J Med 2001 May 17;344(20):1564. Livingood, JR [corrected to Livengood, JR].

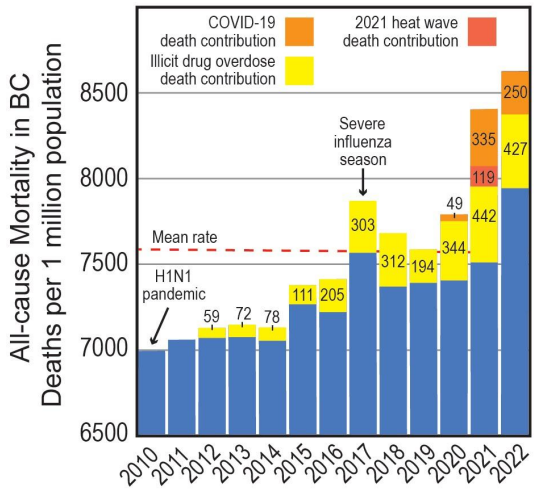
[131130] https://makismd.substack.com/p/18-videos-of-collapses-on-stage-and?utm_source=substack&utm_medium=email#play

[132131] https://goodsciencing.com/covid/athletes-suffer-cardiac-arrest-die-after-covid-shot/

[133132] https://calgary.ctvnews.ca/deaths-with-unknown-causes-now-alberta-s-top-killer-province-1.5975536

119. Although there was virtually no increase in overall excess all-cause mortality in the 2020, the first year of the COVID-19 pandemic, in Canada and elsewhere, it has increased significantly here and in many other countries in 2021 and 2022, since the introduction of the COVID-19 vaccines.[134133,135134,136135] In a recent study of all-cause mortality in 31 European countries, this was positively correlated with increased COVID-19 vaccination.[137136] Figure 9 shows measurements of all-cause mortality increases in B.C. Most of the increased all-cause mortality in 2022 cannot be attributed to COVID-19.

Figure 9. British Columbia annual all-cause and COVID-19 mortality rates from October 1 to September 31 and illicit drug deaths rates from January 1 to December 31.[138137]



134133 Rancourt, D.G. (2022) Probable causal association between India's extraordinary April-July 2021 excess-mortality event and the vaccine rollout. Correlation Research in the Public Interest. https://correlation-canada.org/report-probable-causal-association-between-indias-extraordinary-april-july-2021-excess-mortality-event-and-the-vaccine-rollout/

135134 Rancourt, D.G., Baudin, M. and Mercier, J. (2022) Probable causal association between Australia's new regime of high all-cause mortality and its COVID-19 vaccine rollout. Correlation Research in the Public Interest. https://correlation-canada.org/report-probable-causal-association-between-australias-newregime-of-high-all-cause-mortality-and-its-covid-19-vaccine-rollout/

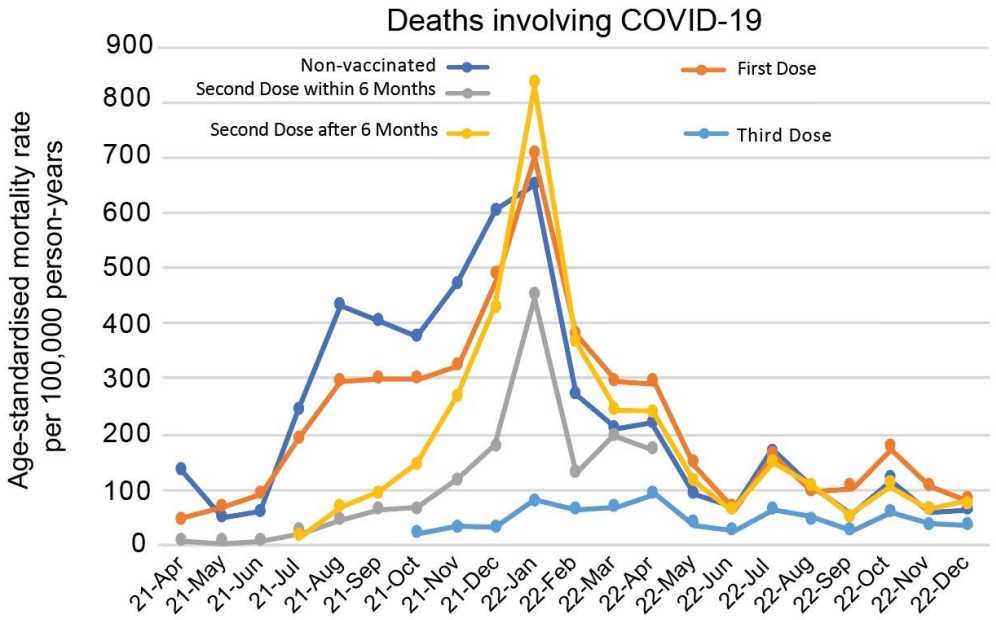
136135 Rancourt, D.G., Baudin, M., Hickey, J. and Mercier, J. (2023) Age-stratified COVID-19 vaccine-dose fatality rate for Israel and Australia. Correlation Research in the Public Interest. https://correlation-canada.org/report-age-stratified-covid-19-vaccine-dose-fatality-rate-for-israel-and-australia/

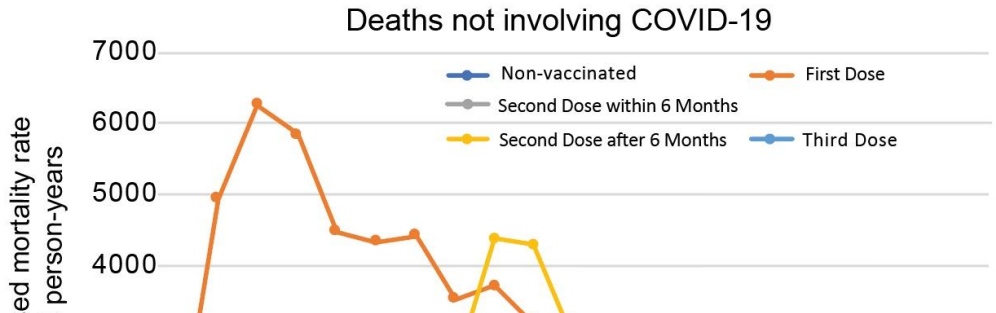
137136 Aarstad, J., Kvitastein, O.A. (2023) Is there a link between the 2021 COVID-19 vaccine uptake in Europe and 2022 excess all-cause mortality? doi:10.20944/preprints202302.0350.v1 https://www.preprints.org/manuscript/202302.0350/v1

138137 Data sourced from https://bccdc.shinyapps.io/Mortality_Context_ShinyApp/ and https://www2.gov.bc.ca/gov/content/lifeevents/death/coroners-service/statistical-reports (retrieved February 24, 2023)

120. The United Kingdom is one of the few jurisdictions where all-cause and COVID-19 linked mortality has been correlated with COVID-19 vaccination status, age and sex, and this data is available for public scrutiny.[139][138] Graphic representation of some of the findings are shown in Figure 10. The data indicate that with the emergence of Omicron variants, there has been no real benefit of single or double COVID-19 vaccination for preventing COVID-19 deaths compared to not being vaccinated at all against SARS-CoV-2. There is evidence that triple vaccination might have reduced COVID-19 deaths prior to September 2022, but not significantly afterwards. However, with all-cause mortality, especially with the first dose of the COVID-19 vaccines early in the vaccination program, and the second dose subsequently after September 2021, the inoculations are associated with higher rates of death. After May 2022, there is little support that even a third shot of COVID-19 vaccines provided any significant benefit in reducing all-cause mortality. Interpretation of the data in Figure 10 is complicated, since the virulence of the SARS-CoV-2 steadily reduced with the evolution of new variants and the extent of natural immunity in the UK population also increased.

Figure 10. England monthly all-cause and COVID-19 mortality rates from April 1, 2021 to December 31, 2022 as a function of COVID-19 vaccine status.[138]





[139][138] Da
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ets/de
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121. In view of the mounting and disturbing data about the limited efficacy and serious safety issues associated with the COVID-19 genetic vaccines, health regulatory agencies around the world have begun one after another to discourage or ban the use of these vaccines, especially in younger people. Denmark was the first nation in Europe to invoke this step by stopping vaccination invitations on May 14, 2022.[140][139] By autumn 2022, Denmark recommended vaccination only to those over 50 years old and some vulnerable populations.

122. Many European countries as well as Australia and some US states such as Florida have stopped recommending vaccinations for COVID-19 to anyone under 40, 50 or 60 years of age and especially children. Even in 2021, France and Scandinavian countries did not recommend the Moderna vaccine for people under 30 years of age.[141][140],[142][141] The United Kingdom Joint Committee on Vaccination and Immunisation (JCVI) no longer recommends vaccination of

[140][139] https://www.msn.com/en-in/money/topstories/covid-19-denmark-currently-not-offering-booster-shots-to-those-under-50/ar-AA11TTwi

[141][140] https://www.france24.com/en/live-news/20211109-france-advises-against-moderna-for-under-30s-over-rare-heart-risk

[142][141] Lehto, E. (2021) Finland joins Sweden and Denmark in limiting Moderna COVID-19 vaccine. https://www.reuters.com/world/europe/finland-pauses-use-moderna-covid-19-vaccine-young-men2021-10-07/

healthy individuals under 50 years of age in the UK except for those in clinical risk groups or those attending to such individuals.[143][142] The Federal Office of Public Health in Switzerland also no longer recommends COVID-19 vaccination for healthy people in all age groups, and will not pay for COVID-19 vaccination for anyone, unless medically indicated by a physician for an individual patient with a clear risk-benefit analysis.[144][143] The Australian government has advised that a booster dose is **not recommended** for children as of February 2023 for children and adolescents up to 18 years who do not have any risk factors for severe COVID-19, and only for those 18-64 years of age who have undergone a risk-benefit analysis with their health care provider.[145][144] The German Federation of Hospitals (DKG) has called for the mandatory vaccination obligation of healthcare personnel to be revoked after the German Ministry of Health admitted that 1 in 5,000 COVID-19 vaccination shots led to serious side-effects.[146][145]

Section I. The Extent and Robustness of Natural Immunity to SARS-CoV-2

123. When infected with SARS-CoV-2, most people clear this virus from their body by mounting a robust, long-lasting immune response that targets multiple components of the virus. These people will be afforded protection from re-infection with the same variant of SARS-CoV-2 and, due to the breadth of a natural immune response, should have resistance against emerging new variants of SARS-CoV-2. If re-infection does occur, it should be less severe and less life threatening. Indeed, most people who have naturally acquired immunity should not be at risk of developing severe disease even if variants arise that can effectively bypass the narrower immunity conferred by COVID-19 vaccines that are

[143][142] https://www.gov.uk/government/publications/covid-19-vaccination-programme-for-2023-jcvi-interim-advice-8-november-2022/jcvi-statement-on-the-covid-19-vaccination-programme-for-2023-8-november-2022

[144][143] https://www.bag.admin.ch/bag/en/home/krankheiten/ausbrueche-epidemien-pandemien/aktuelle-ausbrueche-epidemien/novel-cov/impfen.html#21889874

[145][144] https://www.health.gov.au/our-work/covid-19-vaccines/advice-for-providers/clinical-guidance/clinical-recommendations

[146][145] https://rairfoundation.com/german-hospital-federation-demands-withdrawal-of-vaccination-mandate-after-massive-side-effects-revealed/

focused on a single component of SARS-CoV-2, such as the Spike protein. Natural immunity from prior exposure to the virus itself can last for years and likely decades.

124. Individuals that have previously recovered from infection with SARS-CoV-1 in 2002 and 2003 were observed to have appreciable antibodies levels (~54% of peak levels) against SARS-CoV-1 Spike protein even three and a half years later.[147146,148147] While antibody levels are expected to decline when a pathogenic virus eventually disappears from the environment, the B cells that produced these antibodies should survive for years, although they hibernate in a resting state as memory or plasma B cells. When eight survivors of SARS-CoV-1 were vaccinated with the Pfizer/BioNTech COVID-19 vaccine nearly two decades later, they develop very strong antibodies that recognize the original SARS-CoV-1 Spike protein, just as well as the SARS-CoV-2 protein.[149148] This arose from the stimulation of pre-existing memory or plasma B cells. T-cell responses have also been shown to persist even 11 years after infection with SARS-CoV-1.[150149] Following infection with MERS-CoV (the coronavirus that caused Middle East respiratory syndrome), antibody levels against this virus have also been shown to persist for up to 34 months in recovered patients.[151150]

125. Harvard Medical School Professor Martin Kulldorff, a biostatistician and epidemiologist, likewise concluded that natural immunity offers exponentially more protection than vaccines.[152151] One study

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[147146] Wu, L.-P., Wang, N.-C., Chang, Y.-H., Tian, X.-Y., Na, D.-Y., Zhang, L.-Y., Zheng, L., Lan, T., Wang, L.-F. and Liang, G.-D. (2007) Duration of antibody responses after severe acute respiratory syndrome. *Emerging Infectious Diseases* 13 (10), 1562-1564. https://pubmed.ncbi.nlm.nih.gov/18258008/

[148147] Cao, W.-C. Liu, W., Zhang, P.-H., Zhang, F., Richardus, J. H. (2007) Disappearance of antibodies to SARS-associated coronavirus after recovery. *N. Engl. J. Med.* 357, 1162–1163 (2007). doi: 10.1056/NEJMc070348

[149148] Mallapaty, S. (2021 August 18) Decades-old SARS virus infection triggers potent response to COVID vaccines. Nature 596,471-472. *doi: https://doi.org/10.1038/d41586-021-02260-9*

[150149] Ng, O.-W., Chia, A., Tan, A.T., Jadi, R.S., Leong, H.N., Bertoletti, A., Tan, Y.-J. (2016) Memory T cell responses targeting the SARS coronavirus persist up to 11 years post-infection. *Vaccine* 34, 2008–2014. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7115611/

[151150] Payne, D.C., Iblan, I., Rha, B., Alqasrawi, S., Haddadin, A. *et al.* (2016) Persistence of antibodies against Middle East respiratory syndrome coronavirus. *Emerg Infect Dis*. 22(10):1824-1826. doi:10.3201/eid2210.160706 https://pubmed.ncbi.nlm.nih.gov/27332149/

[152151] https://fee.org/articles/harvard-epidemiologist-says-the-case-for-Covid-vaccine-passports-was-just-demolished/

that he referenced found that vaccinated people are at least 13-times more likely to get a symptomatic COVID-19 infection than those with natural immunity.[153][152]

126. The superior protection offered by natural immunity is well demonstrated in countries that have lower vaccination rates. For example, despite a huge, unprecedented spike of over 400,000 deaths from COVID-19 in India in May and June of 2021, by early July, when less than 4% of the Indian population was double vaccinated, the overall cases, hospitalizations and deaths from COVID-19 had returned to its previous low levels. This low rate of COVID-19 cases continued to persist until mid-December 2021. This was primarily attributed to acquisition of natural immunity in about 70% of the Indian population.[154][153],[155][154] While the case counts of COVID-19 dramatically escalated again in January and February of 2022, to near the May and June 2021 peak levels, along with increased double vaccination to 61% of the population in India, the deaths in India from COVID-19 remained remarkably low in comparison.

127. In a Swedish study with 2.04 million individuals tracked, natural immunity from recovery from COVID-19 was found to reduce the risk of a SARS-CoV-2 reinfection by 95% within 3 months, and reduced the risk of hospitalization by 87% after 20 months.[156][155]

128. In another large scale study of 9.3 million individuals of the highly vaccinated population of Portugal (with 98% of the population above 12 years-old vaccinated before 2022), it was estimated at least 86.2% had been previously infected with SARS-CoV-2 variants. The study then analyzed the level of protection conferred against re-infection with Omicron BA.5 following previous infection and found 51.6% protection by original Wuhan variant, 54.8% with Alpha, 61.3% with Delta and 75.3% with

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[153][152] Gazit, S., Shlezinger, R., Perez, G., *et al.* (2021 August 25) Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections. *medRxiv*. Published online .doi:10.1101/2021.08.24.2126241

[154][153] https://www.thehindu.com/news/national/kerala/sero-survey-70-in-kerala-may-have-acquired-natural-immunity-against-covid-19/article37070013.ece

[155][154] https://www.aljazeera.com/news/2021/11/24/india-worst-covid-pandemic-third-wave-coronavirus

[156][155] Nordström, P., Ballin, M., Nordstrom, A. (2022) Risk of SARS-CoV-2 reinfection and COVID-19 hospitalisation in individuals with natural and hybrid immunity: a retrospective, total population cohort study in Sweden. *Lancet Infect Dis*. https://doi.org/10.1016/S1473-3099(22)00143-8

Omicron BA.1 and BA.2 combined.[157156] It is likely in these studies, that the extra protection afforded against BA.1 and BA.2 was actually due to the natural immunity from infection rather than from the COVID-19 vaccinations.

129. Within an immune response, only a small portion of the antibodies can specifically neutralize the ability of a virus to enter into host cells by binding to those parts of viral proteins through which they can attached to cell receptors. However, a much larger proportion of antibodies that are produced are still able to bind to proteins on the surface of the virus and enable its recognition by immune cells for attack and removal. The fixation of COVID-19 researchers in publications to focus solely on the presence of neutralizing antibodies that target just the receptor binding domain of the SARS-CoV-2 Spike protein to inhibit its interaction with ACE2 on the surface of the host cells is hard to fathom, and its underestimates the true effectiveness of the immune system to defeat a viral infection.

130. There are four main classes of antibodies (IgA, IgE, IgG and IgM) that differ in their sites of production and durability, and their utility for a respiratory infection with a pathogenic virus or bacteria. In particular, at mucosal surfaces, the IgA and IgM classes of antibodies are found in the upper respiratory tract. IgM and IgA class antibodies are secreted into these spaces to assist the innate immune system, particularly macrophages, to recognize and remove viruses and other pathogens. IgA and IgM antibodies have short half-lives of 4 to 5 days. Antibodies of the IgG class are found much deeper in the respiratory tract and play a more important role than IgA at that location. Since natural exposure to the respiratory virus SARS-CoV-2, which is taken in via the upper respiratory tract in an aerosol-bound form, and later can move down to lower regions of the tract, this has a propensity to generate both IgA in the upper track and IgG antibodies in the lower airway to various components of the virus. The IgG class antibodies are the most commonly found in the blood circulation, and they are longer lasting antibodies that typically persist with half-lives of about 20-24 days. Conversely, intramuscular vaccination (*e.g.,* in the deltoid muscles of the arm) is known to preferentially generate IgG, but not necessarily mucosal IgA in the airway passages and upper lungs. Consequently, upon re-exposure, people who have previously been exposed to the live virus will quickly generate a robust

[157156] Malato, J., Ribeiro, R.M., Leite, P.P., Casaca, P., Fernandes, E., *et al.* (2022) Risk of BA.5 infection among persons exposed to previous SARS-CoV-2 variants. *N Engl J Med*. doi: 10.1056/NEJMc2209479

and broad-based set of innate and adaptive immune responses, both IgA and IgG, along with other cellular immune responses.

131. The reduced levels of IgG that occur at the initial sites of infection can explain why double vaccinated individuals can still become infected and transmit SARS-CoV-2 at viral loads that are found in unvaccinated people with COVID-19. As a respiratory virus, SARS-CoV-2 can still enter via the airways through the mouth and nose and propagate in the nasal and upper airway passages with less resistance in vaccinated individuals, because they have such low levels of IgG antibodies produced by B cells at these locations. With naturally derived immunity following exposure to and recovery from SARS-CoV-2, high levels of effective IgA and IgM antibodies are mostly secreted by B cells into the airway spaces and upper lungs.

132. As discussed earlier, naturally acquired immunity is very durable, often lasting beyond the length of the declared pandemic. In contrast, vaccine-induced immunity is clearly shorter term and must lack the breadth of immunity following natural exposure, since the response is limited only to the viral Spike protein. Moreover, as mentioned earlier, it appears that the COVID-19 vaccines appear to have difficulty in establishing long term immunity as demonstrated by the need for repeated booster shots.

133. Daniel Horowitz wrote one of the earliest reviews on the superiority of natural immunity to COVID-19 vaccine induced immunity in which he highlighted 15 studies from the scientific literature that supported this view.[158][157] My colleagues at the Canadian Covid Care Alliance and I have published a review that further elaborated on these studies.[159][158] Dr. Paul Elias Alexander at the Brownstone Institute has also documented over 146 studies that affirm that "*naturally acquired immunity is equal to or more robust and superior to existing vaccines*."[160][159]

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[158][157] https://www.theblaze.com/op-ed/horowitz-15-studies-that-indicate-natural-immunity-from-prior-infection-is-more-robust-than-the-covid-vaccines

[159][158] Mallard, B.A., Karrow, N., Bridle, B., Speicher, D., Sturgess, L., Shaw, C., Pelech, S. (2021) Which is better for future COVID-19 prevention: Immunity following natural infection or vaccine-induced immunity. Canadian Covid Care Alliance. 2021. https://www.canadiancovidcarealliance.org/media-resources/natural-vs-vaccine-induced-immunity/

[160][159] https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

134. In the clinical study at Kinexus that I lead, we have assayed over 4,500 people primarily from Ontario and British Columbia for diverse SARS-CoV-2 antibodies in their blood samples, and determined that about 90% tested positive for evidence of previous infection with this virus, which includes over 138 children between ages 2 to 11 years. As shown in Figure 11, over 1,500 of the participants reported having COVID-19-like symptoms up to November 9, 2021, and remarkably about three-quarters of these people first had these symptoms in December 2019, and January, February and March of 2020. This reveals that not only does there appear to be a high degree of natural immunity in the Canadian population, but it spread much earlier on in the COVID-19 pandemic than generally appreciated. In an earlier study performed in collaboration with the BC Children's Hospital Research Centre, we reported that in May of 2020, 90% of 276 health adults had antibodies that recognized the SARS-CoV-2 antibodies using our tests as well as an independent test developed by MesoScale Devices for SARS-CoV-2 antibodies against the Spike and Nucleocapsid proteins.[17]

135. In view of the wide-spread natural immunity prevalent in the Canadian population in 2022 and 2023, and the high degree of lasting immunity afforded by natural infection, the question arises whether subsequent inoculations with COVID-19 vaccine is desirable or even advisable. For someone with natural immunity, receiving the first dose of a COVID-19 vaccine is effectively similar to receiving a second dose in a person that is double vaccinated, but without prior exposure to the virus. This may possibly produce more severe vaccine adverse events, especially if this individual follows up with another booster shot of the vaccine within a month or two later. In this regard, it has been reported that elderly residents in nursing homes and hospitals in Quebec that receive a third shot of COVID-19 vaccine are at much greater risks of severe side-effects if they have previous had COVID-19.[161160,162161] Figure 12 shows the increased numbers of new hospitalizations as a function of vaccination status in Quebec. Interestingly, while the British Columbia and other provincial health authorities have discounted natural immunity in the issuing of vaccine passports, the BC COVID Therapeutics

[161160] https://trialsitenews.com/quebec-changes-course-for-elderly-in-nursing-homes-covid-19-booster-not-required-due-to-pervasive-side-effects/

[162161] https://vaccintrackerqc.ca/cas_et_hospitalisations/#selon-le-statut-vaccinal

Committee in their "Clinical Practice Guide for the Use of Therapeutics in Mild-Moderate COVID-19" stated that "*previous infection alone is equivalent to 2-dose vaccination*."[163][162]

Figure 11. Number of monthly symptomatic COVID-19 cases reports in the Kinexus SARS-CoV-2 antibody testing study from October 2019 to November 2021. The number of first cases with COVID-19 symptoms each month are shown (circles), including those that were confirmed by PCR (triangles) and apparently with a second bout of COVID-19 (squares).

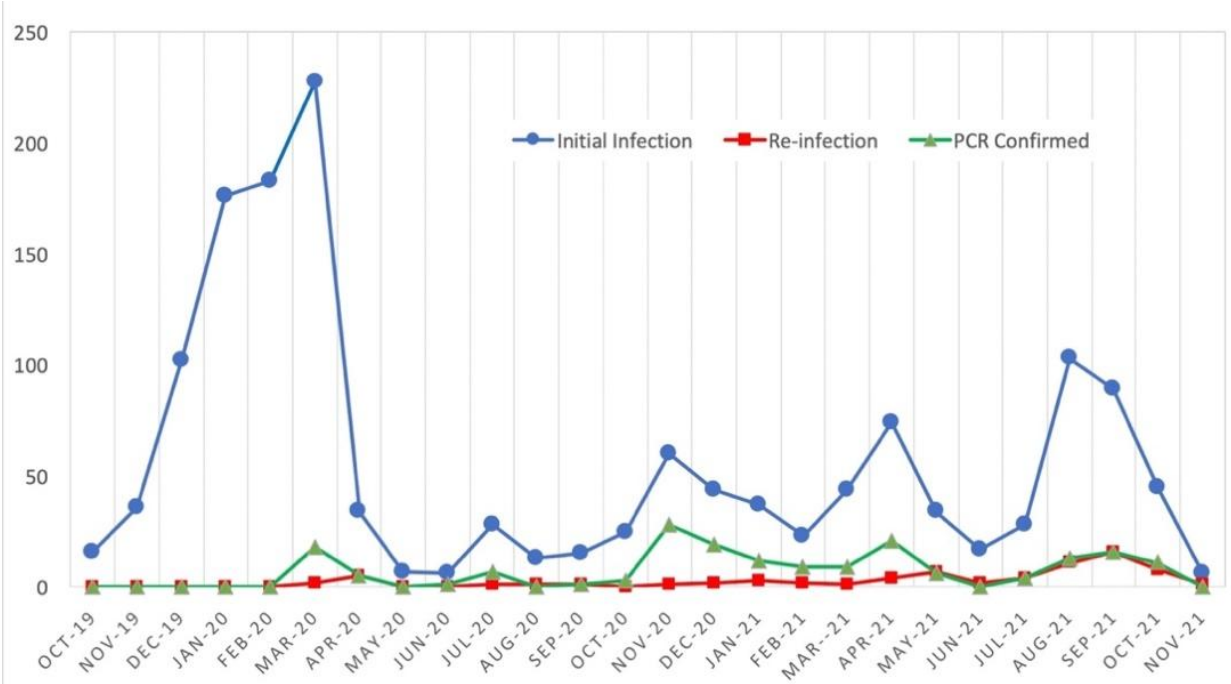
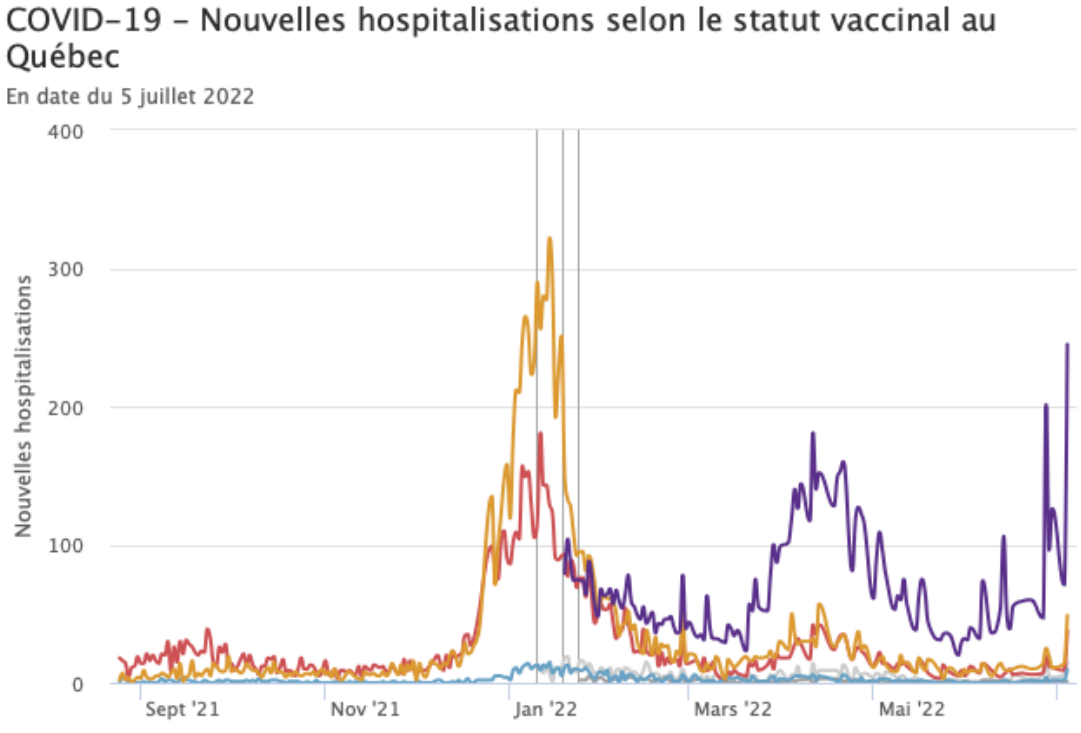


Figure 12. Absolute numbers of new hospitalization in Quebec (website consulted on September 18, 2022). Note the higher number of 3-dose hospitalized patients represented by the purple line.



163[162] H
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136. Of concern in 2022, there has been a trend toward increased COVID-19 deaths in triple vaccinated individuals relative to unvaccinated individuals over 70 years of age, which is evident from examination of recent Public Health Data in British Columbia[164163] and Ontario.[165164,166165] It is possible that some people that have recovered from COVID-19 and acquired natural immunity might actually compromise that protection with further vaccination.

137. Moderna's 30,000-participant study of persons 18 years or older for its RNA vaccine has indicated that subsequent production of antibodies against the Nucleocapsid protein of SARS-CoV-2 was evident in only 40% of previously vaccinated individuals with COVID-19 compared to 93% of unvaccinated peoples who acquired COVID-19.[167166] Even an unvaccinated person with a mild case of COVID-19 had a 71% chance of showing Nucleocapsid antibodies in their blood compared to a 15% chance with a vaccinated person that recovered from mild COVID-19. These disturbing findings

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[164163] http://www.bccdc.ca/health-professionals/data-reports/covid-19-surveillance-dashboard COVID-19 health outcomes by vaccination status, BC, 17 Apr. - 14 May, 2022

[165164] https://www.canadiancovidcarealliance.org/wp-content/uploads/2022/02/Scientific-Review-Dispelling-the-Myth-of-a-Pandemic-of-the-Unvaccinated.pdf

[166165] https://covid-19.ontario.ca/data, 7 May - 20 May, 2022

[167166] Follmann, D., Janes, H.E., Buhule, O.D., Zhou, H., Girard, B., Marks, K., Kotloff, K., Desjardins, M., Corey, L., Neuzil, K.M., Miller, J.M., El Sahly, H.M., Baden, L.R. (2022) Anti-nucleocapsid antibodies following SARS-CoV-2 infection in the blinded phase of the mRNA-1273 Covid-19 vaccine efficacy clinical trial.
medRxiv 2022.04.18.22271936; doi: https://doi.org/10.1101/2022.04.18.22271936

indicate that COVID-19 vaccination may actually reduce pre-existing natural immunity. Such reduced broad immunity in COVID-19 vaccinated individuals may explain recent higher rates of death per capita that has been observed in 2022 in elderly, triple vaccinated persons compared to unvaccinated people in BC [2.3-fold higher][163] and Ontario [1.4-fold higher].[164,165]

138. It is very likely that unvaccinated individuals with natural immunity will continue to be exposed to SARS-CoV-2 by natural encounters, and so vaccination is really unnecessary for them. This phenomenon is apparent in SARS-CoV-2 antibody testing clinical study undertaken by my company Kinexus with individuals that had COVID-19 and were tested a couple of months after their recovery, and then again about 10 months later. Positive reactivity of the antibodies in the serum of these individuals against 111 different parts of ten of the SARS-CoV-2 viral proteins appear as dark spots on these immunoblot tests. As shown in the examples provided in Figure 2, it is evident that while everyone tested had a different profile as to which of the parts of the viral proteins that they best targeted with their antibodies, each pattern was stable when tested nearly a year later. In our study, SARS-CoV-2 protein-reactive antibodies are clearly detectable even two and a half years after the study participants first acquired COVID-19.

139. In view of the wide extent of natural immunity, the effect of subsequent COVID-19 vaccination on that immunity has become an important question. Public health authorities have even recommended that individuals become vaccinated as soon as about a month after recovery from COVID-19 to boost their natural immunity. This was recently extensively investigated in the context of immunity against the Omicron variants in triple mRNA vaccinated healthcare workers (HCW) with different SARS-CoV-2 infection histories.[168][167] B and T cell immunity against previous variants of concern was enhanced in triple vaccinated individuals, but the magnitude of T and B cell responses against BA.1 spike protein was reduced. Immune imprinting by infection with the earlier Alpha variant resulted in less durable binding antibody against BA.1 spike protein. Some imprinted combinations, such as infection during the Wuhan Hu-1 and Omicron waves, confer particularly impaired responses. For example, if one was first infected with Wuhan Hu-1, then vaccinated, and then infected with Omicron, their neutralizing

[168][167] Reynolds, C.J., Pade, C., Gibbons, J.M., Otter, A.D., Lin, K.-M., *et al.* (2022) Immune boosting by B.1.1.529 (Omicron) depends on previous SARS-CoV-2 exposure Science 10.1126/science.abq1841. DOI: 10.1126/science.abq1841

antibody levels against the receptor binding domain of the Spike protein were lower than in those who had not been infected. The numbers of memory B cells capable of producing antibodies reactive against Spike S1 subunit were increased by a third injection relative to two injections, regardless of whether or not the subject was previously infected, but **in the case of Omicron, these levels dropped after either two or three doses of vaccine**. These effects were independent of prior virus infection history.[167]

140. In the same study, the T cell responses were significantly reduced for the Omicron Spike protein recognition in triple-vaccinated HCW 2-3 weeks after the third vaccine dose, who were either infection-naïve or had been infected during the Wuhan Hu-1, Alpha or Delta wave. Overall, **more than half (27/50; 54%) made no T cell response against Omicron BA.1 Spike protein, irrespective of previous SARS-CoV-2 infection history, compared to 8% (4/50) that made no T cell response against ancestral Wuhan Hu-1 Spike protein**. In summary, in these HCW that were infected with the original Wuhan strain, then vaccinated, then re-infected with Omicron, they produced much lower neutralizing antibody or T cell responses to Omicron.[167]

141. The underlying mechanisms of reduced or negative efficacy with the booster shots of the COVID-19 RNA vaccines may results from an acquisition of tolerance. Generation of IgG4 antibodies by class switching has recently been documented by a preprint German study: "Class switch towards non-inflammatory IgG isotypes after repeated SARS-CoV-2 mRNA vaccination."[169168] This study clearly raises the prospect of generating immune tolerance to the vaccinal spike protein in some individuals, similar to repeated allergen administration to mitigate allergies, with undesirable consequences for the control of future SARS-CoV-2 infections.

142. Guidance and advice related to the handling of the COVID-19 pandemic needs to adapt to the accruing knowledge of the SARS-CoV-2 virus and its evolution of variants with altered transmissibility and virulence. Much has indeed been learned about SARS-CoV-2 and COVID-19 in the past three years, but unfortunately, public health policies have not actually followed the mounting science and

[169168] Irrgang, P., Gerling, J., Kocher, K., Lapeuente, D., Steininger, P*., et al.* (2022) Class switch towards non-inflammatory IgG isotypes after repeated SARS-CoV-2 vaccination. medRxiv. doi: https://doi.org/10.1101/2022.07.05.22277189

come to grips with the failures of the COVID-19 vaccines and the harms that they pose to a significant number of individuals, as well as the relatively modest risk that the SARS-CoV-2 virus now actually poses to the vast majority of people, with an overall lethality rate now that is presently less than 0.1% in those infected with Omicron variants of SARS-CoV-2. It is important to recognize that the total deaths in Canada associated with COVID-19 in 2021 (*i.e.*, ~14,598)[170169] represent only about 5.1% of all causes of deaths (*i.e.*, ~285,270)[171170] recorded in 2019 previous to the pandemic. Most of these deaths with COVID-19 in 2021 would likely have still transpired from other causes, since 90% of COVID-19 deaths in Canada had one or more comorbidities.[172171]

143. Collectively, these and scores of other studies demonstrate that natural immunity provides the best protection against severe COVID-19 and death, and that our society is already close to establishing herd immunity in this respect. The risks of injury appear to increase with each booster injection of these experimental vaccines. The current crop of COVID-19 vaccines have fleeting efficacy and significant harm in a substantial segment of otherwise healthy recipients. In my opinion, the demonstrated and potential injuries from the COVID-19 vaccines have been under represented by the public health authorities in their messaging, whereas the effectiveness of the COVID-19 vaccines have been over-played.

Section J. Summary of the Conclusions with Respect to Natural and COVID-19 Vaccine-Induced Immunity

144. In this report, I have provided compelling data that there may be more risks than benefits for the COVID-19 vaccination for those that are less than 70 years of age and in good health and especially for youth. It is also evident that COVID-19 is not as deadly as originally feared, and natural immunity is quite extensive in the general population. In summary:

[170169] Jackson, H. (2021) Cases, deaths and hospitalizations: Comparing Canada's two years of COVID-19. https://www.ctvnews.ca/health/coronavirus/cases-deaths-and-hospitalizations-comparing-canada-s-two-years-of-covid-19-1.5722463

[171170] https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1310039401

[172171] https://www150.statcan.gc.ca/n1/pub/45-28-0001/2020001/article/00087-eng.htm

a. At least three 3 years since the start of COVID-19 pandemic, with at least seven distinct waves in Canada and relatively low levels of SARS-CoV-2 infections since the end of July 2022, and the higher infectivity of the recent SARS-CoV-2 Omicron variants, most of our population has already acquired a fairly high degree of natural immunity to fight future infections with SARS-CoV-2.

b. Naturally acquired immunity from COVID-19 is superior to vaccine immunity due to:

i. Broader coverage of antibody and T cell responses broadly towards most of the 28 SARS-CoV-2 proteins rather than narrowly just to the Spike protein as occurs with the vaccines;

ii. Immune memory from natural infection persists for years and even decades, whereas the vaccine induced immunity has consistently waned in 3 to 6 months, with reduced efficacy with increasing boosters; and

iii. The appropriate antibodies (IgA and IgM) produced from natural exposure to the air borne SARS-CoV-2 virus are generated at high concentrations in the nasopharyngeal airway spaces and upper lungs, where the respiratory virus enters the body, whereas most of the antibodies (IgG) produced from injection of vaccines into muscle are typically found only at low concentrations at the sites of initial viral entry.

c. The SARS-CoV-2 virus is rapidly evolving as expected into a more infectious, but less deadly endemic virus that will soon be classified as a common cold coronavirus. In 2022, COVID-19 cases were more likely to resolve faster with milder symptoms, with at least a 4- to 8-fold reduction in hospitalizations, ICU admissions and deaths than seen with the earlier variants of SARS-CoV-2.

d. The RNA and adenovirus COVID-19 vaccines have turned out to be failures, in view of their limited efficacy, especially in the youngest, the most elderly, and those with multiple comorbidities. Frequent boosting is required to maintain their efficacy. There is a concern that further boosting may actually reduce immunity to future SARS-CoV-2 infections.

e. Individuals that have been vaccinated are still able to become infected with SARS-CoV-2 and transmit the virus with viral loads that are the same as unvaccinated persons with COVID-19. In fact, there is no clinical trial evidence that shows that vaccination actually reduce infection.

f. The clinical evidence that COVID-19 vaccination actually reduces the severity of subsequent SARS-CoV-2 infections is also lacking, and now complicated in assessment due to the wide spread of natural immunity and reduced virulence of the Omicron strains of SARS-CoV-2.

g. There are also unacceptably high risks of known and potential vaccine injury from the COVID-19 vaccines that ought to preclude their wide usage, especially in those that are otherwise healthy and at low risk of severe COVID-19.

h. As outlined in the next section, there is a growing list of powerful and effective generic and novel medications such as Paxlovid that have proven to be effective for early stage treatment of COVID-19 for those that are at higher risk of severe COVID-19.

Section K. Alternative Treatments for COVID-19

145. COVID-19 vaccinations are not the only means to prevent or reduce the severity of COVID-19 and prevent transmission. To achieve herd immunity in the population, it is neither necessary nor desirable to try to prevent transmission indiscriminately with vaccines that have limited and waning efficacy. Rather, transmission must be allowed in a controlled, stratified fashion, that allows the young and healthy adults to develop natural immunity, while protecting the old and the frail through prophylaxis and early treatment, with a wide range of promising existing drugs and new antiviral medications from companies like Merck and Pfizer that have been developed specifically for combating SARS-CoV-2.

146. Several Health Canada approved medications are now available, and some of these are widely used for early treatment. On July 27, 2021, Health Canada approved the use of Veklury (Remdesivir), which targets the RNA polymerase enzyme encoded by the SARS-CoV-2 virus genome, to initially treat hospitalized COVID-19 patients.[173][172] On January 17, 2022, Health Canada also approved the use of

[173][172] https://www.ualberta.ca/folio/2022/01/building-better-antivirals.html

Pfizer's oral anti-viral drug Paxlovid, which potently inhibits the SARS-CoV-2 protease, which is an enzyme that facilitates the penetration of the virus into cells.[174][173] A wide range of monoclonal antibodies that target the receptor binding domain region of the SARS-CoV-2 Spike protein have also been used widely in the US and have been available in Canada for early treatment.[175][174],[176][175],[177][176],[178][177] Unfortunately, due to mutations in the receptor binding domain associated with Omicron and some of the other variants of concern, some of these monoclonal antibodies are less effective, because they specifically target the receptor binding domain of the virus. Health Canada is presently reviewing Molnupiravir, which is already approved in the US and UK, and this drug also targets the SARS-CoV-2 protease.[179][178] Merck's clinical trial showed molnupiravir cut the rate of hospitalization or death by 30% when the drug was given within five days of symptoms onset.

147. Furthermore, there is overwhelming evidence that COVID-19 is highly treatable prior to hospitalization, with safe, effective, and inexpensive, generic drugs that can be administered in combination for successful early treatment, and even prevention, with none of the adverse effects of the current COVID-19 vaccines. These include drugs such as ivermectin, hydroxychloroquine, fluvoxamine quercetin, budesonide, and vitamins such as vitamin D3. Canadians tend to have lower than recommended vitamin D3 levels in the winter months, which is a vitamin that is important for proper

[174][173] https://www.canada.ca/en/public-services-procurement/news/2022/01/government-of-canada-receives-first-delivery-of-covid-19-oral-antiviral-treatment.html

[175][174] Canada H. EVUSHELD. COVID-19 vaccines and treatments portal. Accessed May 12, 2022. https://covid-vaccine.canada.ca/evusheld/product-details

[176][175] Canada H. Bamlanivimab (bamlanivimab). COVID-19 vaccines and treatments portal. Accessed May 12, 2022. https://covid-vaccine.canada.ca/bamlanivimab/product-details

[177][176] Canada H. Casirivimab (casirivimab) and imdevimab (imdevimab). COVID-19 vaccines and treatments portal. Accessed May 12, 2022. https://covid-vaccine.canada.ca/casirivimab-and-imdevimab/product-details

[178][177] Canada H. Sotrovimab (sotrovimab). COVID-19 vaccines and treatments portal. Accessed May 12, 2022. https://covid-vaccine.canada.ca/sotrovimab/product-details

[179][178] https://www.canada.ca/en/public-services-procurement/news/2022/02/government-of-canada-signs-new-covid-19-antibody-therapy-agreement.html

immune function.[180][179] The Ontario Science Table recommends fluvoxamine and budesonide for adults with a standard risk of hospitalization of less than 5%.[181][180]

148. A systematic review of 15 clinical trials indicated that the anti-parasitic drug ivermectin, which permitted the awarding of a Nobel prize to its discovers, can be successfully applied to the treatment of viral diseases, including COVID-19, and reduces infection by an average of 86%.[182][181] Another report of 64 clinical trials, 30 of them randomized and controlled, indicated 67% effectiveness in prophylaxis, 84% in early treatment, and 20% in late treatment in protocols including ivermectin at different doses and for different periods of time.[183][182]

149. In a ground breaking study of 1,195 healthcare workers in Argentina in the pre-vaccine era, none of the 237 cases of COVID-19 occurred in the treatment group, receiving ivermectin and wearing personal protective equipment (PPE), compared to the control group wearing PPE, where all cases occurred.[184][183] Another meta-analysis of 18 randomized controlled trials of ivermectin treatment of COVID-19 found large, statistically and clinically significant, reductions in mortality, time to clinical recovery, and time to viral clearance.[185][184] Many examples of ivermectin distribution campaigns – in Mexico City, several states in India, and several Argentinian provinces – have demonstrated rapid

[180][179] Nakatsu, K., Karrow, N. (2021) Vitamin D3 and COVID-19: A brief for family physicians and patients. https://www.canadiancovidcarealliance.org/wp-content/uploads/2022/01/21DE5_Vitamin-D-Review-for-CCCA- website.pdf

[181][180] Clinical practice guideline summary: Recommended drugs and biologics in adult patients with COVID-19. Ontario COVID-19 Science Advisory Table. doi:10.47326/ocsat.cpg.2022.11.0

[182][181] Bryant, A., Lawrie, T.A., Dowswell, T. *et al.* (2021) Ivermectin for prevention and treatment of COVID-19 infection: A systematic review, meta-analysis, and trial sequential analysis to inform clinical guidelines. *Am J Ther*. Publish Ahead of Print. doi:10.1097/MJT.0000000000001402

[183][182] Ivermectin for COVID-19: real-time meta analysis of 64 studies. c19early.com. Accessed October 26, 2021. https://ivmmeta.com/

[184][183] Carvallo, H., Roberto, H., Psaltis, A., Contreras, V. (2020) Study of the efficacy and safety of topical ivermectin + iota-carrageenan in the prophylaxis against COVID-19 in health personnel. *J Biomed Res Clin Investig*. 2(1). https://media.marinomed.com/8b/7a/c7/nota-journal-of-biomedical-research-safety-adn-efficacy-iota-carrageenan-and-ivermectin.pdf

[185][184] Kory, P., Meduri, G.U., Varon, J., Iglesias, J., Marik, P.E. (2021) Review of the emerging evidence demonstrating the efficacy of ivermectin in the prophylaxis and treatment of COVID-19. *Am J Ther*. 28(3):e299. doi:10.1097/MJT.0000000000001377

population wide decreases in morbidity and mortality, indicating the safety and effectiveness of this oral agent in all phases of COVID-19.[186185]

150. In a recent study conducted with 159,561 subjects in Itajaí, Brazil, 113,845 (71.3%) were regular ivermectin users and 45,716 (23.3%) were non-users.[187186] Of these, 4,311 ivermectin users were infected, among which 4,197 were from the city of Itajaí (3.7% infection rate), and 3,034 non-users (from Itajaí) were infected (6.6% infection rate), with a 44% reduction in COVID-19 infection rate. Non-use of ivermectin was associated with a 12.5-fold increase in mortality rate and a seven-fold increased risk of dying from COVID-19 compared to the regular use of ivermectin.

Section L. Qualifications and Acknowledgements as an Expert on COVID-19

151. I am a full Professor in the Department of Medicine and Division of Neurology at the University of British Columbia (UBC), where I have been on faculty since 1988. I was one of the founding senior scientists of The Biomedical Research Centre at UBC in 1987. I hold B.Sc. Honours (1979) and Ph.D. (1982) degrees in Biochemistry from UBC. My post-doctoral training was at the University of Dundee with Sir Philip Cohen, and at the University of Washington in Seattle with Nobel laureate Dr. Edwin Krebs.

152. I have previously completed several courses in microbiology, immunology and virology during my B.Sc. undergraduate training, and I was a founding and senior scientist for six years at The Biomedical Research Centre, which was an immunology focused institute located at UBC, where I have remained on faculty as a professor in the Department of Medicine for 34 years. Over a dozen of my scientific research articles have appeared in specialty immunology journals, including the *Journal of Immunology, Blood, Molecular Immunology, Immunology, Infectious Immunology, Cancer*

[186185] Chamie J. (2021) The latest results of ivermectin's success in treating outbreaks of COVID-19. FLCCC | Front Line COVID-19 Critical Care Alliance. Accessed October 26, 2021. https://COVID-19criticalcare.com/ivermectin-in-COVID- 19/epidemiologic-analyses-on-COVID-19-and-ivermectin/

[187186] Kerr, L., Baldi, F., Lobo, R., Assagra, W.L., Proenca, F.C., *et al.* (2022) Regular use of ivermectin as prophylaxis for COVID-19 led up to a 92% reduction in COVID-19 mortality rate in a dose-response manner: Results of a prospective observational study of a strictly controlled population of 88,012 Subjects. *Cureus* 14(8): e28624. doi 10.7759/cureus.28624

Immunology and Immunotherapy, *International Journal of Vaccine Theory, Practice and Research* and *Vaccines*. These studies document some of my work to understand the molecular mechanisms by which different immune cells, including macrophages, T and B cells become activated. My lectures in formal graduate level courses include teaching in immunology and virology at UBC. I have presented my research at over 100 national and international scientific conferences. My UBC lab and spin-out companies have been engaged in the production and testing of over 1600 antibodies for our internal research programs and for commercial sale for over 28 years. My research has routinely involved for over 34 years, the use of standard and novel immunological techniques developed in my lab, such as Western blotting, dot blotting, antibody microarrays, reverse lysate microarrays and epitope mapping for determination of where antibodies specifically bind their targets.

153. I have authored over 250 scientific publications in peer-reviewed journals and book chapters about cell communication systems important for cell survival and function and implicated in the pathology of cancer, diabetes, neurological and immunology-related diseases. My accolades include the 1993 Martin F. Hoffman Award for Research at UBC, and the 1993 Merck Frosst Canada Prize from the Canadian Society of Biochemistry and Molecular Biology. I was the 2001 Distinguished Lecturer for the Faculty of Medicine at UBC for the Basic Sciences. I have served on grant review panels for the US National Institutes of Health, the Canadian Institutes for Health Research, the National Research Council of Canada, the Michael Smith Health Research Foundation, Genome Alberta, Genome Prairie, the Canadian National Cancer Institute, the Canadian Heart and Stroke Foundation and the American Heart Association, and I have acted as an external reviewer for 22 other agencies including the U.S. National Science Foundation and the Israel Science Foundation. I have also been an external reviewer for 28 different scientific journals, including those that are focused on immunology and vaccines.

154. I was the founder and president of Kinetek Pharmaceuticals Inc. from 1992 to 1998, and the founder, president and chief scientific officer of Kinexus Bioinformatics Corporation from 1999 to the present. Kinetek was engaged in the development of drugs that inhibit protein kinases, primarily for oncology application and diabetes. Kinexus has produced over 1600 antibody products against cell regulatory proteins, and employs these antibodies in novel, immunology-based, high throughput methods such as antibody microarrays to monitor cell communication systems in biological specimens from over 2000 academic and industrial clients in over 35 countries over the last 22 years. These antibody

products include those that specifically recognize parts of the Spike, Nucleocapsid, Membrane and other SARS-CoV-2 proteins encoded by the genome of this virus.

155. My expertise has been sought specifically with respect to understanding the immunological mechanisms by which a natural immune response is elicited by SARS-CoV-2, the causative agent of COVID-19, and the immunity afforded by the lipid nanoparticle Spike RNA- and adenovirus Spike DNA-based COVID-19 vaccines. This has been informed, in part, by clinical studies undertaken in the last 2 and a half years at my company Kinexus in which we have investigated the nature and production of antibodies against the 28 different proteins that constitute the SARS-CoV-2 virus particle, by examination of blood samples from over 4500 participants from across Canada. In this independent ethics review board approved clinical study, I am the lead investigator, and I have been in direct communication with all of the participants. Some of our preliminary findings have already been published in *JCI Insights*, which is the flagship journal of the American Society for Clinical Investigation in 2021.[17] Additional manuscripts that document our SARS-CoV-2 antibody testing study are currently in preparation, and we are now engaged in a second antibody testing study to determine the extent of immunity against the Omicron variants and the duration effectiveness of the COVID-19 vaccines.

156. I have also been investigating the use of drugs to inhibit the replication of the SARS-CoV-2 virus in infected host cells. My expertise on enzymes known as protein kinases has permitted me to predict and then verify that compounds that inhibit a protein kinase known as GSK3-beta can block the production of the Spike of the virus, and assembly of SARS-CoV-2 virus particles. A provisional patent based on this work has already been filed with the University of British Columbia (UBC) and a manuscript that describes this work has been accepted for publication.[188187] I have also spearheaded the development commercial antibodies against many of the SARS-CoV-2 proteins and verified their utility in another published scientific article in the peer-reviewed journal Microbial Factories.[189188]

[188187] Shapira, T., Rens, C., Pichler, V., Rees, W., Steiner, T., Jean, F., Winkler, D.F.H., Sarai, I., Pelech, S., Av-Gay, Y. (2022) Inhibition of glycogen synthase kinase-3-beta (GSK3β) blocks nucleocapsid phosphorylation and SARS-CoV-2 replication. *Molecular Biomedicine.* 3, 43. https://doi.org/10.1186/s43556-022-00111-1

[189188] McGuire, B.E., Mela, J.E., Thompson, V.C., Cucksey, L.R., Stevens, C.E., McWhinnie, R.L., Winkler, D.F.H., Pelech, S., Nano, F.E. (2022) *Escherichia coli* recombinant expression of SARS-CoV-2 protein

157. In addition to the direct study of the SARS-CoV-2 and immune responses to this virus in people, I am also a co-founder and vice president of the Canadian Covid Care Alliance (CCCA) and very active within this organization. The CCCA's membership include over 600 biomedical scientists, medical doctors and other health practitioners, and the CCCA examines the scientific literature and data from public health authorities to ascertain the threat of COVID-19 and the various strategies available to mitigate its effects. In my capacity as the co-chair of the Scientific and Medical Advisory Committee (SMAC) of the CCCA, I oversee the activities of a panel of 36 scientists and medical doctors that seeks to provide a scientific evidence-based and balanced, independent, but critical assessment of health care policies related to COVID-19. This Committee has met weekly over the last year and a half by Zoom, but typically has daily correspondences by e-mails. The fruits of our efforts are published on the CCCA website (www.canadiancovidcarealliance.org) and in peer-reviewed scientific journals. In particular, I was a coauthor on a CCCA report that critiqued the original 6-months clinical study performed by Pfizer/BioNTech on their BNT162b2 RNA vaccine,[190][189] a published review about COVID-19 vaccines and pregnancy in the peer-reviewed journal *Vaccines*,[191][190] and another manuscript published in the peer-reviewed journal *International Journal of Vaccine Theory, Practice and Research*.[192][191] In addition, I am a coauthor on several other publications that have been posted on the CCCA website that relate to the manufacturing and quality issues associated with the BNT162b2 mRNA COVID-19 vaccine,[193][192] the efficacy and safety of the BNT162b2 mRNA COVID-19 vaccine based on phase III trial

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fragments. *Microbial Cell Factories*. 21:21. https//doi.org/10.1186/s12934-022-01753-0. *bioRxiv* pre-print. https://doi.org/10.1101/2021.06.22.449540)

[190][189] Bridle, B.W., Martins, I., Mallard, B.A., Karrow, N.A., Speicher, D.J., Chaufan, C., Northey, J.G.B., Pelech, S., Shaw, C.A., Halgas, O. (2021) Concerns regarding the efficacy and safety for BNT162b2 mRNA coronavirus disease (COVID-19) vaccine through six months. www.CanadianCovidCareAlliance.org (January 10, 2022) 1-10 https://www.canadiancovidcarealliance.org/wp-content/uploads/2022/01/Final-CCCA-Critique-Thomas-COVID-19-Vaccines-6-months-NEJM-Jan-10-22.pdf

[191][190] Karrow, N.A., Shandilya, U.K., Pelech, S., Wagter-Lesperance, L., McLeod, D., Bridle, B, Mallard, B.A. (2021) COVID-19 vaccination and potential impact on fetal and neonatal development. *Vaccines.* 2021, *9*, x. https://doi.org/10.3390/xxxxx

[192][191] McLeod, D., Martins, I., Pelech, S., Beck, C., Shaw. C.A. (2022) Dispelling the myth of a pandemic of the unvaccinated. *Int. J. Vaccine Theory Practice Res.* 2(1):267-286.

[193][192] Gutchi, M., Speicher, D. J., Natsheh, S., Oldfield, P., Britz-McKibbon, P., Palmer, M., Karrow, N., Massie, B., Mallard, B., Chan, G. Pelech, S. (2022) An independent analysis of the manufacturing and quality control issues of the BNT162b BioNTech/Pfizer vaccine identified by the European Medicine Agency. www.Canadian Covid Care Alliance.org (October 29, 2022) 1-5

results,[194][193] and the vaccination of children with COVID-19 vaccines.[195][194]

158. I believe that my formal training, experience and published research, demonstrates my expertise in immunology, and my recent activities specifically related to SARS-CoV-2 over the last two years, places me in an excellent situation to comment upon related matters. Consequently, I have been sought as an Expert Witness for several court challenges with respect to government and private employer mandated vaccination and family disputes over the vaccination of children.

159. A listing of some court cases related to COVID-19 matters that I have been asked to furnish sworn affidavits includes, but is not limited to:

a. COURT FILE NUMBER
COURT

JUDICIAL CENTRE
APPLICANT
RESPONDENT

b. COURT FILE NUMBER
COURT
APPLICANT
RESPONDENTS

https://www.canadiancovidcarealliance.org/wp-content/uploads/2022/11/22OC29_EMA-Analysis-of-BNT162b-Manufacture.pdf

[194][193] Bridle, B.W., Martins, I., Mallard, B.A., Karrow, N.A., Speicher, D.J., Chaufan, C., Northey, J.G.B., Pelech, S., Shaw, C.A., Halgas, O. (2021) Concerns regarding the efficacy and safety for BNT162b2 mRNA coronavirus disease (COVID-19) vaccine through six months. www.CanadianCovidCareAlliance.org (January 10, 2022) 1-10 https://www.canadiancovidcarealliance.org/wp-content/uploads/2022/01/Final-CCCA-Critique-Thomas-COVID-19-Vaccines-6-months-NEJM-Jan-10-22.pdf

[195][194] Payne, E., Rennebohm,R., Bridle, B., Mallard, B., Karrow, N., Massie, B., Northey, K., Shoemaker, C., Pelech, S., Chaufan C., McLeod, D., Hardie, J., Pinto, C., Britz-McKibbin, P., Shaw, C. (2022) Request to halt vaccinations of children. www.CanadianCovidCareAlliance.org (July 14, 2022) 1-28 https://www.canadiancovidcarealliance.org/wp-content/uploads/2022/07/CCCA-Halt-vaccination-of-children-Officials-Letter-Jul-14-22.pdf

c. COURT FILE NUMBER
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JUDICIAL CENTRE
APPLICANTS

RESPONDENTS

d. COURT FILE NUMBER
COURT
APPLICANTS

RESPONDENT
OF ONTARIO

e. COURT FILE NUMBER
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JUDICIAL CENTRE

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RESPONDENT

f. COURT FILE NUMBER
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g. COURT FILE NUMBER

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RESPONDENT

k. COURT FILE NUMBER
COURT
APPLICANTS

RESPONDENT

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