Okanagan Health Care Professionals - *Reference of Evidence Against BC Public Health Order - Summary*

The response to COVID-19 in British Columbia has been a gross overreaction, characterized by blatant inconsistencies, unscientific measures, and political overreach. In conjunction with directives from Adrian Dix (Minister of Health), David Eby (Attorney General) and Premier John Horgan, Dr. Bonnie Henry has declared restrictions and mandates via public health orders and/or notices since March 17, 2020 ('*Notice Declaring COVID-19 Public Health Emergency*'). These declarations have been incongruent with contrasting evidence sourced from credible scientific literature and international surveillance data.

The following is an executive summary of the Okanagan Health Care Professionals *Reference of Evidence Against BC Public Health Order* - a 133 page document - highlighting the main concerns - along with evidence, regarding British Columbia's COVID-19 public health orders, specifically the notice issued November 18, 2021.

- **Emergency Measures:** There has never been justification for the use of emergency measures within the province of British Columbia. Emergency measures were originally instated March 17, 2020, even though the legal requirements for declaring a 'regional event' have never been met — refer to **Section A, points 12 through 18.**

- **Experimental Therapies:** COVID-19 vaccines are currently experimental and confer marginal benefits to the end user. The vaccines have yet to be proven 'safe and effective' — refer to **Section C and Section D.**

- **Severe Risk and Irreversible Harms:** There is evidence of great harm—including death—associated with COVID-19 vaccination, most notable of which occurring in elite athletes and young males — **refer to Section C**.

- **Alternative Therapies:** COVID-19 vaccination is not the only preventive measure against SARS-CoV-2 infection. Refusal to acknowledge affordable, effective, and widely available therapeutics is negligent — refer to **Section N**.

- **Discrimination:** Treating unvaccinated persons differently than vaccinated persons is unscientific, based on reputable scientific literature. It is also an act of segregation and discrimination. Vaccinated *and* unvaccinated persons experience similar disease transmission and disease severity risks — refer to **Section F and Section L**.

- **Natural Immunity**: Albeit the existence of 150+ scientific studies that support the reality of long-lasting natural immunity to SARS-CoV-2 (deeming vaccination unnecessary), naturally acquired immunity is ignored — refer to **Section K**.

The Okanagan Health Care Professionals *Reference of Evidence Against BC Public Health Order* clearly highlights inconsistent and unscientific practices promoted by the provincial government. The messaging tactics utilized by the Government of British Columbia and the Public Health Officer (i.e. lack of informed consent, disinformation, censorship of medical professionals, discrimination, and segregation) constitute dangerous and illegal acts of coercion. The four prima facie principles of the art of medicine are **respect for autonomy, beneficence, non-maleficence, and justice**. This document emphasizes how past and present COVID-19 public health orders—in addition to the actions of the government—have violated these principles. Every individual has a right to conduct their own personal risk assessment regarding COVID-19. Furthermore, every Canadian has a right—as per **Section 7 of the Canadian Charter**—to security of the person and bodily autonomy. It is of utmost importance that all individuals receive full and informed consent prior to a medical procedure such as COVID-19 vaccination, including but not limited to description of the clinical therapy, unforeseeable risks, benefits, alternative treatments, and compensation/medical treatment in the event of an injury. The November 18, 2021 public health order fails to accurately address these concerns, and blatantly misinforms the public on several accounts.

Okanagan Health Care Professionals request a robust evaluation of the data presented in this document; furthermore, an immediate halt and reversal of all provincial mandates and regulations regarding COVID-19 policies is demanded.

November 18, 2021 Health Order of BC PHO Dr. Bonnie Henry

Who is really spreading misinformation and mandating orders that are ignoring scientific evidence?

Note: This is not a letter, rather a reference document with over 400 sources of information along with links to source studies and data used to prove or disprove statements made by Dr. Bonnie Henry in the November 18, 2021 Order. You can search for an area of interest (i.e., PCR, death counts, certain source of media, like CTV, etc.) or use the table of contents, beginning on page 8, to navigate to a section of the Order.

This document has not been updated since Jan 26th, so the past several weeks of newly released research, studies and information has not been added, and there has been a lot. Consider the information presented here up to date as of Jan 26th, anything later is not here.

We are a group of concerned health professionals in the Okanagan Valley, B.C. Our previous 2 letters were sent to Dr. Henry, Mr. Dix and Mr. Horgan, and AG David Eby. [1] [2] Although these letters were well received and widely distributed, by medical professionals, academics, and citizens across Canada and around the world, we have yet to receive a reply from government officials or the Provincial Health Officer. Based on the evidence presented within this document, **we earnestly implore Dr. Bonnie Henry to cease and desist with all COVID-19 vaccine mandates and other restrictions being forced upon the citizens of British Columbia.**

The evidence overwhelmingly demonstrates the vaccines are not effective and are causing severe injuries. The COVID-19 restrictions and mandates are also causing irreparable harm. The Government continues to use coercion, threats, intimidation and segregation to further their goal to get as many people vaccinated with as many shots as possible. Many upstanding, highly trained and law-abiding citizens in healthcare, public service and private industry have been forced out of their jobs due to vaccine mandates. Coercion is not informed consent. The threats and coercion contained in the B.C. Public Health Orders and press conferences have nothing to do with health or elimination of a virus. Rather, these orders revolve around punishment of the non-compliant. The behavior and actions of the B.C. government and B.C. Public Health Officer (PHO) related to the "pandemic" complete disregard our democratic rights and freedoms.

This letter specifically addresses the claims made by the B.C. Public Health Officer set out in her Order of November 18, 2021. This letter serves to challenge multiple aspects of the Order with the B.C. Government's own data, scientific primary literature, communications from medical doctors, and data from other provincial, national, and international databases. To date, the B.C. Government has failed to provide any evidence to support their claims that the unvaccinated are a health hazard or that B.C. is in a state of emergency. Claiming to be "following the science" is not sufficient. If this "science" existed, there would be no reason to hide it from the public.

The intent of this document is to draw public attention to the fact that the current COVID-19 B.C. Public Health Orders are without merit. Volumes of evidence now exist that prove that the vaccines are neither safe or effective. The evidence demonstrates that unvaccinated persons do not experience any meaningful difference in SARS-CoV-2 transmission rates, nor COVID-19 illness, compared to vaccinated persons. Immediate early outpatient treatment for COVID-19 is imperative for mitigation of the highly publicized, yet debatable, burden of hospitalizations and deaths amongst both vaccinated and unvaccinated persons. Early treatment protocols are abundant and have been proven effective in many countries, yet these simple, affordable, and accessible interventions are currently being blocked by our government in favor of unproven COVID-19 vaccines. Finally, natural immunity which has long been recognized, is suddenly being ignored, even prior to the distribution of COVID-19 vaccines. The following rebuttal to the current COVID-19 B.C.

[1] https://canadahealthalliance.org/wp-content/uploads/Open_Letter_to_Henry_Dix_Horgan_Eby_Oct_6_2021.pdf

[2] https://canadahealthalliance.org/open-letter-to-dr-henry-mr-dix-mr-hogan-9-september-2021/

Public Health Orders demonstrates not only a lack of evidence for the currently instated mandates, but also highlights scientific literature and medical opinions that contrast the statements in the associated COVID-19 health and emergency orders enacted by Dr. Bonnie Henry, Mr. Adrian Dix, Mr. John Horgan, and Mr. David Eby.

We would like to take this opportunity to explain our rationale for choosing anonymity rather than publicly exposing our names and professional status. Whether obvious to everyone reading this letter or not, health care professionals everywhere are being censured and disciplined for simply raising questions regarding current Public Health measures. It is interesting that the individuals presenting the facts are highly questioned and requested to reveal their identity in order to be taken seriously, yet the same request is not made of the so-called social media "fact checkers". Who are the fact checkers? What are their backgrounds? What greater knowledge do the anonymous "fact checkers" possess that affords them the ability to blatantly discredit professionals within their field? The evidence presented in this document is the focus of this letter, not the identity of the authors.

Many of the aforementioned professionals have lost their jobs. High profile scientists and physicians worldwide (including in Canada) have had their medical licenses threatened or revoked, or their college standing removed. This is of serious concern to the remaining health care professionals who have families to support and careers to protect, but who still want to stand on truth and provide context to the general public.

It is shameful that our government has allowed this. If 'science' cannot be questioned, discussed, or debated then it is not science. Rather, it is propaganda. History demonstrates this many times over, yet it is not fully recognized by many who are teetering on the precipice of history repeating itself.

This letter provides you with robust evidence and data analysis, using BCCDC, CDC, and Pfizer's own data, regarding the COVID-19 public health measures and vaccine information that the Canadian and British Columbian governments, in partnership with big tech organizations, deliberately censor and discredit, which prohibits the general public from weighing and evaluate all available data.

For readers who are wanting to be fully informed, you are invited to study the evidence provided within this document and to draw your own conclusions.

An honest review of the following analyses, studies, and news reports should guide the reader to a better understanding (and broader knowledge) of our current situation in B.C. regarding all things COVID-19. The information shared in this document demonstrates how to critically review the data. This information is not dependent on *who* we are as health professionals. Rather, this compilation of data demonstrates the findings and commentary of numerous brilliant minds — the Okanagan Healthcare Professionals group are simply disseminating this information in a condensed format. Any individual *can* and *should* be doing this type of critical thinking and analysis for themselves. The responsibility to be informed falls equally on everyone's shoulders, not just one group, entity, or field of professionals. As British Columbians, we all have a role to play: we are all called to participate in preventing the government from overreach and acting unscrupulously by stripping us of our innate freedom of choice and bodily autonomy.

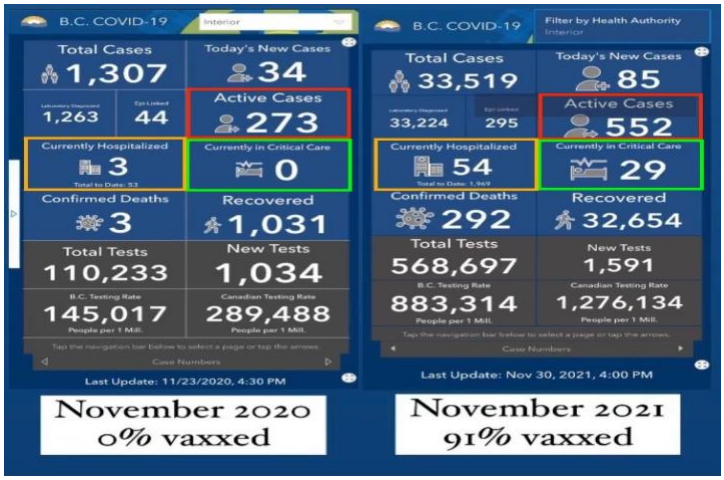
BC Public Health Order Hospital and Community — November 18th, 2021

- https://www2.gov.bc.ca/assets/gov/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/COVID-19/COVID-19-hospital-and-community-vaccination-status-information-preventive-measures.pdf

All four COVID-19 vaccines authorized for use in Canada have a single purpose. The vaccines were originally developed to—and have only been shown to—potentially lessen the occurrence of severe COVID-19 symptoms and death. Pfizer clinical trials suggested that the Absolute Risk Reduction (ARR – see **Section C - #80 & #81**) protection

against COVID-19 for the end user would be 0.84%. Therefore, how are unvaccinated persons considered a threat to their peers when COVID-19 vaccines only offer miniscule potential to reduce severity of symptoms for the end user? Ensuing data and evidence within this document clearly demonstrate that these claims are unvalidated; it is implausible that unvaccinated individuals are the sole cause of heightened risk of SARS-CoV-2 transmission and COVID-19. Data extracted directly from the manufacturers previously disclosed this information. COVID-19 vaccines only lessen symptoms. The vaccines do not stop transmission of SARS-CoV-2, nor do they *prevent* an individual from developing COVID-19. In fact, most people who receive a COVID-19 vaccine experience COVID-19 illness within a 2-to-3 week period following vaccination (see data presented by Dr. Christy Reich **Section C #79**.)

It is convenient to blame the unvaccinated for an increase in cases, hospitalizations, and ICU admissions; however, the majority of Canadians were unvaccinated through December 2020. It is necessary to highlight that COVID-19-related cases, hospitalizations, and ICU admissions (Interior Health Authority) were significantly less in November 2020 compared to November 2021 (see below), despite a large percentage of the population now being fully vaccinated (91.2%). It is irresponsible for the PHO to blame unvaccinated individuals for a rise in cases and development of variants. Breakthrough cases are thoroughly discussed throughout this document. Therefore, the logic of "*get vaccinated so that you are protected, but avoid unvaccinated persons to prevent illness*" is without merit.



Furthermore, the current COVID-19 vaccines are fundamentally different from all historical vaccines. Any reference to, or comparisons made between previous generations of vaccinations and the current COVID-19 vaccines is dangerous, illogical, and not based on truth. These products are not the same. Of note, these vaccines are non-sterilizing vaccines and are not capable of conferring complete immunity nor protection against COVID-19. The contents, technology utilized, and timing of administration (double & triple dosing) of COVID-19 vaccines is entirely novel. In addition, the lack of well-designed and peer-reviewed clinical trials, clinical review, and study follow-up time frames in the history of vaccination are unprecedented. In fact, serious allegations of fraud and misconduct within the Pfizer clinical trial have been exposed by whistleblower Brook Jackson.

The Okanagan Healthcare Professionals team is not alone in their findings. Many truth-seekers have discovered that our leaders have failed to demonstrate the existence of a true emergency. The onus is on the government to demonstrate just cause when imposing restrictions that lead to harm beyond the COVID-19 'pandemic' (e.g. suicide, depression, loss of friends and family relationships, alcoholism, substance use, weight gain, loss of income, etc.). Government officials and public health officers claim COVID-19 is an emergency; however, the data presented does not align with—nor support—the definition of a genuine emergency, by government standards. The data presented thus far has revealed manipulative tactics and deception utilized in reporting, and requires greater transparency.

A growing group of international medical and scientific experts have unearthed the evidence that COVID-19 is not an emergency. They have also effectively demonstrated that COVID-19 vaccines are neither safe, nor effective. Yet, these experts are dismissed and discredited and offers for open debate are completely dismissed.

IMMUNITY vs PROTECTION:

The true definition of immunity does not apply to the COVID-19 "vaccine" as these injections (injection being a more appropriate term) are a form of protection, which will always dissipate. PROTECTION ≠ IMMUNITY**.** These vaccines offer limited and waning protection and thus we see examples such as the New Market (Ontario, Canada) hockey team. Even though the entire team was double vaccinated (as required to play), they had limited protection from their double dose of vaccinations and all got sick with the very illness the vaccination was to protect against. One team member unfortunately died. COVID-19 breakthrough cases are happening in many areas with many fully vaccinated groups. The NHL Senators hockey team, cruise ships, and the Kelowna Cottonwoods long term care facility are examples where all persons were double vaccinated, yet many became very sick. Some even died. As protection wanes, the original robust natural immunity is now in permanent decline for vaccinated people. The current Omicron explosion of cases amongst the fully vaccinated provides clear evidence that the COVID-19 inoculations do not provide immunity, nor in this case protection from acquiring COVID-19.

EVIDENCE:

Data from the BCCDC—the same data that the government points to—will be utilized to demonstrate counter-arguments to claims made by Dr. Bonnie Henry in the PHO for hospital and community healthcare workers, dated November 18th, 2021. Key information and data is negligently misrepresented when shared with the public. The BCCDC data will also be used to demonstrate trends that have not been shared publicly, and misinformation will be countered.

WHERE ARE WE AT?

The number of deaths anticipated, since SARS-CoV2 was identified, was greatly over estimated, based solely on modeling. As of January 6, 2022, BC has recorded 2,430 deaths with COVID-19 over the last two years. For the year prior to COVID-19, 8,511 deaths were attributable to influenza and pneumonia in Canada. Over the last two years, there was and still is, no physician recommended at home course of treatment for an individual with a positive COVID test. Other countries, including China have a public treatment plan that reduces both hospitalizations and deaths.

Keep in mind a very small percentage, approximately 5.0%, of COVID-19 deaths are solely attributed to COVID-19 per US CDC, i.e. no other known comorbidities. Thus, a death "with" COVID-19 is not the same as a death "because of" COVID-19. The standard practice throughout the pandemic was to list COVID-19 as a cause of death if a person tested positive within 28 days prior to their demise, regardless of whether they suffered from the illness at the time of death.

It is important to recall that PCR testing for COVID-19 resulted in a high percentage of false positive results, especially when an asymptomatic person is tested. Moreover, false case counts have occurred when individuals, who are hospitalized with other illnesses and injuries (i.e. cancer, diabetes, heart disease, Alzheimer's, car accident, etc.), incidentally test COVID-19 positive. They will have been counted as a COVID-19 hospitalization, and death, if that is applicable.

Starting early January 2022, Dr. Bonnie Henry, Dr. Tony Fauci, and Rochelle Walensky have all finally explained their original counts included patients who had been hospitalized or died "with" COVID-19 which means COVID-19 was not the primary cause of those hospitalizations or deaths. CDC Director Rochelle Walensky stated, "The overwhelming number of deaths, over 75%, occurred in people who had at least 4 comorbidities".

IN B.C.

Of a total population of 5.7M, as of December 2021, in almost 24 months of dealing with COVID-19, ZERO (0) school aged children (5 to 19) have died of or with COVID-19. This text is from the BC CDC website on Jan 16th, 2022

- **Outcomes:** Serious outcomes from COVID-19 infections continue to be rare among all school-age children in BC. Hospitalization among 12-17 year-olds is less common in those who have at least one dose of vaccine compared to those who are unvaccinated. There have been no deaths among school-age children in BC.

Source: http://www.bccdc.ca/Health-Info-Site/Documents/COVID_sitrep/K12_Situation_Report/SitRep_K-12_December_2021.pdf

However, two (2) children under the age of five (5) have died with COVID-19. These children were found to have been fighting stage 4 leukemia, so they may have died with COVID-19, but they did not die of COVID-19. **For people 60 and under, 208 deaths have occurred in the province with COVID-19. Utilizing the above 6.0% value, that suggests that only twelve (12) individuals out of the 208 actually died of COVID-19.** It is necessary to highlight that 94.0% of people have one (1) or more other significant health factors (i.e. comorbidities) which influence whether they have died "of" or "with" COVID-19.

Table 3: Age distribution: COVID-19 cases, hospitalizations, ICU admissions, deaths, and BC population by age group Jan 15, 2020 (week 3) – Jan 01, 2022 (week 52) (N= 265,722)[a]

Age group (years)	Cases n (%)	Hospitalizations n (%) [b]	ICU n (%)	Deaths n (%)
<10	20,447	180 (<1)	16 (<1)	2 (<1)
10-19	29,481	149 (<1)	29 (1)	0 (<1)
20-29	57,822	781 (1)	101 (<1)	6 (<1)
30-39	50,632	1,417 (3)	280 (1)	30 (<1)
40-49	38,727	1,510 (4)	352 (1)	54 (<1)
50-59	31,355	2,081 (7)	631 (2)	139 (<1)
60-69	20,407	2,444 (12)	780 (4)	285 (1)
70-79	9,784	2,367 (24)	671 (7)	539 (6)
80-89	4,965	1,617 (33)	226 (5)	792 (16)
90+	2,102	556 (26)	23 (1)	583 (28)
Total	**265,722**	**13,102**	**3,109**	**2,430**
Median age [c]	**34**	**61**	**62**	**82**

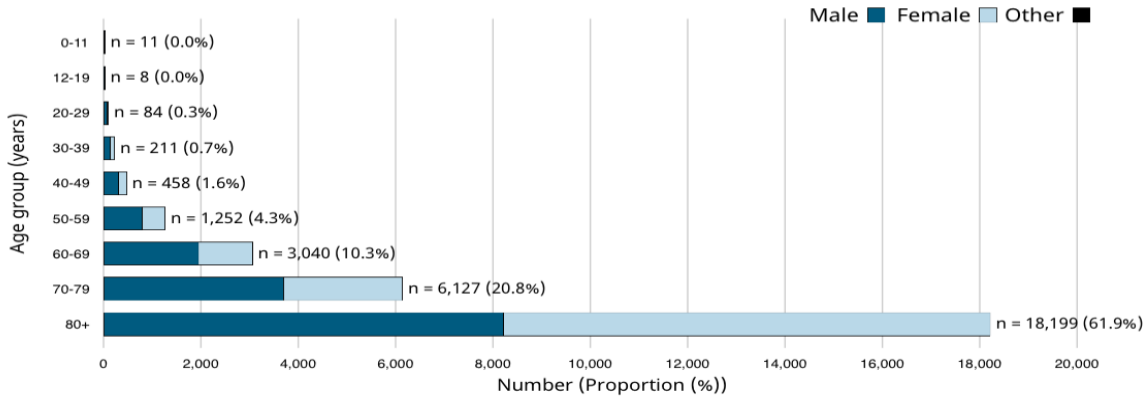
a. Among those with available age information only.
b. Data sources: Health Authority case line lists and a subset of PHSA Provincial COVID19 Monitoring Solution (PCMS) data for children <20 years of age. PCMS data were included as of June 8 2021. Due to this change in data source, additional admissions that occurred since the start of the pandemic are now included in age groups 0-9 and 10-19 years.
c. Median ages calculated are based on Health Authority case line lists only.

Source: Week_52_2021_BC_COVID-19_Situation_Report.pdf (bccdc.ca)

IN CANADA:

A total population of 33M, as of December 2021, in almost 24 months of dealing with COVID-19, a total of nineteen (19) children have died with COVID-19. In the same 24-month period, for people ages 60 and under a total of 2,024 across all of Canada have died with COVID-19. Utilizing the above 6.0% value, **6.0% of all of those <60 years of age that died OF COVID-19 would equate to 121 persons.**

Figure 7. Age and gender [4] distribution of COVID-19 cases deceased in Canada as of November 26, 2021, 7 pm EST (n=29,390 [1])



Source: https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html#a9
Source: 6.0% of deaths solely attributable to COVID-19 — https://trialsitenews.com/the-costs-of-inoculating-children-against-covid-19-far-outweigh-the-benefits/
Source: CDC, 94.0% deaths with comorbidities — https://www.sciencedirect.com/science/article/pii/S221475002100161X#bib0030

CONSENT:

Regardless of how one might feel about the virus or the vaccine, every person should acknowledge that the right of choice is paramount in an ethical, free and democratic society. This fact has been lost on much of the population, where many individuals now support enforcement of the mandates.

INFORMED REFUSAL:

Our courts have reaffirmed repeatedly a patient's right to refuse treatment even when it is clear treatment is necessary to preserve the life or health of the patient. Justice Robins of the Ontario Court of Appeal explained:

> "The right to determine what shall, or shall not, be done with one's own body, and to be free from non-consensual medical treatment, is a right deeply rooted in our common law. This right underlines the doctrine of informed consent. With very limited exceptions, every person's body is considered inviolate, and, accordingly, every competent adult has the right to be free from unwanted medical treatment. The fact that serious risks or consequences may result from a refusal of medical treatment does not vitiate the right of medical self-determination. The doctrine of informed consent ensures the freedom of individuals to make choices about their medical care. It is the patient, not the physician, who ultimately must decide if treatment — any treatment — is to be administered."

VOLUNTARY CONSENT:

According to *Consent: A Guide for Canadian Physicians* (2021):

> “Patients must always be free to consent to or refuse treatment, and be free of any suggestion of duress or coercion. Consent obtained under any suggestion of compulsion either by the actions or words of the physician or others may be no consent at all and therefore may be successfully repudiated. In this context physicians must keep clearly in mind there may be circumstances when the initiative to consult a physician was not the patient's, but was rather that of a third party, a friend, an employer, or even a police officer. Under such circumstances the physician may be well aware that the patient is only very reluctantly following the course of action suggested or insisted upon by a third person. Then, physicians should be more than

usually careful to assure themselves patients are in full agreement with what has been suggested, that there has been no coercion and that the will of other persons has not been imposed on the patient."

Source: https://www.cmpa-acpm.ca/en/advice-publications/handbooks/consent-a-guide-for-canadian-physicians
Source: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#a7.2

Within the province of B.C., the *Health Care (Consent) Act and Care Facility (Admission) Act* states the following:

Consent rights

4 Every adult who is capable of giving or refusing consent to health care has

(a) the right to give consent or to refuse consent on any grounds, including moral or religious grounds, even if the refusal will result in death,
(b) the right to select a particular form of available health care on any grounds, including moral or religious grounds,
(c) the right to revoke consent,
(d) the right to expect that a decision to give, refuse or revoke consent will be respected, and
(e) the right to be involved to the greatest degree possible in all case planning and decision making.

Source: https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/96181_01#section4

TABLE OF CONTENTS – WHEREAS Statements

WHEREAS statements November 18, 2021 Order

WHEREAS:

A. On March 17, 2020 I provided notice under section 52 (2) of the Public Health Act that the transmission of the infectious agent SARS-CoV-2, which has caused cases, clusters and outbreaks of a serious communicable disease known as COVID-19 among the population of the Province of British Columbia, constitutes a regional event, as defined in section 51 of the Public Health Act;

DR. BONNIE HENRY CLAIMS: — Cases & clusters equate to a serious communicable disease.

FACT CHECK: **FALSE** — A case is not a diagnosis of COVID-19, it is only evidence of a positive PCR test.

1. Evidence: As per the CDC, "*...[a] surveillance case definition is a set of uniform criteria used to **define a disease** for public health surveillance. ...Surveillance case definitions are **not intended to be used by healthcare providers for making a clinical diagnosis...***."

   Source: https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/

2. Evidence: The BC CDC states right on their website that MOST people will recover on their own:

   "Most people with COVID-19 will recover on their own. Please refer to our If you are sick page for more information about how to manage your symptoms when you have been diagnosed with COVID-19."

   Source: http://www.bccdc.ca/health-info/diseases-conditions/covid-19/about-covid-19/treatments

3. Evidence: According to the BCCDC**:**
   A true diagnosis of infection with SARS-CoV-2 requires either:

   a) The detection of at least one specific gene target by a validated laboratory-based nucleic acid amplification test (NAAT) assay (e.g. real-time PCR or nucleic acid sequencing) performed at a community, hospital, or reference laboratory (the National Microbiology Laboratory or a provincial public health laboratory),

   b) The detection of at least one specific gene target by a validated point-of-care (POC) nucleic acid amplification test (NAAT) that has been deemed acceptable to provide a final result (i.e. does not require confirmatory testing), or

   c) Seroconversion or diagnostic rise (at least four-fold or greater from baseline) [a] in viral specific antibody titer in serum or plasma using a validated laboratory-based serological assay for SARS-CoV-2.

   Probable cases (not diagnosed with any of the aforementioned testing methods) are denoted by:

a) symptoms compatible with COVID-19,

b) high-risk exposure with a confirmed COVID-19 case (i.e. close contact)

OR, exposure to a known cluster or outbreak of COVID-19 AND a laboratory-based NAAT assay for SARS-CoV-2 and the result is **inconclusive**

OR, the presence of SARS-CoV-2 antibodies in a single serum, plasma, or whole blood sample

OR, a POC NAAT or POC antigen test for SARS-CoV-2 test that is **presumed** to be positive

OR, a validated POC antigen test for SARS-CoV2 test that is deemed positive.

Probable epi-linked cases (not confirmed cases) are determined by:

a) the presence of COVID-19 symptoms AND high-risk exposure with a confirmed COVID-19 case (i.e. close contact)

OR, exposure to a known cluster or outbreak of COVID-19 AND **completion** of a laboratory-based NAAT assay for SARS-CoV-2.

Source: http://www.bccdc.ca/health-professionals/clinical-resources/case-definitions/COVID-19-(novel-coronavirus)

DR. BONNIE HENRY CLAIMS: — COVID-19 cases can be identified based on a positive PCR test.

FACT CHECK: **FALSE** — A PCR test cannot distinguish between a cold or a flu, or COVID-19, or whether the genetic material detected is infectious or not, or alive or dead.

4. Evidence: The World Health Organization (WHO) originally stated that PCR tests were the "gold standard" for COVID-19 testing, recommending it as the universal test. Now the WHO admits that the PCR test is not an accurate diagnostic tool, and is in fact recommending a completely different testing protocol. This reflects what scientists have been saying since the beginning of the pandemic. Also, the U.S. Centre for Disease Control (CDC) has said that it will ask the U.S. Food and Drug Administration (FDA) to withdraw its emergency use authorization (EUA) of the PCR test as of December 31, 2021.

   Source: PCR amplification cycles (35-40) threshold — https://www.jccf.ca/covid-stats/
   Source: https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng
   Source: https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html

5. Evidence: Dr. Michael Yeadon, Pfizer Ex-Vice President and Chief Science Officer, claims that "almost all" of the tests being conducted for COVID-19 are "false positives". This phenomenon has been observed in Florida and around the world. Yet, we still continue to use PCR tests as the primary means of COVID-19 determination, which manufactures greater fear and compliance.

   Source: https://brandnewtube.com/watch/dr-mike-yeadon-on-pcr-tests-for-covid19_L2vEhfBrzbkYAyX.html

6. Evidence: It has been stated by the PHO that a case is confirmed based on a positive PCR test; however, evidence proves that these tests are inaccurate (90.0% to 97.0% false positives). Moreover, cycling of PCR tests (often in excess of 35+ amplifications) is being used incorrectly for the detection of this virus. A study published by Oxford Academic in September 2021 on the correlation between 3,790 positive PCR tests and 1,941 SARS-CoV-2 isolates found that at a cycle threshold (CT) of 25, the test was 70 percent reliable. This figure dropped to 20 percent at 30 cycles, and just three percent at 35 cycles. This demonstrated that 97 percent [of PCR tests] were false positives, yet the [PCR test] was used in most laboratories in the USA and Europe. With the knowledge of these inflated false positives, we absolutely should not be using PCR testing as the 'gold star' methodology for determining "cases".

   Source: https://fcpp.org/2021/02/27/pcr-test-is-flimsy-say-inventor-and-courts/
   Source: https://thevaccinereaction.org/2020/09/coronavirus-cases-plummet-when-pcr-tests-are-adjusted/

7. Evidence: Regardless of the PCR tests not being processed properly, the inventor of the PCR test, Kary Mullis, stated many times that "*...PCR tests cannot be used to detect viruses*". It is now admitted that the PCR test cannot tell the difference between a common cold, the flu, any virus or viral variant. Also, the PCR test cannot differentiate between live and dead matter, meaning it cannot determine whether something is infectious (i.e. live) or not (i.e. dead).

   Source: https://brandnewtube.com/watch/kary-mullis-what-he-said-about-the-pcr-test-covid1984_83H2TKPRvA1udPu.html
   Source: https://odysee.com/@Top-Secret:f/Kary-Mullis:d
   Source: https://redstate.com/michael_thau/2020/09/03/ny-times-up-to-90-whove-tested-covid-positive-wrongly-diagnosed-truth-a-whole-lot-worse-pt-2-n253328

8. Evidence: PCR results in a very high number of false positives—between 90.0% to 97.0%—especially in asymptomatic individuals such as in the case of testing performed on healthy people in airports, at work, etc.

   Source: https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC7934325/
   Source: https://brandnewtube.com/watch/dr-mike-yeadon-on-pcr-tests-for-covid19_L2vEhfBrzbkYAyX.html

9. Evidence: The WHO also cautions health care providers not to rely only on the results of a PCR test to detect the SARS-CoV-2 virus, but to "*...consider any result in combination with timing of sampling, specimen type, assay specifics, clinical observations, patient history, confirmed status of any contacts, and epidemiological information.*" In other words, just because a PCR test comes back positive for SARS-CoV-2 should not be the sole consideration for determining if someone has the virus. That determination, according to the WHO, should be based on an analysis of a broader range of factors. The WHO describes PCR test results as an "aid for diagnosis," which suggests they are not the only piece of evidence that should be used to diagnose COVID-19.

   With its new guidance, reportedly the WHO is simply attempting to remind those who administer and evaluate the results of PCR tests to "*...use tests with the proper instructions to ensure accurate results*." Apparently, the WHO had received 10 reports of problems related to PCR tests.

   Source: https://thevaccinereaction.org/2021/02/who-issues-new-guidance-on-use-of-pcr-tests/
   Source: https://thevaccinereaction.org/2020/09/coronavirus-cases-plummet-when-pcr-tests-are-adjusted/
   Source: https://childrenshealthdefense.org/defender/pcr-testing-incorrect-use/
   Source: https://www.hospimedica.com/COVID-19/articles/294786705/who-changes-sars-cov-2-virus-test-criteria-to-reduce-false-positives.html
   Source: https://healthimpactnews.com/2021/cdc-to-withdraw-emergency-use-authorization-for-rt-pcr-test-because-it-cannot-distinguish-between-sars-cov-2-and-the-flu/

10. Evidence: Given the known problems associated with utilizing PCR for diagnosis, public health authorities know better but still rely solely on PCR testing. PCR lab instructions state that PCR is not sufficient for diagnosis, and additional testing or confirmation by active symptoms is required to accurately identify a positive case. The direct wording from the PCR instructions state: "*...positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease*."

    Source: https://www.fda.gov/media/140717/download

11. Evidence: Two peer-reviewed papers compared the results from PCR versus lab cultures, wherein the results of both cultures demonstrated that the optimum PCR cycle threshold (CT) was not between 40 and 45 cycles, as recommended originally by the WHO and Drosten. Unfortunately, PCR CTs between 40 and 45 were adopted world-wide in the early stages of COVID-19 outbreaks. A PCR CT of 13 to 17 has since been demonstrated to produce optimal results. As CTs surpass the 13-17 cycle threshold, the quality of results steadily decreases and are no longer reliable. If the CT was reduced to 17, turnaround time for tests would be quicker. More accurate and portable tests might also be possible to introduce. Most importantly, the incidence of false positives would be greatly reduced by eliminating CTs >35. This would in turn result in more sound public health policies and studies, which currently rely on PCR test results.

    Source: La Scola et al. (2020) — See Figure 1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7185831/
    Source: Singanayagam et al. (2020) — See figures https://pubmed.ncbi.nlm.nih.gov/32794447/
    Source: De Meo, 2021 — https://www.researchgate.net/publication/348550612_A_Critical_Review_of_CDC_USA_Data_on_COVID-19_PCRAntigen_Tests_Cases_Reveal_Herd_Immunity_Only_Do_Not_Warrant_Public_Hysteria_or_Lockdowns

DR. BONNIE HENRY CLAIMS: — Transmission of SARS-CoV-2 among the population of B.C., constitutes a **regional event**, as defined in section 51 of the Public Health Act.

FACT CHECK: **FALSE** — We are not and have never been in a state of emergency nor in a situation that meets the definition of a "regional event". Number of deaths did not significantly increase in 2020 nor in 2021, to date. In other words there is no "significant risk," as defined in section 52 (2) of the Public Health Act, and no justification for Orders and mandates.

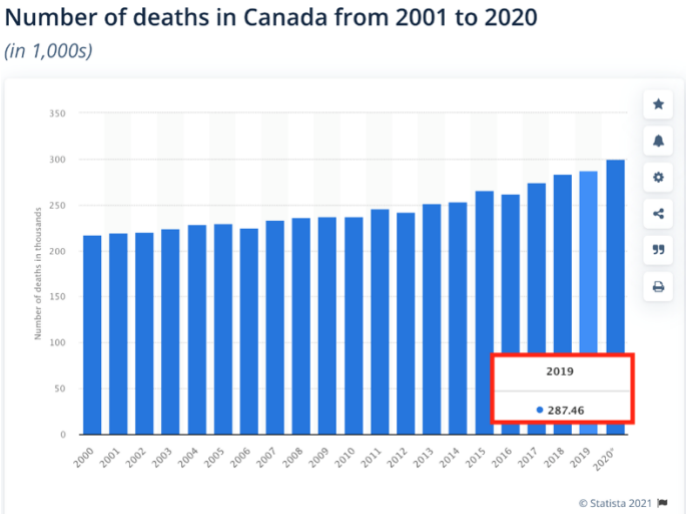
12. Evidence: Data sourced from *B.C. Vital Statistics Reporting* regarding total deaths in B.C. for the years 2019, 2020, and 2021 do not demonstrate a large difference in excess deaths during the time of the declared pandemic. According to *B.C. Vital Statistics*, deaths in B.C. were as follows:

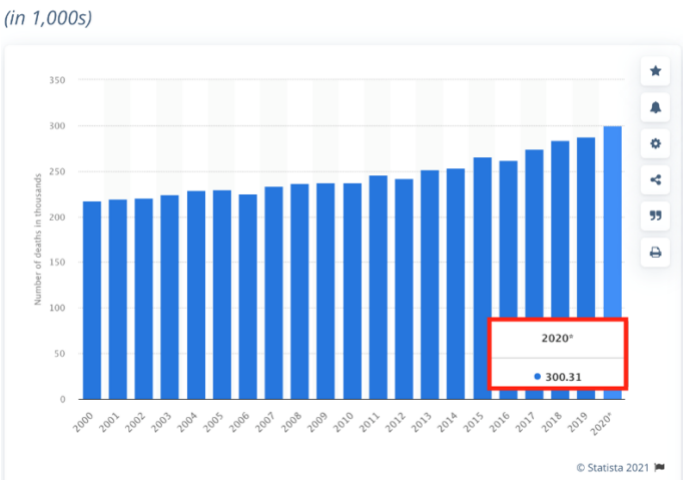
    BC Vital Statistics Reporting:
    - ∉ **2018:** 38,652 = 3189 average deaths/month
    - ∉ **2019**: 38,732 = 3198 average deaths/month
    - ∉ **2020**: 41,464 = 3429 average deaths/month
    - ∉ **2021**: 41,993 — through December 20, 2021

    Overall, this demonstrates that deaths within B.C. have not fluctuated significantly between pre- and mid-pandemic years. Again, justification for the PHO mandates are limited when data is presented accordingly.

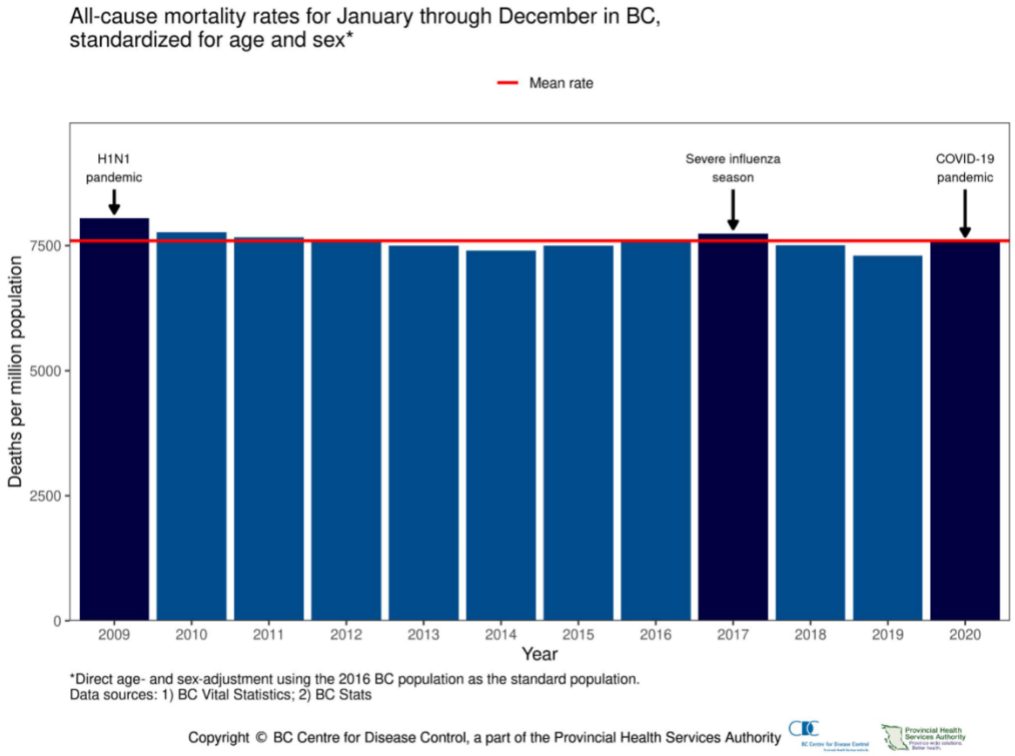
Source: BC Vital Statistics Report - 2018 https://www2.gov.bc.ca/assets/gov/birth-adoption-death-marriage-and-divorce/statistics-reports/death-reports/deaths-by-chsa-2018.pdf
Source: BC Vital Statistics Report - 2019 https://www2.gov.bc.ca/assets/gov/birth-adoption-death-marriage-and-divorce/statistics-reports/death-reports/deaths-by-chsa-2019.pdf
Source: BC Vital Statistics Report - 2020 https://www2.gov.bc.ca/assets/gov/birth-adoption-death-marriage-and-divorce/statistics-reports/death-reports/deaths-by-chsa-2020.pdf
Source: BC Vital Statistics Report - 2021 https://www2.gov.bc.ca/assets/gov/birth-adoption-death-marriage-and-divorce/statistics-reports/death-reports/deaths-by-chsa-2021.pdf

Furthermore, there have been marginal changes in the number of deaths nationally across various age populations over the last five years, through to 2020. Data for 2021 are currently not available. According to the *Statista Research Department*—an objective data partner with participation by 160+ countries globally—deaths in Canada have slowly increased over the last five years, wherein reported deaths increased from 266,000 in 2015 to 300,000 in 2020. Between the years 2019 and 2020 (representing the onset of the COVID pandemic) a small increase in deaths occurred, with 287,000 deaths reported in 2019 and 300,000 reported in 2020. This represents a 4.28% difference in all-cause mortality between the years 2019 and 2020. Does this small increase in deaths—if attributed solely to COVID-19—which has been an ever-increasing trend in Canada dating back to 2000 (as per *Statista Research Department)* warrant a "*significant health risk*" to the public?





All-cause mortality rates for January through December 2020 in B.C (as per the BCCDC) demonstrate that deaths are actually less than other years with severe illness such as the H1N1 pandemic (2009), and the severe influenza season of 2017.



Source: http://www.bccdc.ca/health-info/diseases-conditions/covid-19/data
Source: https://www.statista.com/statistics/443061/number-of-deaths-in-canada/
Source: All-cause mortality - BCCDC Mortality Context Application

13. Evidence: *Statistics Canada* demonstrates that 90.0% of deaths marked as a COVID-19 death were with other pre-existing health issues (i.e. comorbidities). How many Canadians who succumbed to COVID-19 already had a life-threatening illness? On November 16, 2020 Statistics Canada reported: "*Of the over 9,500 COVID-involved deaths between March and July, the majority (90.0%) had at least one other cause, condition or complication reported on the certificate. Dementia or Alzheimer's were listed on the death certificate of 42.0% of the women and one-third of the men (33.0%) in COVID-involved deaths. These results can be explained by the age profile of Canadians whose deaths involved COVID-19 over this period (54.0% were 85 years or older), as well as by their over-representation in long-term healthcare facilities.*"

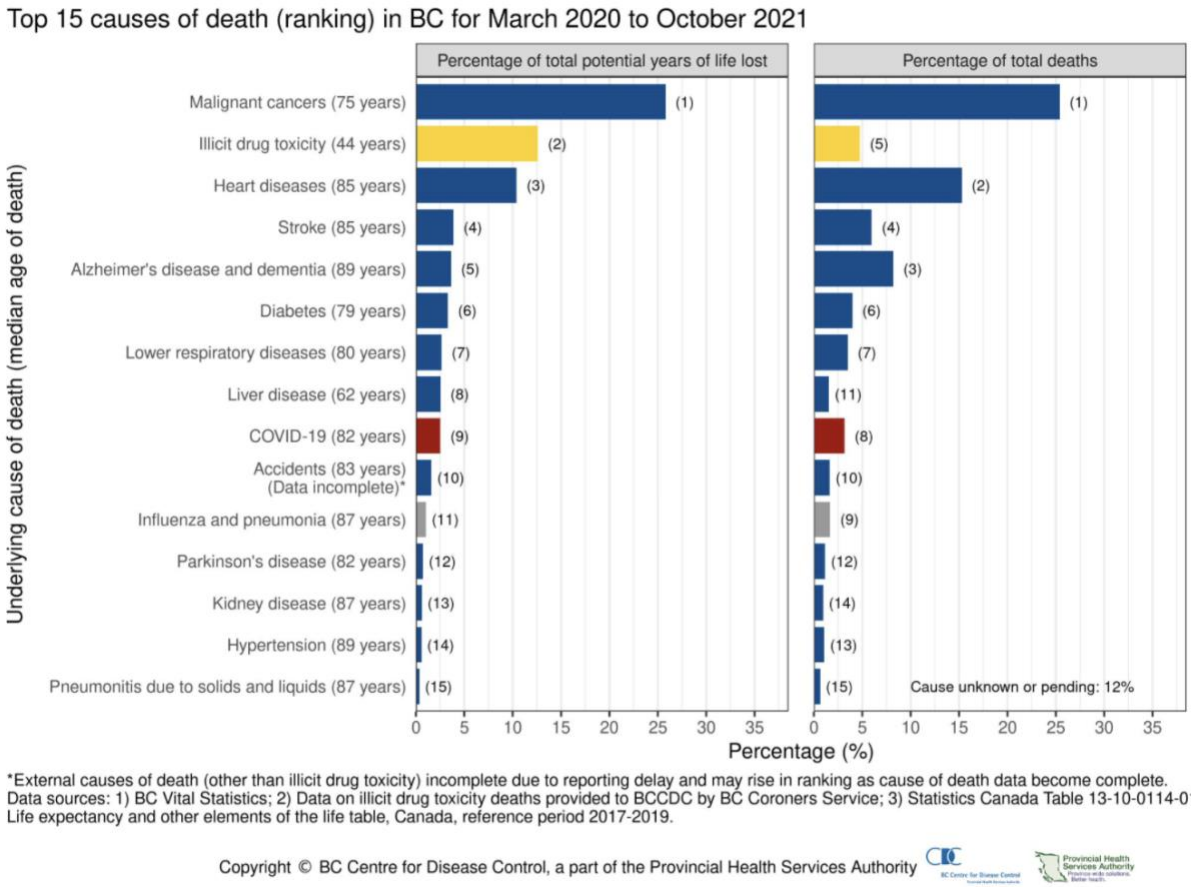
    Statistics demonstrate that healthy people are not dying from COVID-19. If individuals are healthy, and do not want to receive an experimental treatment that has no long-term safety data (which in less than 10 months has been shown to contribute to serious adverse side effects and deaths), why are they being coerced? Individuals are in charge of their own health. Being free citizens allows one to manage their health on their own terms, utilizing preventative measures such as a whole foods diet, exercise, sleep, lifestyle, supplements, and medications when absolutely necessary.

    Source: https://www150.statcan.gc.ca/n1/en/pub/45-28-0001/2020001/article/00087-eng.pdf?st=g1jmJcqV

14. Evidence: The data extracted directly from the CDC and WHO show how low COVID-19 numbers are across the world, within the USA, within Canada, and within B.C., specifically. Therefore, there is no justification for creating a vaccine, let alone mandating that 100.0% of the world's population be injected with it.

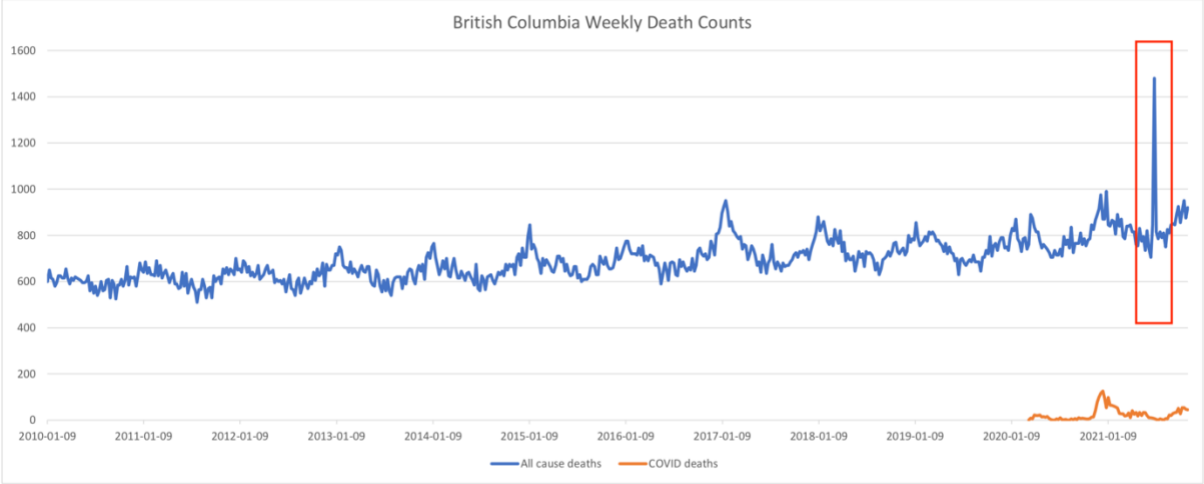
As at January 18, 2022	Worldwide		United States		Canada		BC	
	Number	% of Population	Number	% of Population	Number	% of Population	Number	% of Population
Population	7,874,965,825	100%	332,915,073	100%	38,326,282	100%	5,194,137	100%
Deaths with COVID-19	5,582,617	0.057749%	880,323	0.264429%	31,995	0.083481%	2,492	0.047977%
Healthy or Recovered	7,869,383,208	99.929109%	332,034,750	99.735571%	38,294,287	99.916519%	5,191,645	99.952023%
Cases	339,013,744	4.304955%	69,639,259	20.918025%	2,842,466	7.416493%	301,178	5.798422%
Uneffected by COVID-19	7,535,952,081	95.695045%	263,275,814	79.081975%	35,483,816	92.583507%	4,892,959	94.201578%
Uneffected by COVID-19 Death	7,869,383,208	**99.929109%**	332,034,750	**99.735571%**	38,294,287	**99.916519%**	5,191,645	**99.952023%**

Coupled with the fact that 99.9% of individuals within B.C. were unaffected by COVID-19 deaths, BCCDC data demonstrate that COVID-19 deaths was ranked number eight for total percentage of total deaths, with an average age of death of 82 years.



Sources:
B.C. COVID-19 Dashboard — https://experience.arcgis.com/experience/a6f23959a8b14bfa989e3cda29297ded
Center for Disease Control and Prevention (CDC) — https://covid.cdc.gov/covid-data-tracker/#datatracker-home
Johns-Hopkins University (JHU) — https://coronavirus.jhu.edu/map.html
World Health Organization (WHO) — https://covid19.who.int/
Health Canada — https://health-infobase.canada.ca/COVID-19/epidemiological-summary-COVID-19-cases.html?redir=1
Canada Population — https://www.worldometers.info/coronavirus/country/canada/
Top 15 Causes of Death - BCCDC Mortality Context App (shinyapps.io)

15. Evidence: In the year 2020, B.C. death counts were no more significant than in years predating the pandemic. ***Note:** the spike in deaths (denoted by the red square) in 2021 was attributed to the "heat dome" that occurred in B.C. between June 18, 2021 and August 12, 2021. A report by the CBC states that 595 deaths occurred in a one-week period as a result of the historic heat wave and the failure of the emergency services response. Again, this graph demonstrates the number of COVID-19 deaths (in orange) in contrast to all-cause mortality (in blue) within B.C., which is only a small portion (0.04% - see graph in **section A #13**) of all deaths.



Source: https://www.cbc.ca/news/canada/british-columbia/bc-heat-dome-sudden-deaths-revised-2021-1.6232758
Source: https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm?fbclid=IwAR2pVVLEI6CNGs9QX3DAizXU7ODrrHEPuFMp9Wk11HGgx95EQ5dP6mslNaw

16. Evidence: To contrast these findings, the number of lives lost in B.C. to illicit drug toxicity far exceeds the number of COVID-19-involved deaths. In 2021, 71.0% of those who died as a result of a drug overdose were aged 30 to 59. Males accounted for 79.0% of deaths in 2021. The median age for those dying with COVID-19 is 82 years of age. Deaths due to drug overdose in B.C. should be of more concern to our Public Health officials than a virus that has a high rate of recovery, particularly if treated early. Paramedics and medical dispatchers in B.C. responded to a record-setting 35,525 overdose calls in 2021. An increase of 31 per cent from 2020, according to BC Emergency Health Services.

Table 3: Age distribution: COVID-19 cases, hospitalizations, ICU admissions, deaths, and BC population by age group Jan 15, 2020 (week 3) – Jan 01, 2022 (week 52) (N= 265,722)[a]

Age group (years)	Cases n (%)	Hospitalizations n (%) [b]	ICU n (%)	Deaths n (%)
<10	20,447	180 (<1)	16 (<1)	2 (<1)
10-19	29,481	149 (<1)	29 (1)	0 (<1)
20-29	57,822	781 (1)	101 (<1)	6 (<1)
30-39	50,632	1,417 (3)	280 (1)	30 (<1)
40-49	38,727	1,510 (4)	352 (1)	54 (<1)
50-59	31,355	2,081 (7)	631 (2)	139 (<1)
60-69	20,407	2,444 (12)	780 (4)	285 (1)
70-79	9,784	2,367 (24)	671 (7)	539 (6)
80-89	4,965	1,617 (33)	226 (5)	792 (16)
90+	2,102	556 (26)	23 (1)	583 (28)
Total	**265,722**	**13,102**	**3,109**	**2,430**
Median age [c]	**34**	**61**	**62**	**82**

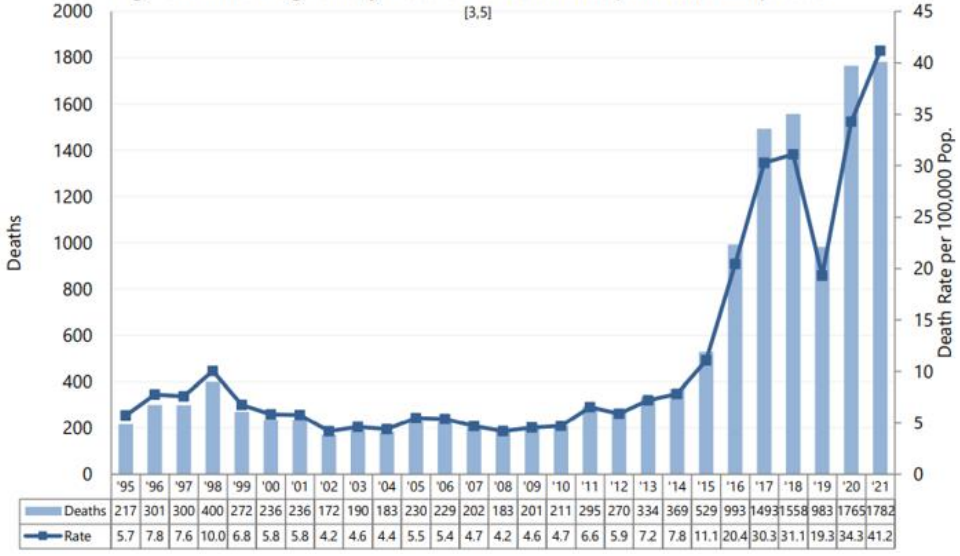
a. Among those with available age information only.
b. Data sources: Health Authority case line lists and a subset of PHSA Provincial COVID19 Monitoring Solution (PCMS) data for children <20 years of age. PCMS data were included as of June 8 2021. Due to this change in data source, additional admissions that occurred since the start of the pandemic are now included in age groups 0-9 and 10-19 years.
c. Median ages calculated are based on Health Authority case line lists only.

In British Columbia	2020	2021	Total 20/21	
Lives lost to illicit drug toxicity	1,736 [1]	1,782 [1]	3,498	(to 31Oct21)
Lives lost to COVID-19	901 [2]	1,529	2,430	(to 1Jan22)
> # of lives lost to Overdose vs COVID-19	815	260	**1,068**	

BC Coroners Service

Illicit Drug Toxicity Deaths in BC
January 1, 2011 to October 31, 2021

Figure 1: Illicit Drug Toxicity Deaths and Death Rate per 100,000 Population



	'95	'96	'97	'98	'99	'00	'01	'02	'03	'04	'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	'16	'17	'18	'19	'20	'21
Deaths	217	301	300	400	272	236	236	172	190	183	230	229	202	183	201	211	295	270	334	369	529	993	1493	1558	983	1765	1782
Rate	5.7	7.8	7.6	10.0	6.8	5.8	5.8	4.2	4.6	4.4	5.5	5.4	4.7	4.2	4.6	4.7	6.6	5.9	7.2	7.8	11.1	20.4	30.3	31.1	19.3	34.3	41.2

Sources:

1. Age Category (gov.bc.ca)
2. Joint statement on B.C.'s COVID-19 response, latest updates | BC Gov News
3. Week_52_2021_BC_COVID-19_Situation_Report.pdf (bccdc.ca)
4. B.C. paramedics, dispatchers responded to record-setting 35,525 overdose calls in 2021 – BCCSU

17. Evidence: There is no official declared state of emergency, as per the 1985 Federal Emergencies Act. Furthermore, section 1 of the Charter states our rights are subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society. Demonstrable justification of mandates and government actions has not been proven anywhere within Canada, to date.

The province previously issued a state of emergency within British Columbia for COVID-19, however this ended June 30, 2021. This was followed by declaration of a wildfire emergency (July 2021), and a flooding emergency (November 2021) but these do not constitute a federal state of emergency. The Federal Emergencies Act states that "*...even in an Emergency, this is declared in the Emergencies Act AND WHEREAS the Governor in Council, in taking such special temporary measures, would be subject to the Canadian Charter of Rights and Freedoms and the Canadian Bill of Rights and must have regard to the International Covenant on Civil and Political Rights, particularly with respect to those fundamental rights that are not to be limited or abridged even in a national emergency*." Furthermore, the 1985 Emergencies Act states "*National emergency: For the purposes of this Act, a **national emergency** is an urgent and critical situation of a temporary nature that (a) seriously endangers the lives, health or safety of Canadians and is of such proportions or nature as to exceed the capacity or authority of a province to deal with it, or (b) seriously threatens the ability of the Government of Canada to preserve the sovereignty, security and territorial integrity of Canada and that cannot be effectively dealt with under any other law of Canada.*"

Source: Federal Emergencies Act (1985) — https://laws-lois.justice.gc.ca/eng/acts/e-4.5/page-1.html

18. Evidence: Section 51 of the Public Health Act states a "regional event" means an immediate and significant risk to public health throughout a region or the province. As the tables above (evidence A #11 & A #13) demonstrate, the impact of COVID-19 illness is negligible and 99.95% of the population is unaffected by COVID-19-associated death.

    A person must not exercise powers under this Part in respect of a "regional event" unless the provincial health officer provides notice that the provincial health officer reasonably believes that at least 2 of the following criteria exist. The provincial health officer has not provided evidence to show at least 2 criteria exist.

    (a) the regional event could have a serious impact on public health;

DR. BONNIE HENRY CLAIMS: — The risk of COVID-19 infections constitute a regional event.

FACT CHECK: **FALSE** — The provincial health officer has provided no evidence to support transmission of SARS-CoV-2 has a serious impact on public health. All CDC, WHO and public data show that the number of deaths with COVID-19 are not resulting in excess mortality rates in B.C. (see Section A #11).

    (b) the regional event is unusual or unexpected;

DR. BONNIE HENRY CLAIMS: — The risk of COVID-19 infections and transmission is unusual or unexpected.

FACT CHECK: **FALSE** — Seasonal flu affects British Columbians every year as new strains circle the globe. SARS-CoV viruses have occurred in prior years and virologists/immunologists state we can expect SARS-CoV-2 will become endemic. The logical science-based option is to move to an endemic approach, which focuses on prevention efforts much like all respiratory illness. Number of deaths related to influenza and COVID-19 comprise a small percentage of all cause mortality (see Section A #13).

(c) there is a significant risk of the spread of an infectious agent or a hazardous agent;

DR. BONNIE HENRY CLAIMS: — There is significant risk of SARS-CoV-2 transmission.

FACT CHECK: CORRECT— It is clear that SARS-CoV-2 is an infectious agent which can easily spread between close contacts regardless of whether they are vaccinated or unvaccinated.

(d) there is a significant risk of travel or trade restrictions as a result of the regional event.

DR. BONNIE HENRY CLAIMS: — SARS-CoV-2 infections and transmission rates could impact trade and travel.

FACT CHECK: **FALSE** — Travel and trade restrictions will not stop a virus. Canada's unspoken strategy has been that of COVID Zero, including strict border quarantines, widespread masking mandates, school closures and more. This is the same ineffective strategy that is being abandoned by Australia and New Zealand and has proven to result in significant economic and health related harms.

Source: https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/08028_01#section51
Source: https://torontosun.com/opinion/columnists/grant-vaccines-will-never-eliminate-covid-so-its-time-to-pivot-our-response
Source: Australia is ending its zero-covid strategy | The Economist
Source: https://www.nytimes.com/2021/10/22/world/new-zealand-abandons-its-goal-of-eliminating-the-coronavirus.html

19. Evidence: Dr. Bonnie Henry has enacted mandates and public health orders that completely contradict the World Health Organizations (WHO) 2019 Global Influenza Programme — "*Non-Pharmaceutical Public Health Measures for Mitigating the Risk and Impact of Epidemic and Pandemic Influenza*". The following image within the WHO document highlights 18 non-pharmaceutical interventions (NPIs, Table 1), **starting on page 3**. The document clearly states that the following are **never recommended under ANY** circumstances when managing a pandemic:

    - contract tracing
    - quarantining of exposed individuals
    - entry and exit screening
    - border closures

    Furthermore, **face masking for the public, school closures, workplace measures (i.e. vaccine mandates)/closures and restrictions on internal travel are only recommended in a "high" or "extraordinary" pandemic severity level.** As detailed in aforementioned evidence points, B.C. and Canada have never been under threat of a "high" or "extraordinary" pandemic threat, yet all of these measures have largely been in place since March 2020. Refer to **Section A #11** for detailed statistics.

Table 1. Recommendations on the use of NPIs by severity level

SEVERITY	PANDEMIC[a]	EPIDEMIC
Any	Hand hygiene Respiratory etiquette Face masks for symptomatic individuals Surface and object cleaning Increased ventilation Isolation of sick individuals Travel advice	Hand hygiene Respiratory etiquette Face masks for symptomatic individuals Surface and object cleaning Increased ventilation Isolation of sick individuals Travel advice
Moderate	*As above, plus* Avoiding crowding	*As above, plus* Avoiding crowding
High	*As above, plus* Face masks for public School measures and closures	*As above, plus* Face masks for public School measures and closures
Extraordinary	*As above, plus* Workplace measures and closures Internal travel restrictions	*As above, plus* Workplace measures and closures
Not recommended in any circumstances	UV light Modifying humidity Contact tracing Quarantine of exposed individuals Entry and exit screening Border closure	UV light Modifying humidity Contact tracing Quarantine of exposed individuals Entry and exit screening Internal travel restrictions Border closure

NPI: non-pharmaceutical intervention; UV: ultraviolet.

Source: WHO Pandemic Planning 2019 Global Influenza Programme — https://web.archive.org/web/20200730195417/https://apps.who.int/iris/bitstream/handle/10665/329438/9789241516839-eng.pdf?ua=1

20. Evidence: The COVID-19 vaccination program is linked to increase in case counts, hospitalizations and deaths. Physicians from the Canadian province of Alberta claim their government's data show COVID-19 vaccines cause short-term jumps in case counts, deaths, and hospitalizations possibly because the "*...vaccine is causing immunosuppression*." Please refer to **Section C #55** regarding Dr. Nagase's claim that COVID-19 vaccines increase cancer risk in children. Dr. Christy Reich details total cases, total hospitalizations, and total deaths following vaccinations (**Section C #79**). The data appears to demonstrate a large spike in cases, hospitalizations, and deaths between one and 30 days following COVID-19 vaccine injections. According to the Western Standard, a specialist from the doctors' group whose name was withheld said directly that the government's data seems to "*... show us that vaccines are contributing to a rise in cases, hospitalizations and deaths*." The specialist added that they are also seeing "*...other diseases and illnesses that have been in remission come back*."

    Source: https://westernstandardonline.com/2021/10/alberta-doctors-group-claims-vaccinations-cause-short-term-spike-in-covid-cases-deaths/
    Source: https://www.marktaliano.net/canadian-docs-say-govt-data-point-to-spike-in-covid-cases-after-jab-suppressed-immune-system-by-anthony-murdoch/

21. Evidence: Although the following was declared in an American court system, it is worth making the point as we have unelected officials pushing these unlawful mandates and policies. We are being told how to live by people that were not even voted in by the populations they are controlling. The following should cause one to stop and consider the same situation within B.C. and Canadian law. The following excerpt was penned by attorney Jeff Childers, who advocates for a responsible government:

    "In a remarkable, strongly-worded opinion, the Cole County Circuit Court of Missouri just ended ALL the state's [COVID-19] measures. In Shannon v. Missouri Department of Health, the Court found that the Department of Health's regulations CANNOT '*abolish representative government in the creation of public*

health laws,' and CANNOT '*authorize closure of a school or assembly based on the unfettered opinion of an unelected official*.' While we've seen other favorable court decisions lately, this one is a true breakthrough. It moves the bar. The Court didn't just find a technical reason to set aside the DOH's emergency rules. Instead, the Court found that the ORIGINAL state statutes giving the DOH its emergency authority were themselves completely invalid, for four separate reasons, because the statutes:

1) violate constitutional separation of powers;

2) violate the state's administrative procedure act;

3) are inconsistent with other public health laws; and

4) violate constitutional equal protection.

The Missouri Court determined that "... the [DOH] regulations break our three-branch system of government….because they place the creation of orders or laws, and enforcement of those laws, into the hands of an **unelected official.**" Likewise, **Dr. Bonnie Henry as an unelected official** is creating policies and mandates in violation of Canadian law. The Court cited a 2020 Michigan Supreme Court case: '*It is incumbent on the courts to ensure decisions are made according to the rule of law, not hysteria … One hopes that this great principle — essential to any free society, including ours — will not itself become yet another casualty of COVID-19*.' The Court found that the Missouri emergency health statutes were constitutionally flawed because they create '*double delegation*.' The judge said the state had delegated rulemaking power to the DOH, which then delegated '***broad rulemaking power to an unelected official.***' This type of double delegation, said the Court, '*is an impermissible combination of legislative and administrative power*.' It also explained that the regulations '*violate the principle of separation of powers by unlawfully placing unguided and unbridled rulemaking power in the hands of a public official*.' Similar considerations should be made within B.C. and across Canada in regards to the overreach of broadly granted powers to the sitting PHO.

Source: https://www.coffeeandcovid.com/p/-coffee-and-covid-thursday-november-0f9

22. Evidence: Canadian Prime Minister Justin Trudeau and Deputy Prime Minister Chrystia Freeland announced unprecedented violations of Canadian citizens' Charter rights on October 6th, 2021 in the form of vaccine mandates and vaccine passports. The notion that these mandates and Charter violations are in place "to keep people safe" and "to prevent the spread of COVID-19" are false and scientifically unjustified based on:

    a. Dr. Patty Daly's (Vice President of Public Health and Chief Medical Health Officer of Vancouver Coastal Health) clarifies that the purpose of vaccine passports is to improve vaccine uptake. According to Patty Daly, restaurants, movies, and gyms (the main locales that vaccine passports are needed for) are not where transmission is occurring.
    b. Rochelle Walensky (CDC Director) stated that what [COVID-19 vaccines] can't do anymore is prevent transmission.

Source: https://www.canadiancovidcarealliance.org/media-resources/are-charter-violations-justified/

B. A person infected with SARS-CoV-2 can infect other people with whom the infected person is in contact;

DR. BONNIE HENRY CLAIMS: — A person infected with SARS-CoV-2 can transmit the virus to others.

FACT CHECK: CORRECT— It is clear that SARS-CoV-2 is an infectious agent which can easily spread between close contacts regardless of whether they are vaccinated or unvaccinated. Any person infected with SARS-CoV-2 can infect others and infection rates are the same, if not greater, in vaccinated individuals versus unvaccinated individuals.

1. Evidence: Fully vaccinated healthcare workers within a major infectious diseases hospital in Vietnam were found to carry up to 251-times the viral load of unvaccinated individuals in their nostrils. Breakthrough Delta variant infections are associated with high viral loads, prolonged PCR positivity, and low levels of vaccine-induced neutralizing antibodies, explaining the transmission between vaccinated individuals.

   Source: Chau et al. (2021) —https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733
   Source: https://www.globalresearch.ca/study-fully-vaccinated-healthcare-workers-carry-251-times-viral-load-pose-threat-unvaccinated-patients-co-workers/5753908?pdf=5753908&fbclid=IwAR3oPOpu9TA8VlKGYmSyGWvUa8BHwwSnEQgDfGMPq6p2qSXBkzCyrGEbiGA

2. Evidence: German government data for the alleged Omicron variant of COVID-19 suggests that "fully vaccinated" population could have full blown COVID-19 vaccine induced acquired immunodeficiency syndrome (AIDS), after confirming that the immune systems of the fully vaccinated have already degraded to an average of minus (-) 87.0%. * As at March 10th, 2022 the Kelowna valley labs

   Source: https://dailyexpose.uk/2022/01/02/german-gov-data-suggests-fully-vaccinated-developing-ade/
   Source: Robert Koch Institut Report - Wochenbericht_2021-12-30.pdf (rki.de)

C. Vaccination is safe, highly effective, and the single most important preventive measure a person can take to protect themselves, their families, and other persons with whom they come into contact from infection, severe illness and possible death from COVID-19. In particular:

a. The vaccines available in British Columbia are highly effective, providing strong protection across all eligible age groups against infection and especially against severe illness;

b. Most British Columbians have strong and durable protection from SARS-CoV-2 resulting from the extended interval between dose one and dose two that is being utilized in British Columbia;

c. A full course of vaccine provides more effective and durable protection against infection and severe illness than natural immunity from prior COVID-19 infection alone, or natural immunity in combination with a single-dose of vaccine; and

d. A full course of vaccine provides highly effective and durable protection from infection and in particular from severe illness resulting in hospitalization or death from the Delta variant with COVID-19, with illness being mostly milder in vaccinated people who become infected than in unvaccinated people.

NOTE: Pfizer considers *"...individuals may not be fully protected until 7 days after their second dose of vaccine..."* however, to be considered vaccinated in B.C., as of the writing of this document, it means a person must be 14 days past their 2nd dose of an approved COVID-19 vaccine. Example: If an individual was 13 days post-receipt of a 2nd dose, they are considered partially vaccinated, or possibly even unvaccinated. Unvaccinated means an individual has not received a COVID-19 vaccine. It is questionable as to whether having 1 shot deems an individual unvaccinated, as no clear timeline has been provided by the province of B.C. These terms are not clearly defined and appear to be arbitrary and contrary to the drug manufacturers recommendations.

Vaccine-associated deaths are only counted in persons who die once fully vaccinated (2 weeks after 2nd shot = 35 days between shot 1 and 2 + 15 days to get 2 weeks past the 2nd shot = 50 days). Individuals who are dying immediately after their first shot, within a few days of receiving either dose of the vaccine, or within 2-3 weeks of the first shot are not counted as vaccine deaths. Data demonstrates that most vaccine deaths are occurring within the first 2 to 3 weeks following a COVID-19 vaccine.

DR. BONNIE HENRY CLAIMS: — The vaccines are safe.

FACT CHECK: **FALSE** — Vaccines are continuing to prove to be demonstrably **unsafe**. It is irresponsible to attest to safety when there is no conclusive evidence, given clinical trials are still underway and the preliminary trials were prematurely unblinded. Manufacturers failed to follow Level 1 Evidence standards for a clinical trial resulting in severely flawed data. COVID-19 vaccine injuries and deaths are breaking historical records.

1. Evidence: **Adverse Reactions & Deaths per Health Canada Adverse Events of Special Interest (AESI)** - up to and including February 25, 2022

TABLE 1 – Count of reported adverse events of special interest up to and including February 25, 2022 (n=6,178)

AESI Category	AESI	Total number of events
Auto-immune diseases	Guillain-Barré Syndrome[1]	122
	Thrombocytopenia (low blood platelets)[1]*	250
	Subtotal	372
Cardiovascular system	Cardiac arrest	41
	Cardiac failure	46
	Myocardial infarction (heart attack)	104
	Myocarditis[1]/Pericarditis (inflammation of the heart muscle and lining around the heart)	1,857
	Subtotal	2,048
Circulatory system	Cerebral venous (sinus) thrombosis	20
	Cerebral thrombosis	10
	Cutaneous vasculitis	35
	Deep vein thrombosis	297
	Embolism	16
	Haemorrhage (bleeding)	67
	Pulmonary embolism	432
	Thrombosis (blood clot)	296
	Thrombosis with thrombocytopenia syndrome (blood clot with low platelets)	108
	Subtotal	1,281
Hepato-gastrointestinal and renal system	Acute kidney injury	57
	Glomerulonephritis (kidney inflammation) and nephrotic syndrome (kidney disorder)	17
	Liver injury	38
	Subtotal	112
Nerves and central nervous system	Bell's Palsy[1]/facial paralysis	834
	Cerebrovascular accident (stroke)	212
	Transverse myelitis (inflammation of spinal cord)[2]	13
	Subtotal	1,059
Other system	Anaphylaxis[2]	788
	COVID-193	357
	Multisystem inflammatory syndrome[2]	13
	Subtotal	1,158
Pregnancy outcomes4	Fetal growth restriction	5
	Spontaneous abortion	71
	Subtotal	76
Respiratory system	Acute respiratory distress syndrome	5
	Subtotal	5
Skin and mucous membrane, bone and joints system	Chilblains	25
	Erythema multiforme (immune skin reaction)	42
	Subtotal	67
All AESI categories	Total	6,178

Additional detailed information on safety signals, other safety updates and deaths

a. **304 reports with an outcome of death were reported** following vaccination
b. **1,857 reports of myocarditis/pericarditis** that meet Level 1 to 4 of of Brighton Collaboration level diagnostic certainty.
    i. Median age of myocarditis/pericarditis is 30 years (age 12 to 93 years old) for Pfizer-BioNTech Comirnaty COVID-19 vaccine.
    ii. Current analyses show the number of reports of myocarditis/pericarditis following Pfizer-BioNTech Comirnaty COVID-19 vaccine **is higher than what would be expected** in the general population of males and females <30 years old, and occurs primarily following the second dose
    iii. Median age of myocarditis/pericarditis is 30 years (age range 17 to 95 years old) for Moderna Spikevax COVID-19 vaccine.
    iv. Current analyses show the number of reports of myocarditis/pericarditis following the Moderna Spikevax COVID-19 vaccine is **higher than what would be expected** in the general population, particularly among males and females less than 40 years old and following the second dose.
c. **122 reports of Guillain-Barré Syndrome (GBS)** that meet Level 1 to 4 of Brighton Collaboration level diagnostic certainty.
    i. The number of reports of GBS following AstraZeneca Vaxzevria/COVISHIELD vaccination are **higher than would normally be expected** in the general population.
d. **108 reports of Thrombosis with thrombocytopenia syndrome (TTS)** that meet Level 1 to 4 of Brighton Collaboration level of diagnostic certainty. Six (6) people died.
e. **Two (2) reports of capillary leak syndrome** that have been medically reviewed to verify the diagnosis.

Source: https://health-infobase.canada.ca/COVID-19/vaccine-safety/#newSafetyIssues

2. Evidence: Health Canada makes the following sobering statement:

"Without question, sudden unexpected death occurring within days of immunization is a major threat to immunization programmes. Sudden death has not yet been added to the AESI list."

If you wanted to know how many have died of the vaccine and/or within days of receiving the vaccines, this information is not available. Health Canada is not releasing this information stating that if the number of deaths were reported, this would create vaccine hesitancy. This would be a threat to the Canadian COVID-19 vaccine program.

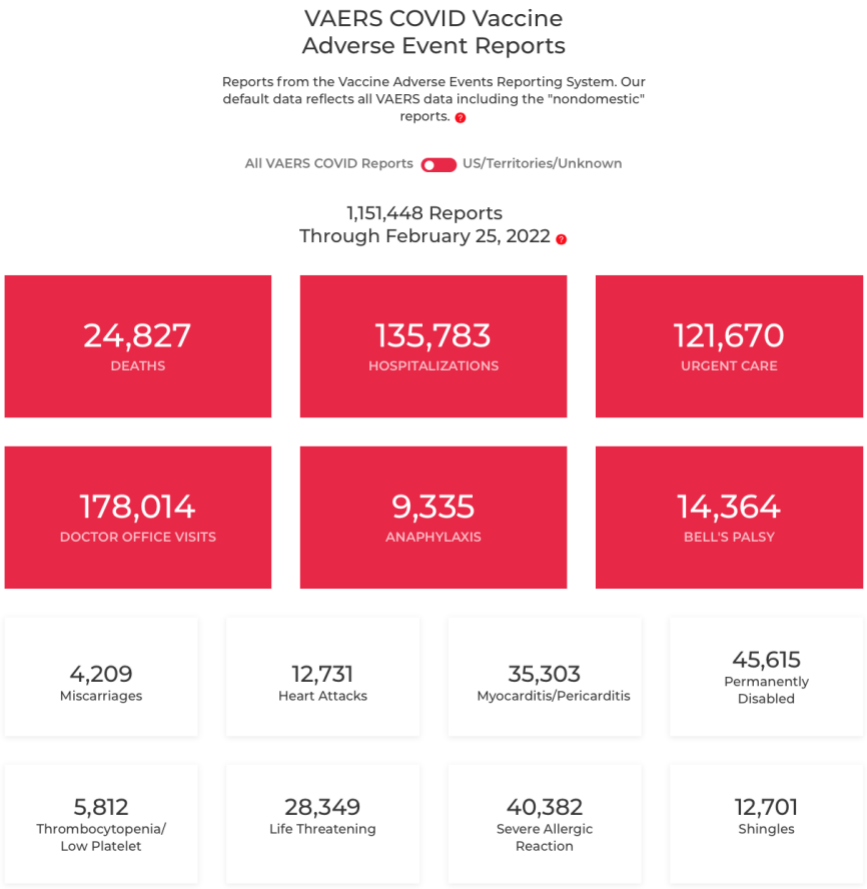
Health Canada continues by stating the following:

"While it has been observed in association with COVID-19 infection, such occurrences are rare and are related to thromboembolic phenomena such as stroke, pulmonary embolus and coronary thrombosis. However, it will be essential to be prepared for such occurrences to enable rapid response in terms of investigation and communication to the public."

The concern with the above quote is that Health Canada states that they will respond with an investigation and communication to the public. However, Health Canada is not investigating nor communicating number of injuries or deaths associated with COVID-19 vaccines.

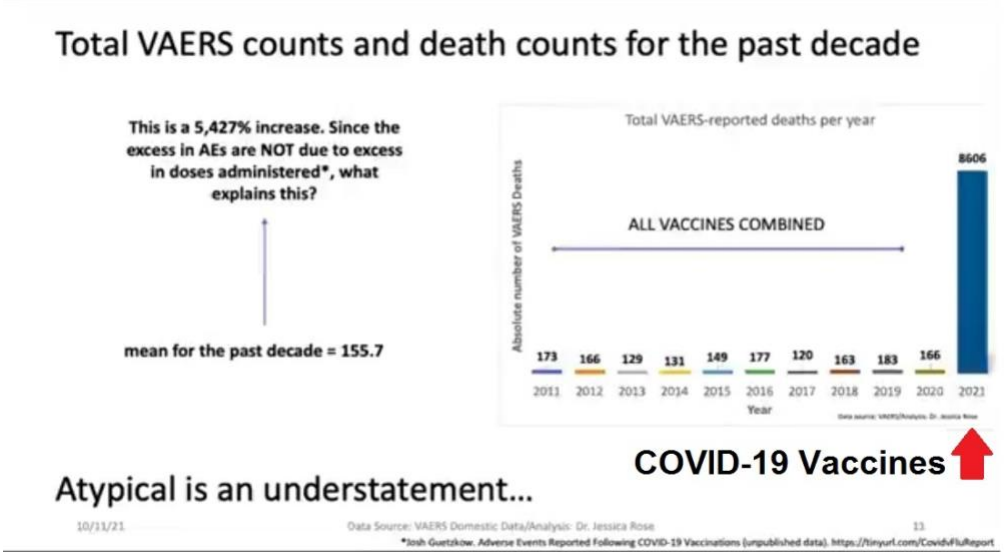
Source: COVID-19 Vaccines – Safety and Surveillance: refer to page 101, section 6.6
https://apps.who.int/iris/bitstream/handle/10665/345178/9789240032781-eng.pdf?sequence=1&isAllowed=y

3. Evidence: Released February 25, 2022 by the CDC (US) included a total of 1,151,448 reports of adverse events from all age groups following COVID vaccines, including 24,827 deaths. VAERS is considered an "early warning system", which is meant to demonstrate early safety signals with vaccination. These numbers continue to climb and can be tracked through the MedAlerts link (below in sources) daily. Where is the stopping point?



Source: https://openvaers.com/covid-data
Source: https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=CAT&EVENTS=ON&VAX=COVID19

4. Evidence: Steve Kirsch is the director of the COVID-19 Early Treatment Fund, a researcher, and a technology philanthropist with advanced education from MIT. Dr. Jessica Rose (PhD, MSc, BSc) is a data analyst, researcher, and mathematician with a background in immunology, molecular biology, computational biology, and biochemistry. As per an October 8, 2021 VAERS analysis, Steve Kirsch and Dr. Jessica Rose suggest that over 150,000 Americans have been killed by COVID-19 vaccines as per data through August 28, 2021. Furthermore, analyses of 2021 VAERS data by Dr. Rose demonstrates a 5,427% increase in deaths following COVID-19 shots and a 1,373% increase in vaccine-induced adverse events following COVID-19 shots when compared to all other vaccines from the last decade. It should also be noted that Steve Kirsch has identified an under reporting factor (URF) of 41 utilizing the CDC's own data. This means that VAERS numbers should be multiplied by 41 (total should be: 150K * 41 = 6.150M deaths) to determine a more accurate number of COVID-19 vaccine-related adverse events and deaths.



Source: https://docs.google.com/document/d/1stq2nHFjAcMHhxJhWiXa33wl6x0Ga1qdIxodZnFixRw/edit#
Source: https://healthimpactnews.com/2021/phd-researchers-analysis-of-vaers-data-reveals-5427-increase-in-deaths-following-covid-shots-compared-to-all-vaccines-the-past-10-years/
Source: Steve Kirsch's URF by 41x explanation — https://www.skirsch.com/covid/Deaths.pdf

5. Evidence: Dr. Paul Alexander holds a Master's degree in epidemiology (York University-Canada) and evidence-based medicine (Oxford), and a doctoral degree in evidence-based medicine and research methods (Assistant Professor at McMaster-Canada). Dr. Alexander has taught clinical epidemiology to masters and doctoral candidates, clinical practitioners, and surgeons in evidence-based medicine and research methodology. Furthermore, Dr. Alexander is a former COVID Pandemic evidence-synthesis consultant advisor to WHO-PAHO Washington, DC (2020) and former senior advisor to COVID Pandemic policy in Health and Human Services (HHS) Washington, DC; he was also appointed at the WHO as a regional specialist/epidemiologist in Europe's Regional office Denmark (2008), worked for the government of Canada as an epidemiologist for 12 years, and was appointed as the Canadian in-field epidemiologist (2002-2004) as part of an international CIDA funded, Health Canada executed project on TB/HIV co-infection and MDR-TB control. Finally, Dr. Alexander's exhaustive resume concludes with his recent employment at Infectious Diseases Society of America (IDSA) Virginia USA (2017-2019) as the evidence synthesis meta-analysis systematic review guideline development trainer. Dr. Alexander is currently a COVID-19 consultant researcher in the US-C19 research group.

   Dr. Alexander warns that COVID-19 vaccines are not safe for children, and that children are at low risk of complications due to natural infection. Vaccination of children is unnecessary because children have low expression of ACE2 receptors within the nasal cavity that allow for entry of COVID-19 into bodily cells. Children also experience a more robust innate immune response to SARS-CoV-2 infection compared to adults, reducing the risk of severe outcomes. Moreover, vaccination may compromise the natural immune response of children. Prior to the declaration of the pandemic, memory B cells with the ability to bind to the SARS-CoV-2 virus were detected in blood samples from children, suggesting that early childhood exposure to the natural virus—versus exposure to viral particles (i.e. the spike protein) through vaccination—is critical for development of humoral immunity. Finally, children experience a very different immune response (i.e. reduced viral replication) to SARS-CoV-2 infection compared to adults, limiting the likelihood of severe COVID-19 in children.

   Source: https://childrenshealthdefense.org/defender/paul-elias-alexander-children-zero-risk-covid/

6. Evidence: Pfizer has added an ingredient to their COVID-19 vaccinations to be used in pediatric doses for children between five and 11 years of age. See page 14 of the "Vaccines and Related Biological Products Advisory Committee Meeting" from October 26, 2021. It is stated that "*authorization is being requested for a modified formulation of the Pfizer-BioNTech COVID-19 Vaccine. Each dose of this formulation contains 10 μg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 that is formulated in lipid particles and supplied as a frozen suspension in multiple dose vials. To provide a vaccine with an improved stability profile, the Pfizer-BioNTech COVID-19 Vaccine for* ***use in children 5-11 years of age uses tromethamine (Tris) buffer*** *instead of the phosphate buffered saline (PBS) as used in the previous formulation and excludes sodium chloride and potassium chloride.*" What is most concerning is that tromethamine is utilized for correction of metabolic acidosis and is known as a stabilizer for heart attack victims.

   Source: Vaccines and Related Biological Products Advisory Committee Meeting — https://www.fda.gov/media/153447/download

7. Evidence: What are child's Risk/Benefit? A child's risk of infection with SARS-CoV-2 is extremely low. In Canada, as we show above, 8M kids between 0 to 19, it's reported that 23 have died 'WITH' COVID-19, between March 2020, to Jan 13, 2022. That equates to 0.0000288%.

   Among the 23 deaths reported, they occurred in children who had one or more underlying health complications such as asthma, obesity, or diabetes mellitus. Therefore, **0% of healthy children in Canada have succumbed solely to COVID-19.**

   While the death of any child is unthinkable, it is important to put into perspective the rate of pediatric deaths due to COVID-19 in contrast to rates of pediatric deaths associated with COVID-19 vaccines.

   Steve Kirsch references Toby Roger's analysis in the US that we would kill 117 kids with the vaccine to save one (1) from COVID-19. Pfizer's own study showed 4X the cardiac deaths in the group that got the vaccine.

   Also worth saying, by the time the kids vaccine roll out was happening, it is clear that many kids already had recovered from COVID-19. Their natural immunity should be considered as it is proven to be much more robust and longer lasting than any vaccine could, as it has always been.

   Source: https://stevekirsch.substack.com/p/we-will-kill-117-kids-to-save-one
   Source: https://tobyrogers.substack.com/p/what-is-the-number-needed-to-vaccinate
   Source: https://tobyrogers.substack.com/p/ten-red-flags-in-the-fdas-risk-benefit
   Source: https://www.statista.com/statistics/444868/canada-resident-population-by-age-group/
   Source: FDA's risk-benefit analysis of Pfizer's mRNA COVID-19 "vaccine" in children 5-11 https://www.fda.gov/media/153447/download
   Source: Canada Population-https://www.statista.com/statistics/1228632/number-covid-deaths-canada-by-age/

8. Evidence: There are several concerns when considering eligibility criteria of participants in the Pfizer clinical trial—which will end May 2, 2023. It should be noted that participants <18 years of age were not included in the original trial, and the study was greatly flawed and did show to be harmful As of Jan 2022, the Pfizer vaccine is currently being used for emergency use only, and is actually not yet fully approved for children ages 5 through 11.

The below Canadian Covid Care Alliance has these pages in their PDF “More Harms Than Good” showing there is ALL Risk and No Benefit for 12 to 15 years old's specifically. The Pfizer study, as small as it was, still shows kids are at zero 0% risk but instead presents a very real risk for vaccine adverse events. With only testing groups of 1,005 in vaccine and 978 in placebo, it is so small that you may not find 1 in 1,005, but they DID have at least one. Maddie de Garey is severely vaccine injured. She can no longer walk, eat, and is in pain all day. Pfizer actually ignored and is still ignoring this child’s adverse reactions.

12-15 ADOLESCENT TRIAL
ALL RISK, NO BENEFIT

- This study was severely underpowered, as **a study this small will not show up risk**.
  - Inoculated group - **1,005** (**0** tested positive for COVID-19)
  - Placebo group - **978** (**18** tested positive for COVID-19)
- Pfizer claimed these were great results, but since adolescents are at statistically 0% risk of death from COVID-19, and very low risk of severe illness, **the inoculation is of little benefit to them.** Instead, it presents a very real risk of adverse events.
- But the adolescent Pfizer study wasn't actually designed to find those. **A serious adverse event**, including death, that occurred at a 1/800 rate **might not even show up in a sample of 1,005** people.
- But in this case, it did. **Among the 1,005 adolescents, there WAS at least one serious adverse event - Maddie de Garay.**

“For children without a serious medical condition, the danger of severe Covid is so low as to be difficult to quantify.”
-COVID AND AGE, Oct 12, 2021, New York Times

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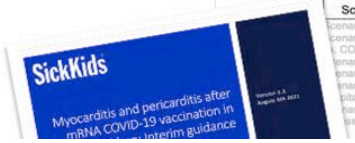
5 - 11 YEAR OLDS
RISKING THEIR HEALTH

Re: the 5 to 11 year old cohort

In this table, **Pfizer, using predictive modelling acknowledges that their inoculations WILL cause myocarditis**, but optimistically **claims there will be zero deaths** from myocarditis in any of their modelled (speculation, level 5 evidence) scenarios.

But **even if it were true,** there is no justification for causing harm to children this way. **FIRST, DO NO HARM.**

There is now such a high expectation of heart problems from the inoculations among children that **Sick Kids is putting out brochures on how to deal with them.**



FDA BRIEFING DOCUMENT
EUA AMENDMENT REQUEST FOR PFIZER-BIONTECH COVID-19 VACCINE
FOR USE IN CHILDREN 5 THROUGH 11 YEARS OF AGE

Table 14. Model-Predicted Benefit-Risk Outcomes of Scenarios 1-6 per One Million Fully Vaccinated Children 5-11 Years Old

	Benefits				Risks			
Sex	**Prevented COVID-19 Cases**	**Prevented COVID-19 Hospitalizations**	**Prevented COVID-19 ICU Admissions**	**Prevented COVID-19 Deaths**	**Excess Myocarditis Cases**	**Excess Myocarditis Hospitalizations**	**Excess Myocarditis ICU Admissions**	**Excess Myocarditis Deaths**
Males & Females								
Scenario 1	45,773	192	62	1	106	58	34	0
Scenario 2	54,345	250	80	1	106	58	34	0
Scenario 3	2,639	21	7	0	106	58	34	0
Scenario 4	58,851	241	77	1	106	58	34	0
Scenario 5	45,773	192	62	3	106	58	34	0
Scenario 6	45,773	192	62	1	53	29	17	0
Males only								
Scenario 1	44,790	203	67	1	179	98	57	0
Scenario 2	54,345	250	82	1	179	98	57	0
Scenario 3	2,639	21	7	0	179	98	57	0
Scenario 4	57,857	254	83	1	179	98	57	0
Scenario 5	44,790	203	67	3	179	98	57	0
Scenario 6	44,790	203	67	1	89	49	29	0
Females only								
Scenario 1	45,063	172	54	1	32	18	10	0
Scenario 2	54,345	250	78	2	32	18	10	0
Scenario 3	2,639	21	7	0	32	18	10	0
Scenario 4	57,938	215	67	2	32	18	10	0
Scenario 5	45,063	172	54	4	32	18	10	0
Scenario 6	45,063	172	54	1	16	9	5	0

Scenario 1: COVID-19 incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
Scenario 2: COVID-19 incidence at peak of U.S. Delta variant surge at end of August 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
Scenario 3: COVID-19 incidence as of
Scenario 4: COVID-19 incidence as of
Scenario 5: COVID-19 case incidence as
hospitalization, COVID-19 death rate 30
Scenario 6: COVID-19 incidence as of
as myocarditis cases 50% of Scenar

Low Level (Level 5 Evidence)
SPECULATION - A Predictive Model

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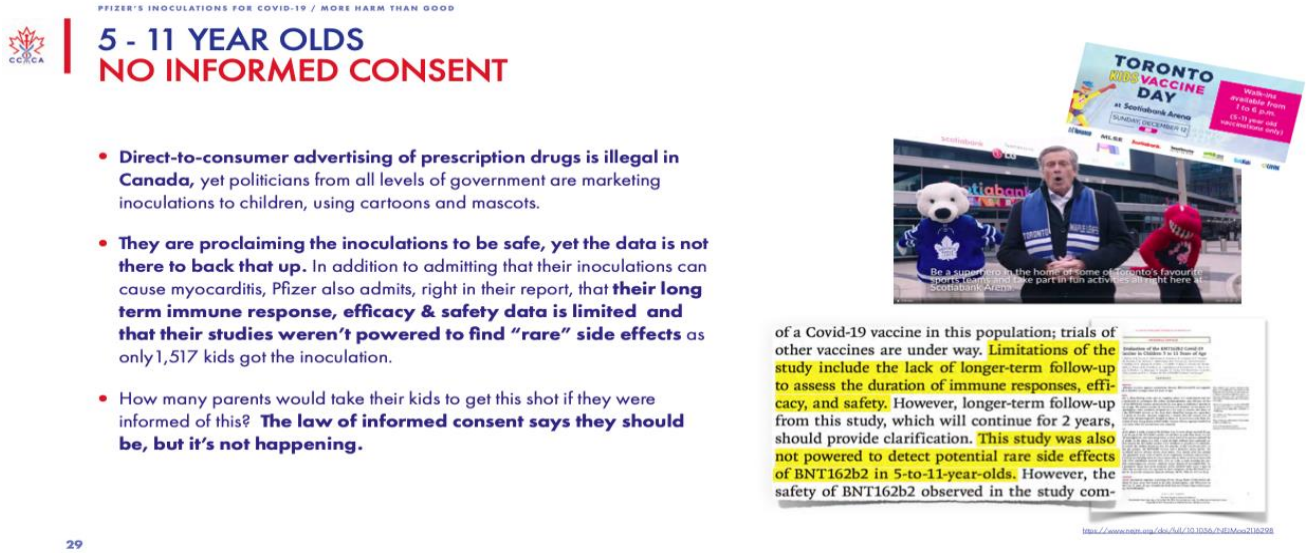


Furthermore, participants were deemed ineligible for participation in this clinical trial if they had: *

- diagnosis of HIV, hepatitis C or B
- a psychiatric condition
- a history of a severe reaction (i.e. anaphylaxis) to a vaccine or any component with the trial vaccine
- receipt of recent use of medications to treat COVID-19
- previous clinical or microbiological diagnosis of COVID-19
- history of chronic disease (i.e. hypertension, diabetes mellitus, chronic pulmonary disease, asthma, autoimmune disease or suspected immunodeficiency)
- current vape or cigarette use
- BMI >30 kg/m2
- anticipation of the use of immunosuppressive treatments within the next 6 months), etc.
- Pregnancy or breastfeeding, etc.*

*see link for exhaustive list of criteria deeming participants ineligible for COVID-19 vaccine clinical trials

"Exclusion Criteria" tells us which populations have not been studied. Therefore it cannot be stated with certainty that it is indeed safe to vaccinate excluded people. ***NOTE**: those with autoimmune disorders (starting their 3rd shots) and those who have previously been diagnosed with COVID-19 were not studied, but are receiving the vaccine. Dr. P McCullough stated "*...if a specific population has not been tested AT ALL in clinical trials, it is absolutely unethical and unlawful to mandate the vaccine in such a population.*"

Exclusion criteria are established in clinical studies to eliminate confounding (or influencing) factors, and to eliminate the inherent risk associated with untested pharmaceuticals in populations that are susceptible to greater injury or harm. Clinical trials currently being conducted by COVID-19 vaccine manufacturers state that there is not enough data to support the use of these therapies in a range of individuals with varying health complications. Of great concern is the current low tolerance of medical exemptions within B.C., as per the Ministry of Health's *COVID-19 Vaccine Medical Deferral* form. Many British Columbians will receive a COVID-19 vaccine without full informed consent regarding vaccine safety and effectiveness regarding their personal health matters. Unfortunately, exemptions are only to be considered on a strict need-be basis and must be officially approved by the sitting Public Health Officer. This makes obtaining a medical exemption an extremely difficult feat.

A prime example of the disconnect in communication to individuals in the population pertains to pregnant women. The province of B.C. is currently encouraging COVID-19 vaccination for pregnant and/or breastfeeding women, suggesting that COVID-19 vaccines "*...can be given safely at any time while trying to conceive, during pregnancy, or while breastfeeding*." This is very misleading marketing towards a vulnerable subset of individuals, risking both the health of a pregnant woman and that of an unborn child. Neither the Pfizer or Moderna COVID-19 vaccine has been tested for safety or efficacy in pregnant women. In fact, both vaccine manufacturers require that participants are not pregnant for either the duration of the trial, or for a set period of time at the outset of the trial (i.e. 3 months). Similar requirements are made regarding breastfeeding. Again, it is worth reiterating that these vaccines have not been sufficiently researched for short- or long-term deleterious outcomes in vulnerable populations. Preliminary clinical trials will be completed by October 2022 (Moderna) and May 2023 (Pfizer).

Source: https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf
Source: BC COVID-19 Vaccine Deferral Form — https://www2.gov.bc.ca/assets/gov/health/forms/2371fil.pdf
Source: BC Pregnancy and Breastfeeding Documentation — http://www.bccdc.ca/Health-Info-Site/Documents/COVID-19_vaccine/COVID19_Vaccine_Perinatal.pdf
Source: Pfizer Clinical Trial — https://clinicaltrials.gov/ct2/show/NCT04368728
Source: Moderna Clinical Trial — https://clinicaltrials.gov/ct2/show/NCT04470427?term=NCT04470427&draw=2&rank=1

9. Evidence: In a letter penned to Prime Minister Justin Trudeau and Chief Public Health Officer of Canada Dr. Teresa Tam, Rath & Company legal representatives state "*...pointing to Table 14 of a US Federal Drug Administration (FDA) briefing, the complainant alleges Pfizer has made a "fraudulent and completely scientifically-unsupportable claim "the Pfizer vaccine, if provided in a two-dose regimen to 5-11-year-old children will prevent between 0 and three deaths of children per million fully-vaccinated children.*" Rath & Company continue "*...the same table goes on to admit the Pfizer vaccine will cause, per million, between 53 and 106 excess myocarditis cases, 29 to 58 excess myocarditis hospitalizations and 17 to 34 excess myocarditis ICU admissions,*" the statement reads.

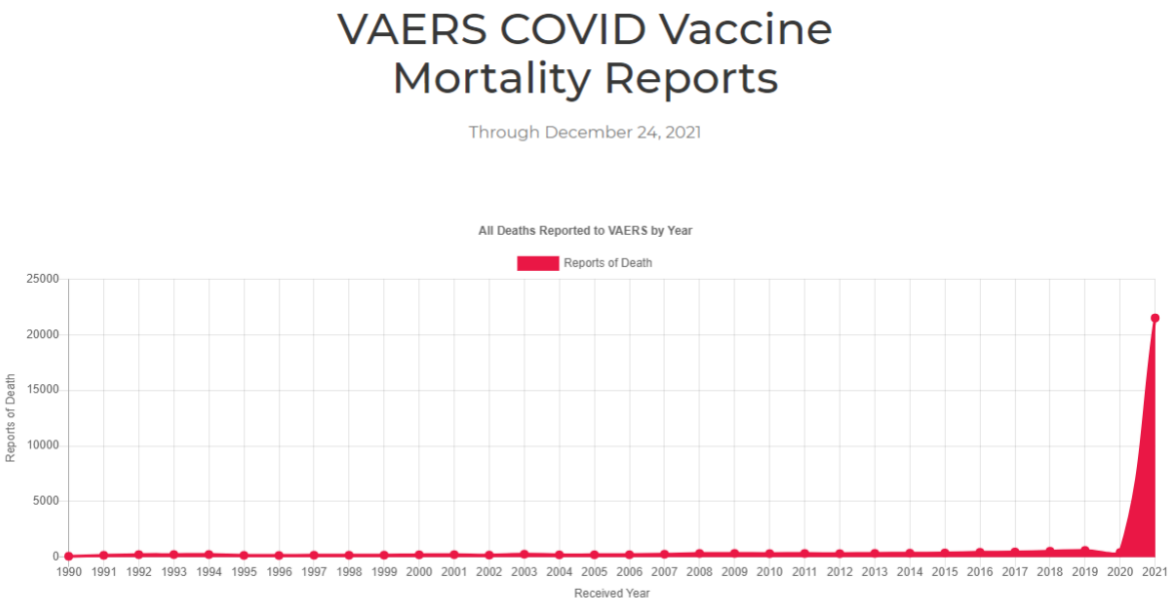
   Source: https://westernstandardonline.com/2021/11/alberta-lawyer-files-complaint-against-pfizer/

10. Evidence: Compilations of data suggest that vaccinating children will lead to "*[one] thousand or more excess deaths*", stated by the inventor of mRNA vaccine technology, Dr. Robert Malone. Three questions have been posed in regards to vaccinating children: 1) Do young children *need* vaccination against COVID-19? 2) Are the vaccinations *safe*? 3) Are unvaccinated children *a threat* to adults? In response, Dr. Paul Alexander states that "*...children don't experience severe [illness with COVID-19 and they] don't die from this infection.*" An exemplary model demonstrating that children are not at a severe risk from COVID-19 is Sweden. Sweden kept schools open during the height of the pandemic, and not a single child perished from COVID-19. Of the 1.95 million children ages 1 to 15 that were included in the study, 15 experienced COVID-19, multisystem inflammatory syndrome (MISC), or both conditions and were admitted to an ICU. This equates to 1 child in 130,000. kids

    Source: https://trialsitenews.com/dont-vaccinate-kids-urgent-message-from-doctors-summit/
    Source: Sweden study — https://www.nejm.org/doi/full/10.1056/NEJMc2026670

11. Evidence: Based on assessment of VAERS data, a large and unprecedented increase in vaccine deaths has occurred in 2021 with the introduction of COVID-19 vaccines compared to the previous 30 years (dating back to 1990) wherein COVID-19 vaccines did not exist. Between 1990 and 2020, an average of 153.3 deaths per annum occurred due to vaccinations of any kind, with a total of 4,599 occurring in a 30 year span.

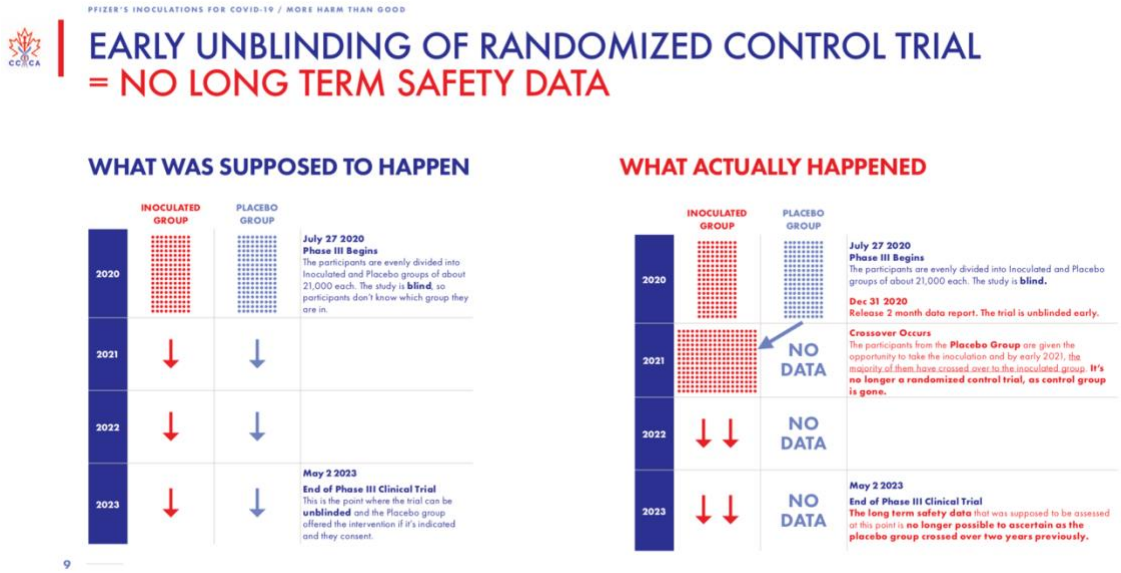
The following graphical representation of VAERS data between 1990 and 2021 begs the question, what has contributed to the drastic increase in vaccine-related deaths?

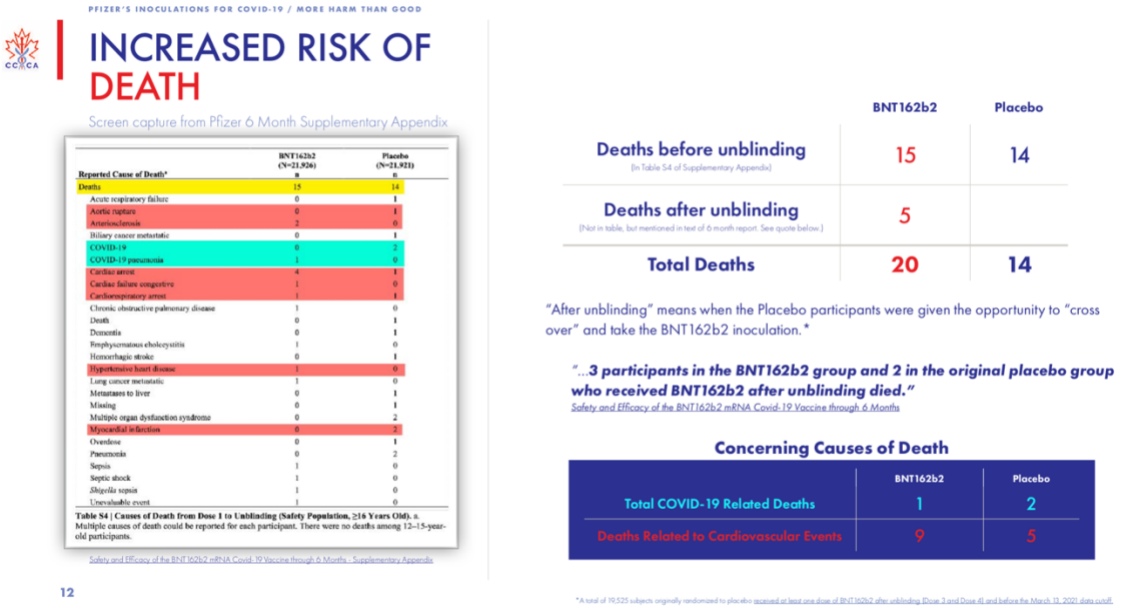


Source: https://peckford42.wordpress.com/2021/10/31/the-vaccine-death-coverup-first-published-in-may-by-virginia-stoner-follow-up-for-this-month-next-blog/
Source: https://openvaers.com/covid-data

12. Evidence: Many questions have been raised regarding the safety of Pfizer's BNT162b2 vaccine. Data included in the Pfizer trial, published by the New England Journal of Medicine, clearly demonstrates flaws in study findings. Vaccine efficacy follows peculiar trends on days 12 and 21, wherein efficacy abruptly jumps at day 12 to 91.7%, and shows no significant increase at day 21 when the second dose was applied to participants. This is in contrast to real-world data that suggests the efficacy of Pfizer to be only 57.0% within the first 12 days of administration.

    Another peculiarity in Pfizer's trial was the unblinding of placebo participants. Almost all participants that were in the placebo group were offered the BNT162b2 vaccine, which ended the placebo-controlled period of the trial. This is unheard of in the research industry, as adverse events and differences in outcomes between treatment (i.e. vaccinated) and control groups (i.e. unvaccinated) would be impossible to track. The data were reported to look as if unvaccinated participants (n = 21) experienced a greater death rate than vaccinated individuals (n = 17); in reality, the death rates after unblinding demonstrated that the Pfizer vaccine caused increased deaths compared to placebo (n = 20; n = 14; respectively).

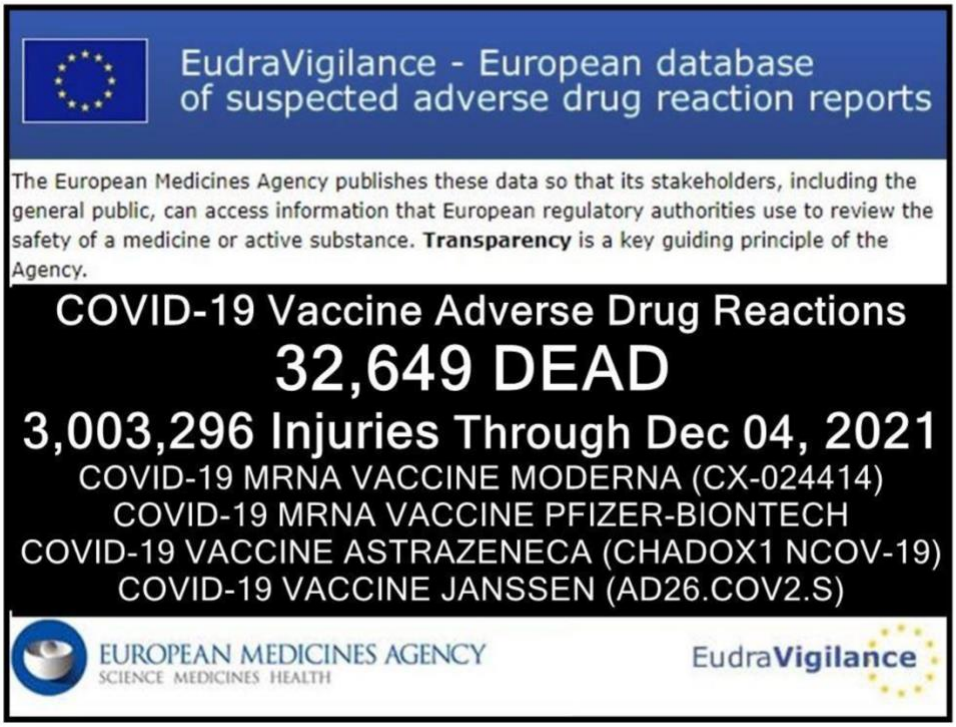




Source: Pfizer, see Post Marketing Doc — https://phmpt.org/pfizers-documents/
Source: Video — https://www.canadiancovidcarealliance.org/media-resources/the-pfizer-inoculations-for-covid-19-more-harm-than-good-2/
Source: Document — https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf
Source: Thomas et al. (2021) — https://www.nejm.org/doi/10.1056/NEJMoa2110345
Source: https://www.bmj.com/company/newsroom/covid-19-vaccine-trials-cannot-tell-us-if-they-will-save-lives/

13. Evidence: The EudraVigilance database within Europe is utilized to track suspected adverse drug reaction reports. Data is collected by the European Medicines Agency. As of December 4, 2021 there are **32,649 deaths** recorded as a result of COVID-19 vaccines. There have been **3,003,296 injuries** associated with

COVID-19 vaccines, wherein nearly half (1,409,643) are considered "serious". "Serious injuries" are classified as "*a medical occurrence that results in death, [is] life-threatening, requires inpatient hospitalization, results in another medically important condition, or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect*." These numbers are associated with the mRNA Moderna and Pfizer vaccines, as well as the AstraZeneca and Janssen vaccines.



Source: https://healthimpactnews.com/2021/32649-deaths-3003296-injuries-following-covid-shots-in-european-database-of-adverse-reactions-as-young-previously-healthy-people-continue-to-die/
Source: https://www.adrreports.eu/en/index.html
Source: WHO VigiAccess Database — http://www.vigiaccess.org/

14. Evidence: The WHO global database of reported potential side effects of medicinal products demonstrates the stark contrast in total adverse drug reactions (ADRs) for common and novel medicines, including the COVID-19 vaccine, dating from as early as 1968. The COVID-19 vaccine adverse reactions far exceed those of all others listed.

World Health Organization

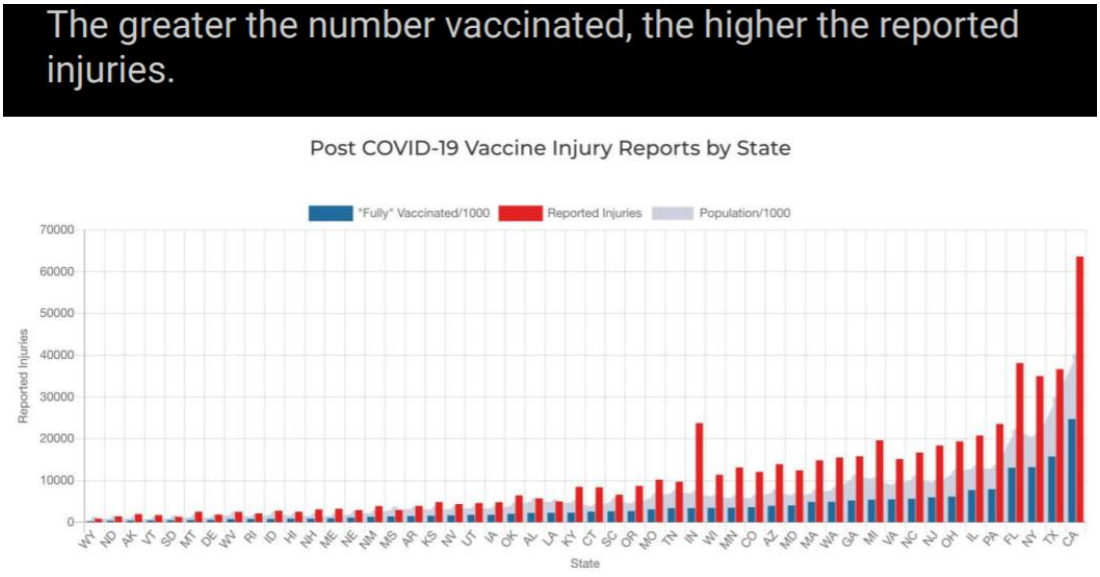
VigiAccess was launched by the World Health Organization (WHO) in 2015 to provide public access to information in VigiBase, the WHO global database of reported potential side effects of medicinal products.

Vaccine or Drug Name	Total ADRs	Years
Mumps vaccine	711	1972-2021
Rubella vaccine	2,621	1971-2021
Ivermectin	5,705	1992-2021
Measles vaccine	5,827	1968-2021
Penicillin nos	6,684	1968-2021
smallpox vaccine	6,891	1968-2021
chloroquine	7,139	1968-2021
tetanus vaccine	15,085	1968-2021
Hydroxychloroquine	32,641	1968-2021
Hepatitis A vaccine	46,773	1989-2021
Benzylpenicillin	51,327	1968-2021
Rotavirus vaccine	68,327	2000-2021
Accutane	70,719	1983-2021
Vancomycin	71,159	1974-2021
Hepatitis B vaccine	104,619	1984-2021
Polio vaccine	121,988	1968-2021
Meningococcal vaccine	126,412	1976-2021
Ibuprofen	166,209	1969-2021
tylenol	169,359	1968-2021
Aspirin	184,481	1968-2021
Pneumococcal vaccine	234,783	1980-2021
Influenza vaccine	272,202	1968-2021
Covid-19 vaccine	2,457,386	2020-2021

www.vigiaccess.org
Updated Nov. 12th 2021

Source: WHO VigiAccess Database — http://www.vigiaccess.org/

15. Evidence: In the US the greater the number of individuals vaccinated, the higher reported injuries become.



Source: CDC COVID Data Tracker
Source: https://openvaers.com/covid-data/adverse-events-by-state

16. Evidence: Clinical trials are imperative for determining safety profiles and efficacy of new pharmaceuticals, vaccines, and therapeutics. According to Health Canada, clinical trials must undergo four (4) phases:
    - **Phase 1:** These trials test an experimental drug on a small group of people for the first time. The purpose is to:
        - look at the drug's safety
        - find out the safe dosage range
        - see if there are any side effects
    - **Phase 2:** The drug is given to a larger group of people (usually 100 or more) to:
        - gather data on how well the drug works to treat a disease or condition
        - check the drug's safety on a wider range of people
        - figure out the best dose
    - **Phase 3:** The drug is given to even larger groups of people (usually 1,000 or more) to:
        - make sure it is still effective
        - monitor side effects
        - compare it to commonly used treatments
        - collect information about the drug that will allow it to be used safely on the market
    - **Phase 4:** These trials take place after the drug is approved and is on the market. Information is gathered on things like the best way to use a drug and the long-term benefits and risks.

    The current COVID-19 vaccines have not undergone sufficient investigation as per Health Canada's clinical trial timeline for pharmaceuticals. A global "clinical trial" is actively underway as individuals receive COVID-19 vaccinations, without full informed consent. Of concern is the lack of robust recording of potential negative side effects, long-term health outcomes, or key safety data following COVID-19 vaccination. These failures in the scientific process are due to negligence and short follow-up periods. Moreover, credible sources are being censored for sounding the alarm over safety signals that have presented in independent data analysis (i.e. data analysis performed outside of major institutions like the WHO, CDC, and vaccine manufacturers themselves). Moderna and Pfizer BioNTech will reportedly only follow clinical trial participants for 2 years following the second vaccination in a series. AstraZeneca and COVISHIELD will reportedly only follow clinical trial participants for 1 year. This begs the question—what comes of those who receive a booster? What clinical study is being performed on the individuals who receive a booster shot(s)? Are the associated risks with any degree of vaccination (i.e. one shot, two shots, three shots, etc.) with a COVID-19 vaccine sufficiently understood at this time, or is the current vaccine campaign negligent?

    Source: https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_approval_process_safety.pdf

17. Evidence: In an interview, Dr. Robert Malone details how the "common technical document"—a dossier of information that is submitted to various government authorities by Pfizer— disclosed that regulatory authorities across the world allowed Pfizer to submit a grossly incomplete document in support of initiating clinical studies, concerning the COMIRNATY product. Dr. Malone states that regulatory authorities allowed Pfizer to utilize data that was not developed from the COMIRNATY vaccine studies. Pfizer used data that was developed from other mRNA vaccines (not the COMIRNATY vaccine) and submitted it in place of the COMIRNATY data. Moreover, Pfizer used data that had been developed for other purposes and did not meet standard regulatory requirements for rigor. The data also didn't meet the norms for ensuring that the studies were performed in a well-controlled fashion. Dr. Malone details that biodistribution studies were done with other RNA proteins (i.e. the protein that makes a firefly tail glow, luciferase) and not with the RNA proteins

that were part of the actual vaccine. Distribution of the fat particles (lipids) were followed, but not the RNA proteins themselves. Watching the entire interview is recommended.

Source: https://thenewamerican.com/dr-robert-malone-this-is-the-largest-experiment-performed-on-human-beings-in-the-history-of-the-world/

18. Evidence: Doubts over the Pfizer vaccine trial and falsified data have been uncovered by a whistleblower, Brook Jackson, previous regional director for Ventavia Research Group, who were overseeing a Pfizer trial site. Concerns included quality control breaches, and "...g*laring inconsistencies and anomalies in specimen handling*."

    Source: https://maryannedemasi.com/publications/f/fresh-doubts-over-data-integrity-in-pfizer-mrna-trial
    Source: https://www.iambrookjackson.com/documentstore

19. Evidence: To further demonstrate the lack of data on COVID-19 vaccine safety, a pediatric study utilizing the Pfizer COVID-19 vaccine suggests that the vaccine is 100.0% effective in the 12-15 year old category. It is important to clarify that pediatric participants were followed for only 1 week following vaccination. No children in the vaccination group (n = 1131) tested positive for COVID-19 within 7-days post-receipt of the second dose (Frenck et al., 2021). Only 16 out of 1129 children tested positive for COVID-19, 7-days post-receipt of the second dose, in the placebo group. These results suggest that there is virtually no benefit for pediatric populations to be vaccinated. Furthermore, it is also important to stress that the number of children utilized in this trial was very small, with a very short median follow-up period (i.e. 2.4 weeks).

    Similar result have been demonstrated in Pfizer's trial in 5-to-11-year-olds, wherein efficacy was determined to be 90.7% within 7-days post-receipt of the second dose (Walter et al., 2021). Within the FDA Pfizer EUA submission for children ages 5 through 11, the following is stated: "*...at the lowest evaluated COVID-19 incidence (corresponding to the June 2021 nadir), the predicted number of vaccine-associated myocarditis cases was greater than the predicted number of COVID-19 hospitalizations prevented for males and for both sexes combined. However, in consideration of the different clinical implications of hospitalization for COVID-19 versus hospitalization for vaccine- associated myocarditis, and benefits related to prevention of non-hospitalized cases of COVID- 19 with significant morbidity, the overall benefits of the vaccine may still outweigh the risks under this low incidence scenario.*"

    A study conducted by Song et al. (2021) in children ages 5 to 11 concluded "...*severe disease course or death is low....in fact, the case fatality could not be calculated due to an absence of cases for children without comorbidities*." Furthermore, it is clearly demonstrated that natural infection with SARS-COV-2 is not a significant threat to children ages 5 to 11; the overall hospitalization rate associated with SARS-CoV-2 infection was 35.9 per 10,000 children, ICU admission rate was 1.7 per 10,000 and case fatality was 0.09 per 10,000. Vaccination of this age demographic is unnecessary due to low incidence of COVID-19. Finally, vaccination of children likely will result in greater harm than benefit.

    Source: Walter et al. (2021) — https://www.nejm.org/doi/full/10.1056/NEJMoa2116298
    Source: Frenck et al. (2021) — https://www.nejm.org/doi/full/10.1056/NEJMoa2107456
    Source: Song et al. (2021) — https://www.medrxiv.org/content/10.1101/2021.11.30.21267048v1
    Source: FDA Pfizer EUA Submission: 5 through 11 years of age — https://www.fda.gov/media/153447/download

20. Evidence: The FDA admits that no studies have been performed on pregnant or breastfeeding women. One of the most vulnerable societal groups is receiving an experimental vaccination wherein data is completely lacking. An excerpt from the official FDA website states: "*Q: Can pregnant or breastfeeding women receive Pfizer-BioNTech COVID-19 Vaccine? A: While there have been no specific studies in these groups, there is*

no contraindication to receipt of the vaccine for pregnant or breastfeeding women. Pregnant or breastfeeding women should discuss potential benefits and risks of vaccination with their healthcare provider."

Source: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-COVID-19/pfizer-biontech-COVID-19-vaccine-frequently-asked-questions

21. Evidence: Recent data from VAERS shows 2,620 fetal deaths associated with COVID-19 vaccination. This alarming data demonstrates more fetal deaths associated with COVID-19 vaccines than all fetal vaccine-related deaths reported regarding all vaccines for the past 30 years, as per VAERS. Ectopic pregnancies are not included in these statistics, which also result in fetal death. Of concern in Vancouver, B.C., Canada, 13 stillborn babies were born in a 24-hour period at a B.C. hospital which has been taken to the RCMP based on medical concerns filed by Dr. Daniel Nagase and Dr. Mel Bruchet. An additional 86 stillbirths (from fully vaccinated mothers) have been reported in a Waterloo, Ontario hospital between January 2021 and July 2021. In a given year, the Waterloo hospital normally experiences 5 to 6 stillbirths annually. Finally, an investigation is being conducted in Scotland as 21 newborn babies have suddenly died within 28 days following birth, equivalent to a rate of 4.9 deaths per 1,000 births. This infant death rate has not been observed since the 1980s; the average infant death rate in Scotland for the years 2016 - 2020 was 2.2 per 1,000, suggesting that an outside variable may be influencing neonatal outcomes.

Source: https://healthimpactnews.com/2021/vaers-data-reveals-50-x-more-ectopic-pregnancies-following-covid-shots-than-following-all-vaccines-for-past-30-years/
Source: Vancouver, B.C., Canada— https://breaking-news.ca/13-stillborn-deaths-in-24-hours-rally-lions-gate-hospital-vancouver-british-columbia/
Source: Waterloo Hospital, Ontario, Canada — https://www.facebook.com/EdmontonFreedomCentral/videos/4278212242308603/?extid=CL-UNK-UNK-UNK-AN_GK0T-GK1C&ref=sharing
Source: https://www.thescottishsun.co.uk/news/8026264/scotland-newborn-deaths-probe/

22. Evidence: According to the news source *The Pulse*, "*...previously confidential Pfizer documents have been released by the FDA revealing that there were tens of thousands of adverse reactions reported worldwide from Pfizer's COVID vaccines within the first two months of 2021. The newly published 91 pages of the documentation is the first drop down of over 300,000 requested pages. A plaintiff group of professors and scientists filed a freedom of information act (FIOA) to access all the information the FDA reviewed before licensing the Pfizer vaccine.*" This demonstrates that Pfizer was aware early on in the COVID-19 vaccine campaign of the dangerous nature of their product.

Source: https://thepulse.one/2021/11/25/pfizer-was-aware-of-over-50k-serious-covid-vaccine-reactions-with-months-of-distribution/
Source: Pfizer documents, direct link — https://phmpt.org/pfizers-documents/

23. Evidence: Dr. Aseem Malhotra, a consultant cardiologist, explains that markers associated with increased heart attack and progression of underlying heart disease risk (within 5 years following vaccination) has significantly increased from 11.0% to 25.0%. A whistleblower from a prestigious British research institute has come forward, stating that they have found similar data and outcomes within the coronary arteries that they have linked to mRNA COVID-19 vaccines. However, the whistleblower states that they are not going to come forward at this time with these findings because they are afraid to lose research funding from the drug companies. These findings are also corroborated by research from Dr. Steven Gundry.

Source: Dr. Aseem Malhotra interview — https://www.youtube.com/watch?v=gJ8t0qQ5R4I

Source: Dr. Steven Gundry report — https://www.coronavirustoday.com/2021/11/22/mrna-covid-19-vaccination-increases-endothelial-inflammatory-markers-and-acs-risk
Source: https://www.thecardiologyadvisor.com/home/topics/acs/acute-coronary-syndrome-acs-biomarkers-mrna-covid19-vaccine/
Source: https://stevekirsch.substack.com/p/significantly-elevated-cardiac-risk

24. Evidence: A regional director who was employed at the research organization Ventavia Research Group has told The BMJ that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson, emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson has provided The BMJ with dozens of internal company documents, photos, audio recordings, and emails.

    Source: https://www.bmj.com/content/375/bmj.n2635
    Source: https://doctors4covidethics.org/explosive-british-medical-journal-expose-COVID-19-researcher-blows-the-whistle-on-data-integrity-issues-in-pfizers-vaccine-trial/

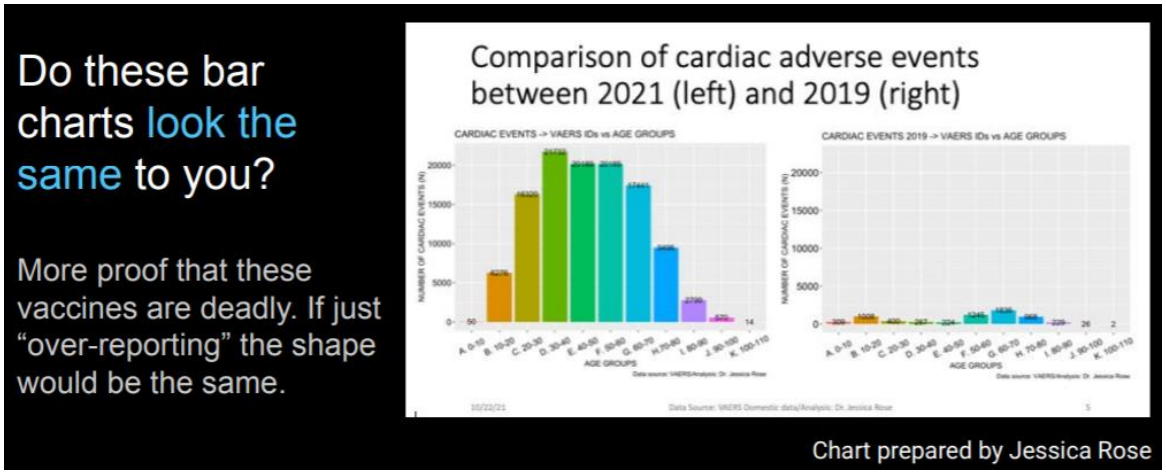
25. Evidence: Health Canada updates Pfizer-BioNTech and Moderna COVID-19 vaccine labels to include advisory on myocarditis and pericarditis — June 30, 2021.

    Source: https://recalls-rappels.canada.ca/en/alert-recall/health-canada-updates-pfizer-biontech-and-moderna-COVID-19-vaccine-labels-include

26. Evidence: Myocarditis appears to be a risk associated with both COVID-19 vaccination and natural infection with SARS-CoV-2. Dr. Peter McCollough details the difference between vaccine-induced myocarditis and myocarditis as a result of a natural infection with SARS-CoV-2. Dr. McCollough states that myocarditis can occur after vaccination with COVID-19 vaccines as lipid nanoparticles enter cardiac tissues. Once in cardiac tissues, the lipid nanoparticles express the spike protein, which is the expected mechanism of action. However, it has been demonstrated that expression of spike protein within cardiac tissues leads to an autoimmune-like attack on self-tissues, leading to heart inflammation. With a natural SARS-CoV-2 infection, the only deleterious marker that has been identified is short-term elevation of troponin.

    Source: https://mobile.twitter.com/TheChiefNerd/status/1453396847792373770?t=JXrWh1G2Wqo_a-BFIgLcuQ&s=09

27. Evidence: Analysis of VAERS data by Drs. Peter McCullough and Jessica Rose after distribution of Pfizer, Moderna, and Janssen COVID-19 vaccines demonstrated significantly higher rates of myocarditis—especially in youths—following both first and second vaccinations. Occurrence of myocarditis was significantly higher in those aged 13 to 23 ($p < 0.0001$), wherein 80.0% of myocarditis cases were reported in males. Assessment of VAERS data within 8 weeks of COVID-19 vaccine distribution showed that children who received a COVID-19 vaccine within the age range of 12 to 15 years old were 19x more likely to experience myocarditis compared to unvaccinated children in the same age range. A 5-fold increase in myocarditis was also observed following dose 2 versus dose 1 in 15-year-old males.

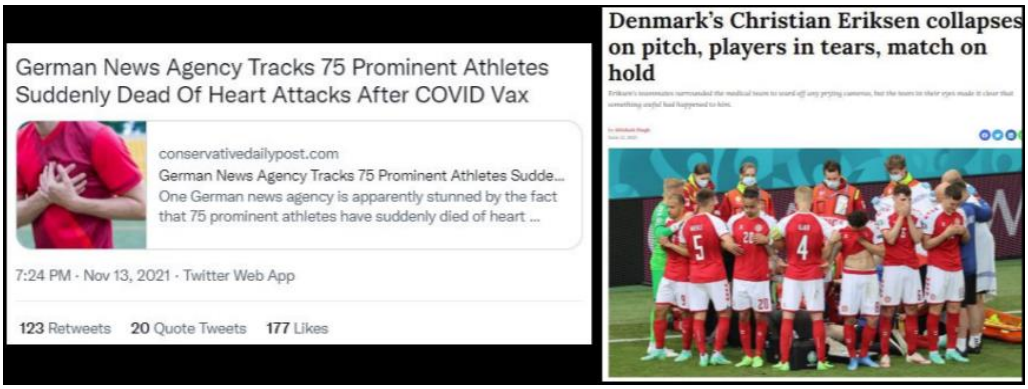


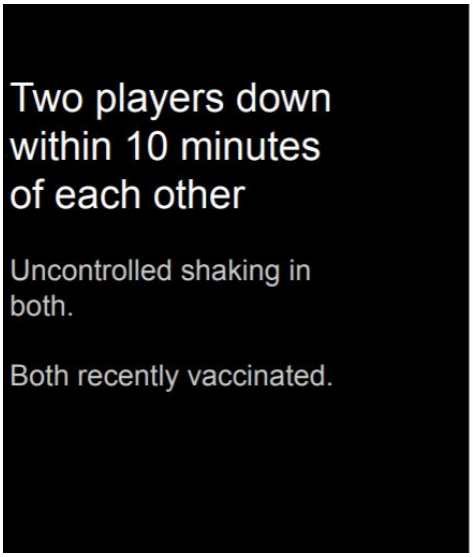
Source: Dr. Jessica Rose and Dr. Peter McCullough — "*A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products*" (PDF in OKHealthProf Letters thread)

28. Evidence: The US CDC is reporting higher-than-expected numbers of myocarditis in young people who have received mRNA-based COVID-19 vaccines, based on VAERS and Vaccine Safety Datalink (VSD) data. Some children experience myocarditis symptoms within as many as 4 days post-vaccination. Dr. Jacob Udell of University of Toronto states "*...[I am] not yet convinced myocarditis is only affecting men, or even just young men. Other unknowns include the degree of cardiac enzyme elevation with myocarditis and whether the ECG changes are consistent across all patients who develop the adverse reaction to mRNA vaccination. Additionally, it's not known if there is any left ventricular dysfunction associated with vaccine-induced myocarditis/pericarditis, he said.*"

    Source: https://www.tctmd.com/news/myocarditis-young-people-after-mrna-COVID-19-vaccination-higher-expected

29. Evidence: Athletes are experiencing a 60x higher rate of cardiac events on sports fields after vaccines rolled out. News articles are filled with similar stories and the video linked below provides a sobering number of healthy and fit athletes collapsing on their field of play. The only viable explanation is that these tragic events were caused by the vaccines.






Home / Sports / Cricket / 2 West Indies women cricketers collapse on field during T20I against Pakistan

2 West Indies women cricketers collapse on field during T20I against Pakistan

Two West Indies players collapsed on the ground within a span of 10 minutes, during the second T20I against Pakistan.

By: Sports Desk | Updated: July 3, 2021 5:25:07 pm


Former Atlanta Hawks guard Brandon Goodwin claims COVID-19 vaccine ended his season

Goodwin left nothing up to the imagination to his Twitch audience recently.

By Rashad Milligan | Oct 3, 2021, 7:00am EDT | | 28 Comments

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Source: https://stevekirsch.substack.com/p/over-a-60x-increase-in-serious-adverse
Source: https://thehighwire.com/videos/why-are-healthy-athletes-collapsing/
Source: https://thefreethoughtproject.com/soccer-player-collapses-star-calls-for-investigation/
Source: https://goodsciencing.com/covid/71-athletes-suffer-cardiac-arrest-26-die-after-covid-shot/
Source: https://stephenc.substack.com/p/5-fold-increase-in-sudden-cardiac
Source: https://thecovidworld.com/world-class-athletes-who-died-or-suffered-severe-injuries-after-covid-19-vaccine/

30. Evidence: Taiwan halts 2nd-dose Pfizer BioNTech vaccinations for ages 12-17 amid concerns of myocarditis. Cases of myocarditis and pericarditis have been reported after Pfizer COVID-19 vaccination of children between 12 and 17 years of age. According to U.S. statistics, the risk of youths experiencing myocarditis after receiving the second Pfizer dose is 10x higher than after the first dose.

    Source: https://www.taiwannews.com.tw/en/news/4340862

31. Evidence: How unlikely is a cluster of 8 pulmonary haemorrhage deaths in newborn babies in one month? It is a genuinely unlikely 'event'.

Source: https://www.normanfenton.com/post/how-unlikely-is-a-cluster-of-pulmonary-haemorrhage-deaths-in-new-born-babies

32. Evidence: A 12-year-old child, included in the Pfizer clinical trial, was hospitalized after being vaccinated with the Pfizer COVID-19 vaccine, ending up on a feeding tube. According to Patrick and Stephanie de Garay, their daughter "*...cannot walk, she cannot pee, she cannot go to the bathroom, she has anxiety now.*" Their daughter is considered "*one in a million", wherein the overseeing doctor, Dr. Robert Frenck, states that "...there is nothing [I] can do now*."

    Source: https://www.armstrongeconomics.com/international-news/disease/child-hospitalized-after-pfizer-vaccine-trial/

33. Evidence: A 39-year-old B.C. healthcare worker experienced a natural COVID-19 infection in April of 2020, and received her first COVID-19 vaccine in April 2021 ensuring a 6-month timespan between natural infection and first vaccination. Dawn Slykhuis experienced sharp shooting pain in her head within one month of her first vaccination, which was closely followed by diminished sensation in her left arm and a "sporadically spiked heart rate".

    Source: https://westernstandardonline.com/2021/10/bc-healthcare-worker-says-shes-still-suffering-adverse-effects-six-months-after-covid-shot/

34. Evidence: A Michigan school district was forced to close its doors after several staff members suffered adverse reactions following COVID-19 booster vaccinations. A school district representative noted that the closure was not due to COVID-19 illness, but rather due to vaccine reaction side effects.

    Source: https://newsrescue.com/michigan-school-shuts-down-after-large-number-of-staff-suffers-adverse-reactions-from-covid-booster-jab/

35. Evidence: Navigate through these 7 websites (more added each week to these sites as injuries increase, and more sites are created), detailing a variety of vaccine injuries. Vaccine injuries are happening on a large scale but are being purposefully buried or are not being associated with the vaccine. To disregard that vaccine injuries are happening and to not mention or acknowledge this in any of the public health officer's TV events is disrespectful. Considering right here in B.C., those who experienced disabling vaccine injuries from the first shot are not being advised to avoid the second shot. Citizens still not walking from the first injection are being treated as unvaccinated and not allowed in public spaces. They are still being told to get a different second shot. This showcases the total disregard for health and the true inability to understand that not all treatments are meant for every 'body'.

    Sources:
    https://nomoresilence.world
    https://www.wewanttobeheard.com
    https://www.c19vaxreactions.com
    https://www.vaxtestimonies.org/en/
    https://www.vaxlonghaulers.com
    https://www.countdowntothekingdom.com/the-tolls
    https://www.realnotrare.com

36. Evidence: A U.S. Army Doctor, Theresa Long a Lieutenant Colonel and Brigade Surgeon for the 1st Aviation Brigade, Ft. Rucker, Alabama has spoken out, stating that she has had to ground 3 out of 3 pilots due to vaccine injuries. Pilots reported feeling "*drunk*."

    Source: *Timestamp 1:12:22 on Rumble link*

https://rumble.com/vokrf7-senn.-johne ison-expert-panel-on-federal-vaccine-mandates.html

37. Evidence: Doctors and COVID-19 vaccine injured persons testify in Washington D.C. to Crimes Against Humanity. Senator Johnson has held meetings with testimony showing how dangerous the COVID-19 vaccines have been, giving a voice to those who have suffered injuries or lost loved ones who died after the shots. As per Senator Ron Johnson, "*If the vaccine worked and stopped transmission, those vaccinated would have no fear of the unvaccinated. If the COVID-19 vaccine does not stop transmission, then mandating them is pointless.*"

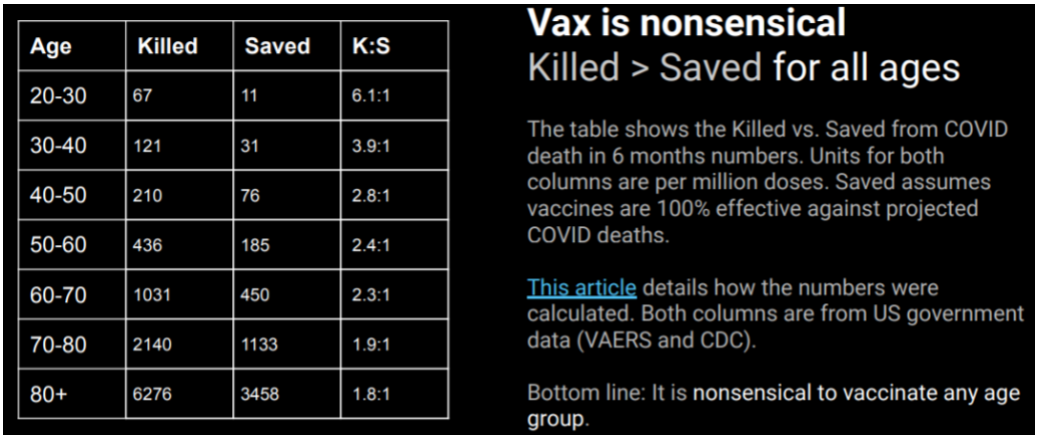
    Source: https://www.globalresearch.ca/doctors-COVID-19-vaccine-injured-testify-washington-dc-crimes-against-humanity-cdc-fda-nih-fauci-no-shows/5760593
    Source: https://rumble.com/vokrf7-senn.-johne ison-expert-panel-on-federal-vaccine-mandates.html

38. Evidence: Brianne Dressen—an AstraZeneca clinical trial participant from Utah and co-founder of the patient advocacy organization *react19.org* —was removed from the AstraZeneca trial due to a vaccine injury. AstraZeneca destroyed six months of clinical safety by eliminating Ms. Dressen from their trial. The National Institute of Health (NIH) instructed AstraZeneca to avoid talking about their research and will no longer accept calls regarding other vaccine injuries as a result of their product. Ms. Dressen states: "*...if the government won't help us….if the drug companies won't help us, who will?*"

    Source: *Timestamp 2:39:13 on Rumble link* https://rumble.com/vokrf7-senn.-johne ison-expert-panel-on-federal-vaccine-mandates.html
    Source: https://nomoresilence.world/miscellaneous/brianne-dressens-interview-with-del-bigtree/

39. Evidence: All therapeutics come with an inherent level of risk. There are no pharmaceutical drugs—nor vaccinations—that have absolute zero associated risk. **In 2010, the Supreme Court of the United States of America confirmed that vaccines are "unavoidably unsafe"** as vaccinations have not been thoroughly tested against inert placebo solutions to determine safety profiles. Specifically concerning the COVID-19 vaccine campaign, the number and severity of adverse reactions is exponentially larger than expected. The number of disabled—or worse, deceased—individuals as a result of this vaccination campaign thus far is alarming.

    The risk/benefit ratio is no longer justified. According to a cost/benefit analysis (by age) performed by Dr. Steve Kirsch, for every one person saved through vaccination, two people will succumb to death via an adverse reaction. For every individual saved by COVID-19 vaccination over the age of 20, six individuals will succumb to a vaccine-associated complication. Furthermore, Dr. Kirsch identifies that individuals ≥65 years of age are 5 times more likely to succumb to a COVID-19 vaccination than to the SARS-CoV-2 infection itself. As children have not been fully vaccinated yet, the values calculated for adults can only be extrapolated to the pediatric population. Thus, Dr. Kirsch's conservative calculations suggest that for every one child that is saved through COVID-19 vaccination, 16 children will succumb to vaccine-related complications.



Source: US Supreme Court of United States — https://www.supremecourt.gov/opinions/10pdf/09-152.pdf
Source: Steve Kirsch, *All You Need to Know About COVID Vaccine Safety* — https://www.skirsch.com/covid/All.pdf
Source: "This article" in graphic above - Steve Kirsch, *VCage* — https://www.skirsch.com/covid/VCage.pdf

40. Evidence: Taiwan's health authorities say that as of October 11, 2021 deaths after vaccination reached 865, while deaths from the virus are at 845, and admit that *"...the cure may be worse than the disease*."

Source: More Die After Vaccination Than From COVID-19 in Taiwan (ntd.com)

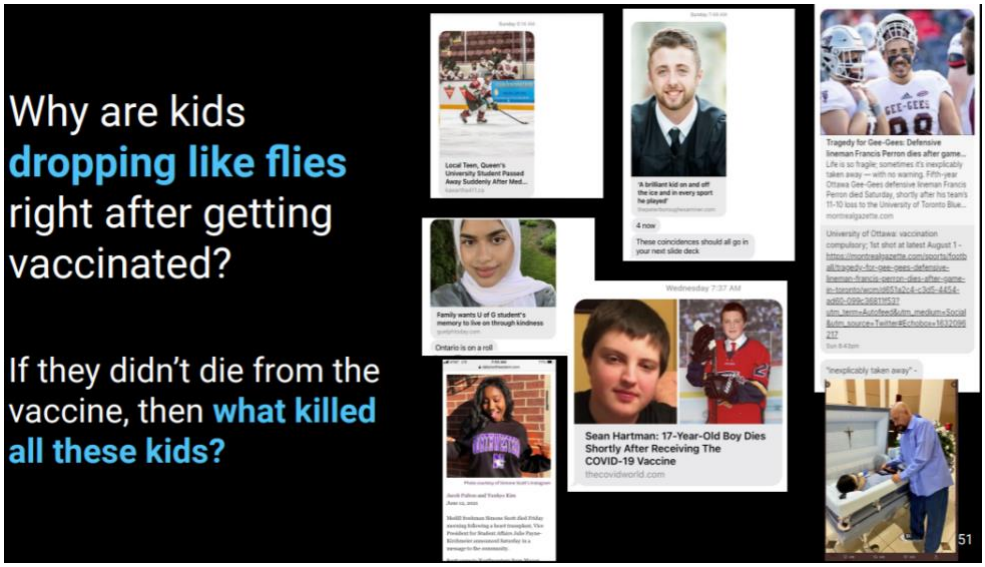
41. Evidence: In Germany, Dr. Stayer and Dr. Kapler demonstrate that excess mortality can be found in all 16 countries. The number of COVID-19-related deaths reported by the Robert Koch Institute in the period under review consistently only represents a relatively small part of the excess mortality, and above all, cannot explain the critical issue: the higher the vaccination rate, the higher the excess mortality. Paper translated in English.

Source: Dr. Stayer and Dr. Kappler report — https://www.skirsch.com/covid/GermanAnalysis.pdf

42. Evidence: Dr. Toby Rogers suggests that for every 1 child that the vaccine is purported to save, 117 children will experience an adverse reaction. The decision to continue this vaccine campaign by our policy makers is clearly contrary to the safety signals.

Similarly, data from an FDA briefing conducted by the advisory committee on September 17, 2021 regarding COVID-19 boosters suggests that for every one person saved via COVID-19 vaccination, two individuals will die as a result of vaccination. This data has been extracted from the VAERS database and verified by

four separate third party, non-USA analytic experts. Approximately 411 excess vaccine-related deaths will occur per 1 million doses of vaccine that are administered, which equates to 150,000 people who have died thus far in the COVID-19 vaccination campaign. Furthermore, VAERS data suggests that myocarditis—inflammation of cardiac tissues—will affect nearly 1 out of 317 boys (ages 16 to 17) following vaccination. With a booster shot, this will increase to 1 out of every 25 boys aged 16 to 17.



Source: Tober Rogers, PhD Report — https://stevekirsch.substack.com/p/we-will-kill-117-kids-to-save-one
Source: FDA panel — September 17, 2021 "*Vaccines and Related Biological Products Advisory Committee*" timestamp 4:20:15 https://www.youtube.com/watch?app=desktop&v=WFph7-6t34M

43. Evidence: According to Dr. Peter McCullough, the USA vaccinated 220 million Americans over a 10-week vaccination campaign against Swine Flu in 1967. Over 10 weeks, 25 sudden deaths (increasing to 53 by the completion of the campaign) and 550 reports of Guillain-Barré syndrome were recorded. Vaccinations were halted.

    Source: https://www.lifesitenews.com/news/covid-expert-dr-peter-mccullogh-urges-unbreakable-resistance-to-vaccines-for-kids

44. Evidence: Demands for more investigations into links to COVID-19 vaccinations after nearly 35,000 women in Britain report irregular menstrual cycles or period pain after receiving Moderna, Pfizer, and AstraZeneca COVID-19 vaccine. Data from the MHRA's Yellow Card Scheme also reports "unexpected vaginal bleeding". Similar incidences are being reported in the USA.

    Source: https://www.dailymail.co.uk/news/article-9993693/More-30-000-women-reported-period-disruption-getting-Covid-vaccine.html

45. Evidence: A study by Shimabukuro et al. (2021) in the New England Journal of Medicine (NEJM) demonstrates that 8 in 10 women experienced a miscarriage following a COVID-19 vaccination. Normal miscarriage rates during pregnancy are between 10.0 and 26.0%. This would suggest an increase in the rate of miscarriages by anywhere between 54.0% and 70.0%. This increase in risk of miscarriage is noteworthy and requires attention.

    Source: Shimabukaro et al. (2021) — https://www.nejm.org/doi/full/10.1056/NEJMoa2104983

Source: https://resistthemainstream.org/researchers-call-for-halt-on-covid-19-vaccines-for-pregnant-women-after-re-analysis-of-cdc-study/

46. Evidence: Alarming safety signals collected via OpenVAERS regarding reproductive health for both men and women have demonstrated concerning events such as miscarriages (3,511 cases), menstrual disorders (20,608 cases), and vaginal/uterine haemorrhaging (7,817 cases across all age categories), which have reportedly been attributed to COVID-19 vaccination. Moreover, adverse events such as testicular pain and swelling (1,406 cases), and erectile dysfunction (502 cases) have been reported in association with COVID-19 vaccination. ***NOTE:** These statistics continue to increase and reflect December 31, 2021 numbers. Check the link for current OpenVAERS data.

    Source: https://openvaers.com/covid-data/reproductive-health

47. Evidence: Multisystem inflammatory syndrome (MISC), a complication of SARS-CoV-2 infection, was reported in an otherwise healthy 17-year-old male adolescent following a second Pfizer-BioNTech COVID-19 vaccine. Onset of symptoms began five days post-vaccination and included vomiting, fever, myalgia, and chest pain. The patient had to be hospitalized two days after symptoms started with elevated systemic inflammatory parameters involving the gastrointestinal tract, skin, central nervous system, kidneys, liver, lungs, and heart. Increased coagulation was also noted. The patient also suffered myocarditis with a reduced ejection fraction of 20.0%.

    Source: MISC Case Study in Male Adolescent — https://onlinelibrary.wiley.com/doi/10.1111/apa.16141

48. Evidence: Reporting on safety signals by Albert Benavides demonstrates over 200 symptoms associated with COVID-19 vaccination that are occurring at a *higher relative rate* than myocarditis, the main post-vaccination symptom of concern in mainstream media. According to this assessment, more adverse events have been associated with COVID-19 vaccinations than all over vaccines (70+) combined over the last 30+ years. Symptoms of concern with extremely elevated 'X-factors'—values that determine the likelihood of association with COVID-19 vaccination— are detailed. An X factor > 10 indicates that a symptom is very likely to be caused by COVID-19 vaccination. Symptoms of concern include heavy menstrual bleeding (X factor = 8820), altered heart rate (X factor = 7973), and poly menorrhea/shortened menstrual cycle (X factor = 3780), Bell's palsy (X factor = 1533).

	Symptoms	C19 Count	Baseline count	X factor
2	Heavy menstrual bleeding	3,528	2	8820
3	Heart rate	3,189	2	7973
4	Magnetic resonance imaging head	1,512	2	3780
5	Angiogram pulmonary abnormal	609	1	3045
6	Weight	570	1	2850
7	Polymenorrhoea (menstrual cycle shortened)	562	1	2810
8	Maternal exposure during pregnancy	955	2	2388
9	Physical examination	470	1	2350
10	Blood pressure measurement	3,617	9	2009
11	Bell's palsy	3,065	10	1533
12	Facial discomfort	281	1	1405
13	Lung opacity	783	3	1305
14	Pain assessment	260	1	1300
15	Illness	4,088	17	1202
16	Vaccination site pruritus	4,179	18	1161
17	Menstrual disorder	2,043	9	1135
18	Disease recurrence	224	1	1120
19	Dysmenorrhoea (painful periods)	1,509	7	1078
20	Vital signs measurement	1,411	7	1008
21	Anosmia (loss of sense of smell)	3,187	16	996
22	Magnetic resonance imaging head abnormal	989	5	989
23	Anticoagulant therapy	1,537	8	961
24	Pulmonary embolism	2,672	14	954
25	Menstruation irregular	2,590	14	925
26	Oxygen saturation	1,031	6	859
27	Pulmonary thrombosis	512	3	853
28	Cerebral venous sinus thrombosis	167	1	835
29	Drug ineffective	2,697	18	749
30	Infusion	143	1	715
31	Poor quality product administered	2,091	15	697
32	Body temperature	9,230	75	615
33	Computerised tomogram neck	369	3	615
34	Oligomenorrhoea (infrequent menstrual periods)	462	4	578
35	Investigation	807	7	576
36	Taste disorder	1,939	17	570
37	Hypomenorrhoea (extremely light menstrual blood flow)	114	1	570

match | no match

Source: https://stevekirsch.substack.com/p/new-vaers-analysis-reveals-hundreds

49. Evidence: An internal memo was released from London Health Sciences Center (LHSC) on October 14, 2021 detailing the introduction of a never before utilized "pediatric stroke code". LHSC is one of Canada's largest acute-care teaching facilities in the Eastern province of Ontario. Starting October 15, 2021, a "Pediatric Stroke Code" was to be introduced at the London Children's Hospital for the purposes of handling "unexpected strokes" in children <18 years of age. In over 30 years, the hospital has not required the use of a pediatric stroke notification system. The introduction of this code coincides with the planned introduction of COVID-19 vaccines in pediatric populations (as young as 5 years of age) in some Canadian provinces. Furthermore, warnings from manufacturers for the risk of clotting associated with COVID-19 vaccines, wherein thrombosis is associated with increased risk for stroke. Finally, a blood thinning medication called *Pradaxa* has been authorized by the FDA for treatment of *venous thromboembolism* (i.e. blood clotting in veins) in pediatric populations, for children ages 3 months through 11 years of age. The simultaneous nature of these events (i.e. introduction of pediatric stroke codes, increased risk of clotting associated with COVID-19 vaccination, distribution of COVID-19 vaccinations to pediatric populations, and development of anti-thrombotic pharmaceuticals for pediatric populations) is cause for concern.

*__NOTE__: While children do experience the greatest incidence of COVID-19, they also experience the mildest symptoms of all age groups. As demonstrated on page 3, in Canada—across a 24-month span of dealing with COVID-19 (to January 13, 2022)—there have only been 23 COVID-19 deaths in the 0 to 19 age range. Meanwhile, in B.C. there have been 2 deaths over the same 24-month period in the 0 to 19 age range. Thus, the question becomes, "*is vaccination of this population necessary?*"

Sources: Internal memo from London Health Sciences Center (LHSC) - see PDF attachment (appendix)

Source: Sick Kids — Myocarditis and Pericarditis after mRNA COVID-19 vaccination in children: interim guidance https://www.sickkids.ca/contentassets/50c1bd3c95e74dcf9fa7c9f6fd707bd7/interim-guidance_myocarditis-pericarditis-after-mrna-COVID-19-vaccination-in-children.pdf
Source: Schools now implementing defibrillators — https://www.cbc.ca/news/canada/nova-scotia/ns-defibrillators-schools-1.5952119
Source: BC Govt https://www2.gov.bc.ca/gov/content/COVID-19/vaccine/plan#register
Source: CTV https://www.ctvnews.ca/health/coronavirus/canada-could-authorize-vaccine-for-kids-5-11-in-one-to-two-weeks-1.5663977
Source: Global News — Dr. Tam announces Pfizer vaccine for children https://globalnews.ca/video/8387167/COVID-19-canadas-top-doctor-provides-details-on-pfizer-vaccine-for-kids-aged-5-11
Source: FDA—*Pradaxa*: Oral Blood Thinning Medication for Pediatric Patients, ages 3 months to 11 years https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-blood-thinning-medication-children

50. Evidence: Dr. Daniel Nagase (MD) physician in both B.C. and Alberta discusses the potential increased cancer risk that mRNA vaccines impose on the pediatric population. Dr. Nagase details how mRNA injections against COVID-19 encourage the body to make foreign proteins, namely the COVID-19 spike protein. During pediatric developmental stages the immune system is vulnerable to influence by foreign proteins (i.e. found in mRNA vaccines). By adulthood, the immune system has learned to kill abnormal proteins, such as from cancer; however, when a child's body is tricked into producing a foreign protein (i.e. spike protein) its innate ability to recognize and destroy foreign protein in adulthood is diminished. The mechanism of COVID-19 vaccines may increase the risk of adulthood cancer incidence in children who receive one of these mRNA-based interventions.

    Source: https://gameruprising.to/index.php?threads/japanese-canadian-doctor-shares-his-concerns-on-cancer-risk-in-children-injected-with-mrna-jabs.30919/

51. Evidence: A UK Public Health England (PHE) Vaccine Surveillance Report and UK Health Security Agency (UKHSA) report demonstrate that double vaccinated individuals between the ages of 40 and 79 years of age have lost approximately 50.0% of their immune system capability. A loss of 5.0% of immune system capability per week (on average) has been demonstrated. Projections suggest that individuals aged 30-49 will have zero immune defense capabilities by January 2022. Vaccine effectiveness is calculated utilizing Pfizer's own vaccine effectiveness formula. According to evidence provided by Dr. Nathan Thompson and Dr. Ralph Baric at Cole Diagnostics in Idaho, USA, everyone ≥30 years of age will have lost 100.0% of their immune capabilities (for staving off illnesses such as viruses and cancers) by week 13, following COVID-19 vaccination.

    Source: https://theexpose.uk/2021/10/15/its-worse-than-we-thought-fully-covid-vaccinated-ade/
    Source: https://dailyexpose.uk/2021/10/30/gov-reports-show-fully-vaccinated-and-children-developing-ade/

52. Evidence: An America's Frontline Doctors article (cited below) details the dishonest and dangerous children's trial protocols which the FDA approved. It is clear that the FDA did not adequately perform their job to ensure safety for children with COVID-19 vaccines. Sadly, this is not the first time such a travesty has occurred under the watch of the FDA. The agency has previously approved drugs and medical products that it knew to be dangerous or untested. These incidents—and the corruption by top officials at the FDA—were clearly expressed in 2009 letters to President Obama and to Mr. John Podesta, written by whistleblowers at the Department of Health and Human Services, and obtained under the FOIA.

    In terms of the data from the trial which was unfortunately conducted upon the people of Israel without their consent (they were told that the vaccine was already FDA approved), this was a sham trial, as the government has not provided a proper reporting system to the citizens/trial subjects (until April 2021 the

Health Ministry form did not even ask for contact information, or allow for a description of adverse events, and any data collected is not made public) and doctors were instructed not to admit that any negative outcomes were connected to the shots. In fact, doctors and nurses are aware that if they speak out about the adverse effects of COVID-19 vaccinations, they will lose their jobs.

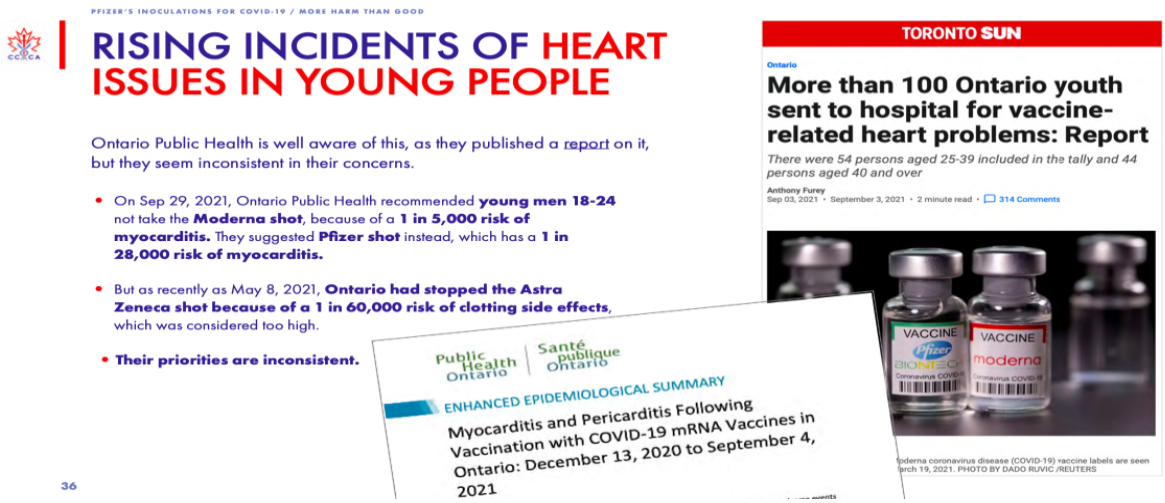
Source:
https://anthonycolpo.com/more-problems-with-the-pfizer-biontech-covid-19-vaccine-trial-data/
Source:
https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data
Source:
https://americasfrontlinedoctors.org/2/frontlinenews/serious-violations-and-manipulations-of-trial-protocol-how-pfizer-obtained-fda-emergency-authorization-for-children/

53. Evidence: There is no FDA approved COVID-19 vaccine available in Canada today. On August 23rd 2021, the FDA granted full approval for a COVID-19 vaccine to Pfizer-BioNtech for a specific product sold under the brand name Comirnaty. The landmark moment — the "full approval" endorsement from the FDA — was heralded by the Biden Administration and countless states, and quickly leveraged to coerce millions into taking the shots. This product, Comirnaty, was fully authorized for the "prevention of COVID-19 disease in individuals 16 years of age and older."

Source: https://dossier.substack.com/p/bait-and-switch-there-remains-no
Source: https://www.lewrockwell.com/2021/12/no_author/federal-judge-rejects-dod-claim-that-pfizer-eua-and-comirnaty-vaccines-are-interchangeable/

54. Evidence: The FDA advisory panel had no data showing these vaccines are safe before they were rolled out to the pediatric population. The FDA stated that a population level roll out was an appropriate way to test for adverse events per Dr. Eric Rubin's comment:

"We're never going to learn about how safe this vaccine is unless we start giving it. That's just the way it goes. That's how we found out about rare complications of other vaccines like the rotavirus vaccine. And I do think we should vote to approve it." Dr. Eric Rubin, FDA Advisory Panel Member, Editor in Chief of the New England Journal of Medicine.



Source: Video FDA Advisory Panel for ages 5 to 11 — https://www.youtube.com/watch?v=laaL0_xKmmA&t=24751s

Source: Kostoff et al., 2021 — https://www.sciencedirect.com/science/article/pii/S221475002100161X
Source: https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf

55. Evidence: Reiner Fuellmich—a leading German lawyer and member of the German Corona Investigative Committee—and a panel of investigators review COVID-19 vaccine injuries. They conclude that statistical graphs and injuries demonstrate intent and malfeasance on the part of COVID-19 vaccine manufacturers. It is evident that damaging health effects and vaccine injuries as a result of COVID-19 vaccination are known, but are being kept hidden from the public. It is clear that COVID-19 vaccine manufacturing companies are creating 'timed' hot lots of vials, leading to surges in health issues and deaths.

    Source: https://www.bitchute.com/video/M0vmjVc5mkQM/

56. Evidence: Dr. Patricia Lee, a fully vaccinated intensive care unit physician and surgeon, stepped forward after witnessing numerous serious injuries in her patients following COVID-19 vaccination. She had a Zoom meeting with six federal health officials, including Dr. Peter Marks of the FDA and Dr. Tom Shimabukuro of the CDC. They all denied her patient injuries were due to the jabs and refused to pursue and/or warn physicians. Now, with the help of a brave and ethical attorney, Aaron Siri, she will escalate to the oversight committee in US Congress.

    Source: Patricia Lee, ICU Whistleblower — https://aaronsiri.substack.com/p/update-on-physician-whistleblower
    Source: Submission of Dr. Lee's patient injuries to Congress — https://www.sirillp.com/wp-content/uploads/2021/12/2021_12_28-House-and-Senate-Comm.-Ltr-from-Dr.-Lee-391d325bab959f2541579f8165f5152d.pdf

57. Evidence: German government data for the alleged Omicron variant of COVID-19 suggests that most of the "fully vaccinated" population will have full blown COVID-19 vaccine induced acquired immunodeficiency syndrome (AIDS) by the end of January 2022, after confirming that the immune systems of the fully vaccinated have already degraded to an average of minus (-) 87.0%.

    Source: https://dailyexpose.uk/2022/01/02/german-gov-data-suggests-fully-vaccinated-developing-ade/
    Source: Robert Koch Institut Report - Wochenbericht_2021-12-30.pdf (rki.de)

58. Evidence: Studies of vaccinated individuals (in the UK, but also showing around the world) are showing a loss of immune system function along with ADE (Antibody Dependent Enhancement) and AIDS (Acquired Immunodeficiency Syndrome). Thus, vaccinated persons are at a much higher risk of getting sick with COVID-19 or any other disease or illness than unvaccinated persons, who still have capable immune systems. According to the PHE Vaccine Surveillance Report for Week 41, "*...in individuals aged greater than 30, the rate of positive COVID-19 tests is higher in vaccinated individuals compared to unvaccinated*."

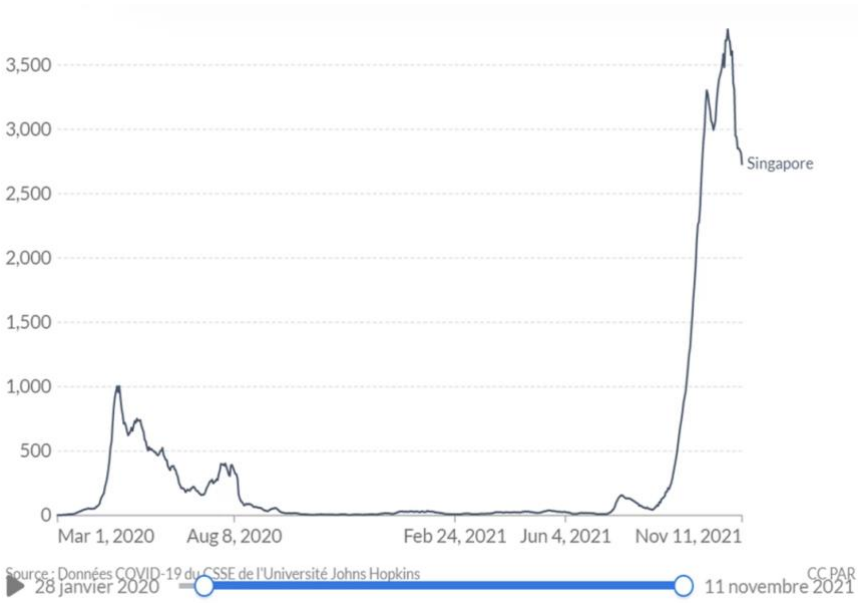
    Source: PHE Vaccine Surveillance Report — Week 41
    https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1025358/Vaccine-surveillance-report-week-41.pdf

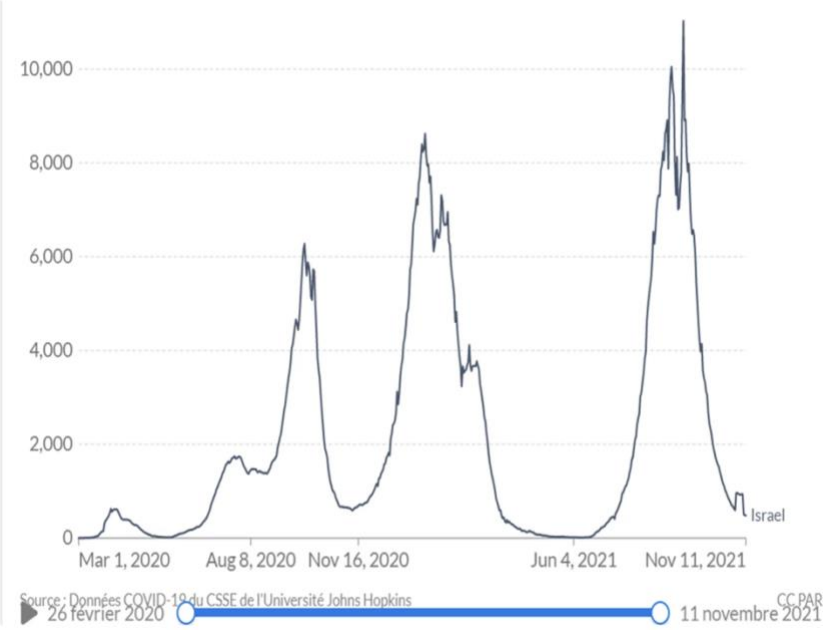
DR. BONNIE HENRY CLAIMS: — The vaccines are effective.

FACT CHECK: **FALSE** — Vaccines are **not as effective** as marketed, wherein persuasive date was improperly utilized to overstate efficacy (i.e. the use of a Relative Risk Reduction (RRR) calculation instead of an Absolute Risk Reduction (ARR) calculator). Breakthrough cases are common, particularly with new variants of concern such as Delta and Omicron. What was initially marketed as a two shot series has morphed into an ongoing series of booster shots.

59. Evidence: The 'champions' of COVID-19 vaccination—namely Israel and the UK—have demonstrated that the current approach to global immunity through vaccination is nonsensical and "mythical". Data procured from Israel following the announcement that herd immunity had been achieved in Spring 2021 in the nation depicts a different outcome. Even following a very high rate of vaccination coverage, the nation still experienced several new waves of daily record cases. It is suggested that the vaccine's effectiveness did not reach even 39.0%, and that it lasted only a few months. Speaking in August of 2021, Dr. Kobi Haviv—medical director of a major hospital in Jerusalem—stated that 85.0-90.0% of hospitalizations were in the vaccinated population, and 95.0% of severe hospitalizations were in vaccinated individuals.

    Similar incidences are occurring globally. Singapore has nearly 90.0% of its population vaccinated and yet is experiencing one of their largest waves of COVID-19 infections. It has been declared by the finance minister, Lawrence Wong, that despite their high vaccination coverage "... *Singapore will not achieve herd immunity during the pandemic.*"





Source: https://www.globalresearch.ca/trends-in-mortality-and-morbidity-in-the-most-vaccinated-countries-twenty-one-proven-facts/5761773

60. Evidence: Dr. Steve Kirsch details 22 reasons why individuals are choosing to not get vaccinated, including concerns regarding safety and all-cause mortality, infection rate reduction, hospitalization rate reduction, death rate reduction, long-haul COVID rate, deaths associated with vaccination, disablements associated with vaccination, and side effects of vaccination. In many cases, the risks associated with COVID-19 vaccination outweigh the risks associated with natural infection by SARS-CoV-2. Furthermore, the efficacy and enhanced benefit of COVID-19 vaccinations over natural immunity is questionable regarding infection rate reduction, hospitalization rate reduction, death rate reduction, and risk of death associated with treatment.

	Current Vaccines	**Early Treatment**
Safety/all cause mortality	Pfizer's 6 month data show higher all cause mortality using the vaccine vs. placebo. This makes the vaccine a complete non-starter no matter how effective it is. There should be at least one study that shows a net mortality benefit BEFORE we ever consider MANDATING a vaccine for anyone.	Extremely safe; drugs used have 40+ year safety track record. Treatment protocols are always beneficial and never make a patient worse.
Informed consent	Not even a single comprehensive risk report or risk-benefit analysis as of Aug 10, 2021	Risks of each drug are well known.
Infection rate reduction (higher is better)	8X (approaching 0 in Israel for Delta)	Over 7X if use ivermectin on alpha variant; 0% if no prophylaxis protocol
Hospitalization rate reduction (higher is better)	25X (approaching 0 in Israel for Delta)	>100X
Death rate reduction (relative risk compared to untreated) (higher is better)	25X (per CDC) (but approaching 0 in Israel; see text below)	>100X (see note)

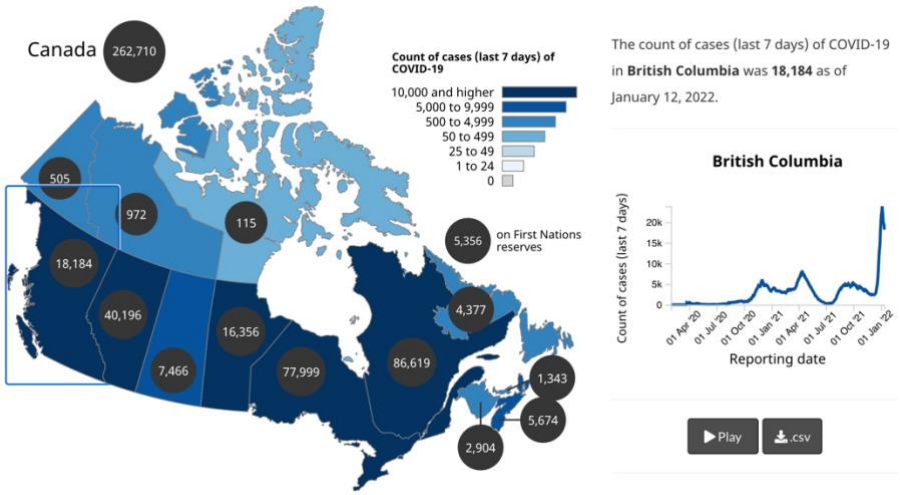
Long-haul COVID rate	~20%	~0% (if it wasn't 0, the NIH would be using that as a talking point)
# of Americans killed by the treatment itself (to date)	Approximately 150,000 (estimated over 10 ways; the CFR method is unassailable)	~0
Risk of death from treatment	~411 deaths per M doses	~.2 per B doses (around 2 million times fewer deaths than the vaccines)
# Americans disabled by the treatment itself to date	~300,000 (based on user surveys shown below as well as Facebook support group sizes of 200,000 or more)	~0 (we haven't found one yet; there are no Facebook early treatment side effects groups)
% of hospitalized patients today compared to # of untreated (lower is better)	9% (from CDC data)	~0% (if it wasn't zero, the NIH would be using that as a talking point)
% of hospitalized patients who die today from COVID compared to untreated (lower is better)	15.1% (from CDC data)	~0%

Source: Dr. Steve Kirsch, *Why are so many Americans refusing to get vaccinated? —* https://docs.google.com/document/u/0/d/1AD0lL3Rm4lDExo4q7McBxeeHOqO8bCWWerlGu7YJubQ/mobilebasic#

61. Evidence: Despite high vaccination rates across B.C.—89.0% of eligible people 12 and older in B.C. have received their first dose of COVID-19 vaccine and 83.0% received their second dose as per the October 15, 2021 B.C. COVID-19 pandemic update. The efficacy of the vaccines is in question and efficacy is highlighted by an October 15, 2021 report by CTV News, stating "*...there are dozens dead, [and] hundreds infected*" and there appears to be a "*...fight to conceal B.C. hospital outbreaks*". This was despite multiple attempts made by CTV News to obtain information and documentation through Freedom of Information Act (FOIA) requests. Fraser Health fought a months-long battle with a freedom of information request, ultimately resulting in 79 pages of written documentation, of which 55 pages' worth were redacted. Every page is marked "Confidential," and some say "Confidential Do Not Distribute."

    Source: https://bc.ctvnews.ca/dozens-dead-hundreds-infected-but-health-authorities-fight-to-conceal-b-c-hospital-outbreak-findings-1.5624106
    Source: B.C. COVID-19 Pandemic Update – October 15, 2021 B.C. COVID-19 pandemic update | BC Gov News

62. Evidence: The current vaccine campaign in B.C. does not appear to be effectively curbing the spread of COVID-19, as per the 'COVID-19 Daily Epidemiology Update', posted January 12, 2022. Data provided by the Government of Canada (for all provinces and territories) demonstrates in real time that the current approach to stopping the spread of SARS-CoV-2 is failing. Cases have increased exponentially after the deployment of COVID-19 vaccines across the province, as evidenced by a significant spike in cases in both May 2021 and August/September 2021, nearly five and eight months, respectively, after deployment of COVID-19 vaccines. Despite 89.0% of the population of B.C. over the age of 5 is fully vaccinated, 79.9% of people who are fully vaccinated account for COVID-19 cases (compared to 16.9% in unvaccinated persons and 3.2% partially vaccinated persons), and 64.1% of hospitalizations are in fully vaccinated persons (compared to 31.5% in unvaccinated persons and 4.4% in partially vaccinated persons).



Source: https://health-infobase.canada.ca/COVID-19/epidemiological-summary-COVID-19-cases.html

63. Evidence: A provincewide booster dose is the next step in B.C.'s COVID-19 immunization plan. "*We are starting to see a gradual decline in protection over time. As a result, we are taking the proactive step of expanding boosters to everyone in our province*," said Dr. Bonnie Henry. This suggests that the initial vaccination program—consisting of two doses for Moderna and Pfizer, and one dose for AstraZeneca (and now Jannsen)—are not as effective as stated. An interim statement issued January 11, 2022 by the WHO on COVID-19 vaccine boosters in the context of the Omicron SARS-CoV-2 strain states that boosters are not a viable strategy and that "new vaccines"—directed at the Omicron variant specifically—would be better for protection against transmission.

    Source: https://news.gov.bc.ca/releases/2021HLTH0189-002044
    Source: https://www.who.int/news/item/11-01-2022-interim-statement-on-covid-19-vaccines-in-the-context-of-the-circulation-of-the-omicron-sars-cov-2-variant-from-the-who-technical-advisory-group-on-covid-19-vaccine-composition

64. Evidence: Ireland has reported their highest COVID-19 numbers in hospital since March 2021, despite 91.0% of the population being vaccinated. Ireland has the highest vaccination coverage in all of the European Union. Ireland's vaccination coverage is representative of the vaccination coverage in B.C. as of November 2021, demanding attention as B.C. case counts continue to rise. Are vaccines as effective as they are claimed to be?

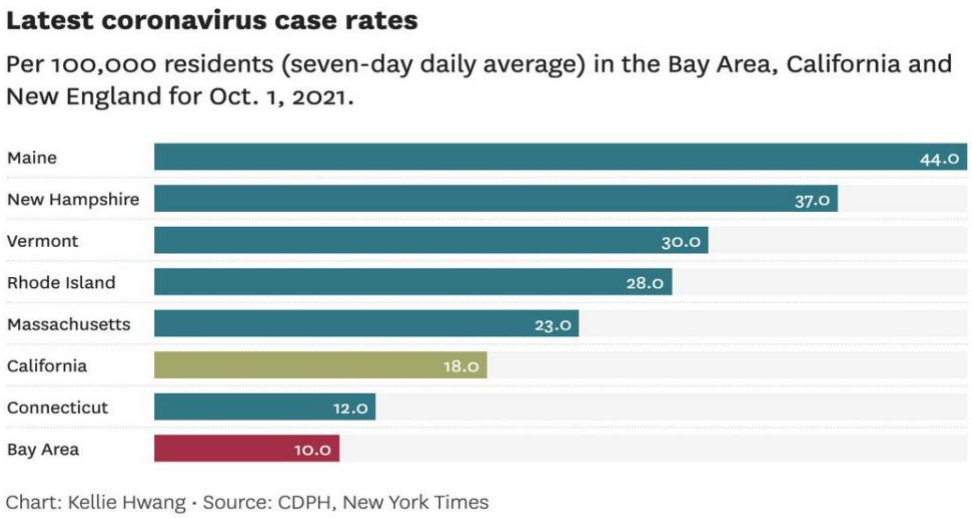
    Source: https://gript.ie/highest-covid-numbers-in-hospital-since-march-despite-91-jabbed/

65. Evidence: A study led by Goldberg et al. (2021) in Israel demonstrated that immunity to Delta strain wanes after Pfizer vaccination across all age groups. Israeli policymakers have now advanced to recommend regular boosters as a means to counteract the low efficiency of the vaccination campaign. Is this an effective option for controlling COVID-19?

    Source: https://www.theepochtimes.com/pfizer-COVID-19-vaccine-immunity-waned-regardless-of-age-israeli-study_4076286.html
    Source: Goldberg et al. (2021) — https://www.nejm.org/doi/pdf/10.1056/NEJMoa2114228?articleTools=true

66. Evidence: As per data analysis of 68 countries and 2947 US counties, vaccination rates are not linked to lower rates of COVID-19. In an article published October 15, 2021, the American state of Vermont—with an

exceptionally high vaccination coverage (99.9% of individuals > 65 years of age, and 74.0% of individuals ages 18-64)—experienced its greatest case rate of 30 cases per 100k residents. As reported by Subramanian and Kumar (2021) after examination of 68 countries and 2947 US counties "*...the trend line suggests a marginally positive association [between vaccination coverage and COVID-19 cases] such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people*." Furthermore, Subramanian and Kumar (2021) report "*...there also appears to be no significant signaling of COVID-19 cases decreasing with higher percentages of population fully vaccinated.*" Data gathered from regions around the world continue to demonstrate that high vaccination coverage does not translate to lower COVID-19 case rates.



Source: https://fee.org/articles/vaccination-rates-not-linked-to-lower-covid-rates-epidemiology-paper-finds/
Source: Subramanian and Kumar (2021) — https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/

67. Evidence: According to the CDC, there is effectively no difference between natural infection and vaccination regarding antibody synthesis and longevity of protection. Further research is needed to determine efficiency of the immune response to both COVID-19 vaccines and natural infection. Thus, enforcement of vaccination as a condition of employment, normal movement in one's community (i.e. patronizing a restaurant, movie theatre, sporting facility, etc.) based on the premise that natural immunity is not equivalent to immunity through vaccination is unfounded. As per the CDC: "*...available evidence shows that fully vaccinated individuals and those previously infected with SARS-CoV-2 each have a low risk of subsequent infection for at least 6 months. Data are presently insufficient to determine an antibody titer threshold that indicates when an individual is protected from infection*." Finally, the CDC claims "*...the immunity provided by vaccine and prior infection are both high but not complete (i.e., not 100.0%).*" Current British Columbian PHO mandates that suggest artificial immunity conferred through vaccination is superior are not only non-scientific, but are also discriminatory.

    Source: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html#

68. Evidence: A review of 15 studies performed by the Canadian COVID Care Alliance Scientific and Medical Advisory Committee concludes that natural immunity to COVID-19 is durable and long-lasting following infection with SARS-CoV-2. Stable B-cell immunity has been observed 6 to 12-months following infection, in the absence of vaccination. Further investigations are being conducted to determine the longevity of the B-cell response, and the underlying memory T cell response.

Source:
https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/10/Natural-Immunity-vs.-Vaccine-Induced-Immunity-FINAL-Oct-8-2021.pdf

69. Evidence: In COVID-19 survivors, important components of the body's immune response called memory B cells continue to evolve and get stronger for at least several months, producing highly potent antibodies that can neutralize new variants of the virus, as determined by Cho et al. (2021). By comparison, vaccine-induced memory B cells are less robust, evolving for only a few weeks and never 'learning' to protect against variants, researchers reported in a paper. Furthermore, Gazit et al. (2021) demonstrate that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity," an Israeli study said

    Source: Cho et al. (2021) https://www.nature.com/articles/s41586-021-04060-7
    Source: Gazit et al. (2021)
    https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1?fbclid=IwAR2h8FJo2kqsExdqIAwS85WfFTI0sBb1ymcWRN_EtV-59oLJiZKVeD1JbDs

70. Evidence: New Harvard healthcare worker study (HCW) shows recovered immunity is far stronger than vaccine protection. None of the patients who recovered from COVID-19 got reinfected. When HCWs (n = 423) were examined with infections occurring before vaccination, no re-infection was observed. This amounted to 74,557 re-infection-free person-days (starting 10 days after initial infection and censoring at the date of receiving their first vaccine dose) in persons who had previously been infected with SARS-CoV-2. In contrast, 49 infections were found in fully vaccinated persons over 830,084 person-days. Following vaccination, previously infected HCWs did not contribute any breakthrough infection events among the vaccinated HCWs.

    Source: https://stevekirsch.substack.com/p/new-harvard-hcw-study-shows-recovered
    Source: Lan et al. (2021) https://www.medrxiv.org/content/10.1101/2021.11.15.21265753v1.full

71. Evidence: In an article by Dr. Toby Rogers, it is revealed that the CDC normally relies upon guiding principles to determine a "number needed to vaccinate" (NNTV), covered in a previously described release titled "*Guidance for Health Economics Studies Presented to the Advisory Committee on Immunization Practices (ACIP), 2019 Update*". The NNTV is utilized to determine a risk-benefit analysis for newly developed therapeutics. Normally the "number needed to treat" (NNTT)—a similar term used to determine the effectiveness of pharmaceuticals—is utilized to determine how many individuals need to receive a pharmaceutical (or vaccine) to prevent a single case, hospitalization, admission to the ICU, or death. Various health economists have determined that the NNTV for COVID-19 vaccines range between 88 and 142 (Brown, 2021) or as high as 256 (Cunningham, 2020). Israeli researchers (Wallach et al., 2021) have estimated that the NNTV is between 200 and 700 to prevent one single case of COVID-19 for the Pfizer vaccination. Based on the same Israeli data, between 9,000 and 100,000 individuals were estimated to require vaccination to prevent a single death. What is most concerning is that the NNTV principles were completely disregarded concerning COVID-19 vaccination of children, ages 5 to 11. Children generally recover from COVID-19 with minimal symptoms and complications; thus, the NNTV for this age group would not warrant the need for vaccination, damaging the current campaign directed towards children.

    Source: Toby Rogers, PhD — NNTV https://tobyrogers.substack.com/p/what-is-the-number-needed-to-vaccinate
    Source: Ronald Brown, 2021 — https://www.mdpi.com/1648-9144/57/3/199/htm
    Source: Cunningham, 2020 — https://www.bmj.com/content/371/bmj.m4347/rr-4
    Source: Wallach et al., 2021 — https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_8c97b2396c2842b3b05975bfbd8254cb.pdf

72. Evidence: A Canadian doctor from Alberta—Dr. Christy Reich—suggests that government data demonstrates a short-term spike in COVID-19 cases, COVID-19 associated deaths, and COVID-19 associated hospitalizations following vaccination, usually within a defined 2-to-3-week period. An alarming number of elderly individuals ages 60+ seem to be disproportionately at risk of death within a 3-week period following COVID-19 vaccination.

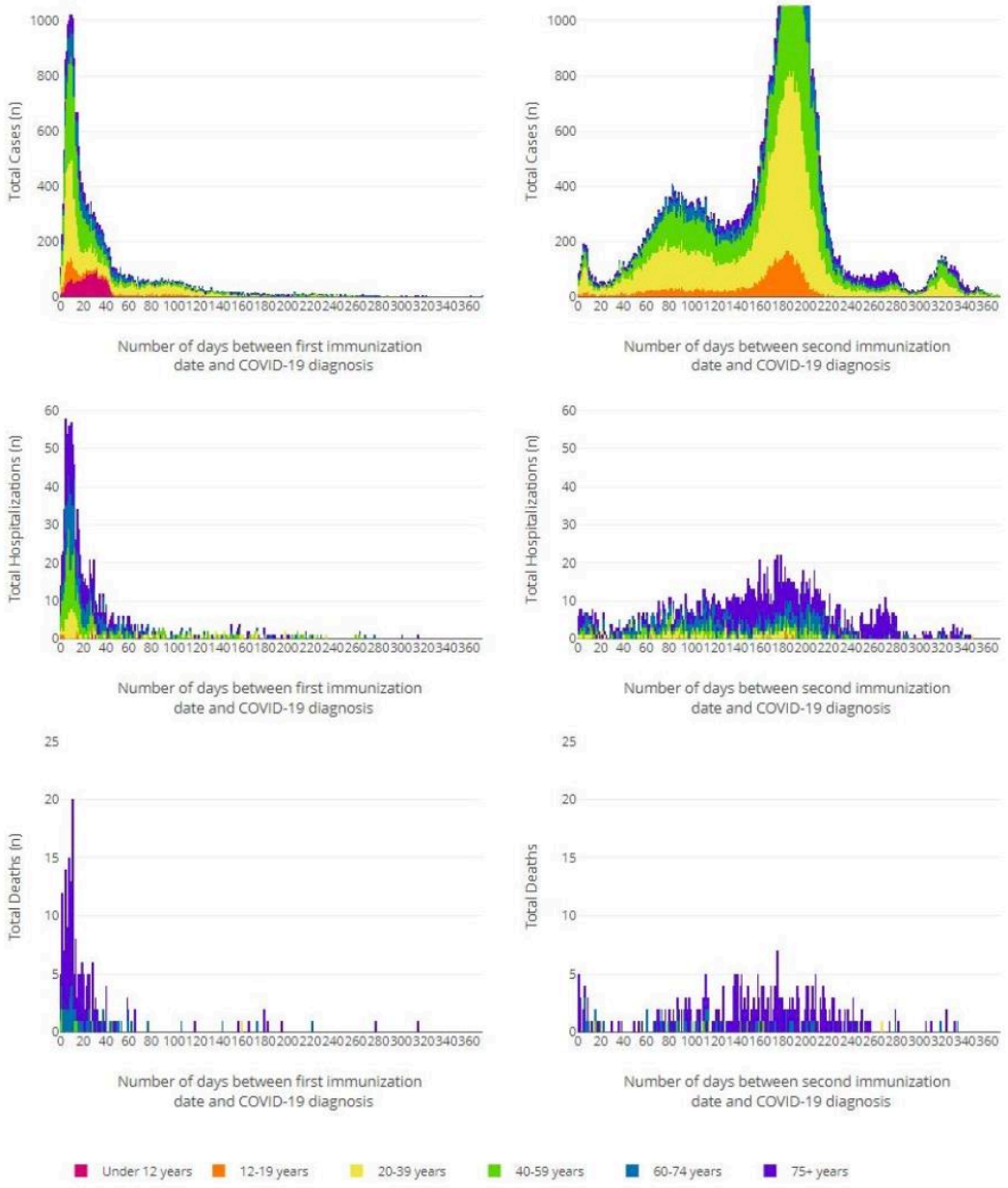


Figure 12: Time from first dose (left) and second dose immunization (right) to COVID-19 diagnosis by age group:
TOP: cases
MIDDLE: of those who became hospitalized
BOTTOM: of those who died from COVID-19
Note: First dose immunization also includes people who became a case prior to their second dose immunization date. COVID-19 hospitalizations reported are not due to immunization events.

Source: https://www.lifesitenews.com/news/canadian-doctors-claim-covid-jabs-causing-immunosuppression-and-the-governments-own-data-shows-this/
Source: https://westernstandardonline.com/2021/10/alberta-doctors-group-claims-vaccinations-cause-short-term-spike-in-covid-cases-deaths/
Source: https://www.alberta.ca/stats/COVID-19-alberta-statistics.htm#vaccine-outcomes
Source: https://metatron.substack.com/p/alberta-just-inadvertently-confessed

73. Evidence: According to a report by GlobalBC, fully vaccinated seniors made up nearly half of B.C.'s COVID-19 deaths in October 2021. A total of 47 out of the 82 deaths attributed to COVID-19 in BC in October 2021 were in persons aged 80+. Similar to the aforementioned data procured from the Alberta Government and Alberta Health Services, the vaccinated elderly people appear to be at a greater risk of COVID-19 associated death.

    Source: https://globalnews.ca/news/8349902/bc-COVID-19-update-november-4/amp/

74. Evidence: The American Heart Association has an eight yearlong study of the PULS score and wrote the following abstract regarding their current findings— abstract 10712: mRNA *COVID Vaccines Dramatically Increase Endothelial Inflammatory Markers and ACS Risk as Measured by the PULS Cardiac Test: a Warning.* They utilize the PLUS Cardiac Test (GD Biosciences, Inc, Irvine, CA) a clinically validated measurement of multiple protein biomarkers which generates a score predicting the 5 year risk (percentage chance) of a new acute coronary syndrome (ACS). The score is based on changes from the norm of multiple protein biomarkers. They conclude that "*...that the mRNA vaccines dramatically increase inflammation on the endothelium and [cause] T cell infiltration of cardiac muscle and may account for the observations of increased thrombosis, cardiomyopathy, and other vascular events following vaccination*."

    Source: https://www.ahajournals.org/doi/abs/10.1161/circ.144.suppl_1.10712

75. Evidence: Dr. Fleming breaks down the RRR and ARR using Moderna and Pfizer's own numbers from the EUA documents. Dr. Fleming also does a good job explaining the difference and there's a table he provides which may help you with wording, if you find it easier to understand. At the 2h:10min mark:

    Source: https://thehighwire.com/videos/live-from-event-2021-in-dallas-tx/

76. Evidence: Promoting the RRR instead of the ARR misleads the general population, exacerbating the non-factual concept that these vaccines prevent getting and spreading COVID-19. The National Library of Medicine website linked below states "*... the absence of the ARR in COVID-19 trials can lead to outcome reporting bias that affects the interpretation of vaccine efficacy*." Declaring that vaccinations are 94.0-95.0% effective is very misleading, as people often assume this means they have a 94.0% chance that they will not become ill with COVID-19. This is not true.

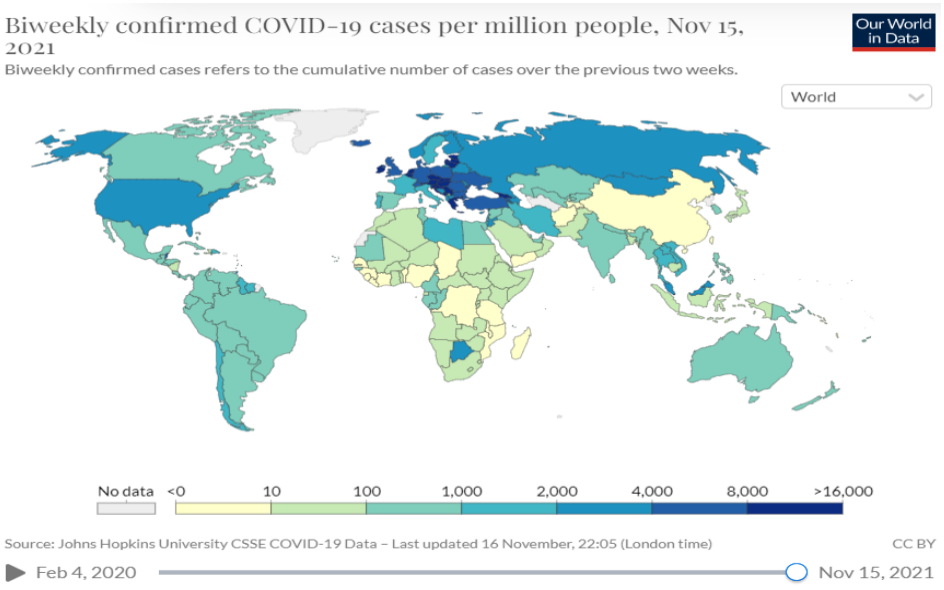
    ***NOTE:** The above published ARR values from the vaccine manufacturers show that COVID-19 vaccines *may* lessen COVID-19 symptoms by 0.84% (Pfizer) in those who receive a COVID-19 vaccine compared to those who do not. Furthermore, the verbiage utilized when describing improvements in outcomes refers to severity, a completely subjective term. The ARR does not demonstrate a significant improvement in outcomes—severe or not—following vaccination between vaccinated and unvaccinated individuals.

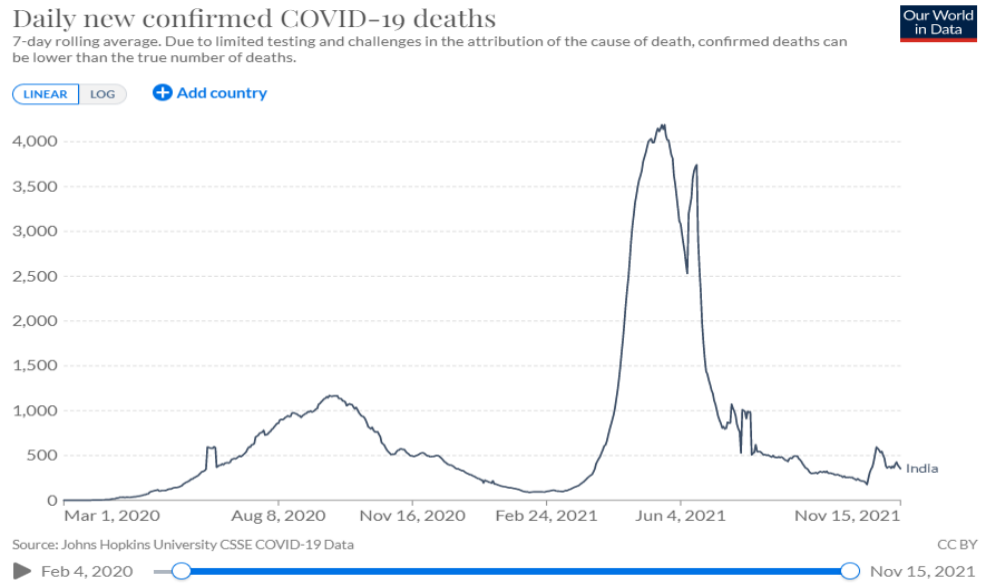
Source: Ronald Brown, 2021 — https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996517/
Source: https://www.instagram.com/p/CTkeaIalklG/?utm_medium=share_sheet

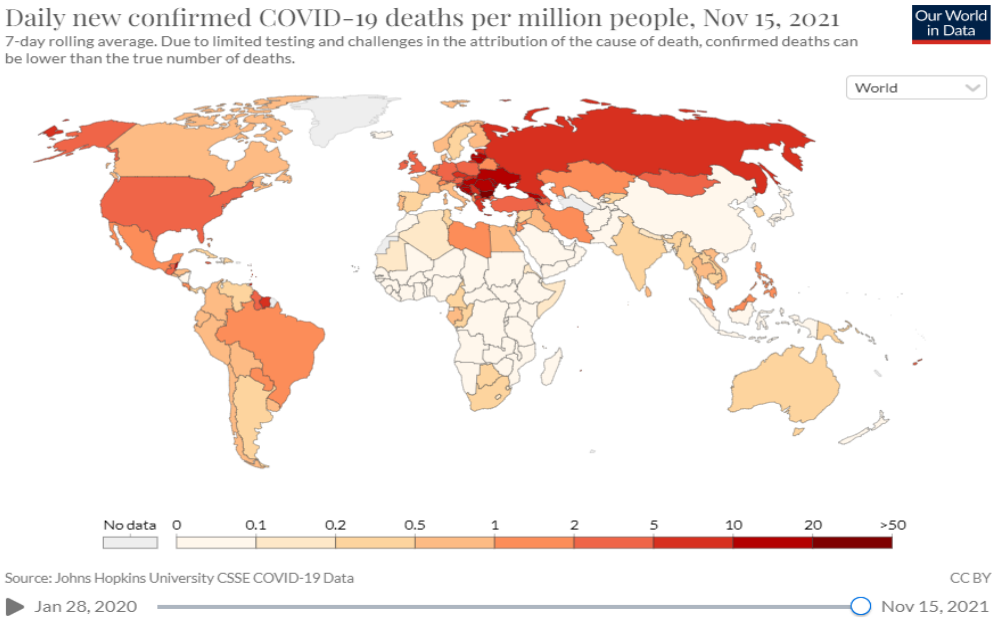
77. Evidence: Vaccines are proving to be ineffective, as per data extracted from Israel. Israel is one of the most vaccinated countries globally, with 80.0% of citizens ≥12 fully inoculated. As of August 24, 2021, Israel reported 9,831 new diagnosed cases, a hairbreadth away from the worst daily figure ever recorded in the country—10,000—at the peak of the third wave. At the same time, India recorded 354 deaths in a day. Israel was reporting 26 deaths and record high cases. See the following table:

Country	Population (M)	Vaccination rate	Covid deaths per million
India	1395	9.5%	0.25
Israel	8.7	80%	2.9

As of November 15, 2021, case rates per million remain low in India, as do the number of daily confirmed COVID-19 deaths. One might ask what is India doing differently than Israel. Could it be related to early treatment and the introduction of Ivermectin in 71of 75 districts?

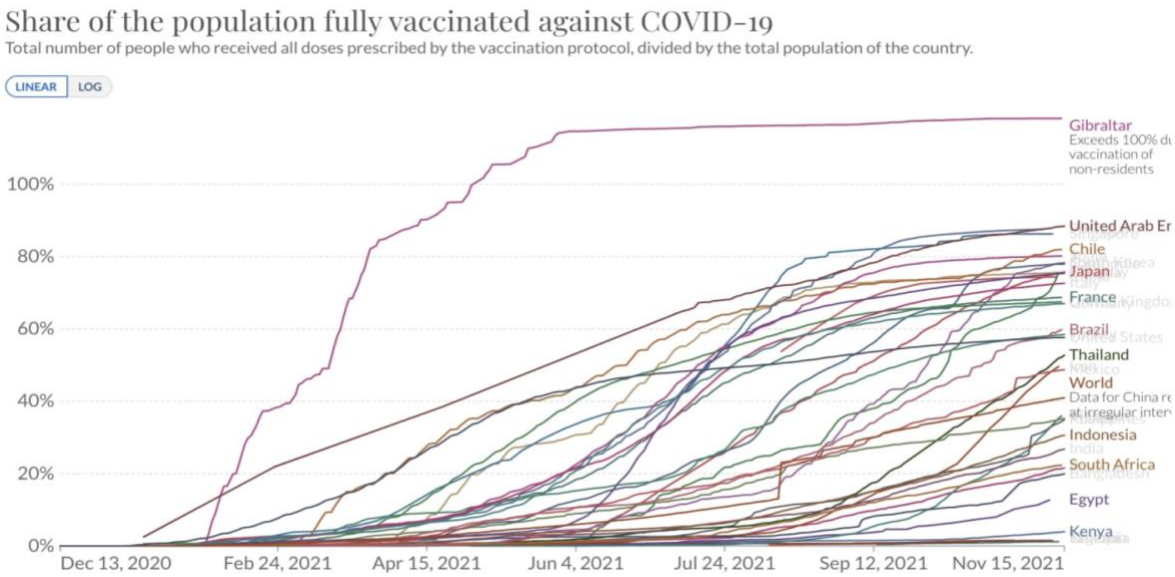






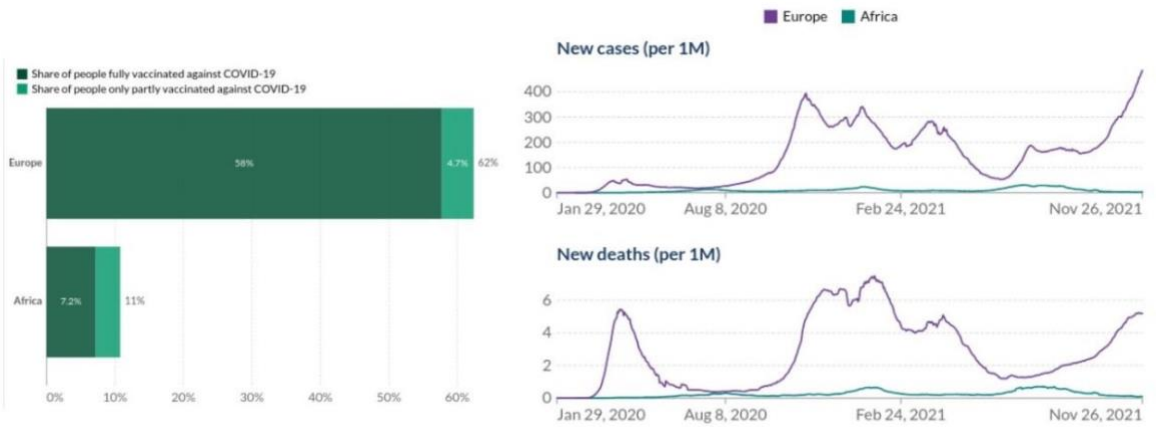
Source: https://ourworldindata.org/coronavirus/country/india
Source: https://www.thegatewaypundit.com/2021/10/update-71-75-districts-uttar-pradesh-india-reported-no-COVID-19-cases-24-hours-implementing-ivermectin-protocol/?utm_source=Gab&utm_campaign=websitesharingbuttons

78. Evidence: Christmas has been canceled in the "most vaccinated place on earth", Gibraltar, Spain. This raises concerns as Gibraltar has experienced an increase in cases, with 66 new daily infections reported on average. This is equivalent to 52.0% of its peak cases reported in January. Gibraltar has administered 94,469 vaccine doses thus far, which is enough to have fully vaccinated 140.2% of the country's population. Clearly the COVID-19 vaccine is failing in this region.



Source: https://www.standard.co.uk/news/world/christmas-cancelled-gibraltar-vaccinations-b966816.html
Source: Gibraltar Image — https://www.news.com.au/world/coronavirus/global/most-vaccinated-place-on-earth-told-to-cancel-holiday-plans-amid-exponential-rise-in-covid-cases/news-story/1954572a25f48e39b7825e562129b9bc

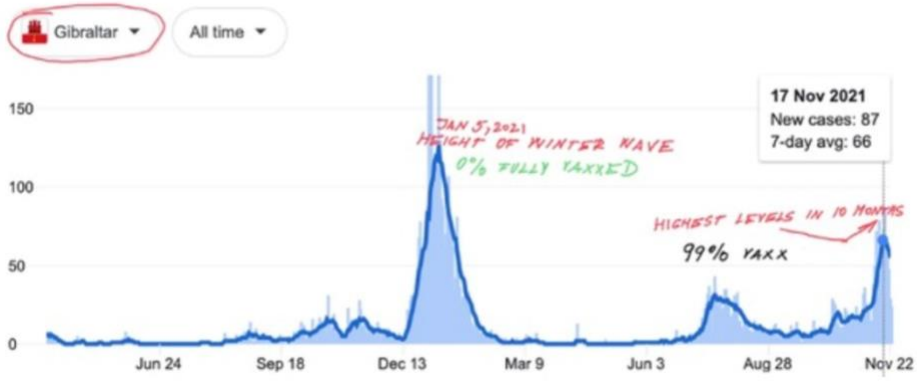
79. Evidence: Share of vaccinated in Europe versus Africa clearly shows vaccination is not reducing cases nor deaths.

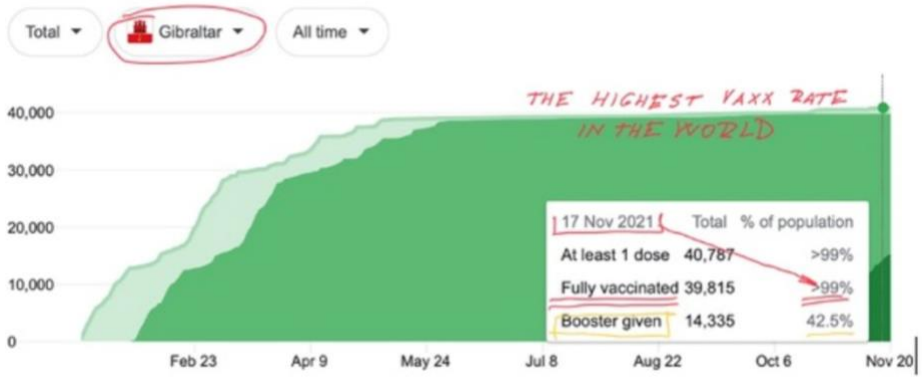


Source: Official data collected by Our World Data https://ourworldindata.org/coronavirus/

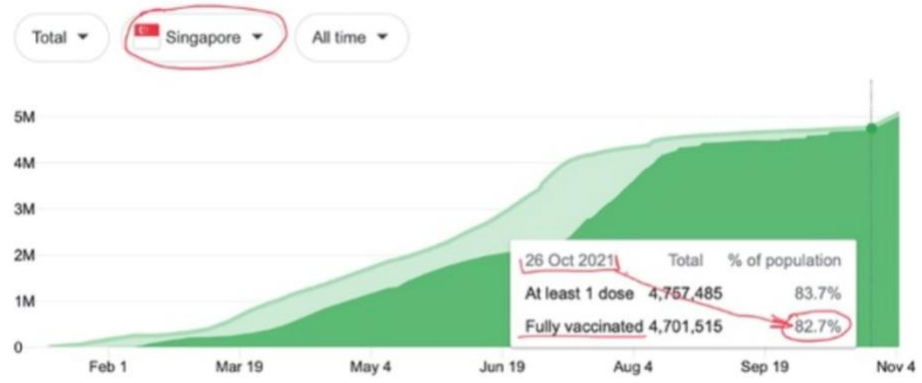
80. Evidence: After nearly twelve months into the worldwide vaccination campaign there are now a number of countries with vaccination rates of between 60.0% and 70.0%. Some countries and geographical areas have rates of 80.0%+ vaccination coverage. While precise figures that would confer herd immunity against COVID-19 are not clear, one thing is certain: if the vaccines are effective, vaccination rates of more than 60.0% should result in a significant reduction in its incidence. The following charts demonstrate that the COVID-19 vaccine campaign is ineffective, at best, and leading to more cases, at worst.

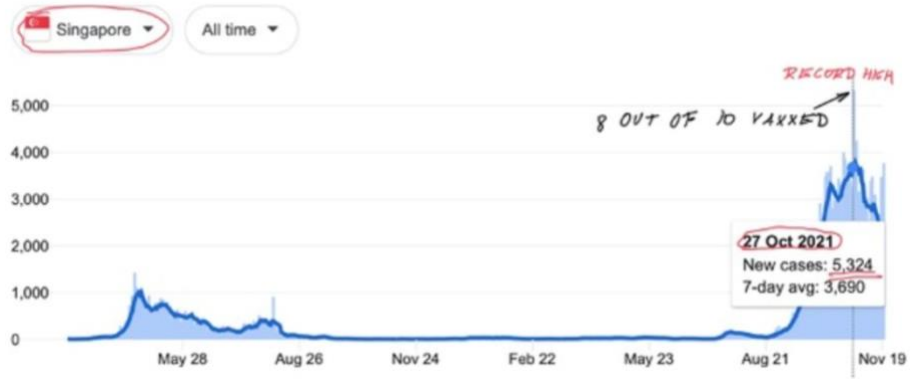
Example: Gibraltar, Spain (99.0% vaccination coverage)

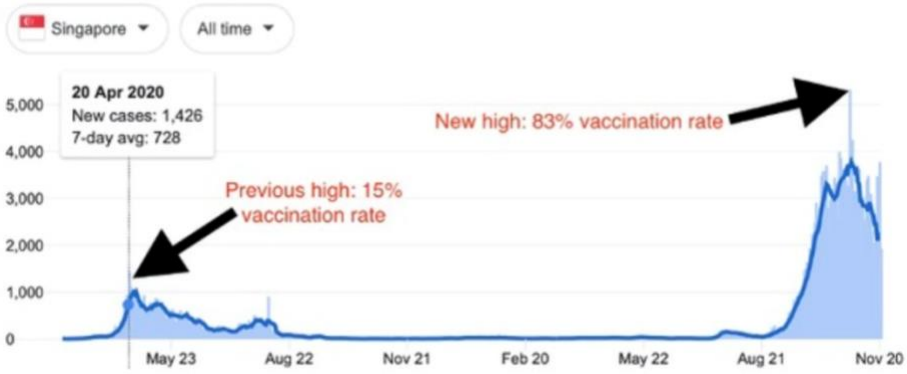




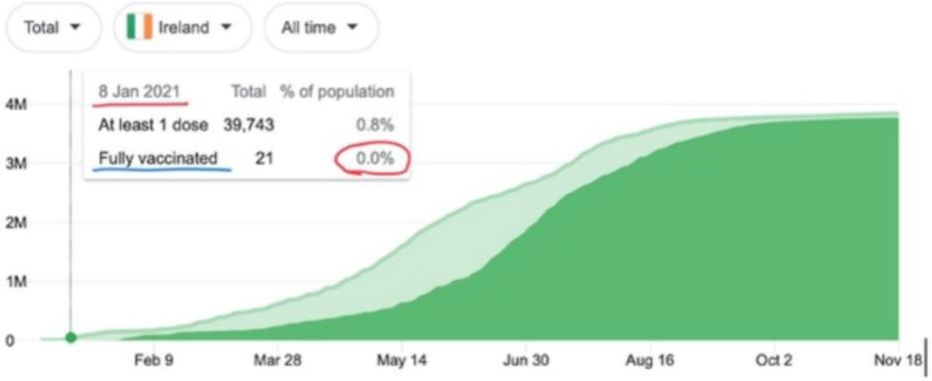
Example: Singapore (82.7% vaccination coverage)

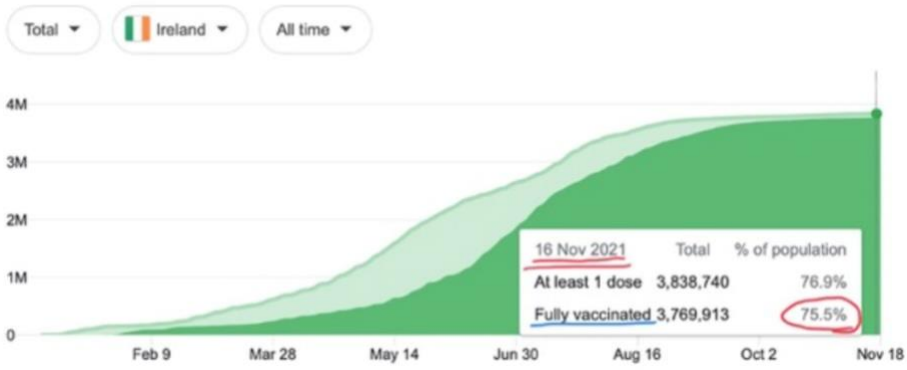


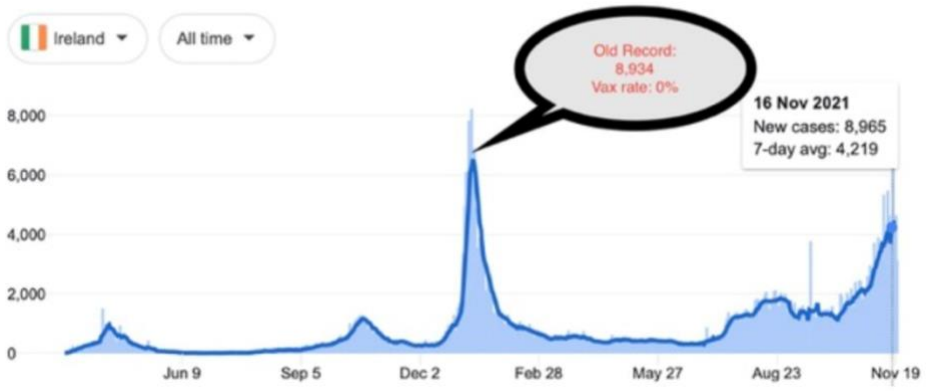




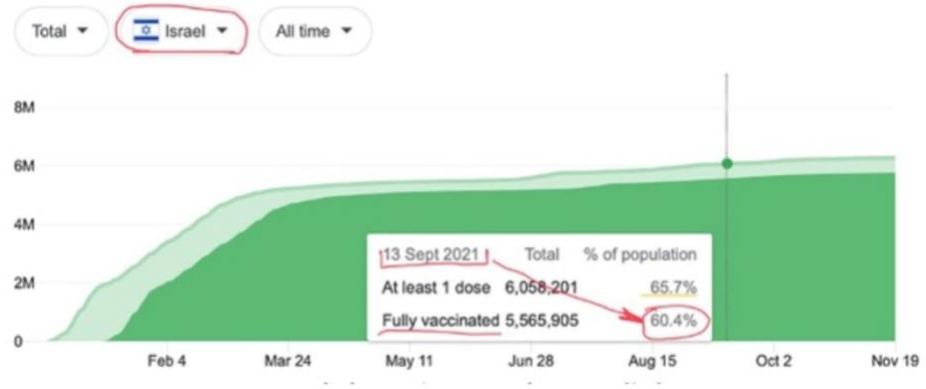
Example: Ireland (75.5% vaccination coverage)

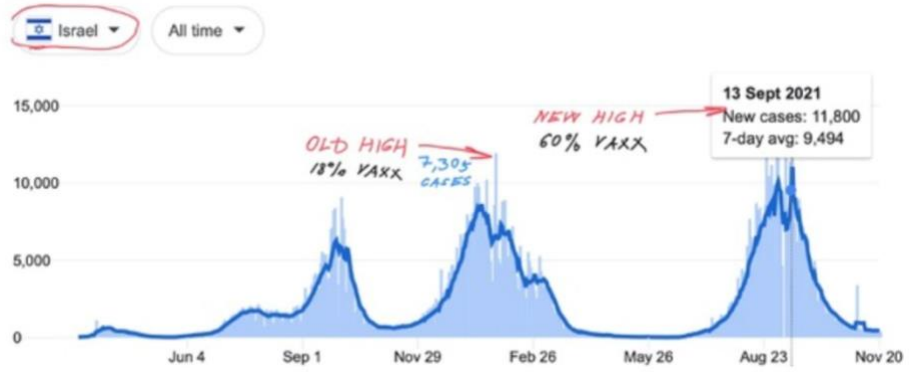






Example: Israel (60.4% vaccination coverage – with booster)





Source: https://www.americanthinker.com/articles/2021/11/hard_data_shows_the_covid_vaccines_dont_work.html

81. Evidence: According to the *Brownstone Institute*, "*...a federal appeals court in New Orleans has stopped the vaccination and testing requirement for private businesses as ordered by the Biden administration and the Labour Department's regulatory division for workplace safety.*" Brownstone Institute shares the court decision (BST Holdings, L.L.C. vs OSHA, November 12, 2021) which points out several flaws in vaccine mandates and the logic of vaccination for different people groups. First, COVID-19 vaccines were authorized or approved by the FDA for the purpose of protecting vaccinated persons against severe illness or death from

COVID-19. Once again, this highlights that COVID-19 vaccines do not provide 100.0% protection or immunity for COVID-19.

Furthermore, sweeping mandates do not factor in risk of different individuals (i.e. a 65-year-old prison janitor versus a 28-year-old trucker who sits in a vehicle's cab for the majority of their workday). Finally, it was demonstrated that vaccine mandates were implemented not for the purpose of enhancing workplace safety (as they do not prevent transmission), but rather for the purpose of increasing vaccine uptake. The concerns raised in this court decision echo the concerns of British Columbians pointing out inconsistencies in vaccine effectiveness, risk assessment, and the harms of mandates.

Source: https://brownstone.org/articles/excerpts-from-the-5th-circuit-court-judgement-against-osha/

DR. BONNIE HENRY CLAIMS: — The vaccines are the most important preventive therapeutic.

FACT CHECK: **FALSE** — Vaccines are **not** the best nor the most important preventative therapeutic. In fact, vaccines do not prevent illness. If an individual becomes ill, early treatment protocols have been demonstrated to be important and effective in other countries, namely within the USA (see FLCCC example below), India (Uttar Pradesh example below), and Japan. There are many alternative health supporting therapeutics and lifestyle modifications that can prevent or reduce severity of COVID-19. These include dietary alterations, improved sleep hygiene, stress reduction techniques, exercise, vitamins and minerals (i.e., zinc, vitamin D, vitamin C, vitamin A, selenium, etc.).

82. Evidence: On the "What You Need to Know" WHO page for Pfizer BioNTech COVID-19 vaccine, the question "*...does it prevent infection and transmission?*" is asked. The following is the answer statement: "*A. There is currently no substantive data available related to the impact of the Pfizer BioNTech vaccine on transmission or viral shedding. In the meantime, we must maintain and strengthen public health measures that work: masking, physical distancing, handwashing, respiratory and cough hygiene, avoiding crowds, and ensuring good ventilation.*"

    Similar statements are made on the WHO website regarding whether the Moderna, AstraZeneca and Jannsen vaccines prevent transmission or contribute to viral shedding.

    Source: WHO Pfizer — WHO Pfizer — "What You Need To Know"
    Source: WHO Moderna — https://www.who.int/news-room/feature-stories/detail/the-moderna-covid-19-mrna-1273-vaccine-what-you-need-to-know
    Source: WHO AstraZeneca — https://www.who.int/news-room/feature-stories/detail/the-oxford-astrazeneca-covid-19-vaccine-what-you-need-to-know
    Source: WHO Janssen — https://www.who.int/news-room/feature-stories/detail/the-j-j-covid-19-vaccine-what-you-need-to-know

83. Evidence: The ACTIV-6 clinical trial which commenced in June 2021 at a Texas university is examining the effectiveness of Ivermectin (antiparasitic), fluvoxamine (antidepressant), and fluticasone (inhaled steroid) for COVID-19 treatment. The National Institutes of Health (NIH) have granted Texas Tech University Health Sciences Center - El Paso $1.7 million dollars to spearhead more clinical trials. This study is investigating the repurposing of these drugs for COVID-19, specifically for treatment of non-hospitalized patients with mild to moderate illness.

Source: https://thehill.com/policy/healthcare/577844-texas-clinical-trial-to-examine-ivermectin-in-fight-against-covid-19

84. Evidence: A study from November 2020 has demonstrated promise for the drug fluvoxamine as an anti-inflammatory agent in the treatment of COVID-19. Fluvoxamine is also a sigma-1 receptor agonist. This is key to understand because the sigma-1 receptor, when bound, prevents the synthesis of inflammatory cytokines (chemical messengers) implicated in the severe inflammatory stage of COVID-19. As fluvoxamine can bind and effectively block the synthesis of these cytokines, it is a sound choice for the treatment of COVID-19.

    Source: https://psychopharmacologyinstitute.com/section/fluvoxamine-vs-placebo-and-clinical-deterioration-in-outpatients-with-symptomatic-covid-19-2604-5082

85. Evidence: Dr. Fauci himself has known since 2005 that chloroquine is an effective inhibitor of coronaviruses. Dating back to research published in 2005, chloroquine—a more potent form of hydroxychloroquine—was demonstrated to be a potent inhibitor of SARS-CoV infection and transmission, *in vitro*. The use of chloroquine and hydroxychloroquine as a prophylactic to prevent SARS-CoV-2 transmission and is used as a treatment for COVID-19 in China, as well as documented in several studies to date.

    Source: https://nw-connection.com/opinion-fauci-knew-about-hcq-in-2005-nobody-needed-to-die/
    Source: China COVID-19 Treatment Plan – Chloroquine http://en.nhc.gov.cn/2020-09/01/c_81537.htm
    Source: Vincent et al. (2005) — https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC1232869/
    Source: Liu et al., (2020) — https://www.nature.com/articles/s41421-020-0156-0

86. Evidence: The Front Line COVID-19 Critical Care (FLCCC) Alliance has demonstrated the efficacy of Ivermectin for the treatment and prevention of COVID-19. The FLCCC Alliance has published a comprehensive narrative review in *The American Journal of Therapeutics* (April 2021), showcasing the utility of Ivermectin by scrutinizing a wide variety of published literature, including meta-analysis, clinical trials, randomized clinical studies, observational clinical studies, epidemiological studies, and pharmacology studies. *In-vivo* studies conducted in animal models demonstrate that Ivermectin is capable of reducing time to recovery, hospitalization rates, and mortality (Covid Analysis, 2021). Furthermore, a compilation of randomized controlled trials (n = 27) conducted in humans demonstrated that Ivermectin increases SARS-CoV-2 viral clearance from the host, and quickens recovery time from COVID-19 (Hill et al., 2021). Prophylactic use of Ivermectin has been demonstrated to reduce contraction of COVID-19 with an average protection level of 86.0%. More frequent dosing of Ivermectin has shown to increase protection rates beyond 86.0% (FLCCC Alliance).

    Source: FLCCC Alliance https://covid19criticalcare.com/wp-content/uploads/2021/08/SUMMARY-OF-THE-EVIDENCE-BASE-FINAL.pdf
    Source: COVID-19 Critical Care, Ivermectin FAQ — https://covid19criticalcare.com/ivermectin-in-covid-19/faq-on-ivermectin/
    Source: Covid Analysis, 2021—https://ivmmeta.com/
    Source: Hill et al., 2021—https://academic.oup.com/ofid/advance-article/doi/10.1093/ofid/ofab358/6316214
    Source: COVID-19 early treatment: real-time analysis of 1,159 studies (c19early.com)

87. Evidence: Following the distribution of Ivermectin as part of a treatment protocol for COVID-19 in Uttar Pradesh, India—with a population of 241 million—daily reports of COVID-19 have gone from over 35,000 in May 2021, to an average below 100 from July 1, 2021, through to December 31, 2021. Ivermectin was administered through 71 out of 75 districts, wherein zero new cases of COVID-19 were reported in Uttar Pradesh as of October 19th, 2021. The remaining 4 districts reported a total of 12 cases across a 24-hour period. Forty-two districts still remain COVID-19-free following administration of Ivermectin, highlighting the efficacy of Ivermectin as part of a treatment plan as a quick acting COVID-19 treatment. Uttar Pradesh's

fully vaccination rate on July 1, 2021, was 4.3% and was 43.7% on December 31, 2021. Canada's fully vaccination rates were 32.1% and 77.4% respectively for the same timeframes.

Source: https://www.thegatewaypundit.com/2021/10/update-71-75-districts-uttar-pradesh-india-reported-no-COVID-19-cases-24-hours-implementing-ivermectin-protocol/?utm_source=Gab&utm_campaign=websitesharingbuttons

88. Evidence: Convalescent antibodies from patients who have recovered from COVID-19 are protective against 23 other strains of SARS-CoV-2. This identifies the strength of natural immunity derived from a SARS-CoV-2 infection and highlights the potential utility of convalescent antibodies as a novel therapeutic treatment. Similarly, monoclonal antibodies—the synthetic form of convalescent antibodies—are being utilized successfully for the treatment of COVID-19.

    Source: https://www.news-medical.net/news/20210705/Scientists-identify-natural-SARS-CoV-2-super-immunity-against-23-variants.aspx
    Source: NIH Monoclonal Antibody Treatment — https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/

89. Evidence: Aspirin has been proven to be an effective, affordable, and accessible therapeutic for the purposes of decreasing ventilation, ICU admissions, and in-hospital mortality for hospitalized COVID patients (Chow et al., 2021). These findings are further substantiated through a systematic review and meta-analysis concerning the use of aspirin for COVID-19 treatment. Analysis of six trials (n = 13,993 patients) demonstrated that low-dose aspirin may reduce mortality from COVID-19.

    Source: Chow et al. (2021)— https://journals.lww.com/anesthesia-analgesia/Fulltext/2021/04000/Aspirin_Use_Is_Associated_With_Decreased.2.aspx?context=FeaturedArticles&collectionId=4
    Source: Martha et al. (2021) — https://www.sciencedirect.com/science/article/pii/S1201971221004173

90. Evidence: German studies on vitamin D have identified a linear relationship between vitamin D levels and mortality from COVID-19. Essentially zero morbidity is found in individuals with a vitamin D level above 50.0 ng/mL. Studies have demonstrated that individuals with a vitamin D deficiency are 14-times more likely to die from COVID-19. In specific, a meta-analysis of 23 studies (n = 11,901) found that those who are deficient are 3.3-times more likely to get infected with SARS-CoV-2. Vitamin D should be recommended to all as a cheap and safe prophylactic treatment.

    Source: https://www.theblaze.com/op-ed/horowitz-studies-show-an-aggressive-vitamin-d-campaign-could-have-prevented-nearly-all-covid-deaths
    Source: Borsche et al. (2021) — https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8541492/
    Source: Ghasemian et al. (2021) — https://pubmed.ncbi.nlm.nih.gov/34322971/

91. Evidence: Please refer to this compilation of effective and lifesaving early COVID-19 treatment protocols, utilizing alternative therapeutics.

    Source: https://c19protocols.com/

    ***NOTE:** The current narrative delivered by B.C. PHO Dr. Bonnie Henry is that vaccination is the only solution for ending COVID-19 transmission and illness. However, the aforementioned data clearly identifies that this is not true. Both local and international evidence demonstrates that alternative therapeutics are capable of saving lives and reducing illness. Many of these alternative treatments are ignored or completely censored. Additional alternative treatments and prophylactic therapies exist and are actively being studied.

As per the Front Line COVID-19 Critical Care Alliance protocol documentation, Section 1.3. Overview of the treatment of COVID-19:

"*While there is no cure or "Magic-bullet" for COVID-19, recently, a number of therapeutic agents have shown great promise for both the prevention and treatment of this disease including Ivermectin, Vitamin D, Quercetin, Melatonin, Fluvoxamine, Corticosteroids, Curcumin (turmeric), Nigella Sativa and Antiandrogen Therapy. It is likely that no single drug will be effective in treating this complex disease and that multiple drugs with different mechanisms of action used in specific phases of the disease will be required). Furthermore, a growing body of evidence suggests that many of these agents may act synergistically in various phases of the disease. [4-6] The relentless malpractice of deliberately withholding early effective COVID treatments, of forcing the use of toxic remdesivir, may have unnecessarily killed up to 500,000 Americans in hospitals*"

Source: https://covid19criticalcare.com/wp-content/uploads/2020/12/FLCCC-Protocols-%E2%80%93-A-Guide-to-the-Management-of-COVID-19.pdf

Other Home (Out-Patient) & Early Treatment COVID-19 Protocols

Source: Tess Lawrie/Trozzi (World Council for Health) — https://worldcouncilforhealth.org/resources/early-covid-19-treatment-guidelines-a-practical-approach-to-home-based-care-for-healthy-families/
Source: America's Frontline Doctors Protocols — https://americasfrontlinedoctors.org/covid/hydroxychloroquine/treatment-protocols/
Source: AAPS Home Treatment Guide (Peter McCullough) — https://aapsonline.org/early-treatment-saves-lives/
Source: Dr. Zelenko Protocol — https://vladimirzelenkomd.com/treatment-protocol/

D. Vaccines, which prevent or reduce the risk of infection with SARS-CoV-2, have been and continue to be readily available in British Columbia and while substantial progress has been made in vaccinating the population of British Columbia 12 years of age and older, a portion of the public remains unvaccinated and there are communities where vaccination rates are low;

DR. BONNIE HENRY CLAIMS: — Vaccines prevent or reduce the risk of infection.

FACT CHECK: **FALSE** — Vaccines, while readily available, increasingly show they do not prevent or reduce the risk of infection, while alternative therapeutics and natural immunity are continually ignored even though their utility has been demonstrated in various countries globally.

1. Evidence: There are currently **no** vaccines that prevent COVID-19 infection (Birhane et al., 2021). Breakthrough cases are being regularly recorded. One of the largest evaluations of data assessing breakthrough infections demonstrated that 10,262 cases of COVID-19 occurred in fully vaccinated individuals within the USA as of April 2021. Of these individuals, 27.0% were asymptomatic, 10.0% were hospitalized, and 2.0% died.

   Source: Birhane et al. (2021) https://pubmed.ncbi.nlm.nih.gov/34043615/

2. Evidence: According to COVID-19 vaccine manufacturer Johnson & Johnson "*…it is reasonable to believe that the Janssen COVID-19 vaccine may be effective for the prevention of COVID-19 in individuals as specified in the Full EUA Prescribing Information*." According to Pfizer-BioNTech "*…the Pfizer-BioNTech COVID-19 vaccine is a vaccine and may prevent you from getting COVID-19.* ***There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.***" According to an AstraZeneca COVID-19 FAQ sheet, the VAXZEVRIA COVID-19 vaccine "*...may not fully protect those who receive it. It is not yet known how long people who receive the vaccine will be protected*." Finally, according to Moderna: "*…the Moderna COVID-19 vaccine is a vaccine and may prevent you from getting COVID-19.* ***There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.*"**

   Source: Pfizer EUA Fact Sheet — attach PDFs in appendices
   Source: Jannsen Fact Sheet — attach PDFs in appendices
   Source: AstraZeneca EUA — attach PDFs in appendices
   Source: Moderna EUA — attach PDFs in appendices

   ***NOTE:** Until recently, the statements made in EUAs and FAQ sheets from COVID-19 manufacturers demonstrated that COVID-19 vaccines *may* prevent COVID-19. The newest EUA documents from these manufacturers now suggest that the COVID-19 vaccines unequivocally prevent COVID-19, which is a falsehood based on the aforementioned data detailing breakthrough cases that has been presented, not to mention the recent Omicron outbreaks that are impacting the fully vaccinated at similar rates to that of the unvaccinated.

   Source: Pfizer Comirnaty EUA November 2021 — https://www.fda.gov/media/153716/download
   Source: Pfizer EUA, children 5-11 October 2021— https://www.fda.gov/media/153717/download
   Source: Moderna EUA November 2021 — https://www.cdc.gov/vaccines/covid-19/eua/modernatx.html
   Source: AstraZeneca EUA, not available — https://www.cdc.gov/vaccines/covid-19/eua/astrazeneca.html
   Source: Janssen EUA November 2021 — https://www.cdc.gov/vaccines/covid-19/eua/janssen.html

3. Evidence: From FDA Q&A for Comirnaty (COVID-19 Vaccine mRNA)

   Q. If a person has received Pfizer Comirnaty, will the vaccine protect against transmission of SARS-CoV-2 from individuals who are infected despite vaccination?

   A. Most vaccines that protect from viral illnesses also reduce transmission of the virus that causes the disease by those who are vaccinated. While it is hoped this will be the case, the scientific community does not yet know if Comirnaty will reduce such transmission.

   Source: https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna

4. Evidence: Furthermore, British Columbia COVID-19 related policies—namely vaccination passports—have been implemented as a way to prevent the spread of COVID-19. The provincial vaccine passport program is faulty (and discriminatory) and has been introduced solely under coercive directives. Dr. Patty Daly, Chief Medical Health Officer for Vancouver Coastal Health, has divulged that **vaccine passports are an "*incentive to get higher vaccination rates*" and not to stop the spread of COVID-19.** Dr. Daly was also quoted saying "*...the vaccine passport requires people be vaccinated to do certain discretionary activities such as go to restaurants, movies, gyms not because these places are high risk. We're not actually seeing COVID transmission in these settings*." Daly was reported saying that *"...the vaccine passport is for non-essential opportunities and it is really to create incentive to get higher vaccination rates*."

   Source: https://rumble.com/vnf2m9-vaxpass-its-really-to-create-an-incentive.html
   Source: https://www.lifesitenews.com/news/vaccine-passport-just-an-incentive-and-not-about-health-vancouver-medical-officer
   Source: https://www.riotimesonline.com/brazil-news/modern-day-censorship/covid-19-22-scientific-studies-show-that-vaccine-mandates-are-not-based-on-science/

5. Evidence: As per SECTION H of the Face Coverings Order in B.C., dated October 29th, 2021: "*..people who are vaccinated can contract the SARS-CoV-2 virus and be a source of transmission of the SARS-CoV-2 virus to others, further perpetuating the transmission chain*".

   Source: https://www2.gov.bc.ca/assets/gov/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/COVID-19/COVID-19-pho-order-face-coverings.pdf

6. Evidence: Pfizer confirms that individuals vaccinated for COVID-19 can 'shed' spike proteins and harm the unvaccinated. Pfizer's own internal report (on page 69) warns health care workers about being exposed to people who have been vaccinated — which is rather ironic considering most health care workers are required to be vaccinated themselves. The following excerpt demonstrates the risks of vaccine shedding:

   *"**8.3.5.3. Occupational Exposure***
   An occupational exposure occurs when a person receives unplanned direct contact with the study intervention, which may or may not lead to the occurrence of an AE. Such persons may include healthcare providers, family members, and other roles that are involved in the trial participant's care. The investigator must report occupational exposure to Pfizer Safety within 24 hours of the investigator's awareness, regardless of whether there is an associated SAE. The information must be reported using the Vaccine SAE Report Form. Since the information does not pertain to a participant enrolled in the study, the information is not recorded on a CRF; however, a copy of the completed Vaccine SAE Report Form is maintained in the investigator site file"

   Source: Pfizer Internal Report, see page 69 — https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf

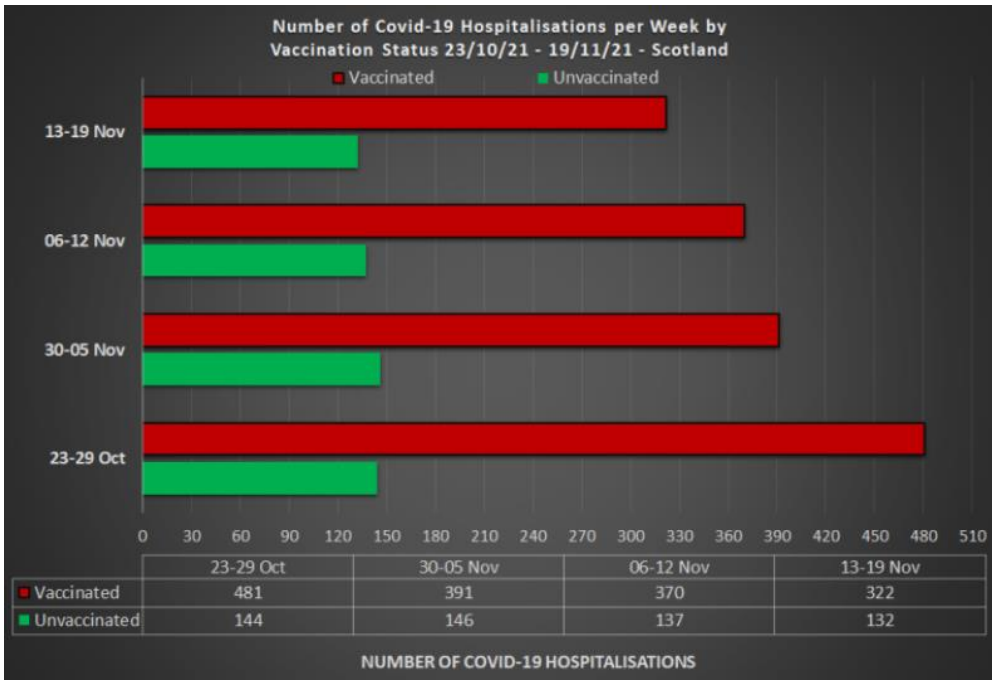
E. Communities with low vaccination rates have experienced rapid spread of SARS-CoV-2, causing serious illness and increases in hospitalizations and intensive care admissions, primarily in unvaccinated people. By contrast, communities with high vaccination rates have seen corresponding lower transmission, case rates;

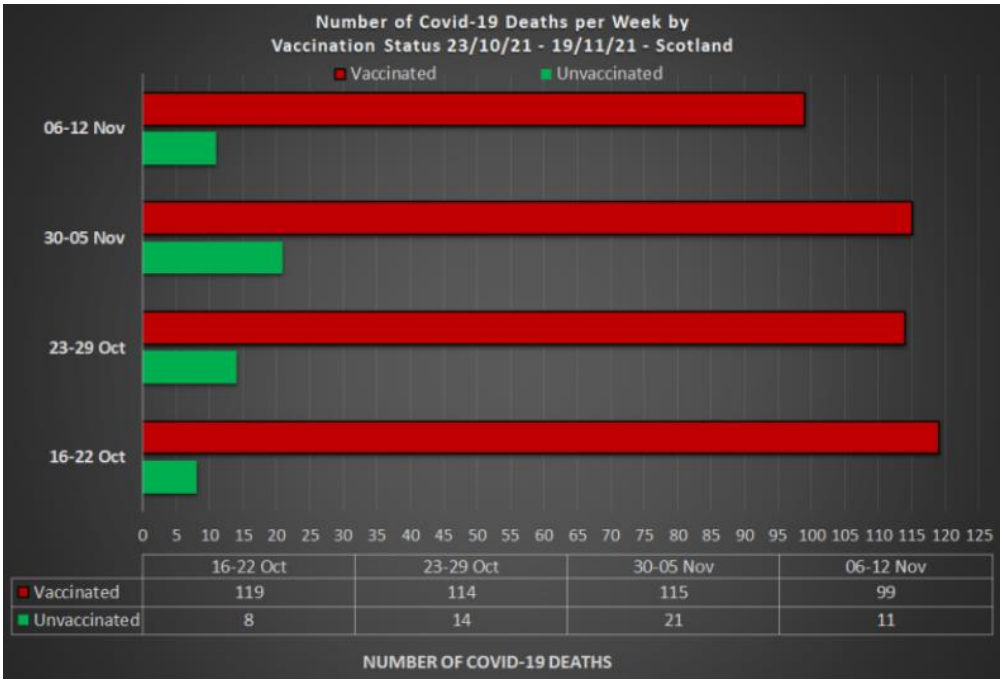
DR. BONNIE HENRY CLAIMS: — Vaccination rates are directly linked to whether a community can expect to experience spread of infection and that serious illness and hospital admissions are primarily in unvaccinated people.

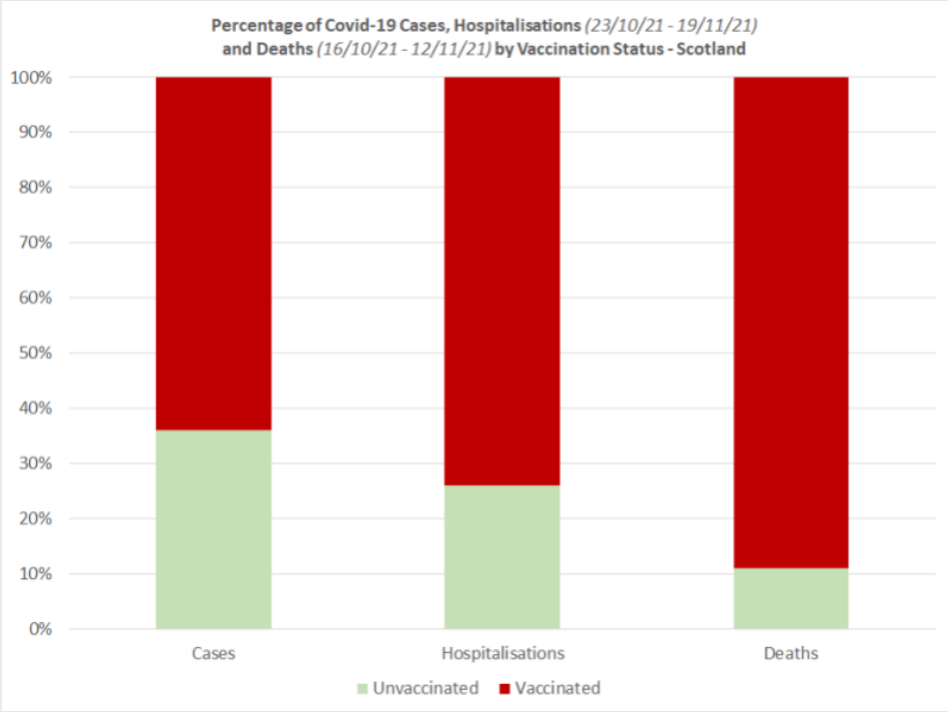
FACT CHECK: **FALSE** — Due to the lack of clear evidence that unvaccinated persons are the primary cause of SARS-CoV-2 transmission, it is discriminatory to place the blame of the rapid spread of COVID-19 on unvaccinated persons. This has become increasingly evident with the current spread of Omicron amongst fully vaccinated individuals. Furthermore, 89.0% of eligible British Columbians are fully vaccinated, leaving a very small minority of people as unvaccinated.

1. Evidence: Provided in **Section C - #57, #64, #79-80, and #83, and Section K - #9** referring to Israel and Gibraltar, Spain.

2. Evidence: According to the latest public health data, 89.0% of Scotland's COVID-19 deaths are among the fully vaccinated. This suggests that this is a "pandemic of the fully vaccinated", and suggests the vaccinated are more likely to be hospitalized and die.







Source: Public Health Scotland COVID-19 Statistical Report pg. 53
Source: 89% of Covid-19 Deaths among the Fully Vaccinated – Latest Public Health Data proves this is a 'Pandemic of the Fully Vaccinated' and suggests the Vaccinated are more likely to die – The Expose (dailyexpose.uk)

3. Evidence: The Infection Fatality Rate (IFR) is the total number of deaths divided by the total number of people that carry the infection. This, whether they display clinical symptoms or not. In the U.S., the Centre for Disease Control has determined the Infection Fatality Rate of COVID-19 for various age groups, based

on the likely number of deaths per million infections. In its current best estimate, the CDC proposes for different age-groups:

- 0-17: 20 deaths per million infections (0.002%)
- 18-49: 500 deaths per million (0.05%)
- 50-64: 6,000 deaths per million (0.60%)
- 65 and over: 90,000 (9.0%)

In other words, older people are significantly more vulnerable to COVID-19 than younger people. Even when younger people do contract SARS-CoV-2, their chances of survival are high.

Source: https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html
Source: https://www.cdc.gov/flu/spotlights/2019-2020/2019-20-pediatric-flu-deaths.htm
Source: Kids: flu 2-3 times more problematic than COVID and the real Covid Fatality Rate — https://imprimis.hillsdale.edu/sensible-compassionate-anti-covid-strategy/

F. Unvaccinated people are at a significantly greater risk than vaccinated people of being infected with SARS-CoV-2, and those who are infected, experience significantly higher rates of hospitalization, ICU-level care and invasive mechanical ventilation, complications and death when compared with vaccinated people. Unvaccinated people are also at higher risk of transmitting SARS-CoV-2 to other people, including vaccinated people;

DR. BONNIE HENRY CLAIMS: — This is a pandemic of the unvaccinated. Also stated by government officials' numerous times in the media.

FACT CHECK: **FALSE** — A different perspective is warranted. Data from around the world shows this is a "pandemic of the **fully vaccinated** ".

1. Evidence: According to the BC COVID-19 Pandemic Update for the week of January 5th 2022 through January 12, 2022 there were 18,062 cases reported. Of these, 3,160 (17.5%) occurred in unvaccinated persons, 637 (3.5%) occurred in partially vaccinated persons, and 14,265 (79.0%) occurred in fully vaccinated persons. This demonstrates provincial breakthrough cases, specifically as Omicron becomes the predominant variant circulating within B.C.

   Source: BC COVID-19 Pandemic Update — https://news.gov.bc.ca/releases/2022HLTH0002-000050

2. Evidence: More recent data from Subramanian and Kumar (2021) is showcasing that there is no connection between the percentage of fully vaccinated individuals in a population and new COVID-19 cases. When considering data from the five most heavily vaccinated countries around the globe (with a vaccination rate between 84.3% and 99.9%), the US CDC has officially indicated that four out of these five countries have a "high" associated risk of transmission.

   Source: Subramanian and Kumar (2021) — https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/

3. Evidence: While the blame is continually shifted to unvaccinated persons, this notion is misguided. An individual who is unvaccinated on paper may very well have equal or superior natural immunity compared to a fully vaccinated individual. Abu-Raddad et al. (2021) have demonstrated through SARS-CoV-2 antibody positivity testing that reinfection is rare, and that natural infection leads to robust protection lasting a minimum of seven months with a 95.0% efficacy. Furthermore, the Brownstone Institute has compiled significant volumes of studies and commentary on the topic — see the following sources.

   Source: Abu-Raddad et al. (2021) — https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8079668/
   Source: https://brownstone.org/articles/how-likely-is-reinfection-following-covid-recovery/

4. Evidence: Moreover, a study by Turner et al. (2021) has demonstrated that while antibody protection may wane following clearance of even mild SARS-CoV-2 viral infection, memory B cells and bone marrow plasma cells maintain robust antigen-specific protection for years following natural infection. This demonstrates development of robust natural immunity.

   Source: Turner et al. (2021) — https://www.nature.com/articles/s41586-021-03647-4

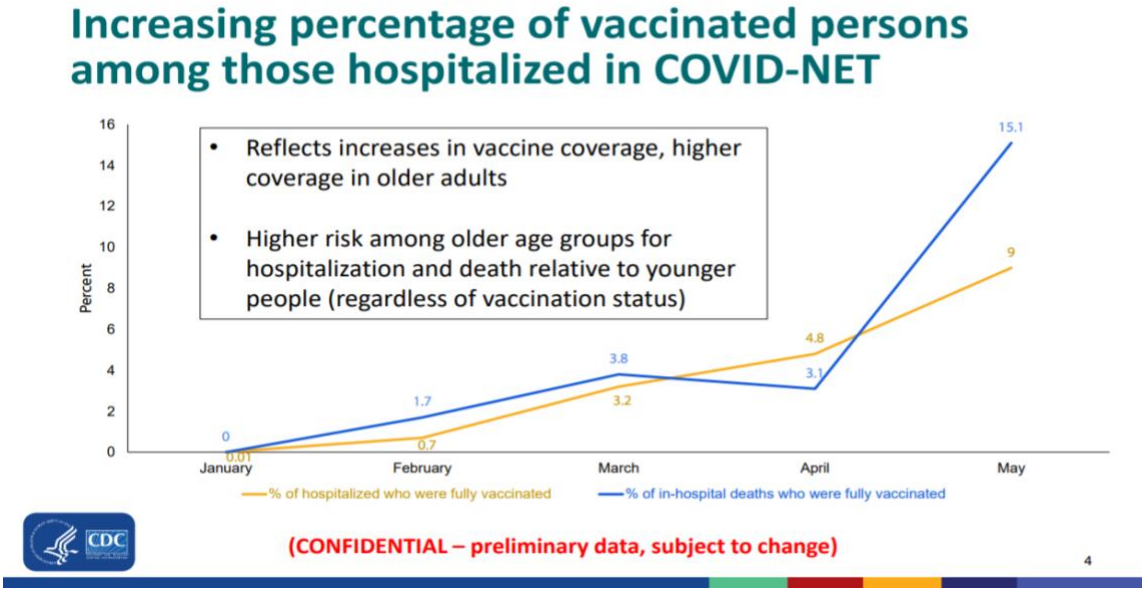
5. Evidence: Please refer to **Section E - #2** wherein data from Scotland demonstrates that this is a "pandemic of the fully vaccinated."

DR. BONNIE HENRY CLAIMS: — Unvaccinated people experience higher rates of hospitalization.

FACT CHECK: **TRUE** — However, the overall rates of hospitalizations and deaths are low (usual and expected based on historical flu activity) and could be lower if effective treatment plans were in place.

It must be noted that "unvaccinated" refers to both truly unvaccinated persons (i.e. individual has received zero vaccinations) and partially vaccinated persons (i.e. individual has received only one vaccine out of the series, or is 13-days post-receipt of their second vaccine). Thus, a more thorough breakdown of provincial statistics is necessary to understand the current strain of the healthcare system by unvaccinated, partially vaccinated, and fully vaccinated persons.

6. Evidence: The accompanying graphic demonstrates that 9.0% of patients in the hospital were in fact fully vaccinated, debunking the CDC's initial claim. Further, 15.1% of patients in the hospital who succumbed to COVID-19 were fully vaccinated (when 57.0% of Americans aged ≥18 had received one dose as of May 22, 2021).



Source: https://context-cdn.washingtonpost.com/notes/prod/default/documents/8a726408-07bd-46bd-a945-3af0ae2f3c37/note/57c98604-3b54-44f0-8b44-b148d8f75165.#page=4
Source: BMJ Open Letter Re: Facebook and Pfizer Whistleblower — https://www.bmj.com/content/375/bmj.n2635/rr-80
Source: https://www.cdc.gov/mmwr/volumes/70/wr/mm7025e1.htm

DR. BONNIE HENRY CLAIMS: — Unvaccinated have higher rates of death.

FACT CHECK: **FALSE** — The largest percentage of deaths per 100 cases of infection occured within long term care facilities, hospitals and correction institutions due to infection control issues, a lack of early and effective treatment and the presence of one or more comorbidities.

7. Evidence: Early treatment is demonstrated to result in less hospitalizations and less deaths. Individuals who were given early treatment for COVID-19 with fluvoxamine—a mood stabilizer and antidepressant—were 66.0% less likely to be hospitalized compared to a placebo group, and were 91.0% less likely to die compared to placebo. Of note, the CDC just recently promoted "depression and anxiety disorders" right underneath obesity as an indicator for high risk of serious COVID-19 infection and death.

   Source: Reis et al. (2021) — https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(21)00448-4/fulltext

8. Evidence: Outbreaks in government managed and funded settings such as long term care (LTC), retirement homes, hospitals and healthcare, and corrections, shelters, and congregate living led to the greatest number of deaths per 100 cases. In Canada, 75.0% of all COVID-19 related deaths are linked to outbreaks in those government managed settings, which house or provide services and care to approximately 292,000, comprised of mostly elderly with comorbidities and at-risk persons.

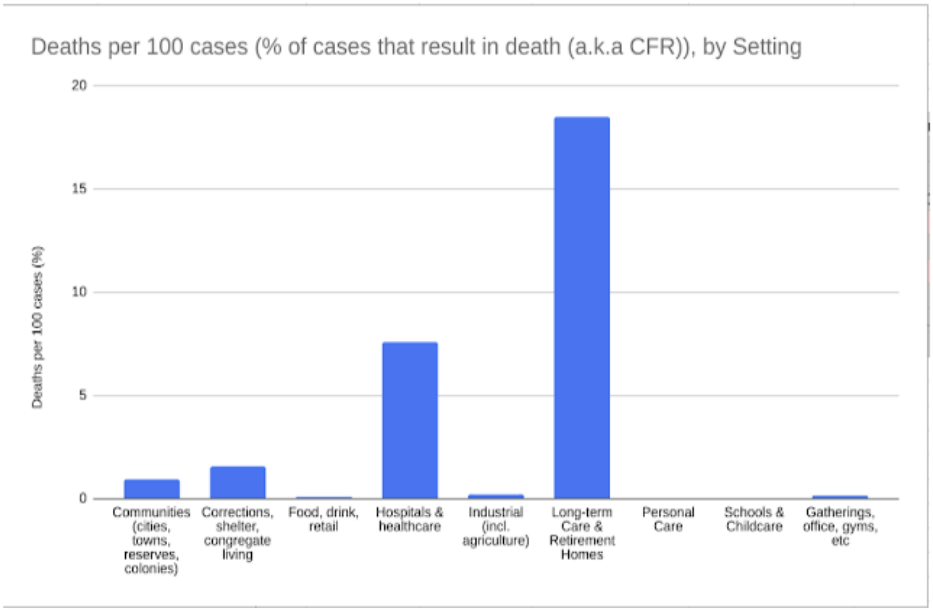


Figure 13: Percent of cases that lead to death in outbreaks, by setting. (reported deaths ÷ reported cases x 100)
Tall columns = high risk of death. Short columns = low risk of death. From data shown in Figure 8, calculations in the notes.

Note 18,275 (75%) of the COVID-19 deaths in Canada resulted within the very small group of 292,000 people in government managed and funded settings mainly LTC, retirement homes, hospitals, healthcare, and prisons. Versus only 6,127 (25%) of the COVID-19 deaths resulted within our population of 38,000,000 functioning and active citizens. The disproportionate response, in settings where COVID-19 risk of death was very low, which included lock downs and suppression of the general populous resulted in an immediate

negative impact on our children, youth, businesses, and economy. The full cost and long term impact of these measures are yet to be fully understood.

**Note: This data only considers reports through May 2021.*

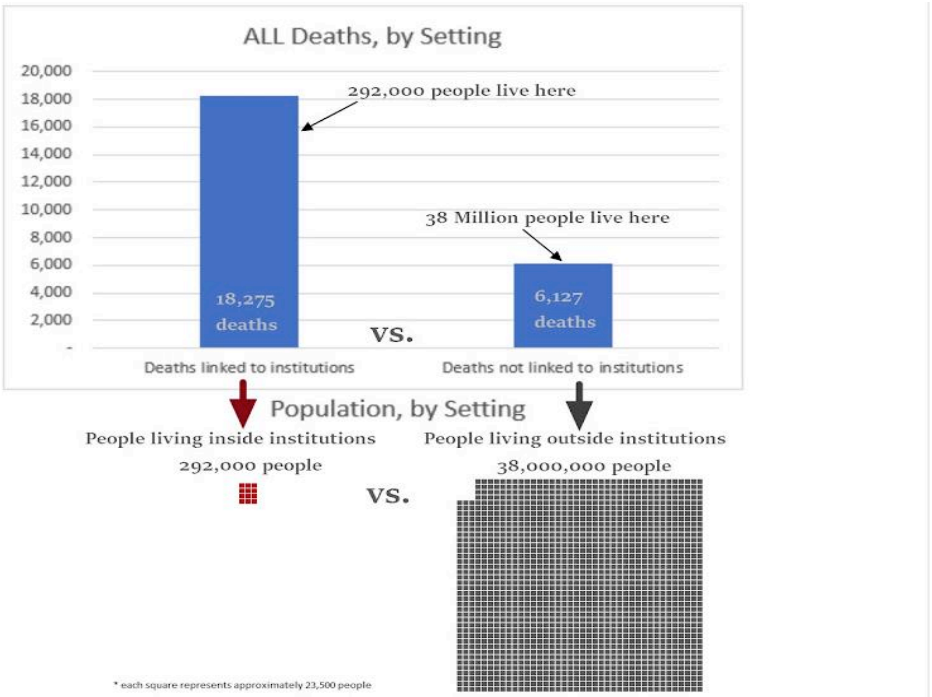


Figure 24: The government can't even protect the 292,000 people under its care. The public seems to be doing just fine by comparison.

Source: https://www.juliusruechel.com/2021/05/the-lies-exposed-by-numbers-fear.html

DR. BONNIE HENRY CLAIMS: — Unvaccinated persons are at higher risk of transmitting SARS-CoV-2 to other people, including vaccinated people.

FACT CHECK: **FALSE** — Community transmission is similar for both vaccinated and unvaccinated persons. Data is available which demonstrates breakthrough infections in fully vaccinated persons are more common in household settings.

9. Evidence: As per Singanayagam et al. (2021), community transmission of the delta strain is similar in both vaccinated and unvaccinated individuals; however, breakthrough infections in fully vaccinated individuals appears to be more common in close quarters such as household settings (Singanayagam et al., 2021).

   Source: Singanayagam et al. (2021) - https://www.thelancet.com/action/showPdf?pii=S1473-3099%2821%2900648-4

10. Evidence: Iceland and Portugal, both of which have more than 75.0% of their populations fully vaccinated, have more COVID-19 cases per 1 million people than Vietnam and South Africa, where only ~10.0% of their populations are fully vaccinated.

    Source: https://www.top-meds.org/covid-vaccines-do-not-impact-infection/
    Source: Subramanian and Kumar (2021) — https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/

11. Evidence: The Wall Street Journal is now reporting that there have been 1.89 million cases of COVID-19 within fully vaccinated persons, nearly 72,000 hospitalizations due to COVID-19 in fully vaccinated persons, and 20,000 deaths from COVID-19 in fully vaccinated persons in 2021. The number of breakthrough cases has reportedly risen from 0.049% in June 2021 to 1.15% in October 2021.

    Source: https://100percentfedup.com/nearly-2-million-fully-vaccinated-people-have-tested-positive-for-covid-72000-hospitalized-20000-deaths/
    Source: https://ehrn.org/articles/breakthrough-covid-19-cases-on-the-rise-still-rare-for-vaccinated-people

12. Evidence: As of December 30th, 2021, five new COVID-19 outbreaks have been declared at Lower Mainland health-care facilities. Interestingly, all visitors and staff within B.C. healthcare facilities have had to be fully vaccinated since October 26th, 2021 to gain entrance or visitation rights.

    Source: https://bc.ctvnews.ca/covid-19-outbreaks-declared-at-5-lower-mainland-health-care-facilities-including-ubc-s-psychosis-program-1.5722669

G. People who are vaccinated can be infected with SARS-CoV-2, but experience less severity of illness than unvaccinated people, especially in younger populations. Vaccinated persons who contract COVID-19 are also generally contagious for shorter periods of time, are less symptomatic, and are less likely to transmit SARS-CoV-2, when compared to unvaccinated infected persons.

DR. BONNIE HENRY CLAIMS: — Severity and length of illness is greater for an unvaccinated person.

FACT CHECK: **FALSE** — This may be true for the first month following vaccination; however, after a short time period a vaccinated individual is just as much at risk of catching COVID-19 as an unvaccinated individual. This phenomenon was documented in Section C - #68 by Dr. Reich. Furthermore, as detailed in Section F - #15, vaccinated individuals have a reduced immune capacity and are more susceptible to viral mutations and subsequent variants. Finally, it should be noted that current COVID-19 vaccines were specifically tailored to the Alpha SARS-CoV-2 strain, which is no longer the dominant circulating strain.

1. Evidence: As per an article in the Lancet titled "*COVID-19: Stigmatising the Unvaccinated is Not Justified*", there is increasing evidence that vaccinated individuals play a relevant role in transmission of SARS-CoV-2. In Massachusetts, USA, a total of 469 new COVID-19 cases were detected during various events in July, 2021 wherein 346 (74.0%) of these cases were in fully or partially vaccinated people. Of these individuals, 274 (79.0%) were symptomatic. Cycle threshold values—utilized for the PCR test—were similarly low between people who were fully vaccinated (median 22·8) and people who were unvaccinated, not fully vaccinated, or whose vaccination status was unknown (median 21·5), indicating a high viral load even among people who were fully vaccinated.

   Source: Kampf (2021) — https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02243-1/fulltext
   Source: Brown et al. (2021) — https://pubmed.ncbi.nlm.nih.gov/34351882/

DR. BONNIE HENRY CLAIMS: — Younger unvaccinated people experience more severe illness.

FACT CHECK: **FALSE** — The statement lacks sufficient context. Young people are generally healthier (excluding young persons with overt comorbidities), possess a robust immune system, and experience COVID-19 with minimal difficulties. Young persons have a 99.995% recovery rate from COVID-19 with nearly imperceptible symptoms and sequelae, even when early treatment is not implemented.

2. Evidence: Data from the UK demonstrates that 99.995% of children and young people (CYP) with a positive SARS-CoV-2 positive test survive. SARS-CoV-2 is very rarely fatal in CYP, even amongst those with an underlying comorbidity. Smith et al. (2021) state "*...it is important to differentiate between CYP who have died of SARS-CoV-2 and those who have died of an alternative disease process but coincidentally tested positive.*" These findings from the UK should be considered by families, clinicians, and policy makers when considering shielding and vaccination of younger populations.

   Source: Smith et al. (2021) — https://www.researchsquare.com/article/rs-689684/v1

3. Evidence: COVID-19 related deaths in children (0-19), from onset of the pandemic up to May 2021 (18 months), compared to 12-month periods of influenza and pneumonia deaths, for prior years, shows the risk of death due to COVID-19 is significantly less. A total of 11 children (age 0 to 19 years) have died of COVID in Canada (8 million children) in those 18 months. By contrast, as the chart below demonstrates, an average of 25 children (age 0 to 19 years) die of influenza and pneumonia every year:

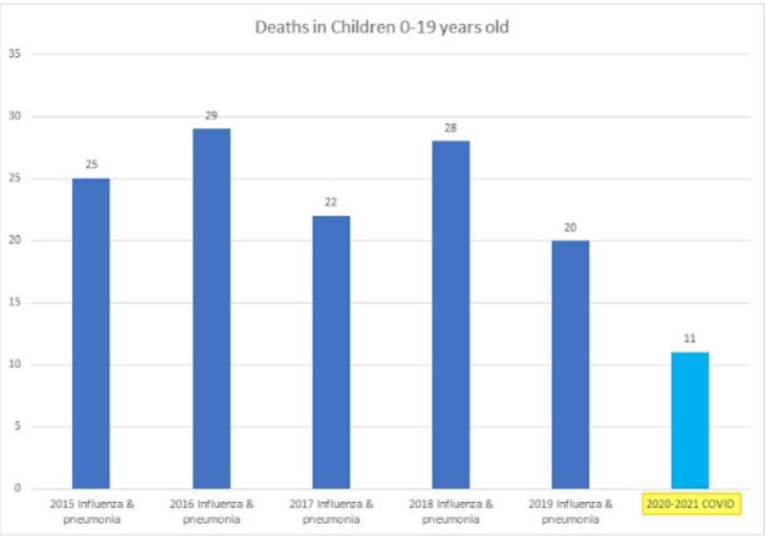


Figure 4: Comparing COVID deaths to influenza and pneumonia deaths in children aged 0 to 19 years of age. Sources: Statistics Canada and Government of Canada daily epidemiology report for May 7th, 2021

Source: Julius Ruechel: The Lies Exposed by the Numbers: Fear, Misdirection, & Institutional Deaths (An Investigative Report)

4. Evidence: Refer to **Section C - #4, #6, #8, and #20 (Song et al., 2021)** to understand the low risk of severe illness imposed by COVID-19 on children.

H. This situation has been exacerbated by the highly transmissible Delta variant of SARS-CoV-2, which is now the dominant variant of SARS-CoV-2 circulating in British Columbia, causing significantly more rapid transmission and increased severity of illness, particularly in younger unvaccinated people. Absent vaccination, British Columbia would be in a far more challenging situation than the fragile balance our current immunization rates have provided, but the transmissibility of the Delta variant means that higher vaccination rates than previously expected are now required to maintain this balance, control transmission, reduce case numbers and serious outcomes, and reduce the burden on the healthcare system, particularly hospital and intensive care admissions;

DR. BONNIE HENRY CLAIMS: — The Delta variant is more dangerous for younger unvaccinated people.

FACT CHECK: **FALSE** — The Delta variant is less virulent, although more contagious. The variants are accompanied by similar concerns as the Alpha strain. SARS-CoV-2 infection is mainly problematic for the elderly, those with chronic health issues, or individuals with compromised immune systems. Furthermore, it should be emphasized again that the current COVID-19 vaccines were developed against the Alpha strain, which is no longer the dominant circulating strain. Requiring a higher vaccination coverage to offset for the heightened transmissibility of the Delta strain is also nonsensical as the proceeding literature demonstrates that vaccinated persons pose a similar or greater risk for harboring SARS-CoV-2 as unvaccinated persons.

1. Evidence: Vaccines are driving Delta strain development (and other variants) and will continue to create variants in the same way that inappropriate antibiotic use leads to antibiotic resistance. Bacteria and viruses learn to survive by mutating if interventions are overused and/or applied incorrectly (i.e. the case of 'leaky vaccines'). Read et a. (2015) suggests that the inappropriate use of vaccines that allow the host to survive an infection but *do not prevent transmission* (such as the current COVID-19 vaccines) lead to development of viral evolution (i.e. mutation) and greater pathogen transmission. Eventually, this allows for "hotter" strains of virus (more virulent and deadlier) to re-emerge, much like in the case of antibiotic resistance. Perpetual misuse of antibiotics for decades has led to the emergence of deadly superbugs such as MRSA and VRSA. Inappropriate application of "leaky" COVID-19 vaccines will drive the emergence of more viral strains. Liu et al. (2021) demonstrate that this is no longer a hypothesis. Breakthrough variants have developed in response to application of the Pfizer-BioNTech vaccine, wherein the Delta variant has been shown to escape completely from neutralizing antibodies (Liu et al., 2021). Future vaccinations will likely further drive development of viral variants.

   Source: Li et al. (2021) — https://www.biorxiv.org/content/10.1101/2021.08.22.457114v1
   Source: Read et al. (2015) — https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002198

2. Evidence: The transmission potential of vaccinated and unvaccinated persons infected with the SARS-CoV-2 Delta variant was measured in a federal prison (July-August 2021). The study found that vaccinated prisoners were just as infectious as unvaccinated prisoners, and there was no difference in the length of sickness between the vaccinated and unvaccinated. Salvatore et al. (2021) state "*...during a high-transmission outbreak of the SARS-CoV-2 Delta variant in a prison setting, we failed to find different durations of RT-PCR positivity, CT values, or durations of viral culture positivity in fully vaccinated persons compared with persons who were not fully vaccinated.*"

Moreover, a study conducted by Magalis et al. (2021) concluded that "*direct virus transmission among vaccinated individuals infected by the Delta variant was, indeed, confirmed by contract tracing*." These findings refute the Order section H 'whereas' statement that falsely claims the Delta strain is responsible for heightened SARS-CoV-2 transmission amongst unvaccinated persons.

Source: Salvatore et al. (2021) — https://www.medrxiv.org/content/10.1101/2021.11.12.21265796v1
Source: Magalis et al. (2021) — https://www.medrxiv.org/content/10.1101/2021.11.10.21266134v1

3. Evidence: A study by Chau et al. (2021) demonstrates that SARS-CoV-2 in the form of "breakthrough cases" transmits between vaccinated healthcare workers, without discrimination. It is concluded that "*...breakthrough Delta variant infections are associated with high viral loads, prolonged PCR positivity, and low levels of vaccine-induced neutralizing antibodies, explaining the transmission between the vaccinated people. Physical distancing measures remain critical to reduce SARS-CoV-2 Delta variant transmission.*" These findings suggest that Delta variant transmission is more of a concern within the vaccinated population than with the unvaccinated population.

   Source: Chau et al. (2021) — https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733

4. Evidence: Refer to **Section C - #4, #6, #8, #20 (Song et al., 2021), the *NOTE* with C - #52** and **Section G - #2** to understand the low risk that COVID-19 and variants pose to children and young persons.

5. Evidence: Increased risk of infection with SARS-CoV-2 Beta, Gamma, and Delta variant compared to Alpha variant in vaccinated individuals.

   Source: Andeweg et al. (2021) — https://www.medrxiv.org/content/10.1101/2021.11.24.21266735v1

6. Evidence: Memo of Aug. 31, 2021 where CMOH Moore told Ontario's MOs that the vaccinated are just as infectious as the unvaccinated & recommends additional measures. CMOH had knowledge & memo pre-dates Ontario's announcement of vaccine passports. They also acknowledge the emergence of vaccine immune escape variants.

   Source: https://twitter.com/Roman_Baber/status/1455867129526460422

I. Preserving the ability of the public health and health care systems to protect and care for the health needs of the population, including providing care for health needs other than COVID-19, is critical. High incidence of transmission and illness in one or more regions have spill-over effects on health care delivery across the Province, including in critical care and surgical services. Our public health and health care systems are **currently experiencing severe stress**, and are stretched beyond capacity in their efforts to prevent and respond to illness resulting from the transmission of COVID-19 in the population, primarily among unvaccinated people;

DR. BONNIE HENRY CLAIMS: — COVID infected individuals requiring hospitalization are causing the current strain on health care systems.

FACT CHECK: **FALSE** — Hospitals **are** under severe stress, and are chronically understaffed. For years, the Canadian healthcare system has operated at >100.0% capacity and has suffered staffing shortages—now is no different. If our province and nation is indeed in the midst of a pandemic, why would this be the time for dismissal of a large number of unvaccinated—yet healthy and able-bodied—healthcare workers many of whom may have natural immunity. This discriminatory and thoughtless act is forcing surgery cancellations and increasing stress on remaining staff who are expected to work shorthanded.
Additionally, early and preventative treatments have never been approved nor offered in an effort to prevent hospital admissions. In fact, several effective treatment options were actively discredited and prohibited by the PHO and ultimately the College of Physicians & Surgeons and BC College of Midwives and Nurses.

1. Evidence: The BC Nurses Union is sounding the alarm over the looming (and now implemented) vaccination mandate for all healthcare workers, both in the private and public sector. While the BC Nurses Union states that "*vaccinations are key*", they do not condone any government action that "*...could lead to any nurses leaving their jobs*." The BC Nurses Union describes the situation as "dire" and that "*...nurses are going home, they're crying during their shifts because they don't have the resources available — and those resources are more bodies — to help them do their work*." The union Vice President Aman Grewal states that "*...rapid testing, the use of personal protective equipment, and reassigning nurses who are not vaccinated to different roles are all alternatives to requiring proof of immunization and putting unvaccinated nurses on unpaid leave.*" Finally, Grewal states that she is looking at "*...creative [options] since the nursing shortage that's been looming for decades is here — and COVID-19-related burnout has accelerated the crisis*."

   Long-term care health professionals in B.C. were placed on unpaid leave starting October 12, 2021 wherein employees were given the opportunity to get vaccinated by October 26, 2021 to retain employment. All other healthcare professionals in B.C. were placed on unpaid leave beginning October 26, 2021 and were given two weeks to get vaccinated to retain employment. Unvaccinated healthcare professionals were officially terminated the week of November 15, 2021. While exemptions are offered under certain circumstances by the PHO, Dr. Bonnie Henry, exemptions are far and few between.

   Source: https://vancouver.citynews.ca/2021/09/14/bc-health-care-mandatory-vaccine-nurses/
   Source: https://globalnews.ca/news/8191286/bc-nurses-fear-health-care-system-crash-vaccine-mandate/

2. Evidence: Two surgical operating rooms have been shuttered temporarily due to COVID-19 vaccine mandates at Kelowna General Hospital, while inpatient surgeries have been canceled at Royal Inland Hospital in Kamloops, B.C. As of November 15, 2021, Health Minister Adrian Dix reports that 1,018 (5.0%) British Columbian healthcare workers have not been fully vaccinated against COVID-19 and remain on

unpaid leave. The mandates have also affected the South Similkameen Health Centre in Keremeos wherein a "large percentage" of the already small staff employed at the south Okanagan facility remains unvaccinated. Termination of these employees is expected as of November 15, 2021. Dr. Bonnie Henry misses the mark on vaccine mandates, stating that "*...if people are in our healthcare system and [are] not recognizing the importance of vaccination, then [a position in healthcare] is probably not the right profession for them.*" Pressure continues to mount within the already burdened healthcare system within B.C. where most employees are only requesting freedom of choice over personal medical decisions. Mandates and deployment of coercive tactics are not the solution to support a crumbling provincial healthcare sector.

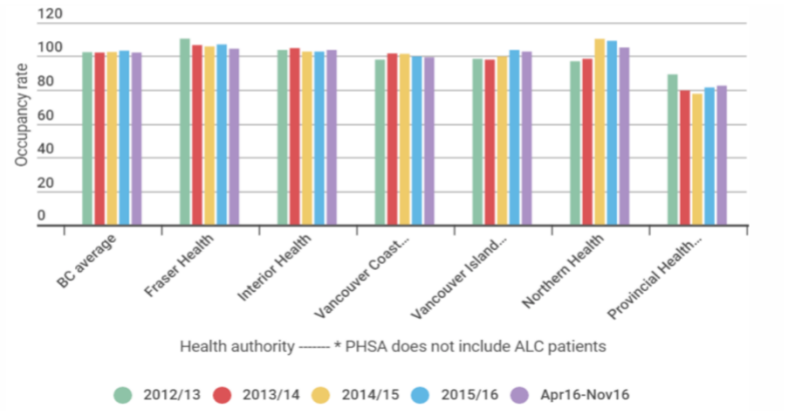
Source: https://www.castanet.net/news/Kelowna/350322/2-operating-rooms-temporarily-closed-at-KGH-due-to-staffing-shortages-after-vaccine-mandate

3. Evidence: The provincial government of British Columbia acknowledged that it created a medical staffing shortage after placing more than 4,000 healthcare professionals on leave because they chose not to get the COVID jabs. Health Minister Adrian Dix made the announcement last Tuesday, saying thousands of surgeries have been postponed as a result of placing so many workers on leave.

   Source: https://www.lifesitenews.com/news/vaccine-mandates-lead-to-critical-shortage-of-healthcare-workers-in-canadian-province/

4. Evidence: The entire B.C. hospital system has been operating over capacity since 2012, according to records extracted from the Ministry of Health, reported in 2017. The figure below demonstrates hospitals being overcapacity from 2012 through 2016.

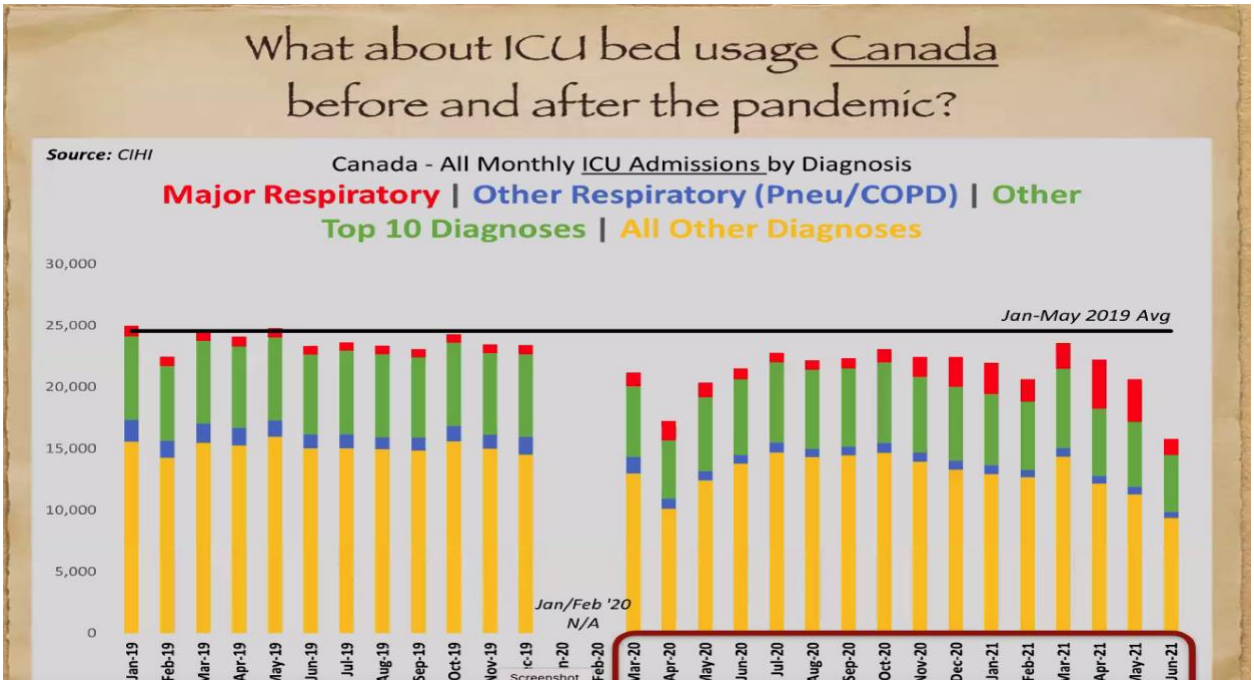
"The entire British Columbia hospital system has been operating over capacity since 2012, according to Ministry of Health figures obtained by The Abbotsford News."



Furthermore, the provincial hospital system has operated >100.0% capacity for the last five years. In 2018, the provincewide occupancy rate was 103.2%, which was an increase from the previous two years (102.7%). As per this 2019 report, only three health regions within B.C. operated below 100.0% capacity: East Kootenay, Kootenay Boundary, and Vancouver. This clearly demonstrates that over capacity within B.C. hospitals due to the declared COVID-19 pandemic in 2020/21 is not attributed solely to COVID-19 hospitalizations.

Source: https://www.surreynowleader.com/news/b-c-hospital-system-has-been-operating-over-capacity-for-five-years/
Source: https://www.abbynews.com/news/infographic-b-c-s-most-crowded-hospitals-are-in-fraser-valley-northern-b-c/

5. Evidence: Intensive Care Unit (ICU) bed usage in Canada before and after the pandemic shows LESS ICU beds occupied than in previous years for all respiratory illness.



Source: Dr. Francis Christian's slide created with data from https://www.cihi.ca/en/access-data-and-reports

6. Evidence: Uttar Pradesh is an stunning example of the benefits of Ivermectin. A population of 240 million, with less than 50% vaccination rates as of December 31 2021, was down to 0 to 2 deaths per day noted in July 2021 when the vaccination rate was only 4.3%. When the state began distributing the drug Ivermectin to everyone, cases plummeted quicker and sharper than anywhere else we've seen in the world, and the gains have held for months with record low cases.

   Source: https://newsrescue.com/the-undeniable-ivermectin-miracle-indias-240m-populated-largest-state-uttar-pradesh-horowitz/

J. Both the public health and the health care systems are using disproportionate amounts of their resources in their efforts to prevent and respond to the transmission of SARS-CoV2, and to provide care for those who become ill with COVID-19, primarily unvaccinated people who comprise the majority of hospitalizations and ICU admissions;

DR. BONNIE HENRY CLAIMS: — A disproportionate amount of healthcare resources is dedicated to COVID care primarily for unvaccinated people.

FACT CHECK: **FALSE** — This claim is unsubstantiated by a lack of evidence. Clarification of—and a definition of—the term '*disproportionate*' is required for context. Furthermore, it is pertinent that the financial costs of the resources being utilized for the COVID-19 response are detailed and compared to previous years within B.C. . The healthcare system is already experiencing increasing admissions of vaccine injured persons along with rising cases of all causes (sudden onset or return of cancer, heart conditions, strokes, etc.).

1. Evidence: Within the hospital system, how many individuals are hospitalized for COVID-19-related complications versus other reasons? Claims such as the 'whereas' statement for section J should be supported by evidence. If hospital beds are full of non-COVID-19 patients yet the public is being informed that the hospital system is over capacity, then the public is being deliberately misled.

   If the public is being informed that the hospital system is over capacity but in reality the hospital is over capacity because of staffing shortages, then the public is being misled. The public may not be aware that hospitals are legally required to maintain a specific nursing-to-patient ratio. If there are not enough nurses to offset the patient load—perhaps due to a recent mass termination of non-vaccinated staff—then the situation is more a problem of inadequate staffing.

   Context is key. In order to understand the impact and portion of COVID-19 admissions on hospital capacity, we need comparative data showing an analysis of the pressure influenza hospitalizations had on the health care system in previous years. "Code Purple", a commonly used term for a hospital operating at overcapacity, is common each influenza season. See **Section I - #4.**

   Additionally, Adrian Dix said B.C. was at 103.0% capacity prior to COVID-19. Looking to October 5th, 2021, Adrian Dix stated—in B.C.'s 4th wave—that the provincial numbers were as follows: B.C.'s hospital beds 78.2% occupied (October 5, 2021) and were 77.1% filled a week prior. On September 3rd, 2021, B.C.'s hospital beds had a were 78.5% full.

   The original adage was "two weeks to flatten the curve". It is now two years later, and health officials are continuing with the same ineffective approach, including ignoring early and effective treatment options.

   Source: https://biv.com/article/2021/10/bc-hospital-occupancy-stays-relatively-flat-past-month

2. Evidence: Ontario hospital beds have never exceeded 90.0% during COVID-19, and NHS England also demonstrated similar lower bed use during the year 2020. We are aware hospitals reduced elective surgeries to prepare for a surge in demand. However, that demand never materialized, causing delayed treatment and late diagnosis. Additionally, people in need of emergency care, failed to seek treatment due to fear of contracting a SARS-CoV-2 infection.

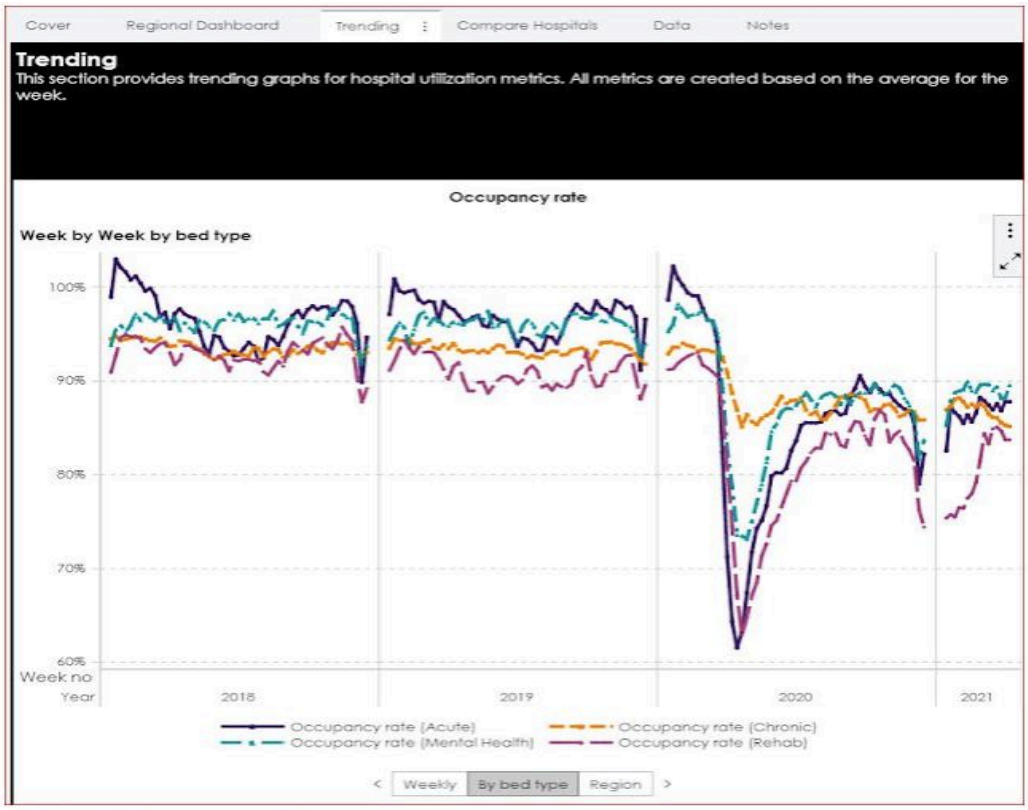


Figure 56: Ontario hospital occupancy rates never rose above 90% throughout the pandemic (source: @Milhouse_Van_Ho on Twitter).

Ontario's bed capacity is also mirrored by official data from the UK's NHS England, which lends additional weight to its credibility.

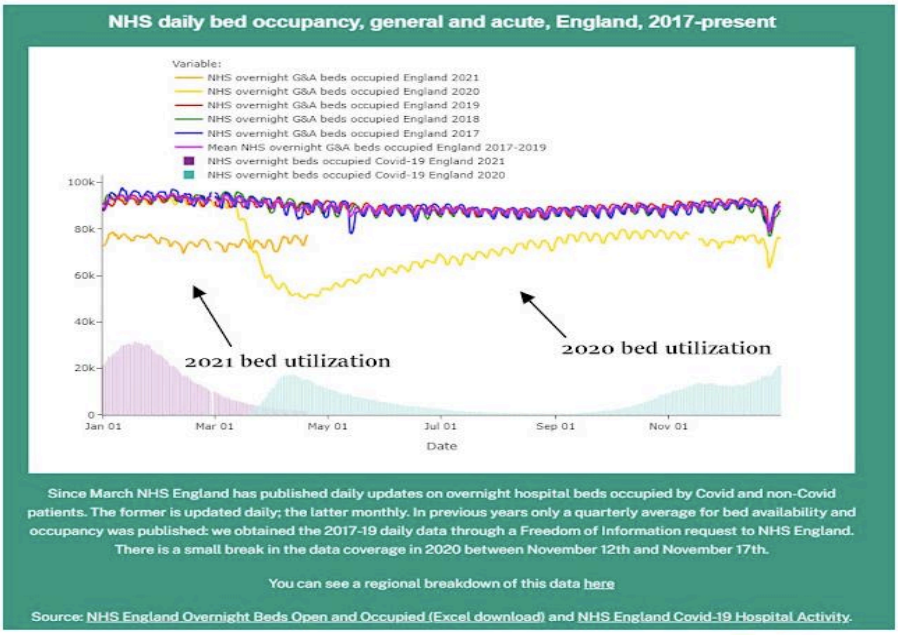


Figure 57: NHS daily bed occupancy, general and acute, England, 2017-present (Source: The Uk's response to Covid-19, in facts and figures - http://www.coviddashboard.live)

Source: https://www.juliusruechel.com/2021/05/the-lies-exposed-by-numbers-fear.html#Pyramid

3. Evidence: While it is claimed that a disproportionate amount of resources is being utilized to prevent and respond to the transmission of SARS-CoV-2, it feels necessary to point out that not enough attention is being afforded to investigation of vaccine adverse reactions. In a recent FDA report, one of the documents produced is the *Cumulative Analysis of Post-Authorization Adverse Event Reports of [the Vaccine]* received through February 28th, 2021. This report accounts for merely 2.5 months of data after the Pfizer vaccine received emergency use authorization (EUA). This document reflects adverse events following vaccination that have completed Pfizer's "workflow cycle," both in and outside the U.S., up to February 28, 2021.

   Pfizer explains on page 6 of the document that "*...due to the large numbers of spontaneous adverse event reports received for the product, [Pfizer] has prioritized the processing of serious cases…*" and that Pfizer "*...has also taken a [sic] multiple actions to help alleviate the large increase of adverse event reports"* including *"...increasing the number of data entry and case processing colleagues*" and "*...has onboarded approximately [REDACTED] additional full time employees (FTEs).*"

   As for the volume of reports in the 2.5 months following EUA, Pfizer received a total of 42,086 reports containing 158,893 "*[adverse] events*." Most of these reports were from the U.S. and disproportionately involved women (29,914 women vs. 9,182 men) and those between 31 and 50 years of age (13,886 vs 21,325 for all other age groups combined, with another 6,876 whose ages were unknown). Also, 25,957 of the events were classified as "*nervous system disorders*." While British Columbia does not have an equivalent populace as the USA or even large states, it is still necessary to allocate resources for investigating the adverse events and deaths associated with COVID-19 vaccinations within the province.

   Source: https://phmpt.org/pfizers-documents/
   Source: https://aaronsiri.substack.com/p/fda-produces-the-first-91-pages-of

K. While people who have contracted SARS-CoV-2 may develop some natural immunity for a period of time following infection, the strength and duration of that immunity varies depending on a multitude of factors, including severity of infection. The risk of reinfection and hospitalization is significantly higher in people who remained unvaccinated after contracting SARS-CoV-2 than in those who were vaccinated post-infection. Vaccination, even after infection, remains an important measure to protect against reinfection. It does so by providing a stronger immune response that is known to be effective for a longer period of time and against a wider variety of strains of SARSCoV-2 that are currently circulation in British Columbia, including the Delta variant;

DR. BONNIE HENRY CLAIMS: — Natural immunity following infection is insufficient to protect against reinfection and hospitalization.

FACT CHECK: **FALSE** — The superiority and efficacy of natural and baseline immunity has been thoroughly documented and is superior to non-sterilizing vaccines. There is no substantiated evidence that any individual naturally infected by SARS-CoV-2 who develops COVID-19 has gone on to become reinfected.

1. Evidence: In a *Brownstone Institute* submission, Dr. Paul Alexander summarizes 146 scientific studies (growing each day) that demonstrate greater protection from a natural SARS-CoV-2 infection compared to COVID-19 vaccination. Naturally acquired immunity is continually proving to be superior as natural infection with COVID-19 confers protection to several components of the SARS-CoV-2 virus (i.e. several outer coat proteins). COVID-19 vaccines only confer partial protection, wherein immunity is only developed against the single SARS-CoV-2 spike glycoprotein from the original strain of the virus. Of note, all currently available COVID-19 vaccines were developed against the original SARS-CoV-2 strain, which is no longer the dominant circulating strain.

   Source: https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-COVID-19-documented-linked-and-quoted

2. Evidence: As per documentation requested from the CDC by the Informed Consent Action Network (ICAN), there is no substantiated evidence that any individual naturally infected by SARS-CoV-2 who develops COVID-19 has gone on to become reinfected, transmitting the virus to another individual. There are, however, several cases of fully vaccinated individuals becoming infected with SARS-CoV-2 and transmitting the virus to others. This is termed a "breakthrough case" and has been reported in numerous studies, including those conducted by Brown et al. (2021), Chau et al. (2021), Saade et al. (2021), and Reimersma et al. (2021). Individuals who recover from natural SARS-CoV-2 infection and COVID-19 experience greater protection rates (99.0%) compared to those who are vaccinated (95.0%). Synthetic protection by way of vaccination also wanes quickly, negating efficacy of COVID-19 vaccines.

   Source: https://aaronsiri.substack.com/p/cdc-admits-crushing-rights-of-naturally
   Source: Brown et al. (2021) — https://pubmed.ncbi.nlm.nih.gov/34351882/
   Source: Chau et al. (2021) — https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733
   Source: Saade et al. (2021) — https://pubmed.ncbi.nlm.nih.gov/34176436/
   Source: Reimersma et al. (2021) — https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4.full.pdf

3. Evidence: Waning immunity following a natural infection with SARS-CoV-2 is a fallacy. Individuals who have recovered from COVID-19 have been shown to possess both a memory B and T cell response as part of their acquired immune system. This has been documented in several studies, including by Wang et al. (2021) who demonstrated a neutralizing capacity one year post infection. Zuo et al. (2021) have also identified a

robust T-cell immune response 6 months post infection. Natural infection with SARS-CoV-2 and recovery from COVID-19 also provide broad-spectrum immunity to approximately 20 SARS-CoV-2 epitopes, suggesting that naturally acquired T-cell immunity provides protection to many variants.

Source: Wang et al. (2021) — https://www.nature.com/articles/s41586-021-03696-9
Source: Zuo et al. (2021) — https://www.nature.com/articles/s41590-021-00902-8
Source: https://www.pandata.org/should-covid-recovered-take-vaccine/
Source: Quadeer et al. (2021) — https://pubmed.ncbi.nlm.nih.gov/34056627/

4. Evidence: Natural immunity is actively being discounted while public health agencies such as the CDC admit that there is no record of documentation for individuals who have "*...(1) never received a COVID vaccine; (2) [were] infected with COVID once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected.*" A Freedom of Information Act request submitted in the USA by the Informed Consent Action Network (ICAN) determined that this information is currently not of interest to public health officials. Meanwhile, public health officials continue to strip citizens of their rights based on deceptive information and faulty data collection.

   Source: https://childrenshealthdefense.org/defender/cdc-data-natural-immunity-covid/

5. Evidence: According to data from the UK Health Security Agency (UK-HSA) titled "*COVID-19 Vaccine Surveillance Report - Week 42*", unvaccinated individuals who have obtained natural immunity through a natural SARS-CoV-2 infection have better long-term immunity outcomes. Page 23 of the UK-HSA document demonstrates that individuals who receive a COVID-19 vaccine series have been shown to produce *less antibodies* following vaccination compared to those who have acquired immunity naturally to SARS-CoV-2. The direct quote is: "*N antibody levels appear to be lower in people who acquire infection following two doses of vaccination.*" This suggests that vaccinated individuals are actually more susceptible to viral mutations and variants than the unvaccinated (or individuals with naturally acquired immunity).

   Source: https://alexberenson.substack.com/p/urgent-covid-vaccines-will-keep-you/comments
   Source: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027511/Vaccine-surveillance-report-week-42.pdf

6. Evidence: Young-Xu et al. (2021) demonstrated the superiority of natural immunity compared to vaccination in a USA study. After tracking the data through August 2021—when delta was the most predominant strain circulating in the USA—natural immunity was found to provide an equivalent level of protection as vaccination with either Moderna or Pfizer, namely in `those ≤ 65` years of age.

   Source: Young-Xu et al. (2021) — https://www.medrxiv.org/content/10.1101/2021.09.27.21264194v1
   Source: https://www.theatlantic.com/science/archive/2021/09/sterilizing-immunity-myth-covid-19-vaccines/620023/

7. Evidence: Natural immunity is proving to provide longer-lasting and superior protection compared to COVID-19 vaccines, as demonstrated in an exhaustive list of primary literature citations.

   Source: *Natural Immunity Cheat Sheet* — https://covidreason.substack.com/p/your-natural-immunity-cheat-sheet
   Source: https://www.biznews.com/undictated/2021/12/16/best-2021-immunity-covid-19-vaccine

8. Evidence: The absence of antibodies following natural infection with SARS-CoV-2 should not negate the possibility that an individual has protection against COVID-19. Swadling et al. (2021) demonstrate that protective T-cell immunity has been detected in individuals who have experienced a clinical infection, even in the absence of antibodies. This suggests that COVID-19 can be cleared prior to immunological seroconversion,

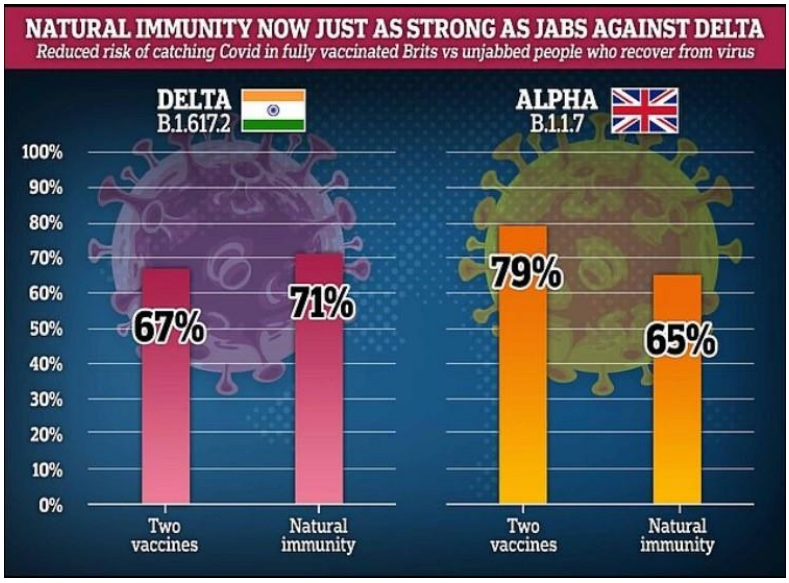
a term utilized to describe the timeframe between clearance of a viral infection and development of antibodies by B cells. Thus, vaccination of all individuals in a population is not warranted to achieve population-based immunity. Some individuals will have an underlying T-cell immunity and no detectable B-cell immunity. Measurement of T-cell immunity is not commercially available, and thus is more difficult (and expensive) to prove within a large population. While this complicates detection of immunological protection in a population, this does not diminish the fact that an underlying level of baseline protection against SARS-CoV-2 exists in a population.

Source: Swadling et al., (2021) — https://www.medrxiv.org/content/10.1101/2021.06.26.21259239v1.full.pdf

9. Evidence: An Israeli study by Gazit et al. (2021) has found that individuals who have never been infected with SARS-CoV-2 but have been vaccinated are six to 13 times MORE likely to experience a breakthrough infection with the Delta strain of COVID-19 when compared to unvaccinated counterparts who have previously experienced a natural SARS-CoV-2 infection. Furthermore, a natural infection with delta was shown to confer a 27-fold benefit for prevention of symptom development and an 8-fold improvement in protection against hospitalization in those 33 to 36 years of age.

   Source: Gazit et al. (2021) — https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1?fbclid=IwAR2h8FJo2kqsExdqIAwS85WfFTI0sBb1ymcWRN_EtV-59oLJiZKVeD1JbDs
   Source: Being fully vaccinated against COVID puts you at 6-13x greater risk of getting delta strain https://childrenshealthdefense.org/defender/fully-vaccinated-pfizer-more-likely-get-delta-than-natural-immunity/

10. Evidence: Office for National Statistics (ONS) report published on October 2021 suggests that double vaccination offers the same protection as recovery from a natural COVID infection with both the Delta strain (67.0% vs. 71.0%, respectively) and the Alpha strain (79.0% vs 65.0%, respectively) based on 8000 tests conducted in the UK between May and August 2021.



Source: Coronavirus (COVID-19) Infection Survey, UK - Office for National Statistics
Source: https://www.dailymail.co.uk/news/article-10103003/Double-jabbed-people-likely-not-catch-Covid-recovered-infection.html

11. Evidence: Refer to **Section C - #60, #67-70 & Section F - #3, #4** for comments on the efficacy of natural infection and immunity to SARS-CoV-2.

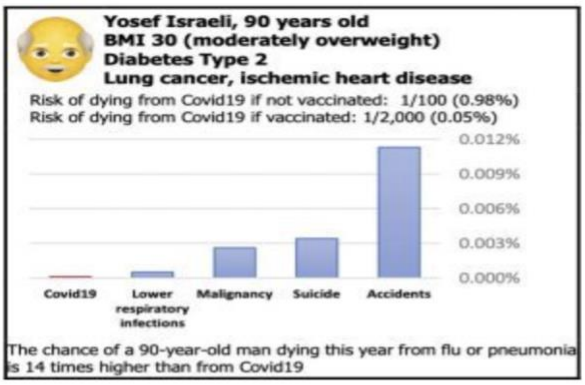
L. Unvaccinated people in close contact with other people can promote the transmission of SARS-CoV2 and increase the number of people who develop COVID-19 and become seriously ill.

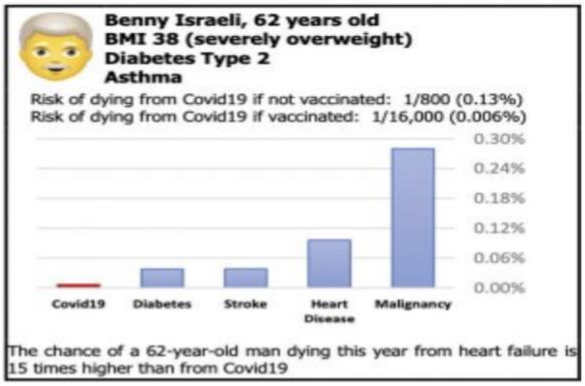
DR. BONNIE HENRY CLAIMS: — Unvaccinated persons are the source of transmission.

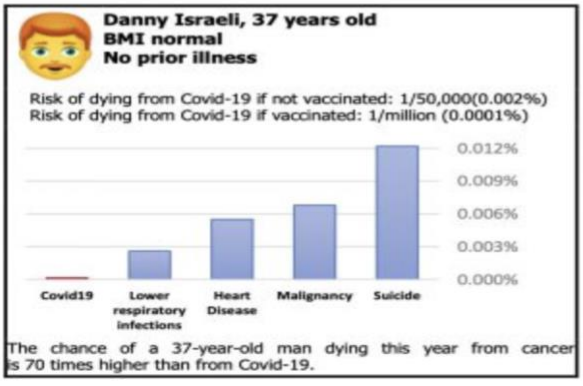
FACT CHECK: **FALSE** — This statement is misleading and requires more context. Both unvaccinated **and** vaccinated persons in close contact with other people can promote the transmission of SARS-CoV-2 and increase the number of people who develop COVID-19 and become seriously ill, as detailed in Section C. An unvaccinated person does not equate to a person infected with SARS-CoV-2.

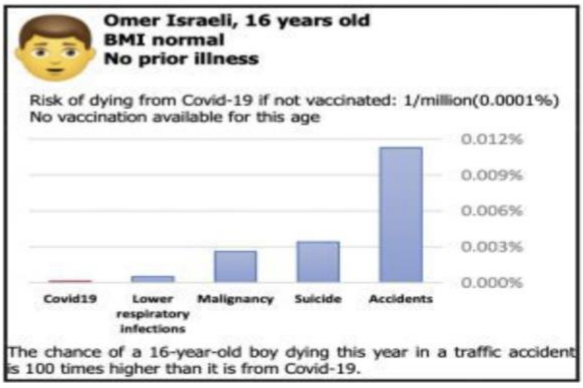
1. Evidence: Epidemiology risk assessment is necessary for determining the threat of an unvaccinated person against a vaccinated person. Graphics procured from *The Israeli Public Emergency Council for the COVID-19 Crisis* demonstrate a hypothetical situation regarding a family residing in a region hit hard with a COVID-19 outbreak, where only one individual in the family is vaccinated. Efficacy of the vaccine is based on Pfizer's initial report of 95.0% efficacy.

   The *Israeli Public Emergency Council for the COVID-19 Crisis* concluded with the following: "*...based on an epidemiological analysis and stringent conditions and data regarding the vaccine, it appears that for a person who has been vaccinated, it no longer matters whether the people around her or him have been vaccinated. The risk of dying from [COVID-19] has become negligible—lower than the risk of ordinary seasonal flu. Considering how insignificant the risk from an unvaccinated person is vis-à-vis those who are vaccinated, there is clearly no epidemiological reason to suspend one's civil rights in order to protect the health of the general public. Furthermore, the separation of the vaccinated population from the unvaccinated is not any more necessary than it would be in the case of any other respiratory virus.*"

2. 







M. Persons receiving health care, personal care or home support in hospital or community settings often are of an advanced age, have chronic health conditions or compromised immune systems which make them particularly vulnerable to severe illness and death from COVID-19, even if they are vaccinated;

DR. BONNIE HENRY CLAIMS: — Elderly, particularly those with comorbidities or compromised immune systems are vulnerable and the vaccination has **not** reduced their risk.

FACT CHECK: **CORRECT**— Vaccination **does not provide absolute protection** against development of COVID-19, nor does vaccination prevent transmission of SARS-CoV-2 particularly for those most at risk. The vaccine has proven to be ineffective for the most vulnerable for whom this Order is purporting to protect.

1. Evidence: Since everyone has the same vulnerability to SARS-CoV-2 infection—even if vaccinated—why are health authorities and the British Columbian government forcing everyone to get vaccinated? It has been thoroughly demonstrated that risk of SARS-CoV-2 transmission is similar between vaccinated and unvaccinated individuals.

2. Evidence: Statement F in the November 18, 2021 PHO contradicts and undermines the efficacy of COVID-19 vaccinations by stating that persons of advanced age, those with chronic health conditions, or those with compromised immune systems are vulnerable to severe illness and death even if they are vaccinated, Why is there so much weight placed on vaccinating an entire province—and further ostracizing a portion of society—if COVID-19 vaccines do not prevent transmission, severe illness, or death within healthy and compromised subsets of the population?

   Source: November 18, 2021 PHO — https://www2.gov.bc.ca/assets/gov/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/COVID-19/COVID-19-hospital-and-community-vaccination-status-information-preventive-measures.pdf

N. Vaccination is the single most important preventive measure health professionals, visitors to hospitals, providers of care or services in hospital or community settings, and the staff or contractors of an organization which provides care or services in hospital or community settings can take to protect patients, residents and clients, and the health care and personal care workforce, from infection, severe illness and possible death from COVID-19;

DR. BONNIE HENRY CLAIMS: — Vaccination is the most important preventive measure to protect those receiving care from COVID-19 and possible death.

FACT CHECK: **FALSE** — COVID-19 vaccines are not the single most important preventive measure. In fact they do not offer prevention, at best they may offer a reduction in severity of illness.

1. Evidence: Highly effective alternative early treatment options are available and have been/are being investigated. Furthermore, consideration should be made for non-pharmaceutical preventative measures such as diet, exercise, healthy lifestyle choices, participation in outdoor activities, and socialization should be recommended for good health. The B.C. government has not engaged in recommending lifestyle choices that have the potential to curb COVID-19 illness; rather, the B.C. government is fixated on a pharmaceutical campaign.

   Source: Please refer to **Section C - #79 and #88-96.**

2. Evidence: While vaccines are continually pushed as the single most preventive measure for various population groups and professions, it must be reiterated that breakthrough cases have been clearly documented. Thus, vaccination is not the single most important preventative solution to COVID-19.

   Source: Please refer to **Section B - #1, Section C - #70, Section D - #1, Section F - #1, #8, #9, and #10, Section H - #1 and #3, and Section K - #2 and #9** for evidence pertaining to breakthrough cases and their implications.

3. Evidence: Early treatment efficacy summary as of December 1, 2021. Analysis of 30 early COVID-19 treatments with ≤3 studies with distinct authors or with <50 control events are shown in grey (where evidence is less robust). Looking at the green diamonds (on the left hand side of the graph) demonstrates early COVID-19 treatments are more effective than placebo. The shorter the line across the green diamond, the more robust and reliable the results. ****NOTE:** Hydroxychloroquine, Ivermectin, Vitamin D, and overall results.

   Source: https://c19adoption.com/

O. There are clear, objective criteria for determining whether a person has a medical deferral to a COVID-19 vaccination, and very few people fall into this category;

DR. BONNIE HENRY CLAIMS: — Medical deferral, based on very narrow criteria, is the only option for a person to refuse vaccination.

FACT CHECK: **FALSE** — If an individual suffers a severe adverse reaction to an initial COVID-19 vaccine (i.e. anaphylaxis, myocarditis, neurological disorder) **or** has medical or religious concerns that would constitute grounds for an exemption, there is **no ability** to get a vaccine exemption.

1. Evidence: Within B.C. the only exemption to a COVID-19 vaccine is an "*...anaphylactic reaction to components of mRNA and adenovirus vector vaccine (i.e. polyethylene glycol and polysorbate 80).* In addition, individuals with a receipt of SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19 [may be] deferred from [receiving] a COVID vaccine for at least 90 days." An individual with a diagnosis of multisystem inflammatory syndrome (MIS) will be deferred from a COVID vaccine until they have fully recovered from the disease or for a 90 day period. Finally, an individual who has experienced myocarditis or pericarditis—confirmed by a physician—can be granted a deferral until the risk of recurrence [following a second vaccination] is fully assessed. Other medical and/or religious exemptions are not accepted by the BC government at this time.

   The province [of BC] states the following reasons are not contraindications to getting the COVID vaccine in B.C.:

   - History of an anaphylactic reaction to a previous dose of mRNA or adenovirus vector vaccine. Someone may receive their 2nd dose using a vaccine of [a] different type.
   - History of an anaphylactic reaction to any component of one type of vaccine. Someone may receive a vaccine of [a] different type.
   - History of thrombosis with thrombocytopenia following a previous dose of an adenovirus vector COVID-19 vaccine. Someone may receive [an] mRNA vaccine.
   - History of capillary leak syndrome. Someone may receive [an] mRNA vaccine.
   - History of cerebral venous sinus thrombosis (CVST) with thrombocytopenia, unrelated to adenovirus vector COVID-19 vaccination, or heparin-induced thrombocytopenia (HIT). Someone may receive [an] mRNA vaccine.

   Dr. Bonnie Henry is not allowing those who have had severe reactions to their first COVID-19 shot to be exempt from future vaccines, However Health Canada states that the clinical trials EXCLUDED those who had a history of reactions, allergy or otherwise. These shots are not tested on those who have had any severe reactions, including anaphylaxis.

   "Clinical trials of the authorized COVID-19 vaccines excluded individuals with a history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. However, studies are ongoing."

   Source: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#a7.8

Due to limitations in the number of participants and duration of follow-up from COVID-19 clinical trials, medium- and long-term evidence on vaccine safety is limited. However, post-licensure vaccine pharmacovigilance is ongoing and safety signals around the world are detected and communicated globally. Clinical trials of the authorized COVID-19 vaccines excluded individuals with a history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. However, studies are ongoing.

Source: https://globalnews.ca/news/8199359/reasons-cant-get-covid-vaccine-bc/

2. Evidence: The BC CDC states that there are no medical exemptions for COVID-19 vaccines within the province, dated November 16, 2021.

   Source: http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccine-considerations

3. Evidence: While COVID-19 vaccines have not been forced in B.C. they are considered 'mandatory' to engage in certain events (i.e. dine in a restaurant, attend a movie theatre, board a plane/train/bus, work in many jobs, etc.) Thus, mandatory vaccines infringe upon sections 2 (a) and (b) of the Canadian *Charter of Rights and Freedoms.* Furthermore, mandatory vaccines violate section 7 off the Canadian *Charter of Rights and Freedoms*. Finally, mandatory vaccines also violate section 10 of the *Health Care Consent Act* of B.C. in that mandatory vaccines require informed consent. Furthermore, the introduction of COVID-19 vaccine passports within B.C. are a violation of section 7 of the Canadian *Charter of Rights and Freedoms.*

   Canadian *Charter of Rights and Freedoms*

   Fundamental freedoms

   2 Everyone has the following fundamental freedoms:

   > **(a)** freedom of conscience and religion;
   > **(b)** freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication;

   Legal Rights — Life, liberty and security of person

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

   Source: Canadian Charter — https://laws-lois.justice.gc.ca/eng/const/page-12.html
   Source: *Health Care Consent Act* https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/96181_01#section10

4. Evidence: Exemptions based on conscientious and/or religious objections to the use of fetal cells within research and development of COVID-19 are not acknowledged within B.C.

   According to *ImmunizeBC*, "*...fetal cell lines were used to make the Janssen (Johnson & Johnson) vaccine and the AstraZeneca (Vaxzevria) vaccine. However, the vaccines themselves do not contain fetal cells or tissue. The purification process removes nearly all the cell components so that only trace amounts of DNA and protein may be present in the vaccine. Fetal cell lines were not used to make the Moderna (Spikevax) and Pfizer-BioNTech (Comirnaty) COVID-19 mRNA vaccines. However, the cell lines were used in the very early stages of research and development of these vaccines to test 'proof of concept' (to test that the vaccines could work).*"

   For clarification on which fetal cell lines were utilized, ImmunizeBC states the following: "*...the AstraZeneca (Vaxzevria) vaccine uses the HEK 293 fetal cell line, and the Janssen (Johnson & Johnson)*

vaccine uses the PER.C6 fetal cell line. However, the vaccines themselves do not contain fetal cells or tissue. The purification process removes nearly all the cell components so that only trace amounts of DNA and protein may be present in the vaccine. The Moderna (Spikevax) and Pfizer-BioNTech (Comirnaty) COVID-19 vaccines used the fetal cell line HEK 293 in the very early stages of research and development. It was not used to make these vaccines. The HEK 293 and PER.C6 fetal cell lines descend from cells taken from fetuses aborted in the 1970s and 1980s. The fetuses were not aborted to make vaccines."

Source: https://immunizebc.ca/ask-us/questions/do-covid-19-vaccines-contain-aborted-fetal-cells

5. Evidence: Individuals who have immune disorders are not eligible for an exemption, even though the COVID-19 manufacturers explicitly state that the COVID-19 vaccines have not been tested in this subset of individuals. Clinical trial exclusion criteria states that individuals with immunodeficiency or those utilizing immunosuppressive treatments were not included. The ImmunizeBC website does not offer much clarity on the risks associated with COVID-19 vaccines in individuals with these medical concerns.

   Source: Moderna Trial — https://clinicaltrials.gov/ct2/show/NCT04470427?term=NCT04470427&draw=2&rank=1
   Source: Pfizer Trial — https://clinicaltrials.gov/ct2/show/NCT04368728?term=NCT04368728&draw=2&rank=1
   Source: https://immunizebc.ca/ask-us/questions/it-safe-me-get-covid-19-vaccine-if-i-am-immunocompromised-treatment-or-illness-0

P. There are difficulties and risks in accommodating persons who are unvaccinated, since no other measures are nearly as effective as vaccination in reducing the risk of contracting or transmitting SARS-Co-2, and the likelihood of severe illness and death;

***NOTE:** A description of effectiveness is necessary for context. Again, COVID-19 vaccines do not reduce the risk of contraction, or transmission, of COVID-19. COVID-19 vaccines *may* only reduce severe COVID-19 symptoms. Again, a definition of severe is necessary for context, as severity is a subjective measurement. Furthermore, limitation of accommodations and/or religious/medical exemptions effectively puts the lives of all B.C. residents at the mercy of the sitting PHO, Dr. Bonnie Henry. It can be recognized that there are situations wherein certain individuals cannot take a specific medication (or even consume something as simple as a specific food type) based on safety and health concerns. A decision so grand as to whether one should or should not vaccinate should thus be left to patients and their personal medical doctors. However, even this basic level of medical autonomy has been stripped away from B.C. residents as medical doctors are not able to write exemptions without fear of reprimand. One-size-fits-all, blanket medicine is not only coercive, but it is incredibly dangerous and negligent.

DR. BONNIE HENRY CLAIMS: — It is difficult and risky to accommodate unvaccinated persons and that nothing is as effective as vaccination.

FACT CHECK: **FALSE** — There are many other measures that have been shown to be as effective—or more effective—than COVID-19 vaccines. British Columbians deserve to see the evidence used to support the claim. Also, this statement requires context or data to explain why it's difficult or risky to 'accommodate' unvaccinated persons.

1. Evidence: Accommodating unvaccinated persons may take the form of exemptions, or dismissal from the B.C. COVID-19 passport system. It should be reiterated that vaccine passports are not about ensuring the public's health and safety. As spoken by Dr. Patty Daly, Chief Medical Health Officer for Vancouver Coastal Health, vaccine passports are an "*incentive to get higher vaccination rates*" and not to stop the spread of COVID-19.

   Dr. Daly was also quoted saying "*The vaccine passport requires people be vaccinated to do certain discretionary activities such as go to restaurants, movies, gyms not because these places are high risk. We're not actually seeing COVID transmission in these settings*." Daly was reported saying that *"…the vaccine passport is for non-essential opportunities and it is really to create incentive to get higher vaccination rates*." about creating an incentive to increase vaccine uptake within the province.

   Source: Refer to **Section D - #4.**

2. Evidence: Please refer to **Section C** for presentation of data on lack of vaccine safety and effectiveness, along with options for and alternative therapeutics.

Q. I have considered and continue to consider based on the currently available generally accepted scientific evidence whether other measures, such as natural immunity, PCR testing or rapid antigen testing, are as effective as vaccination in reducing the risk of transmission SARS-Co-2 and or the severity of illness if infected;

DR. BONNIE HENRY CLAIMS: — She considers scientific evidence to determine if other measures are as effective as vaccination.

FACT CHECK: **FALSE** — The Okanagan Health Professionals open letters provided to Dr. Bonnie Henry and others is readily available and includes generally accepted scientific evidence which is mounting as each day passes. It is clear based on the many false statements in the Order that this evidence is not being considered. A prime example is complete disregard of the data on the benefits and superiority of natural immunity. There is strong evidence that early treatments greatly reduce the hospitalizations and deaths of COVID-19 positive cases.

Okanagan Health Professionals Open Letters:

- Open Letter to Dr. Bonnie Henry, Adrian Dix, and Premier John Horgan Sept 2021
- Open Letter to Dr. Bonnie Henry, Adrian Dix, Premier John Horgan and Attorney General David Eby Oct 2021

1. Evidence: Please refer to **Section C - #58, #67-70, Section F - #3 and #4,** as well as **Section K** for supportive research of natural immunity.

2. Evidence: Please refer to **Section A** for information regarding the PCR test, and why it is not valid. In addition, it should be noted that the rapid test was approved for different purposes compared to what it is currently being utilized for. Please refer to **Section R - #2**.

   Source: https://rumble.com/vpra5j-showing-the-science-dr.-byram-bridle.html

3. Evidence: CORONAVIRUS Official Public Health England Data Says COVID infection rates are higher in vaccinated persons than unvaccinated persons. The data is being used to show it is not effective. After Public Health England (PHE) published the data, government bureaucrats began to panic that people would use it to suggest vaccines were not that effective. Office for Statistics Regulation director Ed Humpherson called an urgent meeting with U.K. Health Security Agency, during which he [stated that he] worried about the data having "*...the potential to mislead*."

   Source: https://www.thetimes.co.uk/article/covid-in-scotland-john-swinney-urged-to-scrap-vaccine-passports-7dp6chl8d
   Source: https://summit.news/2021/11/19/official-public-health-england-data-says-covid-infection-rates-higher-in-vaxxed-then-unvaxxed/?fbclid=IwAR0MqSEG8Dtw1ao29DrQZLwjXvNIH8VrXACW_RzwBfbD0g8DfYfgWqETgGA

4. Evidence: New BC CDC report confirms on page 20 that between October 24 and November 20, 51.2% of COVID-19 deaths were in the "fully vaccinated" group. Those who died within 21 days of their first vaccination are counted in the "unvaccinated" group, so the number of deaths among the vaccinated is likely underreported.

   BC CDC claims that greater than 90.0% of those dying amongst the vaccinated are at least 80 years of age, but those same details are not provided in summary form for the unvaccinated.

In the same period, 1.2% of deaths from COVID-19 included those "vaccinated, 3 doses." This report states that 19.4% of the BC population remains unvaccinated.

Page 5 shows only 78.0% of the total BC population have had two doses of a COVID-19 vaccine, while 81.0% have had at least one dose. Meanwhile, 91.0% of children aged 12+ have had one shot and 87.0% have had two shots.

The new report shows data for people with three doses of the vaccine as "vaccinated, 3 doses" but the *Data Notes* page providing the meaning of all terms used has not been updated to include a definition for those with more than two doses.

Page 5 states that cases and hospitalizations are declining, deaths are relatively low and stable, and 100.0% of infections are of the Delta variant.

Source: http://www.bccdc.ca/Health-Info-Site/Documents/COVID_sitrep/2021-11-25-Data_Summary.pdf

***NOTE:** To access the *Data Notes* click on the link below. Above the blue ribbon titled "BC Centre for Disease Control," click on the arrow on the grey tabs on the far right to uncover the hidden *Data Notes* tab where you will find the definitions.

Access for *Data Notes*: http://www.bccdc.ca/health-professionals/data-reports/covid-19-surveillance-dashboard

R. Routine COVID-19 testing of asymptomatic people is not recommended in BC and PCR testing capacity is reserved for people who may be ill with COVID-19 to promote public health case identification, follow up and control measures. Asymptomatic testing increases the likelihood of generating false positive tests, which can unnecessarily consume public health resources in following up false positive tests. Similarly, rapid testing, which is followed up with confirmatory PCR testing for positive tests, is reserved for specific settings in which additional layers of protection are needed to protect people at higher risk of serious outcomes of COVID-19, such as in long-term care and assisted living facilities, or in remote communities where obtaining results of PCR testing may be delayed.

DR. BONNIE HENRY CLAIMS: — Asymptomatic testing unnecessarily consumes public health resources and drives false positive results.

FACT CHECK: **CORRECT**— Asymptomatic testing drives false positives and has done so for the past 18+ months (see **Section A - #4, #5, #7, and #10**). It should be questioned why Dr. Bonnie Henry no longer feels that it is necessary to test asymptomatic individuals in an effort to preserve public health resources. It is also peculiar that asymptomatic testing is still required for travel and for some workplaces, but not for the general public. Furthermore, one might question why PCR and rapid antigen testing are approved for travel and certain workplace settings, but these same options were not given to healthcare workers. Instead, healthcare workers were forced to either vaccinate, or be terminated (see **Section I - #1**).

1. Evidence: Please refer to **Section A - #2 through #10** for more details on diagnostics for COVID-19.

2. Evidence: Dr. Byram Bridle explains the confusing conflict between what the rapid test instructions say it is to be used for and has been tested for (i.e. symptomatic cases) versus what the Ontario (and other Canadian) health agencies are using it for (i.e. asymptomatic). Dr. Bridle shows that these tests have zero public health value as the rapid tests were never meant to be used as a TEST, and were never tested on asymptomatic people.

   Yet, from the Ontario government COVID-19 directives, the following is stated: "...*antigen testing is a screening tool and **does not diagnose COVID-19.***" Furthermore, "... *antigen screening tests **should only be used on asymptomatic individuals**. They should not be used for symptomatic individuals, or individuals who have had close contact with known positive cases in the context of this program. Symptomatic individuals, or individuals who have had close contact with known positive cases should be directed to a designated testing center for testing*."

   Source: https://covid-19.ontario.ca/provincial-antigen-screening-program
   Source: https://rumble.com/vpra5j-showing-the-science-dr.-byram-bridle.html

3. Evidence: Not only is asymptomatic testing unnecessarily consuming public health resources and driving false positive results, the actual tests themselves state in their own information and instruction pamphlets that these tests should be utilized only for symptomatic testing — these tests have not been tested for use in asymptomatic persons. These tests have only been tested and recommended for use in persons with symptoms.

   Source: https://www.fda.gov/media/141570/download

S. The public needs to have confidence that when they receive health care from a health professional they are not putting their health at risk;

DR. BONNIE HENRY CLAIMS: — Unvaccinated health professionals put the public at risk when they are providing health care.

FACT CHECK: **FALSE** — There is no difference between an unvaccinated and vaccinated individual in regards to potential risk of infection and/or transmission. Recent data suggests that vaccinated persons are more likely to transmit SARS-CoV-2 to others because they may not be symptomatic, but still harbor the virus. Enforcing mandatory vaccination across healthcare professions as a means to ensure public confidence is discriminatory, neglectful, violates Canadian law (see **Section O - #3**), and is not rooted in science - it will not stop transmission in health care settings.

1. Evidence: Please refer to the following to demonstrate a lack of differences between unvaccinated and vaccinated individuals, regarding transmission of SARS-CoV-2 and development of COVID-19.

    a. **Section C - #72 and #78**
    b. **Section F - #3, #6, #8, and #10**
    c. **Section H - #2**
    d. **Section L - #1**
    e. **Section M - #1**

2. Evidence: The public is lacking confidence in information provided by the government, particularly concerning a lack of evidence for case numbers, number of ICU beds utilized, and hospital outbreaks. To build and ensure public trust, provincial data and hospital reports should be widely distributed throughout the public, and should not be protected by "freedom of information requests" riddled with redactions.

    Source: https://bc.ctvnews.ca/dozens-dead-hundreds-infected-but-health-authorities-fight-to-conceal-b-c-hospital-outbreak-findings-1.5624106

3. Evidence: Dr. Bonnie Henry recently states that B.C. health officials are looking for ways to accommodate fully vaccinated healthcare staff who have mild COVID-19 symptoms or who are asymptomatic, yet test positive. These healthcare staff would be considered "low risk", and would mitigate staffing shortages. In contrast, unvaccinated staff who were not sick were terminated from their positions within B.C. as of October 26th, 2021 as they were deemed unfit to work, and a health risk. How is this measure non-biased and based in science? How does one measure if allowing fully vaccinated, COVID-19-positive staff members to continue coming in to work while sick any more—or less risky—than allowing unvaccinated and COVID-19-positive staff members to attend work? Furthermore, do patients get to choose who they will be exposed to?

    Source: https://bc.ctvnews.ca/b-c-may-allow-some-covid-positive-health-care-workers-to-keep-working-top-doctor-says-1.5722800
    Source: https://www.castanet.net/news/BC/355746/B-C-considering-allowing-some-COVID-positive-healthcare-workers-back-on-the-job

T. Preserving the ability of the public health and health care systems to protect and care for the health needs of the population is critical;

DR. BONNIE HENRY CLAIMS: — Removing unvaccinated health professionals from the workforce will protect the system.

FACT CHECK: **FALSE** — This has proven to be a poorly conceived plan. Removing competent workers from the health care system—based on the false and unsupported claims of this Order—has proven to create the opposite effect.

1. Evidence: Surgeries have been cancelled and two operating rooms at Kelowna General Hospital were closed. Interior Health has been hard hit by the exodus of 1,018 employees who were put on unpaid leave after not getting a COVID-19 vaccination. The remaining staff are forced to work in unsafe conditions with unmanageable workloads due to severe shortage of qualified health care workers. In the absence of unvaccinated staff, COVID-19 outbreaks are continuing to plague our healthcare system. A recent example is Royal Inland Hospital in Kamloops, Kelowna General Hospital and throughout breakrooms across Interior Health.

From: IH Communications <ihcommunications@interiorhealth.ca>
Sent: Tuesday, January 18, 2022 9:12 AM
To: __IHA Managers (Restricted) <IHAManagers@interiorhealth.ca>
Subject: Safety in Breakrooms
Importance: High

Interior Health

FROM Karen Bloemink, VP, HR, Population Health & Pandemic Response
Dr. Sue Pollock, Interim Chief Medical Health Officer

DATE January 18, 2022

RE: Safety in Breakrooms

As the incidence of COVID-19 transmission increases across Interior Health, breakrooms continue to be commonly implicated in staff exposure events.

Related resources

- Guidelines for Common Areas, Break Rooms and Physical Distancing for COVID-19
- Workplace Health & Safety Questions and Answers
- COVID-19 Safety Huddles: Minimizing Exposure; Physical Distancing; PPE – Doffing

We recognize and acknowledge that we are collectively gathered on the traditional, ancestral, and unceded territories of the seven Interior Region First Nations. This region is also home to 15 Chartered Métis Communities. It is with humility that we continue to strengthen our relationships with First Nation, Métis, and Inuit peoples across the Interior.

Subject: CEO Message - IH Temporary Service Reductions
Date: Tuesday, January 18, 2022 2:41:55 PM
Attachments: image001.png

January 18, 2022

Today, Interior Health is announcing a series of temporary service reductions across Interior Health. Like other communities across the province, COVID-19 and the Omicron wave have caused new and additional challenges throughout the region and increased pressures in areas where our staffing was already stretched.

We need to take action now to keep core health services open and to ensure the safety of our patients and clients, and each other.

Effective on Monday, Interior Health began the temporary redeployment and reassignment of staff throughout the region to stabilize services where they're needed most, including in emergency departments and long-term care. These temporary measures will vary by region and community including:

- Closing inpatient services in Clearwater, Invermere, and Lillooet to stabilize emergency departments in those communities;
- Reducing overnight hours at the Ashcroft Community Health Centre and the Slocan Health Centre in New Denver to stabilize daytime services in those communities;
- Closing the Barriere and District Health Centre to redeploy staff to nearby emergency departments;
- Temporarily rescheduling all non-urgent surgeries; temporarily reducing services across IH to some outpatient services; some primary care services, adult day programs and some non-urgent home health services.

The decisions we are making have been reviewed carefully to ensure the right measures are implemented and while I expect the service reductions to remain in place into February, we will return to normal operations as soon as possible.

Source: Kelowna General Hospital closes two operating rooms as staff shortage sets in | Globalnews.ca
Source: Kamloops Mayor 'wants answers' as Royal Inland Hospital faces health-care crisis - Okanagan | Globalnews.ca
Source: COVID-19: Outbreak at Kamloops hospital, visitor restrictions announced | Globalnews.ca
Source: COVID-19 outbreak on general surgery ward at Kelowna General Hospital - Kelowna News - Castanet.net

2. Evidence: Contrary evidence demonstrates that it is the COVID-19-recovered health care professionals who are the safest people to be around sick patients, including unvaccinated persons. In a recent interview, Dr. Peter McCullough speaks of advising India to put all their COVID-19-recovered healthcare workers on the front lines as a means to stem the spread of COVID-19, which was successful.

Source: Dr. McCullough interview — https://www.bitchute.com/video/i0fWCCnXH5xJ/

U. The retention of public confidence in the safety and integrity of the public health and health care systems is critical;

DR. BONNIE HENRY CLAIMS: — Removing unvaccinated health professionals from the health care system will retain safety and integrity of the system.

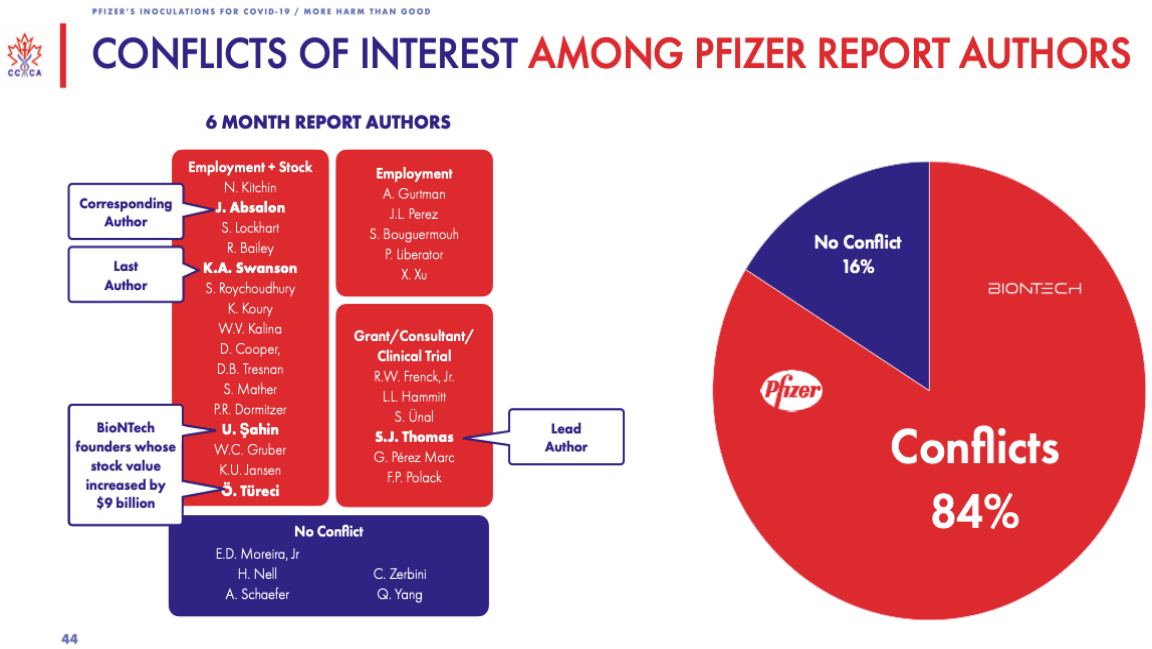
FACT CHECK: **FALSE** — The integrity of the public health system has been completely eroded with ever changing direction and goal posts. For example, in early-to-late 2020 as SARS-CoV-2 infections were mounting, the public was advised that masks do not work to prevent spread. Now, the public—specifically B.C.—has been under a mandatory mask order for the better part of a year. Another example of a "moving goalpost" is the original statement that when vaccines were available, herd immunity would be achieved when 70.0% of the population was inoculated. B.C. has 87.4% of the eligible population inoculated, and the concept of reaching herd immunity is no longer discussed. Rather, a vaccine mandate has been issued along with the introduction of a coercive B.C. COVID-19 vaccine passport. Additionally, public trust in government policies regarding COVID-19 has been eroded due to the uncovering of glaring conflicts of interest between the BCCDC Foundation and major pharmaceutical companies.

1. Evidence: Please refer to **Section C** for the numerous links to concern over safety and effectiveness of COVID-19 vaccines.

2. Evidence: There is concern regarding the integrity of the public health system given the potential conflict of interest with drug companies such as Pfizer, providing "champion" level sponsorship to the BCCDC Foundation.

Source: BCCDC Foundation — https://bccdcfoundation.org/our-donors/

3. Evidence: Regarding integrity, the array of conflicts of interests in the vaccine manufacturers, the patent holders, stockholders, and those demanding their use—as well as the use of other COVID-19 protocols—is undeniable. Dr. Tony Fauci's patent and investment in Moderna is a major conflict of interest.



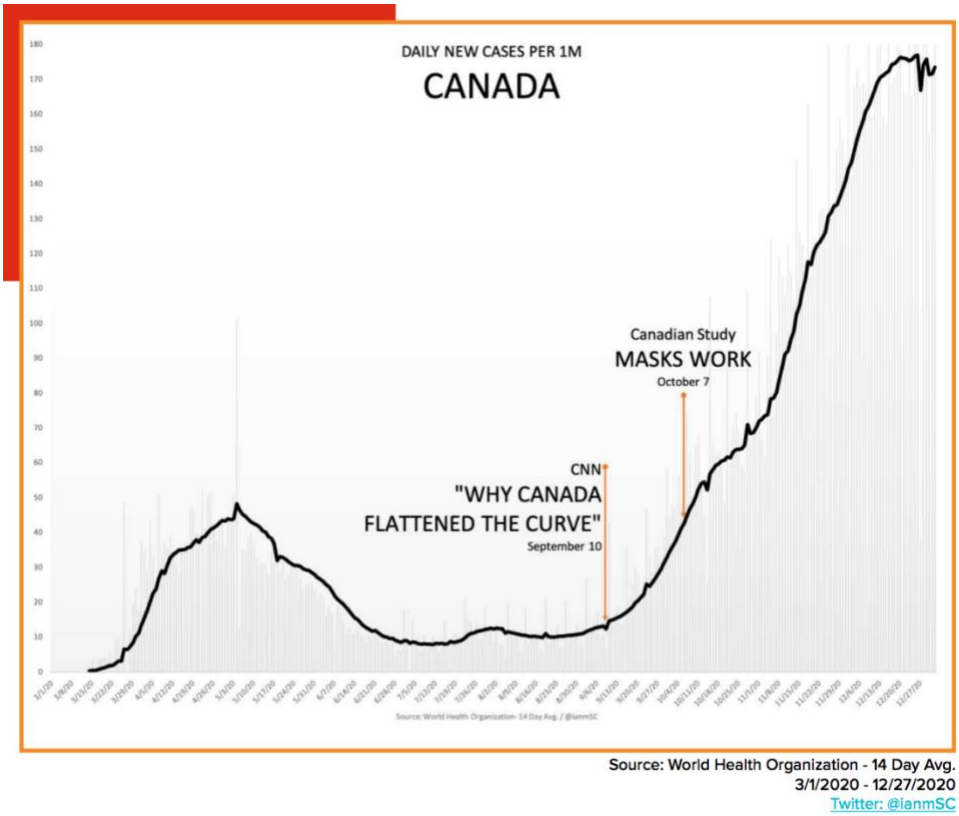
Not only this, <u>the vaccine manufactures have been indemnified for damages in case their inoculations hurt and kill people, they amassing profits to the tune of billions</u> under the Emergency Use Authorization. No reasonable, responsible person would give vaccine manufacturers carte blanche in such a situation. Instead, one would expect to engage in rigorous oversight and hold them to the highest scientific standards. This was not done. There is no incentive to make sure these products are safe. There is no integrity with this setup, and no other medical product, or really any other commercial products (foods, personal items, electronics, vehicles, etc.), other than vaccines, have zero liability for harm.

<u>Source:</u> https://ocla.ca/wp-content/uploads/2021/12/CCCA-Pfizer-Trial-Breakdown-The-COVID-19-Inoculations-More-Harm-Than-Good-Dec.-15-2021.pdf

4. <u>Evidence:</u> Major conflicts of interest exist between FDA commissioners, CEO's and the NIAID director. Please see the following image which clearly demonstrates major opportunities for abuse of power and control.

- **<u>Mark McClellen:</u>** A former FDA commissioner, turned Board of Director for Johnson & Johnson in 2013.
- **<u>Scott Gottlieb:</u>** A former FDA commissioner, turned Board of Director for Pfizer in 2019.
- **<u>Stephen Hahn:</u>** A former FDA commissioner in charge of Moderna regulations, turned Chief Medical Officer of Flagship Pioneering, the venture capital firm for Moderna in 2021.
- **<u>James Smith:</u>** A CEO of Reuters who informs individuals about COVID-19 vaccines is also on the Board of Directors for Pfizer, since 2014.
- **<u>Anthony Fauci:</u>** NIAID Director for the National Institutes of Health who has funded and conducted gain of function research at the Wuhan, China Institute of Virology, where SARS-CoV-2 is said to have originated.

5. Evidence: The province of B.C. has been under a mask mandate for the better part of a year, yet the data demonstrates clearly the inefficacy of masking as a preventative for the spread of SARS-CoV-2. Again, this undermines the integrity of the provincial healthcare system and the PHO, Dr. Bonnie Henry. Dr. Bonnie Henry has contradicted herself several times regarding the efficacy of masks — see here.



Source: https://upviral.s3.amazonaws.com/images/1637108970COVID-Charts-CNN-Forgotpdf.pdf
Source: http://www.nanaimoinfoblog.com/2021/04/bonnie-henry-contradicts-herself.html

6. Evidence: Dr. Paul Alexander, in the Brownstone Institute, has collected 167 comparative studies and articles on mask ineffectiveness and harms. Dr. Alexander holds a PhD, working and teaching in the field of clinical epidemiology, evidence-based medicine, and research methodology. He is a former Assistant Professor at McMaster University. Dr. Alexander presents the masking 'body of evidence' of 167 studies and pieces of evidence, comprised of comparative effectiveness research as well as related evidence and high-level reporting. To date, the evidence has been stable and clear that masks do not work to control the virus and they can be harmful and especially to children.

   Source: https://brownstone.org/articles/more-than-150-comparative-studies-and-articles-on-mask-ineffectiveness-and-harms/

V. Employers need to know the vaccination status of staff in order to enforce preventive measures ordered by me or the medical health officer;

DR. BONNIE HENRY CLAIMS: — It is necessary for staff to reveal personal health information to their employer.

FACT CHECK: **FALSE** — There is no benefit for an employer to know who is, or is not, vaccinated in the workplace. Requiring this information from employees does not reduce rates of transmission in the workplace. Furthermore, forcing an employee to disclose this information is a breach of medical confidentiality.

1. Evidence: Please refer to **Section S - #1** for a detailed description of the lack of differences between vaccinated and unvaccinated persons, regarding transmission of SARS-CoV-2 and development of COVID-19.

2. Evidence: Personal health information is protected under the Privacy Act and there is no justification—no scientific basis/data to declare a regional event—to breach the protection afforded under these laws. Requesting an individual's medical information or proof of exemption based on their medical information violates the Privacy Act. No one has the right to request to see an exemption as it is a violation of privacy rights. This personal medical information is privy to only oneself and their physician. The *Privacy Act* states: *"Pursuant to s. 1 of the Privacy Act of B.C., RSBC 1996 CHAPTER 373, it is unlawful to violate the privacy of another person. Private health issues are strictly between an individual and their physician. There is no legal or any other obligation at law requiring anyone to divulge the nature of their medical conditions with anyone.*"

   Source: https://action4canada.com/charter-right-resources/

W. Medical health officers need to know the vaccination status of staff in order to most effectively respond to exposures to or outbreaks of COVID-19 among patients, residents, clients or staff;

DR. BONNIE HENRY CLAIMS: — It is necessary for staff to reveal personal health information to their medical health officers.

FACT CHECK: **FALSE** — There is no benefit for medical health officers to know who is, or is not, vaccinated in the workplace. Requiring this information from employees does not improve rates of transmission in the workplace. Furthermore, forcing an employee to disclose this information is a breach of medical confidentiality.

1. Evidence: Please refer to **Section V - #1** for details.

2. Evidence: Personal health information is protected under the Privacy Act and there is no justification – no scientific basis/data to declare a regional event – to breach the protection afforded under these laws. Requesting an individual's medical information or proof of exemption based on their medical information violates the Privacy Act. No one has the right to request to see an exemption, it is a violation of your privacy rights. This is your personal medical information between you and your physician. The *Privacy Act* states: *"Pursuant to s. 1 of the Privacy Act of B.C., RSBC 1996 CHAPTER 373, it is unlawful to violate the privacy of another person. Private health issues are strictly between an individual and their physician. There is no legal or any other obligation at law requiring anyone to divulge the nature of their medical conditions with anyone.*"

   Source: https://action4canada.com/charter-right-resources/

X. I recognize the effect which the measures I am putting in place to protect the health of patients, residents and clients and other staff in hospital and community settings may have on people who are unvaccinated and, with this in mind, have engaged and will continue to engage in a process of reconsideration of these measures, based upon the information and evidence available to me, including infection rates, sources of transmission, the presence of clusters and outbreaks, particularly in facilities, the number of people in hospital and in intensive care, deaths, the emergence of and risks posed by virus variants of concern, vaccine availability, immunization rates, the vulnerability of particular populations and reports from the rest of Canada and other jurisdictions, with a view to balancing the interests of the people affected by the Order, including constitutionally protected interests, against the risk of harm created by unvaccinated persons providing health or personal care or other support or services in hospital or community settings;

DR. BONNIE HENRY CLAIMS: — She recognizes the effect of removing scarce medical resources from an already stressed health care system and is balancing the interests and rights of unvaccinated healthcare professionals against persons receiving care.

FACT CHECK: **FALSE** — There is a large and growing volume of credible information and scientific evidence from top medical and scientific experts both in Canada and around the world that is disregarded, including:

- Data on natural immunity
- Ineffectiveness of vaccines
- High false positives with PCR and rapid testing
- Source of transmission (risks vaccinated vs. unvaccinated persons)
- Impact and source of variants
- Associated threat levels to the general population
- Broader impact of the Covid-19 pandemic measures increasing ALL types of illness, injuries and deaths (suicides, overdose, delayed medical treatments, etc.)

It is necessary to consider that COVID-19 vaccines are **not** the only answer to moving forward. COVID-19 vaccines are simply one tool, and should be utilized wisely and appropriately in addition to other available treatment options. A one-size-fits-all mentality coupled with broad overreach from this Order in particular has caused great harm to vaccinated and unvaccinated individuals alike. Outbreaks continue to occur in long term care settings and acute care hospitals even with the elimination of all unvaccinated care providers, demonstrating that this plan has categorically failed to meet the goal of the Order.

1. Evidence: Please refer to evidence in **Sections A through W** for information that contradicts the statements of Order section X.

2. Evidence: A new report commissioned by the Canadian Medical Association (CMA) provides a stark overview of the broader impact the COVID-19 pandemic measures had on Canadians. From delayed or missed treatments to a significant increase in the incidence of mental health and substance use disorders, the report highlights the dire consequences beyond the immediate loss of life and illness caused by the COVID-19 virus.

Source: https://www.cma.ca/news-releases-and-statements/excess-deaths-increased-mental-health-disorders-and-substance-use-new

3. Evidence: Pfizer's original trial report data definitively and undeniably proves the vaccines create "*More Harm Than Good*".

   Source: Video — https://www.canadiancovidcarealliance.org/media-resources/the-pfizer-inoculations-for-covid-19-more-harm-than-good-2/
   Source: Document — https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf

4. Evidence: The head of Indianapolis-based insurance company OneAmerica said the death rate has increased by 40.0% from pre-pandemic levels among working-age people. OneAmerica is a $100 billion insurance company that has had its headquarters in Indianapolis since 1877. The following excerpt details the alarming increase in the death rate:

   > *"We are seeing, right now, the highest death rates we have seen in the history of this business – not just at OneAmerica,"* the company's CEO Scott Davison said during an online news conference this week. *"The data is consistent across every player in that business."*
   >
   > *"And what we saw just in third quarter, we're seeing it continue into fourth quarter, is that death rates are up 40.0% over what they were pre-pandemic,"* [Scott Davison] said. *"Just to give you an idea of how bad that is, a three-sigma or a one-in-200-year catastrophe would be 10.0% increase over pre-pandemic,"* he said. *"So 40.0% is just unheard of."* [Scott Davison] also said at the same time, the company is seeing an "uptick" in disability claims, saying at first it was short-term disability claims, and now the increase is in long-term disability claims.

   The CDC numbers fully agree with this as the CDC weekly death counts—which reflect the information on death certificates and so have a lag of up to eight weeks or longer—show that for the week ending November 6, 2021 there were far fewer deaths from COVID-19 in Indiana compared to a year ago (2020) – 195 verses 336 – but more deaths from other causes – 1,350 versus 1,319. Deaths among 18-64 year-olds (who don't normally die) are up by 40.0% in 2021 versus pre-pandemic levels.

   Source: https://www.thecentersquare.com/indiana/indiana-life-insurance-ceo-says-deaths-are-up-40-among-people-ages-18-64/article_71473b12-6b1e-11ec-8641-5b2c06725e2c.html
   Source: Steve Kirsch, OneAmerica Insurance Analysis of 40% death increase
   https://stevekirsch.substack.com/p/unprecedented-deaths-in-indiana-for

5. Evidence: The great body of evidence (comparative research studies and high-quality pieces of evidence and reporting judged to be relevant to this analysis), shows that COVID-19 lockdowns, shelter-in-place policies, masks, school closures, and mask mandates have failed in their purpose of curbing transmission or reducing deaths. These restrictive policies were ineffective and devastating failures, causing immense harm especially to the poorer and vulnerable within societies. Nearly all governments have attempted compulsory measures to control the virus, but no government can claim success. Additionally, these measures are not recommended in any circumstances by the WHO. The research indicates that mask mandates, lockdowns, and school closures have had no discernible impact of virus trajectories and do cause harm.

Table 1. Recommendations on the use of NPIs by severity level

SEVERITY	PANDEMIC[a]	EPIDEMIC
Any	Hand hygiene Respiratory etiquette Face masks for symptomatic individuals Surface and object cleaning Increased ventilation Isolation of sick individuals Travel advice	Hand hygiene Respiratory etiquette Face masks for symptomatic individuals Surface and object cleaning Increased ventilation Isolation of sick individuals Travel advice
Moderate	*As above, plus* Avoiding crowding	*As above, plus* Avoiding crowding
High	*As above, plus* Face masks for public School measures and closures	*As above, plus* Face masks for public School measures and closures
Extraordinary	*As above, plus* Workplace measures and closures Internal travel restrictions	*As above, plus* Workplace measures and closures
Not recommended in any circumstances	UV light Modifying humidity Contact tracing Quarantine of exposed individuals Entry and exit screening Border closure	UV light Modifying humidity Contact tracing Quarantine of exposed individuals Entry and exit screening Internal travel restrictions Border closure

NPI: non-pharmaceutical intervention; UV: ultraviolet.

Source: https://brownstone.org/articles/more-than-400-studies-on-the-failure-of-compulsory-covid-interventions/
Source: WHO Pandemic Planning 2019 Global Influenza Programme — https://web.archive.org/web/20200730195417/https://apps.who.int/iris/bitstream/handle/10665/329438/9789241516839-eng.pdf?ua=1

6. Evidence: The terminations of unvaccinated healthcare staff has proven to be illogical and a complete failure based on clear evidence vaccinated staff are contracting and spreading the virus and many outbreaks are currently declared. We can see that transmission between employees is happening in health care settings (see January 6, 2022 memo below), staffed exclusively by fully vaccinated individuals. The increase of outbreaks and transmission in all areas of health care continue to grow, even though the PHO Order resulted in terminations of all unvaccinated healthcare workers that were unfairly being blamed for the spread.

   A brilliant analysis was done to show the Number Needed To Exclude (NNE), which further corroborates the irrational and unbalanced reaction of removing scarce talented highly skilled resources from an already burdened health care system. The NNE suggests that at least **1,000** unvaccinated people likely need to be excluded to prevent **one (1)** SARS-CoV-2 transmission event in most types of settings for many jurisdictions, notably Australia, California, Canada, China, France, Israel, and others. That means in BC, where an estimated 3,000 healthcare staff were terminated, we MAY have prevent **three** (3) transmissions. The impact of these terminations has and continues to have far reaching and devastating impact on lives, families, patients, communities, and the overburdened healthcare workers left in the system.

Date: January 6, 2022
Subject: COVID Exposures - Reminder

Good afternoon folks,

Hoping everyone had some time over the Christmas Holiday to rest, relax and enjoy themselves.

Unfortunately I have to be that guy and don't mean to be a downer! Over the break we have been notified of several employee to employee exposures across the Health Authority. I have been sending out individual emails to managers but thought I should relay the same messaging to everyone.

What we are seeing and it may have just been coincidence that it was the holiday season and we've let our guard down or whether we are all just fed up with the restrictions we must stay vigilant. Breaks Rooms and nurses stations in particular have been identified as areas where people are not adhering to 2m(6feet) distancing and reports of masks not being worn in these areas as well. We know that the break rooms are areas where are going to be eating so more important to maintain the distancing. Below are a few things that we can proactively remind our staff of and hopefully we can continue with preventing the spread.

Common Areas & Break Room Guidelines
PPE Guidelines

Key Updates

- **Physical distancing and room/area capacity limits:**
  - In areas where all persons are wearing an approved mask* or respirator, physical distancing and maximum room/area capacities are **not required.**
  - In areas where any person is not, or unable to wear an approved mask* or respirator, physical distancing and current maximum room/area capacities **are required.**
    - For example, break rooms or clients home where other family members are present without masking
  - **Note:** Approved masks are outlined in the IH Mask Requirements Guideline with specific details in the IH Medical Face Mask Guidelines and the IH Non-Medical Mask Guidelines.
- **IH Personal Protective Equipment (PPE) Guidelines:**
  - IH Mask Guidelines have been updated and should be reviewed
  - Eye protection, gowns, gloves are required based on point of care risk assessment or if client/patient/resident is on additional precautions, with the exception of COVID-19 units and outbreak areas.
  - Review the IH PPE Guide for more detailed information, unique to your area

Interior Health Authority
Advisor - Health Safety & Prevention
Workplace Health and Safety – Central Okanagan
Kelowna Health Services Centre

Interior Health
Every person matters
Privacy Ambassador

Source: NNE Document - https://www.medrxiv.org/content/10.1101/2021.12.08.21267162v1

7. Evidence: Seeing this happen in Israel 2 months ago, in the UK and Germany, we in BC are now also seeing a sharp increase of vaccinated infections, hospitalizations and in the ICU. In B.C., **over 80%** of COVID–19 cases in the past week were **fully vaccinated** and 51.4% of new hospitalizations are in the vaccinated (89). Good news is there is less hospitalizations overall as Omicron seems to produce minor symptoms. What the scientists have been saying all along (and censored and smeared for) is coming true, that the vaccines are destroying natural immunity in the vaccinated. Dr. Bonnie Henry has said employers should expect 30% of their employees will be sick shortly. Add to this, the recent change in policy to allow COVID positive healthcare workers to return to work five days post infection regardless of active symptoms such as a cough, sneezing, etc., as long as they do not have a fever. Now sick workers are welcome in the health care setting while healthy unvaccinated workers, many of whom have acquired natural immunity, are excluded.

Source: https://www.kelownanow.com/watercooler/news/news/COVID_19/Over_80_of_COVID_19_cases_were_fully_vaccinated/

Y. I further recognize that constitutionally-protected interests include the rights and freedoms guaranteed by the Canadian Charter of Rights and Freedoms, including the right to life, liberty and security of the person, along with freedom of religion and conscience, freedom of thought, belief, opinion and expression. These rights and freedoms are not, however, absolute and are subject to reasonable limits, prescribed by law as can be demonstrably justified in a free and democratic society. These limits include proportionate, precautionary and evidence-based restrictions to prevent loss of life, serious illness and death, and disruption of our health system and society. When exercising my powers to protect the health of the public from the risks posed by COVID-19, I am aware of my obligation to choose measures that limit the Charter rights and freedoms of British Columbians less intrusively, where doing so is consistent with public health principles;

DR. BONNIE HENRY CLAIMS: — She recognizes she is superseding rights and freedoms of British Columbians.

FACT CHECK: **FALSE** — No law or Order can lawfully supersede the inalienable rights and freedoms of Canadians, especially in light of the fact that the overall death rates in 2020 have not shown a significant health risk exists.

1. Evidence: Canadian Charter of Rights and Freedoms — Equality Rights:

   Section 15. (1) Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, color, religion, sex, age or mental or physical disability.

   Source: Canadian Charter — https://laws-lois.justice.gc.ca/eng/const/page-12.html

2. Evidence: The measures being taken are an unnecessary reaction to the threat of COVID-19. Totalitarian-like measures have been instated by Dr. Bonnie Henry, who is not an elected official. How would you know if your government was slowly and effortlessly moving you towards a totalitarian system? Would the government inform you? Would the media inform you? Would your concerned friends and family who could see a totalitarian system unfolding make you aware?

   Source: https://raellekaia.substack.com/p/how-would-you-know

3. Evidence: Canadian rights and freedoms—inherited through our British Commonwealth and embedded in the Magna Carta—forms our laws and values, and is a system of governance which sets us apart from totalitarian, communist and socialist regimes.

   Section 1 Guarantees the rights and freedoms set out in the subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

   Giving Canadians the freedom to believe, or not to believe, without fear of persecution. Please explore Action4Canada to learn more about the rights and freedoms of a Canadian citizen.

   Source: Canadian Charter — https://laws-lois.justice.gc.ca/eng/const/page-12.html
   Source: https://action4canada.com

DR. BONNIE HENRY CLAIMS: — She has demonstrably justified the overreach of this Order.

FACT CHECK: **FALSE** — No data has been provided nor does it exist that SARS-CoV-2 infections have created a pandemic worthy of such drastic, ineffective and damaging measures. The loss of life from COVID-19 is within normal expectations for an illness such as the flu, and is less than other preventable deaths.

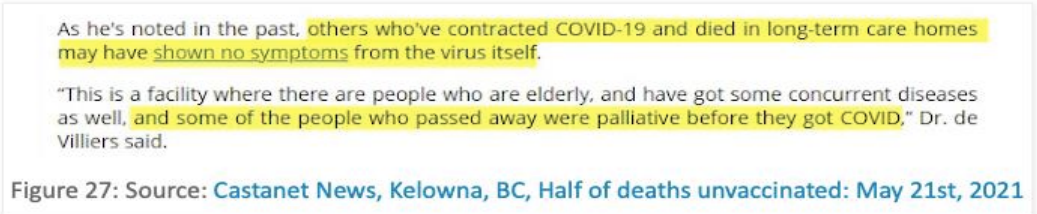
4. Evidence: In the years 2017 and 2018—the most recent bad influenza season—the population of Canada was 36,708,803 (2017). The number of deaths recorded for influenza/pneumonia equated to 8,511. The percentage of the total population who died of flu/pneumonia in 2017 was 0.02%. In short, COVID-19's impact on Canada in 2020 was similar to that of the Asian Flu in 1957, sparing 99.96% of the population. In contrast, the 1968 Hong Kong flu and the more recent 2018 annual flu spared 99.98% of Canada's population. Furthermore, if influenza were measured with the same intensity as COVID-19, it might be a closer comparison yet.

   Influenza occurs every winter and thousands of people are infected. Only the most extreme cases are counted as part of annual flu statistics. When feeling under the weather, most people conclude "I've got the flu" and call in sick. Prior to 2020, no government agency has monitored flu "cases" with the same granular intensity that COVID-19 "cases" are now tracked and recorded, including large "case" numbers of people who are not sick. Prior to 2020, the media never described a healthy person (i.e. testing positive but asymptomatic) as being or representing a "case" of any given illness.

   Thus, the 8,000 Canadians who were reported by Statistics Canada to have died of influenza/pneumonia during the winter of 2017-2018 are markers for a much larger number of unreported cases of influenza during that season.

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

5. Evidence: The following is an analysis of B.C. COVID-19 data by investigative reporter, Julius Reuchel: How severe was the COVID-19 pandemic compared to previous years with normal mortality? The annual total of deaths (all causes) released by Statistics Canada allows us to compare the 2020 COVID-19 year to previous years. The blue column represents the first year with COVID-19 and captures the first and almost the entire second wave (see figure 3 for reference). Yet it barely extends above the trendline laid out by previous bad flu seasons. These numbers may surprise you. The 24,402 deaths reported represents approximately 8.0% of the total number of people that die in Canada every year. The blue column in figure 26 is nowhere near an 8.0% bump over the numbers of previous years, even if measured off the bottom of the 2019 trough. It is easiest to explain this strange phenomenon by looking at this statement in a recent article, made by B.C.'s chief medical officer for the Interior B.C. region, Dr. Albert de Villiers:


As he's noted in the past, others who've contracted COVID-19 and died in long-term care homes may have shown no symptoms from the virus itself.

"This is a facility where there are people who are elderly, and have got some concurrent diseases as well, and some of the people who passed away were palliative before they got COVID," Dr. de Villiers said.

Figure 27: Source: Castanet News, Kelowna, BC, Half of deaths unvaccinated: May 21st, 2021

In other words, what Dr. Albert de Villiers is pointing out is that many COVID-19 deaths are deaths with, but not from, COVID-19. This includes people who died of other causes but also happened to have a positive PCR test, even if they showed no symptoms from COVID-19 itself. This includes people already receiving palliative care — people who are dying, imminently, within days or weeks, and there is no longer anything that can be done to stop it.

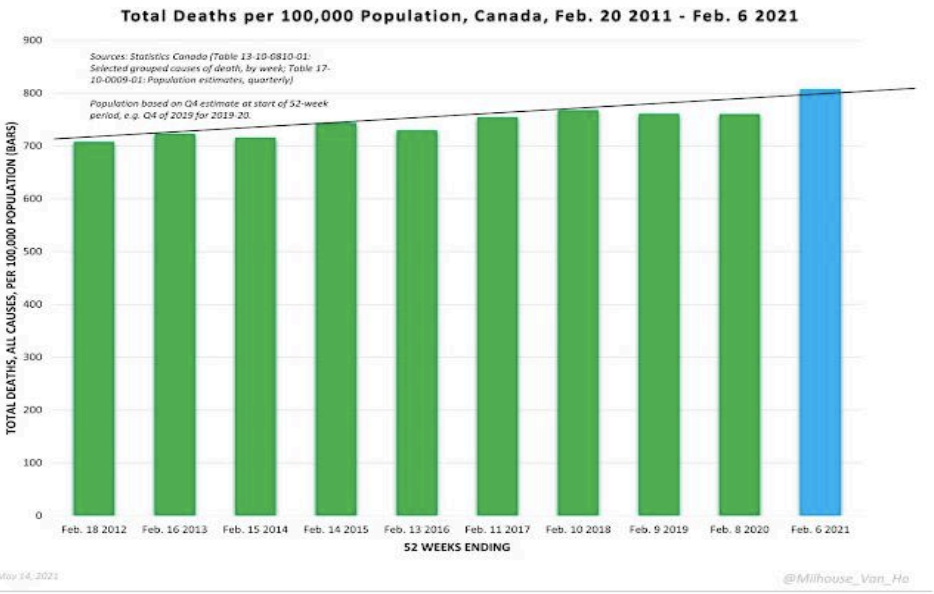
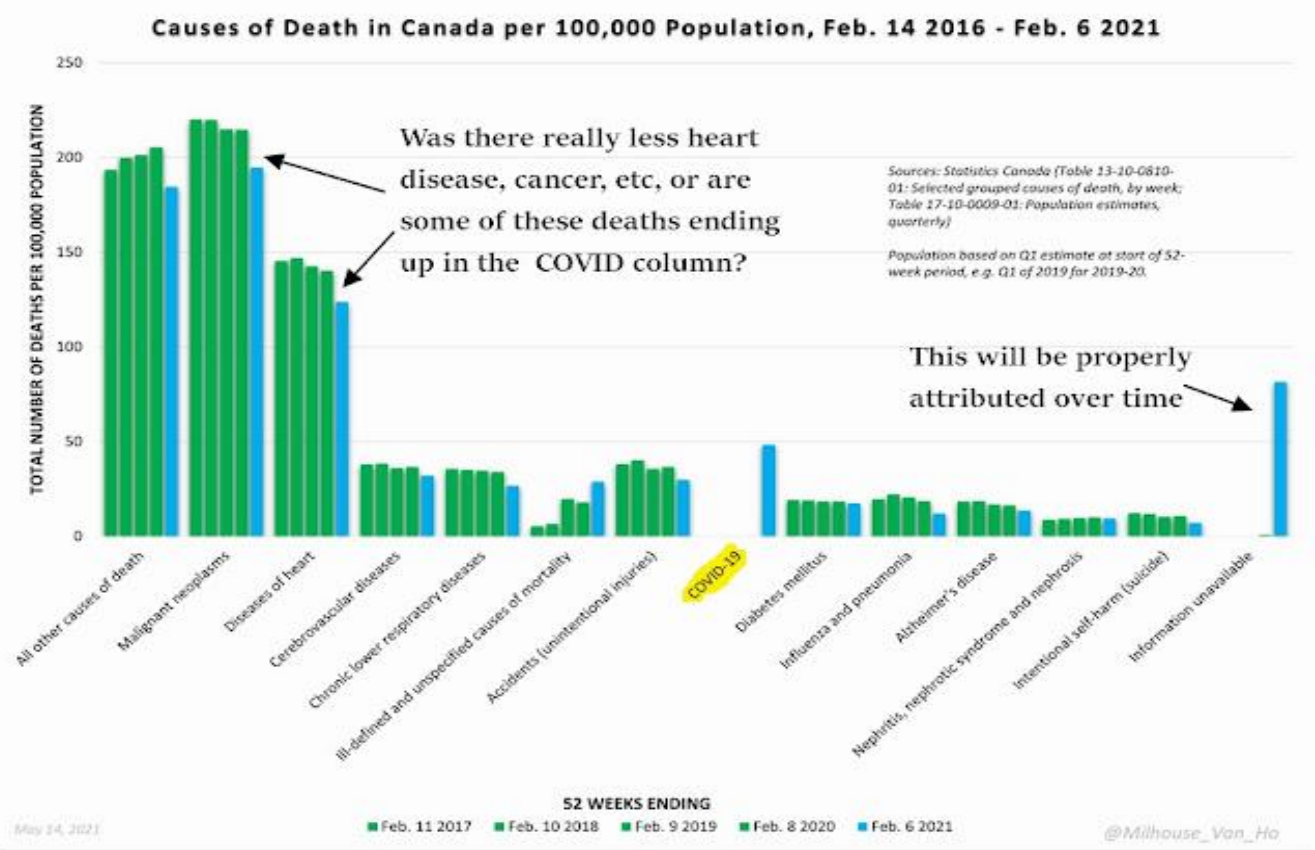


Figure 26: Total annual deaths per 100,000 (adjusted for the growing population size) from February of 2011 to February of 2021. The trendline laid across the top of the peaks illustrates the long-term growth in deaths attributed to an aging population. Extension above this trendline in 2021 illustrates the magnitude of the extra deaths during COVID beyond the peaks of previous bad flu seasons. Extra deaths are either caused by COVID or by the lockdown measures. Source: Adapted from @Milhouse_Van_Ho (link to original) - the most accurate source tracking official Canadian government COVID data on the internet, found exclusively on Twitter with data sourced from Statistics Canada.

Figure 29 (see below) uses Statistics Canada's own data to provide a clue of just how many "COVID-19" deaths may have been deaths with, instead of from, COVID-19. Looking at the first three columns in particular — does COVID-19 cure heart disease and cancer? It seems more likely that heart disease and cancer patients who would have died anyway were either misattributed to COVID-19 Deaths as a result of a concurrent positive PCR testing, as described by Dr. Albert de Villiers in the Castanet news article, or bad management inside long-term care exposed them to the virus, robbing them of the last few weeks or months of their life by pushing their death forward — a proverbial straw that broke the camel's back a few weeks or months early.



The next chart shows the running totals of weekly deaths (all causes) going back over the last 11 years, ending February 6th, 2021. The clear peaks and troughs in Figure 31 represent seasonal variations in death rates caused by the winter flu season. Strong peaks correspond with especially strong winter flu seasons. The strong 2017/18 season is clearly visible.

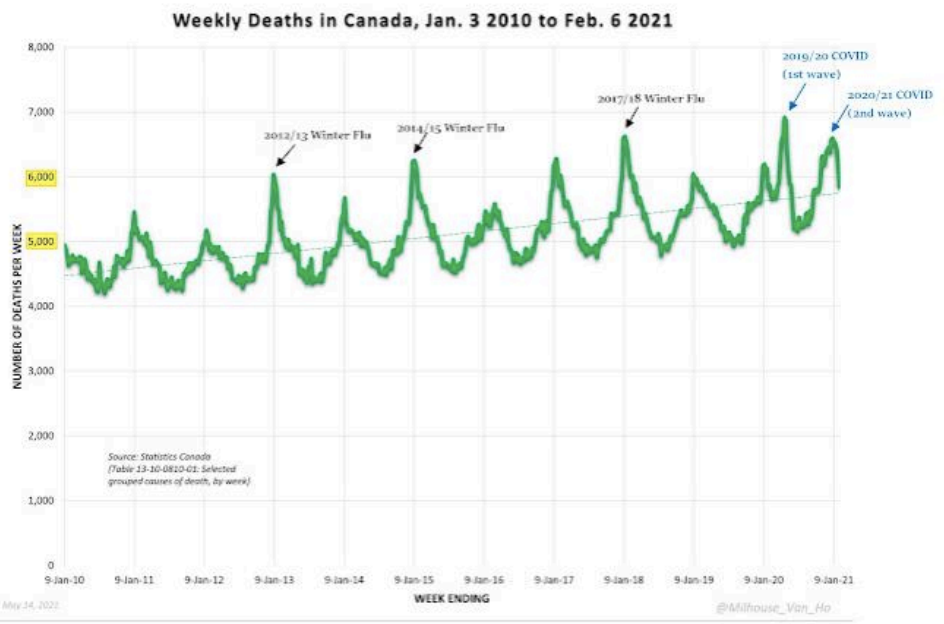


Figure 31: Weekly deaths in Canada over the last 11 years. Adapted from @Milhouse_Van_Ho (link to original), with data sourced form Statistics Canada.

The first two COVID-19 waves of the 2019/20 and the 2020/21 winter seasons are recognizable on the chart in Figure 31, but do not stand out from the pack. A glance to the left shows there are between 5000 and 6000 deaths per week in Canada, every single week of the year, of all causes. In 2019, that added up to a total of 284,082. That's the background of normal mortality in Canada from all causes of death. The gradual rise in death rates over the last decade, which is visible in the chart, is caused by a combination of a growing population and an aging population as the large numbers of baby boomers begin to reach the top of the age pyramid and birthrates fall (a diagram of the changing age pyramid from 1980 to 2020 in the notes at the bottom of this investigative report for those not familiar with how Canada is "aging out"***).

In Figure 31, COVID-19 stands out as a bad flu year—not as a generational pandemic. It looks virtually indistinguishable from previous bad flu years. Measuring from the centerline (dotted line) to the peaks, even the deadly 1st wave of COVID is approximately the same as the scale of the 2012/13, the 2014/15, and the 2017/18 winter flu peaks. And the second wave, when we spent winter in near endless lockdowns, including curfews in Quebec, endless business closures, and the arrest of multiple pastors across Canada who refused to limit church attendance, that second wave barely counts as a moderate winter season. Overwhelmed hospitals were a complete lie (documented in my previous article here), not because some didn't reach near 100% capacity, but because they do so every year. The last 15 months have been significantly less than usual; for the first time in years no-one was practicing any hallway medicine in Canada. But cancer patients had their treatments cancelled and surgeries delayed. They may pay the ultimate price for the panic.

One of the "mysteries" of the COVID-19 pandemic has been the disappearance of the winter flu. COVID-19 is now playing the role that influenza used to play—flu deaths have been displaced by COVID-19 deaths. The chart in Figure 31 make that rather obvious. And the insight we gained from the outbreak data, demonstrating that 75.0% of all deaths are in institutional environments, makes it quite clear that the most vulnerable to COVID-19 are the very same vulnerable people, hanging out in the very same settings, which

would have been at risk of severe outcomes from influenza. Anyone can catch it, but the Grim Reaper stalks the vulnerable. A coronavirus playing the role that influenza used to play.

Another natural phenomenon being used to lie about the supposed effectiveness of lockdowns is that of seasonality. The previous chart in Figure 31 showed the natural rises and falls in deaths every winter. The magnitude may change, but the waves are as predictable as winter snow in Canada. Figure 32, from Ontario Public Health, shows the seasonality of the other coronaviruses (at least 4), which circulate in the community and in long-term care facilities every winter as part of cold and flu season. Just because most members of the public hadn't heard about coronaviruses before doesn't change that they have been around for a long time and a lot is known about them.

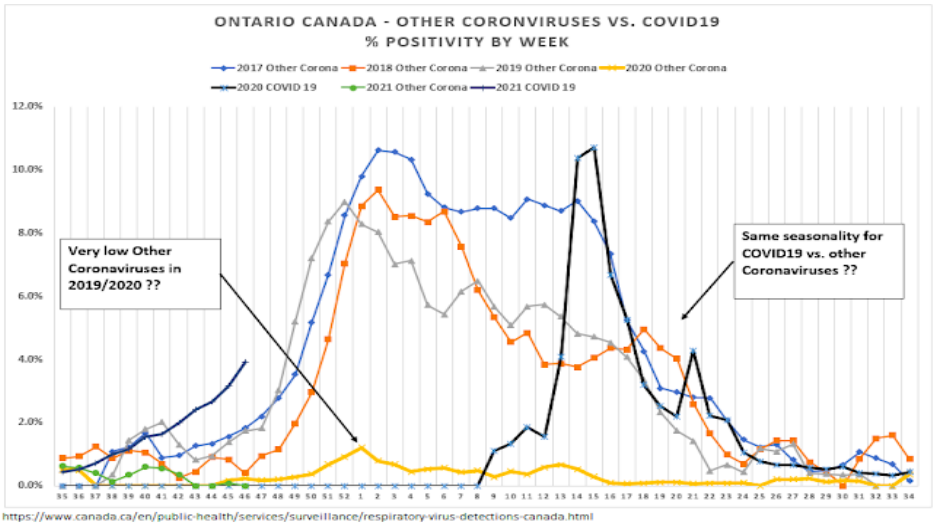


Figure 32: Normal seasonality of all coronaviruses in Canada. COVID-19 is merely the most recent addition. COVID arrived in Canada midway through the 2019/20 winter season (black line), and then tracked the other coronaviruses almost perfectly. And in the 2020/21 season (dark blue), it again appears to be tracking the other coronavirus waves from previous years. There are at least 4 other coronaviruses that have long been part of the regular annual smorgasbord of over 200 respiratory viruses that cause colds and flus every year (source). Chart annotations are mine.

Source: Julius Reuchel analysis — https://www.juliusruechel.com/2021/05/the-lies-exposed-by-numbers-fear.html

6. Evidence: Brian Peckford Newfoundland Premier (1979-1989) and last living contributor to the 1982 Canadian Constitution reminds us that:

Section 52 (1) The Constitution of Canada is the supreme law of Canada, and any law that is inconsistent with the provisions of the Constitution is, to the extent of the inconsistency, of no force or effect.

Peckford states: "*...this should be proclaimed from the rooftops and even from ivory towers like law schools and think tanks in this country—and need I say, Proclaimed by our fourth estate, the Press*."

Source: https://peckford42.wordpress.com/2021/11/22/my-letter-to-canadas-national-post-newspaper-proclaim-from-the-roof-tops-our-supreme-law/
Source: https://peckford42.wordpress.com/author/brianpeckford/
Source: Canadian Charter — https://laws-lois.justice.gc.ca/eng/const/page-12.html

Z. In addition, I recognize the interests protected by the Human Rights Code and have taken these into consideration when exercising my powers to protect the health interests of patients, residents and clients and persons who provide health care, personal care, home support or other services in hospital or community settings;

DR. BONNIE HENRY CLAIMS: — She, as PHO, has the power and justification to override Human Rights.

FACT CHECK: **FALSE** — Based on the definition of an emergency, British Columbia is **not** in an emergency. Thus, the powers that the public health officer is exercising are causing more harm than help.

1. Evidence: Refer to **Section A - #13, #14, and #15** for clarification on what constitutes an emergency.

2. Evidence: The purposes of the Human Rights Code is as follows:
   (a) to foster a society in British Columbia in which there are no impediments to full and free participation in the economic, social, political and cultural life of British Columbia;
   (b) to promote a climate of understanding and mutual respect where all are equal in dignity and rights;
   (c) to prevent discrimination prohibited by this Code;
   (d) to identify and eliminate persistent patterns of inequality associated with discrimination prohibited by this Code;
   (e) to provide a means of redress for those persons who are discriminated against contrary to this Code.

   With this Order, Dr. Bonnie Henry has obliterated Human Rights and created:

   - impediments to unvaccinated persons to participate fully in society, economically, socially and culturally;
   - treated unvaccinated persons as second class citizens, stripping them of their livelihood and ability to find meaningful work for which they are highly educated and trained;
   - incited fellow British Columbians to discriminate against, fear and even hate individuals who are unvaccinated;
   - patterns of inequality where a person's health status determines their entitlement to work and enjoy life;
   - an environment where no consideration or redress is provided for the unvaccinated.

3. Evidence**:** Human Rights Code prevails

   If there is a conflict between this Code and any other enactment, this Code prevails.

   Source: https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/00_96210_01

AA. I am also mindful that the volume of requests for reconsideration of my Orders, and the time and expertise which considering them entails, has become beyond my capacity and that of my office and team of medical health officers to manage, and is using resources which are better directed at assessing and responding to the protection of the public as a whole;

DR. BONNIE HENRY CLAIMS: — The volume of requests for reconsideration are beyond the capability of her team to address them all.

FACT CHECK: **FALSE** — Dr. Bonnie Henry has offered a process for reconsideration and is required to address concerns associated with the Orders that are submitted and openly published, such as the Okanagan Healthcare Professionals letters 1.0, 3.0, and this current submission.

1. Evidence: The blatant disregard for concerns expressed by British Columbian residents—lay people and healthcare professionals, alike—regarding published Orders does not demonstrate that Dr. Bonnie Henry and associated leadership personnel are attempting to "*...[assess and respond] to the protection of the public as a whole.*" While Dr. Bonnie Henry and associated leadership may not be in agreement with the statements and data that are presented thus far in the Okanagan Healthcare Professionals letters, the individuals behind these letters deserve to have their questions and concerns addressed. The blame for the spread of COVID-19 is largely placed on unvaccinated individuals; however, unvaccinated individuals will to a large extent continue to remain unvaccinated until their valid concerns regarding the side effects and risks associated with COVID-19 vaccines (which are supported and substantiated by credible medical professionals around the world) are addressed. Part of protecting the public as a whole includes addressing and investigating the concerns of the persons who are in disagreement with leadership, regardless of a groups categorization (i.e. the unvaccinated population).

BB. This Order does not apply to a place to which the Residential Care Vaccination Status COVID19 Information Order and the Residential Care COVID-19 Preventive Measures Order apply except with respect to the deployment of the staff or students of a post-secondary institution to a residential care facility, and the variance of the reconsideration provisions in the Residential Care COVID-19 Preventive Measures Order;

DR. BONNIE HENRY CLAIMS: — This Order does not apply to long term care facilities.

FACT CHECK: **TRUE** — While this specific Order excludes long term care (LTC), the long term care facility staff, sub-contractors and others working in these sites have been affected by a similar Order with many of the same unsubstantiated statements. The LTC Order led to mass firing of healthcare professionals thereby creating unsafe working conditions for remaining staff and substandard care levels for residents.

1. Evidence: The Residential Care COVID-19 Preventive Measures Order is based on similar Whereas statements as the Whereas statements from the November 18, 2021 Hospital and Community (Health Care and Other Services) Vaccination Status Information and Preventive Measures Order, which are also unsupported by scientific data and are therefore unjustified.

   Source: https://www2.gov.bc.ca/assets/gov/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/covid-19/covid-19-pho-order-residential-care.pdf

CC. For further certainty, this Order does not apply to the First Nations Health Authority, First Nations Health Service Organizations, Treaty First Nations, the Nisga'a Nation, the Métis Nation of BC, or to health care, personal care, home support or other services provided or funded by one of those bodies;

DR. BONNIE HENRY CLAIMS: — This Order does not apply to organizations and staff who are Aboriginal and are therefore protected from discrimination.

FACT CHECK: **FALSE** — The First Nations Health Authority, First Nations Health Service Organizations, Treaty First Nations, the Nisga'a Nation, the Métis Nation of BC along with their funded bodies have implemented similar unjustified measures in the absence of a specific Order.

1. Evidence: Refer to the aforementioned evidence that shows these Order items do not reduce the spread of COVID-19.

2. Evidence: COVID-19 does not discriminate between borders, race, gender, or cultures. Therefore, stating that this Order does not apply to the First Nations Health Authority, First Nations Health Service Organizations, Treaty First Nations, the Nisga'a Nation, the Métis Nation of BC, or to health care, personal care, home support or other services provided or funded by one of those bodies is unfounded. If COVID-19 is indeed as severe of a public health emergency as stated by Dr. Bonnie Henry and other British Columbian leadership, then this Order should either apply to all British Columbians, regardless of borders, race, gender, or culture.

I have reason to believe and do believe that:

a. a lack of information on the part of employers and operators about the vaccination status of staff interferes with the suppression of SARS-CoV-2 in hospital and community settings, and constitutes a health hazard under the Public Health Act;
b. an unvaccinated person who provides care or services in a hospital or community setting puts patients, residents, clients, staff and other persons who provide care or services at risk of infection with SARS-CoV-2, and constitutes a health hazard under the Public Health Act;
c. an unvaccinated staff member of an organization which provides care or services in hospital or community settings puts other staff who provide care or services, and patients, residents and clients in hospital and community settings, at risk of infection with SARS-CoV-2, and constitutes a health hazard under the Public Health Act;
d. in order to mitigate the risk of the transmission of SARS-CoV-2 created by an unvaccinated person as described above, it is necessary for me to exercise the powers in sections 30, 31, 32, 39, 53, 54, 56, 57, 67 (2) and 69 of the Public Health Act TO ORDER as follows:

DR. BONNIE HENRY CLAIMS: — Items a. to d. are reasonable factual statements.

FACT CHECK: **FALSE** — Evidence and scientific data are required to be presented to the public and healthcare employees before declaring items a. through d. are reasonable orders.

1. Evidence: Addressing section a.) above see commentary at **Sections W and V.**

2. Evidence: There is no evidence that the unvaccinated are a "health hazard". A vaccinated individual *may* receive marginal protection (not immunity) for between 4 and 6 months. At this time, a booster is then suggested to ensure enhanced protection. This is coupled with evidence **(Section B - #2 and Section C - #55)** that suggests a loss of immune function occurs in individuals who receive COVID-19 vaccines. Thus, these individuals will struggle to fight any illness in the future (i.e. cold, flu, cancer, etc.)

3. Evidence: While the PHO states that unvaccinated individuals are a "health hazard", this label is unsubstantiated. Dr. Bonnie Henry has not produced data to illustrate the impact of unvaccinated individuals on spread of COVID-19, illness severity, recurrence of COVID-19, hospitalizations, ICU visits, or deaths. Evidence needs to be provided to prove that unvaccinated individuals are the main cause of this "health hazard".
   Source: https://www.canadiancovidcarealliance.org/media-resources/dispelling-the-myth-of-a-pandemic-of-the-unvaccinated/
   Source: https://nscla.org/news/the-ugly-business-of-scapegoating-the-unvaccinated/
   Source: https://www.icandecide.org/ican_press/update-on-ny-vaccinated-vs-unvaccinated-data/
   Source: https://alexberenson.substack.com/p/vaccinated-english-adults-under-60?r=m7jq6&fbclid=IwAR3CkfYQ66OtnZeQibsm21tgFjZpMmOZpLX3gsmC3JhQMMVfADgksHjyCLA
   Source: https://brownstone.org/articles/this-is-not-a-pandemic-of-the-unvaccinated/

Significant and Notable Interviews and Video Evidence:

1. **Joe Rogan and Dr. Peter McCullough** — A 2h 45m interview to go over the lack of COVID-19 early treatments, COVID-19-related vaccine injuries, censorship of doctors and scientists providing treatments, and the manipulation and cover up of data and facts.

   Source: https://open.spotify.com/episode/0aZte37vtFTkYT7b0b04Qz?si=HnIJVmz0TDSodb7S8Y2ykQ
   Source: Slides & Summary: https://popularrationalism.substack.com/p/dr-peter-mccullough-on-the-joe-rogan

2. **Joe Rogan and Dr. Robert Malone** — A 3h 6m interview to go over the lack of COVID-19 early treatment, vaccine injuries, censorship of doctors and scientists providing treatments, and the manipulation and cover up of data and facts. A huge addition to this conversation is the discussion of mass formation psychosis, which is occurring worldwide.

   Source: https://unityprojectonline.com/news/dr-robert-malone-md-on-the-joe-rogan-experience/?fbclid=IwAR11yGqxhgbZE1OYQA04ZrkMXjNSaciUUWHmvQ19Nd6QNSPp4qcfejFgALM

3. **CANUCKLAW** —A library of video evidence and links on Dr. Bonnie Henry's misinformation.

   Source: https://canucklaw.ca/cv-32-b-bcpho-bonnie-henry-admits-no-science-behind-anything-she-does/

Letters that Question the Evidence and Speak to Lack of Justification of Mandates:

1. Canadian Covid Care Alliance — "*More Harm Than Good*" document demonstrating the data in easy-to-understand graphs and information.

   Source: https://ocla.ca/wp-content/uploads/2021/12/CCCA-Pfizer-Trial-Breakdown-The-COVID-1-Inoculations-More-Harm-Than-Good-Dec.-15-2021.pdf

2. Julius Ruechel — "*The Lies Exposed by the Numbers: Fear, Misdirection, & Institutional Deaths (An Investigative Report)*"

   Source: https://www.juliusruechel.com/2021/05/the-lies-exposed-by-numbers-fear.html

3. Response to the Office of the Auditor General vaccine policy, regarding illegality of vaccine mandates according to Canadian law.

   Source: https://thinkwithmabellemichelle.wordpress.com/2021/11/26/oag-employee-questions-medical-experiment/

4. Justice Centre for Constitutional Freedoms — "*10 Reasons Why Canada's COVID Experience Does Not Justify Violating Charter Rights and Freedoms.*"

   Source: https://www.jccf.ca/wp-content/uploads/2021/06/2021-04-27-Covid-in-Canada-nothing-much-to-fear-FINAL-June-28-2021.pdf

5. RATH & Company VS. Trudeau, Dr. Tam Letter.

   Source: https://rathcocovidlitigation.com/wp-content/uploads/2021/11/2021-11-16-LT-Trudeau-et-al-re-Pfizer-Vaccine1.pdf

6. Researched and documented information including background on why these vaccines are needing to be questioned. Such as: no liability, fraudulent past of vaccine makers, etc. These links provide 35 points that are of concern.

   Source: https://www.deconstructingconventional.com/post/18-reason-i-won-t-be-getting-a-covid-vaccine
   Source: https://www.deconstructingconventional.com/post/17-more-reasons-i-won-t-be-getting-a-covid-vaccine
   Source: Dr. Tess Lawrie Letter — https://b3d2650e-e929-4448-a527-4eeb59304c7f.filesusr.com/ugd/593c4f_74a5f6d8ea484e15ac25e87099615bc2.pdf

7. Archbishop Carlo Maria Viganò has decided to make public an October 23, 2021 a letter sent to Cardinal Luis F. Ladaria S.J., Prefect of the Congregation for the Doctrine of the Faith, Archbishop José Gomez, President of the United States Conference of Catholic Bishops, as well as to all the bishops of the United States of America.

   Source: https://www.lifesitenews.com/opinion/abp-vigano-the-catholic-church-has-a-duty-to-resist-deadly-covid-jab-agenda-of-the-globalist-elite/

8. Public Health and Medical Professionals for Transparency (PHMPT) — This nonprofit organization, made up of public health professionals, medical professionals, scientists, and journalists exists solely to obtain and disseminate the data relied upon by the FDA to license COVID-19 vaccines. The organization takes no position on the data other than that it should be made publicly available to allow independent experts to conduct their own review and analyses. Any data received will be made public on this website. Four days after the Pfizer vaccine was approved for ages 16+, we submitted a Freedom of Information Act Request to the FDA for all of the data within Pfizer's COVID-19 vaccine biological product file. We have now sued the FDA for not releasing the data. Click below for court documents and for productions of Pfizer's documents from the FDA.

   Source: https://phmpt.org
   Source: https://phmpt.org/wp-content/uploads/2021/10/IR0546-FDA-Pfizer-Approval-FINAL.pdf

9. An affidavit issued in support of a preliminary injunction by Steve Kirsch to stop the LA (California) school district mandate, wherein vaccine safety and efficacy are summarized.

   Source: https://stevekirsch.substack.com/p/were-suing-the-los-angeles-unified

10. Some of us are more aware then others of the grave danger that humanity is facing at this pivotal time. MACABIM.org is working around the clock to try to wake up each community that we can reach worldwide in order to save all of humanity. Please join us in our endeavor.

    Source: https://macabim.org/wp-content/uploads/2021/12/Open-Letter-to-the-Jewish-People-December-2.pdf

11. Open letter to Bonnie Henry from Dr. Charles Hoffe, detailing the first warning signs he asked questions on (April 2021).

    Source: https://www.jccf.ca/justice-centre-prepares-to-challenge-unscientific-travel-regulations-in-federal-court/?fbclid=IwAR2pfEQmQgab_3LSD3WNyGk_dIeZ5QGmheO-Ldq6iJ4Y4v1KRnRQx5oolhc

12. RCMP members wrote a letter to their commissioner, Brenda Lucki, to expose the issues with the vaccine mandate.

    Source: https://policeonguard.ca/wp-content/uploads/2021/10/Open-Letter-to-Brenda-Lucki.pdf

13. Hasidik Rabbinical Court — The Rabbis forbade the shots to be given to children and young adults. We had a science conference concerning the dangers of these gene therapy "vaccines" on the 26th with a Rabbinical Court Council in New York. On November 1st, the Special New York Rabbinical Court officially decreed that the mRNA COVID shot is "absolutely forbidden" for children, adolescents, young men & women. Here is the eight hours of testimony that was given:

    Source: https://www.dropbox.com/s/2df6b5l0ttrrzjt/asifas%20c19%20ch.mp4?dl=0
    Source: https://sarahwestall.com/major-development-rabbinical-court-decrees-mrna-jab-absolutely-forbidden-for-children-adolescents-young-men-women/

14. On November 3rd 2021, Steve Kirsch made a $1 million dollar request for debate to disprove anything he and other medical professionals have been stating. Steve Kirsch lists team of vaccine safety experts who are willing to debate, but nobody pushing the current narrative will accept. Kirsch states: "*...we think we analyzed the data correctly. We've asked the mainstream narrative experts to correct us if they think we got it wrong. They all refuse to engage us in a scientific discussion to resolve*."

    Source: https://stevekirsch.substack.com/p/my-team-of-vaccine-safety-experts

Summits, Declaration, Discussions with Large Groups of Doctors/Scientists/PhDs:

Many organizations and groups compile factual data, we apologize if we have inadvertently missed your group.

https://globalcovidsummit.org/page/about — Global COVID-19 Summit is the product of an international alliance of doctors and scientists, committed to speaking truth to power about COVID-19 pandemic research and treatment. Thousands have died from COVID-19 as a result of being denied life-saving early treatment. The Declaration is a battle cry from physicians who are daily fighting for the right to treat their patients, and the right of patients to receive those treatments - without fear of interference, retribution or censorship by government, pharmacies, pharmaceutical corporations, and big tech. We demand that these groups step aside and honor the sanctity and integrity of the patient-physician relationship, the fundamental maxim "First Do No Harm", and the freedom of patients and physicians to make informed medical decisions. Lives depend on it.

https://doctors4covidethics.org/about/ — We are hundreds of doctors and scientists from all corners of the globe. We have written three letters to the European Medicines Agency, urgently warning of short term and long term dangers from COVID-19 vaccines, including clotting, bleeding and platelet abnormalities. We first began warning of blood-related risks before media reports of clotting led to vaccine suspensions around the world. In the absence of crucial safety data, we are demanding the immediate withdrawal of all experimental gene-based COVID-19 vaccines. We oppose vaccine passports, which threaten public health and violate Nuremberg and other protections. We are warning that 'health passes' place coercive pressure on citizens to submit to dangerous medical experimentation, in return for freedoms that once were human rights. Read our letters, press releases and educational materials, and watch our videos, to learn more. Follow us on Twitter @Drs4CovidEthics.

https://covid19criticalcare.com/ — Front Line COVID-19 Critical Care Alliance' is now a 501(c)(3) non-profit organization dedicated to developing highly effective treatment protocols to prevent the transmission of COVID-19 and to improve the outcomes for patients ill with the disease.

https://canadahealthalliance.org/ — We are hundreds of doctors and scientists from all corners of the globe. We have written three letters to the European Medicines Agency, urgently warning of short term and long term dangers from COVID-19 vaccines, including clotting, bleeding and platelet abnormalities. We first began warning of blood-related risks before media reports of clotting led to vaccine suspensions around the world. In the absence of crucial safety data, we are demanding the immediate withdrawal of all experimental gene-based COVID-19 vaccines. We

oppose vaccine passports, which threaten public health and violate Nuremberg and other protections. We are warning that 'health passes' place coercive pressure on citizens to submit to dangerous medical experimentation, in return for freedoms that once were human rights. Read our letters, press releases and educational materials, and watch our videos, to learn more. Follow us on Twitter @Drs4CovidEthics.

https://www.canadiancovidcarealliance.org/ - Our alliance of independent Canadian doctors, scientists and health care practitioners is committed to providing top-quality and balanced evidence-based information to the Canadian public about COVID-19 so that hospitalizations can be reduced, lives saved, and our country safely restored as quickly as possible.

https://freenorthdeclaration.ca/ — The Canadian Lawyer Declaration site. We are Canadian lawyers. In our country, civil liberties are under unprecedented attack. Governments, public health authorities, universities, public and private employers, municipalities, and businesses are trampling Canadians' rights and freedoms. Our free society is at risk.

https://gbdeclaration.org - Great Barrington Declaration - As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection.

https://phmpt.org — This nonprofit, made up of public health professionals, medical professionals, scientists, and journalists exists solely to obtain and disseminate the data relied upon by the FDA to license COVID-19 vaccines. The organization takes no position on the data other than that it should be made publicly available to allow independent experts to conduct their own review and analyses. Any data received will be made public on this website.

https://unityprojectonline.com — The Unity Project, a non-partisan, non-profit educational organization, promotes a "children-first" agenda focused on integrity, care, rationality, and evidence-based motivation.

https://childrenshealthdefense.org — Children's Health Defense is a 501(c)3 non-profit organization. Its mission is to end childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable, and to establish safeguards so this never happens again. The way you get democracy to function is by informing the public.

https://bird-group.org/who-are-bird/ — The British Ivermectin Recommendation Development Group (BIRD) is a truly grassroots initiative bringing together clinicians, health researchers and patient representatives from all around the world to advocate for the use of Ivermectin against covid-19.

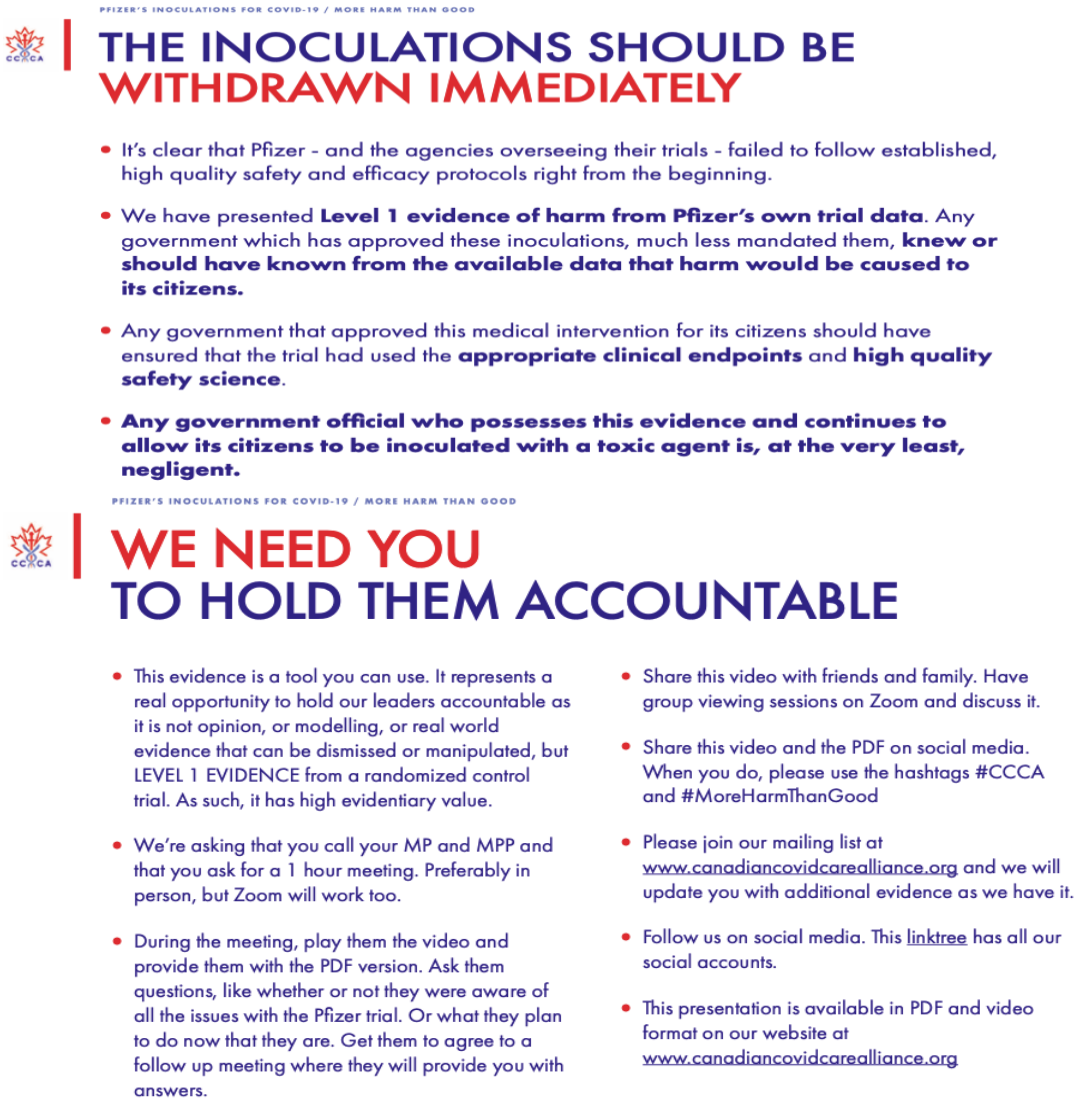
https://www.pandata.org — A group of multi-disciplinary professionals, who perceived the global reaction to COVID-19, and lockdown in particular, as overwrought and damaging to the point of causing a great tear in the fabric of society, established PANDA (Pandemics Data & Analytics) in April 2020. As a politically and economically independent organization, PANDA seeks to develop science-based explanations and test them against international data. Policy recommendations for governments and other institutions can be developed from these. PANDA stands for open science and rational debate, for replacing flawed science with good science and for retrieving liberty and prosperity from the clutches of a dystopian "new normal".

https://thecovidworld.com — The COVID World is a non-partisan, non-profit, independent news organization. We believe the mainstream media is not paying enough attention to adverse reactions from the widespread use of COVID-19 vaccines. Our mission is to give a voice to the voiceless and survivors by providing our readers with verified stories of vaccine-related injuries and deaths.

Conclusion:

Based on the above evidence, of almost 400 sources, the Okanagan Healthcare Professionals group firmly challenge the November 18, 2021 B.C. PHO. There have been zero sources of evidence provided by Dr. Bonnie Henry to support these mandates. If any aforementioned sources are incorrect, civil debate and comparison of data is welcome. The Okanagan Healthcare Professionals feeling strongly that the aforementioned evidence cannot be refuted.

It is clear that the current mandates and vaccine campaign are unjustified, unlawful, and negligent. The mandates and COVID-19 vaccination campaign within the province of B.C. should be halted immediately due to an overwhelming lack of scientific evidence supporting any of the COVID-19 initiatives endorsed and propagated by Dr. Bonnie Henry (B.C. Provincial Health Officer), Mr. Adrian Dix (B.C. Minister of Health), Mr. John Horgan (Premier of B.C.) and David Eby (B.C. Attorney General). The Okanagan Healthcare Professionals group seek clarity and a formal public address from the aforementioned provincial leadership.



Appendix - Fact Sheets of All 4 Vaccines (plus the 5th one - Comirmaty).
*All and details from original insert, as these originals compared to the updated versions had been changed from saying they MAY prevent spread not that they DO prevent spread.

1.) Pfizer Fact Sheet

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?
The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

2.) Moderna Fact Sheet

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

3.) Janssen Fact Sheet

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine may prevent you from getting COVID-19.

Read this Fact Sheet for information about the Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine has received EUA from FDA to provide:

- A single dose primary vaccination to individuals 18 years of age and older.
- A single booster dose to individuals 18 years of age and older who have completed a primary vaccination with Janssen COVID-19 Vaccine.
- A single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Common symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19.

4.) AstraZeneca Fact Sheet

PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

VAXZEVRIA™
COVID-19 Vaccine (ChAdOx1-S [recombinant]),

VAXZEVRIA (manufactured by AstraZeneca) and COVISHIELD (manufactured by Serum Institute of India) are ChAdOx1-S recombinant vaccines developed by AstraZeneca and the University of Oxford. Health Canada has reviewed the manufacturing information for these vaccines and found them to be comparable.

Solution for Intramuscular Injection

Multiple Dose Vial
(8 dose and 10 dose vial presentations)

Active Immunizing Agent

HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 Vaccine UNDER AN INTERIM ORDER
VAXZEVRIA is indicated for: Active immunization of individuals 18 years of age and older for the prevention of coronavirus disease 2019 (COVID-19). The use of VAXZEVRIA is permitted under an interim authorization delivered in accordance with section 5 of the COVID-19 Interim order (IO)*. Patients should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada's IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. * https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html#a2.8

AstraZeneca Canada Inc.
1004 Middlegate Road
Mississauga, Ontario
L4Y 1M4
www.astrazeneca.ca

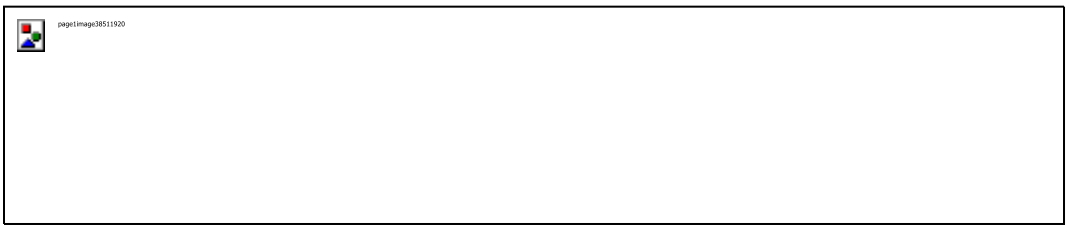
Date of Initial Authorization:
February 26, 2021

Date of Revision:
September 15, 2021

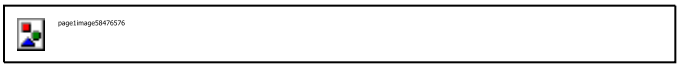
Submission Control Number: 255966

5.) LCHS - London Ontario Health Services - Internal Memo regarding pediatric strokes that they are preparing for as of October 14, 2021.

From: LHSC Communication Broadcast <LHSC_Communication.Broadcast@lhsc.on.ca> **Sent:** October 14, 2021 9:35 AM
Subject: E-Cast for October 14, 2021



October 14, 2021



Starting tomorrow: Paediatric Code Stroke will become operational at Children's Hospital

The Paediatric Code Stroke is a dedicated, multidisciplinary team approach to managing paediatric patients with suspected stroke. Paediatric Code Stroke activation (Oct. 15) will occur for all patients under eighteen years of age presenting to the Pediatric Emergency Department at Children's Hospital with suspected stroke by the paediatric emergency physician in consultation with the on-call paediatric neurologist. For paediatric patients presenting to the Emergency Department at University Hospital, the emergency physician must contact the on-call paediatric neurologist who will activate the Paediatric Code Stroke team and facilitate transfer to the Paediatric Emergency Department via EMS.

RATH & COMPANY

Barristers & Solicitors

ESTABLISHED 1995

November 16, 2021

Our File No. 99000

Prime Minister of Canada Justin Trudeau
Office of the Prime Minister
80 Wellington Street
Ottawa, ON K1A 0A2 justin-trudeau@parl.gc.ca

Dr. Theresa Tam
Chief Public Health Officer of Canada
Publix Health Agency of Canada
130 Colonnade Road
A.L. 6501H
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Attorney General for Canada David Lametti
House of Commons
Ottawa, ON K1A 0A6 david.lametti@parl.gc.ca

Superintendent Brenda Lucki
Royal Canadian Mounted Police
RCMP National Headquarters
73 Leikin Drive
Ottawa, ON K1A 0R2 brenda.lucki@rcmp-trc.gc.ca

Dear Sirs and Mesdames:

Re: Pfizer BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age

Please find attached a copy of the Pfizer EUA Amendment Request for Pfizer BioNTech COVID-19 Vaccine (Pfizer Vaccine) for use in children 5 through 11 years of age.

This letter constitutes a request on behalf of Canadian parents of 5 to 11 year old children that a criminal investigation be immediately opened with regard to fraudulent submissions of Pfizer Corp. regarding the provision of the Pfizer Vaccine to children 5 through 11 years of age.

The attached document has been reviewed by a number of expert physicians specializing in pediatrics, epidemiology, and pathology, all of whom are of the view that the data submitted by Pfizer in support of its FDA EUA Amendment Request is fraudulent. Specifically, the most glaring and obvious example of this fraud, contrary to s. 380(1) of the *Criminal Code of Canada*, is found

282050 Highway 22 West
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www.rathandcompany.com

at Table 14 on p. 34 of the FDA briefing document. That table claims that the Pfizer Vaccine, if provided in a two-dose regimen to 5 to 11 year old children will prevent between 0 and 3 deaths of children per million fully-vaccinated children. That same table goes on to admit that the Pfizer Vaccine will cause between 53 and 106 excess myocarditis cases, 29 to 58 excess myocarditis hospitalizations, and 17 to 34 excess myocarditis ICU admissions.

This same table then remarkably makes the fraudulent and completely scientifically unsupportable claim that the Pfizer Vaccine will then cause **0 EXCESS MYOCARDITIS DEATHS** and fraudulently and misleadingly does not discuss or acknowledge any other potential causes of death. We are advised by our team of expert physicians that the potential causes of death ignored by Pfizer in its emergency use authorization application include anaphylaxis, pericarditis, capillary thrombosis, clotting disorders, strokes and transverse myelitis, to name a few.

In consultation with expert anaesthesiologists and pathologists, we are advised that other risks of death associated with the 17 to 34 "excess myocarditis ICU admissions" include respiratory infections and death associated with ventilators and other ICU-related mortality. This ignores the issue of children with injuries to their hearts significant enough to merit ICU admission not even surviving transport to hospital by ambulance.

It has been well documented that with regard to Pfizer's initial emergency use authorization application in the United States, that data regarding death related to transverse myelitis was scrubbed from the initial application and that Pfizer's original application for 12 to 18 year olds which was similarly fraught with fraudulent mis-statements as to the safety profile of the Pfizer Vaccine.

To suggest to the parents of Canada that this product is safe and will not kill or injure more Canadian 5 to 11 year old children than the notional 0 to 3 "prevented COVID-19 deaths" alluded to by Pfizer in its FDA EUA Application constitutes a fraud on the Canadian public and the Canadian Government.

On a related note, given Pfizer's clear admission of the limited benefit of the Pfizer Vaccine versus the risk of "Excess Myocarditis ICU Admissions", this product should not be approved by any responsible regulator on an emergency basis without at least 5 years of extremely limited testing in randomized controlled trials where parents whose children are being vaccinated are fully and properly informed that the risks to their children from the Pfizer Vaccine by far exceed the risk to those children from contracting COVID-19.

We respectfully request that the Royal Canadian Mounted Police and the Attorney General of Canada confirm that a criminal investigation is being opened with regard to these allegations.

Our office remains available to assist by providing access to the expert physicians that have reviewed this document in support of this criminal complaint.

On a related note, we respectfully request that the Prime Minister of Canada immediately release copies of the Pfizer and Moderna vaccine supply contracts. We are advised that these contracts contain exclusions of liability that confirm that neither Pfizer nor Moderna warrant the safety of

these products on the basis that the products were developed in haste, without adequate studies or testing, under emergency conditions.

Clearly, given that there is not a single documented case of any 5 to 11 year old child in Canada absent severe pre-existing comorbidities having died from COVID-19, there is clearly no urgency in licensing or approving a product that is more likely to kill children than it is to save them from any COVID-19-related mortality.

This letter serves as a notice of liability to Prime Minister Trudeau and Dr. Theresa Tam that in the event that these products are approved absent a complete criminal investigation being conducted, and that any child is harmed or killed by these products, a further complaint with regard to UNLAWFULLY CAUSING BODILY HARM under s. 269 of the *Criminal Code or Canada* or HOMICIDE or a complaint under the *War Crimes and Crimes Against Humanity Act* will be forthcoming as against any party approving the Pfizer Vaccine for 5 to 11 year old children.

Thank you in advance for your prompt acknowledgement of this criminal complaint.

Yours very truly,

RATH & COMPANY

Jeffrey R. W. Rath, B.A. (Hons.), LL.B. (Hons.)
Barrister & Solicitor

Vaccines and Related Biological Products Advisory Committee Meeting
October 26, 2021

FDA Briefing Document

EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age

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1 EXECUTIVE SUMMARY

On October 6, 2021, Pfizer submitted a request to FDA to amend its Emergency Use Authorization (EUA) to expand use of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) for prevention of COVID-19 caused by SARS-CoV-2 in individuals 5 through 11 years of age (hereafter 5-11 years of age). The proposed dosing regimen is a 2-dose primary series, 10 µg mRNA/per dose, administered 3 weeks apart. This EUA request initially included safety data from 1,518 BNT162b2 recipients and 750 placebo (saline) recipients 5-11 years of age who are enrolled in the Phase 2/3 portion (Cohort 1) of an ongoing randomized, double-blinded, placebo-controlled clinical trial, C4591007. Among Cohort 1 participants, 95.1% had safety follow-up ≥2 months after Dose 2 at the time of the September 6, 2021 data cutoff for this cohort. Safety data from an additional 1,591 BNT162b2 recipients and 788 placebo recipients enrolled in the Phase 2/3 portion (Cohort 2) of the trial were provided later during FDA's review of the EUA amendment request to allow for more robust assessment of serious adverse events and other adverse events of interest (e.g., myocarditis, pericarditis, anaphylaxis). The median duration of follow-up in Cohort 2 was 2.4 weeks post Dose 2 at the time of the October 8, 2021 data cutoff for this cohort. Vaccine effectiveness was inferred by immunobridging SARS-CoV-2 50% neutralizing antibody titers (NT50, SARS-CoV-2 mNG microneutralization assay). Neutralizing antibody titers at 1 month post-Dose 2 in children 5-11 years of age were compared to neutralizing antibody titers 1 month post-Dose 2 among a subset of study participants 16-25 years of age randomly selected from efficacy study C4591001 who had previously received two doses of 30 µg BNT162b2. A supplemental descriptive analyses of vaccine efficacy (VE) among Cohort 1 participants (following accrual of 19 total confirmed COVID-19 cases) was also provided during FDA's review of the EUA amendment request.

The immunogenicity analyses evaluated neutralizing antibody titers against the USA_WA1/2020 reference strain, as assessed by microneutralization assay, among study participants with no evidence of prior SARS-CoV-2 infection up to 1 month post-Dose 2. Immunobridging endpoints and statistical success criteria were as follows:

- SARS-CoV-2 neutralizing antibody GMTs measured at 1 month after Dose 2 in study C4591007 Phase 2/3 Cohort 1 participants 5-11 years of age vs. GMTs at 1 month after Dose 2 in a randomly selected subset of study C4591001 Phase 2/3 participants 16-25 years of age, with immunobridging success criteria of >0.67 for the lower bound of the 95% confidence interval around the GMT ratio (5-11 years of age / 16-25 years of age), and a point estimate of the GMT ratio ≥1.0.

- Percentage of participants with seroresponse (≥4-fold rise from baseline [pre-Dose 1]), with immunobridging success criterion of >-10% for the lower bound of the 95% confidence interval around the difference (5-11 years of age minus 16-25 years of age) in seroresponse rates.

Immunobridging statistical success criteria, as described above, were met. Subgroup analyses of immunogenicity by age, gender, race and ethnicity, obesity and baseline SARS-CoV-2 status showed no notable differences as compared with the overall study population, although some subgroups were too small to draw meaningful conclusions. Descriptive immunogenicity analyses, based on an exploratory 50% plaque reduction neutralization test (PRNT), showed that a 10 µg BNT162b2 primary series elicited PRNT neutralizing titers against the reference strain and B.1.617.2 (Delta) strain in participants 5-11 years of age (34 BNT162b2, 4 placebo) with no evidence of SARS-CoV-2 infection up to 1 month post-Dose 2.

In the supplemental descriptive efficacy analysis, VE against symptomatic COVID-19 after 7 days post Dose 2 up to October 8, 2021 (data cutoff) was 90.7% (2-sided 95% CI: 67.4%, 98.3%) in participants 5-11 years of age without evidence of prior SARS-CoV-2 infection. Totals of 3 cases of COVID-19 occurred in the BNT162b2 group and 16 in the placebo group, most of which occurred during July-August 2021 when the Delta variant was prevalent in the United States. At the time of the data cutoff, none of these cases met the criteria for severe COVID-19.

Solicited local and systemic adverse reactions (ARs) reported among Cohort 1 participants generally occurred more frequently after Dose 2, with the most commonly reported solicited ARs being pain at the injection site (71%), fatigue (39.4%), and headache (28%). Most local and systemic reactions were mild to moderate in severity, with median onset 2 days post-vaccination, and most resolved within 1 to 2 days after onset. The most frequently reported unsolicited adverse event (AE) in Cohort 1 BNT162b2 recipients was lymphadenopathy (n=13; 0.9%). More BNT162b2 recipients (n=14; 0.92%) reported hypersensitivity-related AEs (primarily skin and subcutaneous disorder including rash and dermatitis) than placebo recipients (n=4; 0.53%). Overall, from the combined safety database of 3,109 BNT162b2 recipients (Cohorts 1 and 2), 4 participants reported serious adverse events; all were considered by the study investigator and FDA as unrelated to vaccination. There were no reports of myocarditis/pericarditis or anaphylaxis, and no participant deaths. Subgroup safety analyses by gender, race and ethnicity, obesity and baseline SARS-CoV-2 status showed no notable differences as compared with the overall study population, although some subgroups were too small to draw meaningful conclusions.

FDA conducted a quantitative benefit-risk analysis to evaluate predicted numbers of symptomatic COVID-19 cases, hospitalizations, ICU admissions, and deaths that would be prevented per million fully vaccinated children 5-11 years of age over a 6-month period, as compared with predicted numbers of vaccine-associated excess myocarditis cases, hospitalizations, ICU admissions and deaths per million fully vaccinated children 5-11 years of age. The model conservatively assumed that the risk of myocarditis/pericarditis associated with the 10 µg dose in children 5-11 years of age would the same as the estimated risk associated with the 30 µg dose in adolescents 12-15 years of age from Optum healthcare claims data. While benefits of vaccination were highly dependent on COVID-19 incidence, the overall analysis predicted that the numbers of clinically significant COVID-19-related outcomes prevented would clearly outweigh the numbers of vaccine-associated excess myocarditis cases over a range of assumptions for COVID-19 incidence. At the lowest evaluated COVID-19 incidence (corresponding to the June 2021 nadir), the predicted number of vaccine-associated myocarditis cases was greater than the predicted number of COVID-19 hospitalizations prevented for males and for both sexes combined. However, in consideration of the different clinical implications of hospitalization for COVID-19 versus hospitalization for vaccine-associated myocarditis, and benefits related to prevention of non-hospitalized cases of COVID-19 with significant morbidity, the overall benefits of the vaccine may still outweigh the risks under this low incidence scenario. If the myocarditis/pericarditis risk in this age group is lower than the conservative assumption used in the model, the benefit-risk balance would be even more favorable.

This October 26, 2021 VRPBAC meeting is being held to discuss whether, based on the totality of scientific evidence available, the benefits of the Pfizer-BioNTech COVID-19 Vaccine when administered as a 2-dose series (10 µg each dose, 3 weeks apart) outweigh its risks for use in children 5-11 years of age.

2 SARS-COV-2 VIRUS AND COVID-19 DISEASE

SARS-CoV-2 is a zoonotic coronavirus that emerged in late 2019 and was identified in patients with pneumonia of unknown cause. The virus was named SARS-CoV-2 because of its similarity to the coronavirus responsible for severe acute respiratory syndrome (SARS-CoV, a lineage B betacoronavirus). SARS-CoV-2 is an enveloped, positive-sense, single-stranded RNA virus sharing more than 70% of its sequence with SARS-CoV, and ~50% with the coronavirus responsible for Middle Eastern respiratory syndrome (MERS-CoV). SARS-CoV-2 is the causative agent of COVID-19, an infectious disease with respiratory and systemic manifestations. Disease symptoms vary, with many persons presenting with asymptomatic or mild disease and some progressing to severe respiratory tract disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to multiorgan failure and death. Symptoms associated with SARS-CoV-2 infection in individuals less than 18 years of age are similar to those in adults, but are generally milder, with fever and cough most commonly reported.[1,2] Other symptoms in children include nausea and vomiting, diarrhea, dyspnea, nasal symptoms, rashes, fatigue and abdominal pain.[3] Most children with COVID-19 recover within 1 to 2 weeks. Estimates of asymptomatic infection in children vary from 15 to 50% of infections.[4,5] However, COVID-19 associated hospitalizations and deaths have occurred in children (see below), and for some children, COVID-19 symptoms may continue for weeks to months after their initial illness.[6]

The SARS-CoV-2 pandemic continues to present a challenge to global health and, as of October 15, 2021, has caused approximately 239 million cases of COVID-19, including 4.8 million deaths worldwide.[7] In the United States, more than 44 million cases have been reported to the Centers for Disease Control and Prevention (CDC), with over 722,000 deaths. [8,9] Of the total COVID-19 cases reported in the United States to date, 22.3% occurred among individuals <18 years of age, with 8.7% occurring among 5-11-year-olds.[10] Following emergency use authorization of COVID-19 vaccines in December 2020, COVID-19 cases and deaths in the United States declined sharply during the first half of 2021; however, beginning in late June 2021 a rise in cases was observed, including in children, associated with the highly transmissible Delta variant that is now predominant in the United States.[11] As of the week ending October 2, 2021, the Delta variant comprised greater than 99% of tested strains in the United States.[12] During the last week in August 2021, new COVID-19 infections in individuals less than 18 years of age surpassed those in adults 18 to 64 years of age for the first time during the pandemic.[13] In the United States, COVID-19 cases occurring in children 5-11 years now constitute 39% of cases in individuals younger than 18 years of age.[14] Among cases of COVID-19 in individuals less than 18 years of age from the COVID-NET network[a], approximately 4,300 have resulted in hospitalization.[15] As of October 17, 2021, 691 deaths from COVID-19 have been reported in the United States in individuals less than 18 years of age, with 146 deaths in the 5-11 year age group.[16]

The most common underlying medical conditions among hospitalized children were chronic lung disease (29%), obesity (25%) and neurologic disorders (23%). A total of 68% of hospitalized children had more than one underlying condition. Obesity and feeding tube dependence were associated with increased risk of severe disease. Available evidence suggests that highest risk groups include children with special healthcare needs, including genetic, neurologic, metabolic

[a] COVID-NET covers approximately 10% of the U.S. population; The current network covers nearly 100 counties in the 10 Emerging Infections Program (EIP) states (CA, CO, CT, GA, MD, MN, NM, NY, OR, and TN) and four additional states through the Influenza Hospitalization Surveillance Project (IA, MI, OH, and UT); see https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html.

conditions, or with congenital heart disease.[17] As in the adult population, COVID-19 in children disproportionally affects underrepresented racial and ethnic groups, with hospitalizations and deaths more frequent among Native American/Alaskan, Hispanic or Latin American, and non-Hispanic Black children than among White children.[18,19]

Following observation of an increased incidence of myocarditis in 2020 compared with 2019, several studies have suggested an association between COVID-19 and myocarditis.[20,21] While the overall incidence of myocarditis following COVID-19 infection is low, persons with COVID-19 have a nearly 16-fold increase in risk for myocarditis, compared to individuals without COVID-19. The risk is lowest among individuals 25-39 years and higher in persons less than 16 years and older than 50 years of age.[22] Myocarditis may also present as part of the Multisystem inflammatory syndrome in children (MIS-C), usually 3 to 5 weeks after a SARS-CoV-2 infection. MIS-C is a rare but serious COVID-19-associated condition that occurs in less than 1% of children with confirmed SARS-CoV-2 infection.[23] MIS-C presents with persistent fever, laboratory evidence of inflammation, and at least 2 affected organs. In severe cases, hypotension and shock can occur. Most patients have laboratory markers indicating damage to the heart.[24] During the pandemic, a rise in MIS-C cases has generally lagged behind a rise observed in COVID-19 infections by several weeks,[25] with one study demonstrating the peak in MIS-C cases occurring 31 days following the peak in laboratory-confirmed COVID-19 cases.[26] Between May 2020 and October 4, 2021, the CDC received reports of 5,217 cases and 46 deaths that met the definition for MIS-C; the median age of participants was 9 years with half of the cases occurring in children ages 5 to 13 years. Males comprised 60% of cases, and 61% were reported in children who were reported as Hispanic or Black.[27] Up to 66.7% of patients with MIS-C had cardiac involvement, [28] including left ventricular dysfunction, mitral or tricuspid regurgitation, coronary artery aneurysms, and/or arrhythmias.[29] One study of outcomes in children with MIS-C followed up to 9 months found that while 76% children with MIS-C required ICU admission and therapy with inotropes or pressors; most symptoms, including cardiovascular manifestations, resolved within 1 to 4 weeks.[30] Limited data are available on long-term outcomes in MIS-C.

While children and adolescents appear less susceptible to SARS-CoV-2 infection and generally have a milder COVID-19 disease course as compared with adults,[31,32] adolescents and adults have similar SARS-CoV-2 viral loads in their nasopharynx, so adolescents may play a role in community transmission.[33,34] Transmission of SARS-CoV-2 virus from children can occur in both household and school settings.[35,36] In schools, transmission depends on the transmission rates locally, variants circulating in the community, vaccination rates, and other preventive mitigation strategies. Transmission between school staff members may be more common than transmission involving students.[37] There is evidence that SARS-CoV-2 transmission is greater in secondary and high schools than elementary schools.[38,39] Outbreaks of COVID-19 have been reported in settings where children congregate, such as summer youth camps.[40,41]

In addition to morbidity and mortality on an individual level, the continuing spread of SARS-CoV-2 has caused significant challenges and disruptions in worldwide healthcare systems, economies, and many aspects of human activity (travel, employment, education). Other impacts of COVID-19 on children include limited access to basic services such as healthcare and child protective services, and social isolation due to disruption of school, sports, and social group gatherings. The emergence of the Delta variant, variable implementation of public health measures designed to control spread, and continued transmission among unvaccinated individuals are major factors in the recent resurgence of COVID-19. While recently reported cases appear to be declining relative to the Delta variant-associated peak globally and in the

United States, the longer-term effect of the Delta variant and the potential role of other variants on the future course of the pandemic is uncertain.

3 AUTHORIZED AND APPROVED VACCINES AND THERAPIES FOR COVID-19

FDA has issued EUAs for three COVID-19 vaccines as shown in Table 1 below. The Pfizer-BioNTech COVID-19 Vaccine is also FDA approved for use as a 2-dose primary series in individuals 16 years of age and older, under the trade name COMIRNATY (see Section 4).

Table 1. Emergency Use Authorizations of COVID-19 Vaccines

Sponsor	Authorized Use (Interval)	Indicated Population	Date of EUA or EUA Amendment
Pfizer-BioNTech	2-dose primary series (3 weeks apart)	Individuals ≥16 years of age	December 11, 2020
		Individuals ≥12 years of age	May 10, 2021
Pfizer-BioNTech	3rd primary series dose (at least 1 month after the second dose)	Individuals ≥12 years of age with compromised immune systems due to solid organ transplantation or conditions considered to have an equivalent level of immunocompromise	August 12, 2021
Pfizer-BioNTech	Booster dose (at least 6 months after completing a primary series of COMIRNATY and/or Pfizer-BioNTech COVID-19 Vaccine)	• Individuals 65 years of age and older • Individuals 18 through 64 years of age and at high risk of severe COVID-19 • Individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2	September 22, 2021
Moderna	2-dose series (4 weeks apart)	2-dose primary series in adults ≥18 years of age	December 18, 2020
Moderna	3rd dose (at least 1 month after the second dose)	Individuals ≥12 years of age with compromised immune systems due to solid organ transplantation or conditions considered to have an equivalent level of immunocompromise	August 12, 2021
Moderna	Booster dose (at least 6 months after completing a primary series of Moderna COVID-19 Vaccine	• Individuals 65 years of age and older • Individuals 18 through 64 years of age and at high risk of severe COVID-19 • Individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2	October 20, 2021
Janssen	Single dose	Individuals ≥18 years of age	February 27, 2021
Janssen	Booster dose	Individuals ≥18 years of age	October 20, 2021
Pfizer, Moderna and Janssen	Single heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19	Same population(s) as those eligible to receive a booster dose of the vaccine used for primary vaccination	October 20, 2021

Sponsor	Authorized Use (Interval)	Indicated Population	Date of EUA or EUA Amendment
	vaccine (same interval as authorized for a booster dose of the vaccine used for primary vaccination)		

Remdesivir is the only product currently approved by the FDA for treatment of COVID-19 requiring hospitalization, and its approved use is limited to individuals 12 years of age and older. Prior to its approval, remdesivir was authorized for emergency use in adults and pediatric patients and remains authorized for emergency use in hospitalized pediatric patients who are not included in the indicated population under licensure.

Emergency use authorizations of COVID-19 pharmacological products for post-exposure prophylaxis and/or treatment of COVID-19 are as follows:

Table 2. Emergency Use Authorized Pharmacological Products for Post-exposure Prophylaxis and/or Treatment of COVID-19

Product	Date of EUA	Authorized Use and Population
SARS-CoV-2-targeting Monoclonal Antibodies		
• Bamlanivimab/etesevimab	Reissued September 16, 2021	All three products are indicated for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients 12 years and older at high risk for progressing to severe COVID-19[a]
• Sotrovimab	May 26, 2021	
• Casirivimab/imdevimab	Reissued September 9, 2021	
		Casirivimab/imdevimab is also authorized for post-exposure prophylaxis (prevention) for COVID-19 in patients at high risk for progressing to severe COVID-19[b]
Antiviral Drugs		
• Remdesivir	Reissued October 22, 2020 (following FDA approval in adults and some pediatric patients)	Treatment of COVID-19 in hospitalized pediatric patients weighing at least 3.5 kg to <40 kg, or <12 years of age weighing at least 3.5 kg, or ≥12 years and weighing at least 40 kg
Immune Modulators		
• Baricitinib	Reissued July 29, 2021	Treatment of COVID-19 in hospitalized patients[b] receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO
• Actemra	June 24, 2021	
COVID-19 Convalescent Plasma	Reissued March 9, 2021	Treatment of hospitalized patients with COVID-19

a Indicated for adults and pediatric patients 12 years of age and older weighing at least 40 kg
b Indicated for adults and pediatric patients 2 years and older
ECMO extracorporeal membrane oxygenation, EUA emergency use authorization
Source: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs Accessed August 2, 2021.

4 COMIRNATY (COVID-19 VACCINE, mRNA)

On August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA) made by BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.). COMIRNATY is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The vaccine is administered IM as a series of two doses (0.3 mL each) 3 weeks apart, with each dose containing 30 µg mRNA. COMIRNATY contains a nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein of SARS-CoV-2 that is formulated in lipid particles. COMIRNATY is the only vaccine or medical product that is FDA approved for prevention of COVID-19. COMIRNATY is also authorized under EUA for use as a 2-dose primary series in individuals 12 years of age and older, for use as a third primary series dose in individuals 12 years of age and older with certain immunocompromising conditions, and for use as a single booster dose administered at least 6 months after completion of a primary series to individuals 65 years of age and older, individuals 18 through 64 years of age at increased risk of severe COVID-19, and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2. The vaccine authorized under EUA is also known as the Pfizer-BioNTech COVID-19 Vaccine. During clinical development, the vaccine was called BNT162b2.

COMIRNATY is supplied as a concentrated multi-dose liquid formulation (0.45 mL volume) stored frozen at -90°C to -60°C in a 2 mL Type 1 glass vial. A sterile diluent, 0.9% Sodium Chloride Injection, USP, is supplied separately and is stored at 20°C to 25°C. The COMIRNATY Multiple Dose Vial is thawed in a refrigerator (2°C to 8°C) for 2 to 3 hours or at room temperature (up to 25°C) for 30 minutes. Once at room temperature, the COMIRNATY Multiple Dose Vial is diluted with 1.8 mL of the diluent. After dilution, each vial of COMIRNATY contains six doses of 0.3 mL of vaccine. COMIRNATY does not contain preservative.

4.1 Efficacy of a 2-dose primary series of COMIRNATY in individuals 16 years of age and older

Efficacy of BNT162b2 for the prevention of COVID-19 occurring at least 7 days after completion of a 2-dose primary series was evaluated in an ongoing Phase 3 study, C4591001, in approximately 44,000 participants randomized 1:1 to receive two doses of either BNT162b2 or placebo, 3 weeks apart. Participants were enrolled with stratification by age (younger adults: 18 through 55 years of age; older adults: over 55 years of age). The population for the vaccine efficacy analysis that supported approval of COMIRNATY included participants 16 years of age and older who had been enrolled from July 27, 2020, and who were followed for the development of COVID-19 during blinded placebo-controlled follow-up through as late as March 13, 2021. Overall, 60.8% of participants in the BNT162b2 group and 58.7% of participants in the placebo group had ≥4 months of follow-up time after the primary series in the blinded placebo-controlled follow-up period. The overall VE against COVID-19 in subjects without evidence of prior SARS-CoV-2 infection was 91.1% (95% CI: 88.8 to 93.1). The overall VE against COVID-19 in subjects with or without evidence of prior SARS-CoV-2 infection was 90.9% (95% CI: 88.5 to 92.8).

4.2 Safety of a 2-dose primary series of COMIRNATY in individuals 16 years of age and older

In study C4591001, the most commonly reported solicited adverse reactions (occurring in ≥10% of participants) among BNT162b2 vaccine recipients 16 through 55 years of age following any dose were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain

(45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%). The most commonly reported solicited adverse reactions in BNT162b2 vaccine recipients 56 years of age and older following any dose were pain at the injection site (78.2%), fatigue (56.9%), headache, (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

Among participants 16 through 55 years of age, SAEs from Dose 1 up to the participant unblinding date in ongoing follow-up were reported by 0.8% of BNT162b2 recipients and 0.9% placebo recipients. In a similar analysis, in participants 56 years of age and older serious adverse events (SAEs) were reported by 1.8% of BNT162b2 recipients and 1.7% of placebo recipients who received at least 1 dose of BNT162b2 or placebo, respectively. In these analyses, 58.2% of study participants had at least 4 months of follow-up after the primary series. There were no notable patterns between treatment groups for specific categories of SAEs (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to BNT162b2. From Dose 1 through the March 13, 2021 data cutoff date, there were a total of 38 deaths, 21 in the BNT162b2 group and 17 in the placebo group. None of the deaths were considered related to vaccination.

4.3 Effectiveness and safety of a 2-dose primary series of Pfizer-BioNTech COVID-19 Vaccine in adolescents 12-15 years of age

On May 10, 2021, FDA authorized the use of Pfizer-BioNTech COVID-19 Vaccine in individuals 12-15 years of age based on safety and effectiveness data from an ongoing Phase 2/3 randomized, double-blinded and placebo-controlled trial of the Pfizer-BioNTech COVID-19 Vaccine in 2,260 participants 12-15 years of age.

Vaccine effectiveness in the adolescent age group was inferred by immunobridging based on a comparison of SARS-CoV-2 50% neutralization antibody titers (SARS-CoV-2 mNG microneutralization assay) at 1 month after Dose 2 in participants 12-15 years of age with those of young adults 16-25 years of age (the most clinically relevant subgroup of the study population in whom VE has been demonstrated). In the planned immunobridging analysis, the geometric mean ratio (GMR) of neutralizing antibody titers (adolescents to young adults) was 1.76 (95% CI: 1.47, 2.10), meeting the success criterion (lower bound of the 95% CI for the GMR >0.67). In a descriptive immunogenicity analysis, seroresponse rates among participants without prior evidence of SARS-CoV-2 infection were seen in 97.9% of adolescents and 100% of young adults (difference in seroconversion rates: -2.1%; 95% CI: -6.0%, 0.9%). Immunogenicity outcomes were consistent across demographic subgroups, such as baseline SARS-CoV-2 status, comorbidities, ethnicity, race and sex. In the supplemental efficacy analysis, VE after 7 days post Dose 2 was 100% (95% CI 75.3; 100.0) in participants 12-15 years of age without prior evidence of SARS-CoV-2 infection and 100% in the group of participants with or without prior infection. VE between Dose 1 and Dose 2 was 75.0% (95% CI 7.4; 95.5), with divergence of cumulative incidence of COVID-19 cases in BNT162b2 vs. placebo groups beginning at approximately 14 days after Dose 1. Although based on a small number of cases in descriptive analyses, the supplementary VE data provided compelling direct evidence of clinical benefit in addition to the immunobridging data.

Safety data from a total of 2,260 adolescents 12-15 years of age randomized to receive vaccine (N=1,131) or placebo (N=1,129) with a median of greater than 2 months of follow-up after the second dose suggest a favorable safety profile, with no specific safety concerns identified that would preclude issuance of an EUA. The most common solicited adverse reactions after any dose included injection site pain (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%),

muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), all of which were generally mild to moderate and lasted a few days. Severe solicited local and systemic adverse reactions occurred in up to 2.4% of 12-15-year-old BNT162b2 recipients, were more frequent after Dose 2 (most common: fatigue 1.3%, headache 1.0%, chills 0.4%) than after Dose 1 (most common: fatigue 2.4%, headache 2.0%, chills 1.8%) and more frequent after any dose in BNT162b2 recipients than age-matched placebo recipients. Among recipients of BNT162b2, severe solicited adverse reactions/events in 12-15-year-olds occurred less frequently than in 16-25-year-olds. No deaths were observed in this age group during the follow-up period. SAEs, while uncommon (<0.5%), represented medical events expected to occur among individuals in this age group and with the underlying conditions represented in the study population, and available data do not suggest a causal relationship to BNT162b2. There were no notable patterns or numerical imbalances between treatment groups for specific categories of non-serious AEs among study participants 12-15 years of age that would suggest a causal relationship to BNT162b2 vaccine.

4.4 Cases of myocarditis/pericarditis reported in BNT162b2 recipients in ongoing clinical trials of BNT162b2

Two cases of myocarditis have been reported in BNT162b2 recipients in study C4591001:

- A male participant ≥55 years of age, with no medical history, reported myocarditis 28 days after Dose 2 of BNT162b2; the event was assessed by the investigator as not related to the study intervention and was ongoing at the time of the data cutoff.
- A male participant who was randomized to blinded placebo group at age 15 years and subsequently unblinded and crossed over to open label BNT162b2 at age 16 years was diagnosed with myopericarditis beginning 2 days after Dose 2 of BNT162b2. He was hospitalized on Day 3 and treated with IVIG, non-steroidal anti-inflammatory medications and steroids, and discharged the following day. He was followed by a cardiologist and seen for follow-up 2 months after vaccination. At that time the cardiologist recommended limited activity. The investigator concluded that the there was a reasonable possibility that the myopericarditis was related to vaccine administration due to the plausible temporal relationship. FDA agrees with this assessment.

4.5 Post-EUA and post-licensure surveillance

As of October 21, 2021, more than 240 million doses of the Pfizer-BioNTech COVID-19 Vaccine have been administered in the U.S. (CDC COVID Data Tracker, accessed on October 22, 2021). Among all COVID-19 vaccines, 205,046 individuals less than 12 years of age have received at least one dose and 125,656 are fully vaccinated (CDC COVID Data Tracker, accessed on October 22, 2021).

The Vaccine Adverse Event Reporting System (VAERS) was queried for adverse event (AE) reports following administration of the Pfizer-BioNTech COVID-19 Vaccine, and the results are summarized below. Spontaneous surveillance systems such as VAERS are subject to many limitations, including underreporting, variable report quality and accuracy, inadequate data regarding the numbers of doses administered, and lack of direct and unbiased comparison groups. Reports in VAERS may not be medically confirmed and are not verified by FDA. Also, there is no certainty that the reported event was actually due to the vaccine.

As of October 18, 2021, VAERS received 442,763 reports (including 270,342 U.S. reports), of which 854 U.S. reports were in children 5-11 years of age, 9,523 U.S. reports were in children

12-15 years of age, and 5,821 U.S. reports were in adolescents 16-17 years of age. The top ten most frequently reported MedDRA preferred terms (PTs) included:

- Overall most frequent PTs: headache, fatigue, pyrexia, SARS-CoV-2 test, dizziness, pain, nausea, chills, pain in extremity, dyspnoea
- Most frequent PTs in in persons ≤17 years of age: dizziness, syncope, headache, pyrexia, nausea, product administered to patient of inappropriate age, chest pain, fatigue, vomiting, loss of consciousness.

Note that a report may have one or more PTs. An additional query of VAERS for U.S. reports by dose number retrieved the following: 127,747 reports after Dose 1; 100,730 reports after Dose 2; and 5,223 reports after dose 3 (data as of October 18, 2021).

Safety concerns identified from post-authorization safety surveillance data in VAERS are summarized below. Anaphylaxis, myocarditis, and pericarditis are existing safety concerns that have been added to the product Fact Sheets. Review of passive surveillance AE reports and the Sponsor's periodic safety reports does not indicate any new safety concerns, including in adolescents. Most AEs are labeled events and consistent with the safety profile for this vaccine. No unusual frequency, clusters, or other trends for AEs were identified that would suggest a new safety concern.

Anaphylaxis

Post-authorization surveillance has identified a risk of anaphylaxis, occurring at a rate similar to reported rates of anaphylaxis following licensed preventive vaccines, primarily in individuals with history of prior severe allergic reactions to other medications or foods.[42][43] Anaphylaxis is an important identified risk in the pharmacovigilance plan (PVP) and included in the Warnings sections of the vaccine Fact Sheets and Prescribing Information. The estimated crude reporting rate for anaphylaxis in the U.S. is 6.1 cases per million doses at this time based on the above VAERS data.

Myocarditis and pericarditis

Post-EUA safety surveillance reports received by FDA and CDC identified increased risks of myocarditis and pericarditis, particularly within 7 days following administration of the second dose of the 2-dose primary series. Reporting rates for medical chart-confirmed myocarditis and pericarditis in VAERS have been higher among males under 40 years of age than among females and older males and have been highest in males 12 through 17 years of age (~71.5 cases per million second primary series doses among males age 16-17 years and 42.6 cases per million second primary series doses among males age 12-15 years as per CDC presentation to the ACIP on August 30, 2021). In an FDA analysis of the Optum healthcare claims database, the estimated excess risk of myocarditis/pericarditis approached 200 cases per million fully vaccinated males 16-17 years of age and 180 cases per million fully vaccinated males 12-15 years of age.[44] Although some cases of vaccine-associated myocarditis/pericarditis have required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae and outcomes in affected individuals, or whether the vaccine might be associated initially with subclinical myocarditis (and if so, what are the long-term sequelae). A mechanism of action by which the vaccine could cause myocarditis and pericarditis has not been established. Myocarditis and pericarditis were added as important identified risks in the PVP and included in the Warnings sections of the vaccine Fact Sheets and Prescribing Information. The Sponsor is conducting additional post-authorization/post-marketing

studies to assess known serious risks of myocarditis and pericarditis as well as to identify an unexpected serious risk of subclinical myocarditis.

5 EUA AMENDMENT REQUEST FOR THE PFIZER-BIONTECH COVID-19 VACCINE FOR USE IN CHILDREN 5-11 YEARS OF AGE

On October 6, 2021, Pfizer and BioNTech submitted a request to amend this EUA to include use of a 2-dose primary series of the Pfizer-BioNTech COVID-19 Vaccine (10 µg each dose, administered 3 weeks apart) in individuals 5-11 years of age for active immunization to prevent COVID-19 caused by severe acute coronavirus 2 (SARS-CoV-2).

The request is accompanied by safety data from 1,518 BNT162b2 and 750 placebo (saline) Phase 2/3 participants 5-11 years of age in ongoing clinical study, C4591007, of which a total of 1,444 (95.1%) had safety follow-up ≥2 months after Dose 2 at the time of a September 6, 2021 data cutoff, and data from an additional 1,591 BNT162b2 and 788 placebo participants with a median duration of follow-up of 2.4 weeks post-Dose 2 at the time of an October 8, 2021 data cutoff. Vaccine effectiveness in children 5-11 years of age was inferred by immunobridging SARS-CoV-2 50% neutralizing antibody titers (NT50, as assessed by SARS-CoV-2 mNG microneutralization assay) among C4591007 study participants 5-11 years of age following completion of a primary series to antibody titers of those of young adults 16-25 years of age who received two doses of 30 µg BNT162b2 in study C4591001. Efficacy against COVID-19 disease was assessed descriptively in study C4591007 participants 5-11 years of age.

Vaccine formulation

Authorization is being requested for a modified formulation of the Pfizer-BioNTech COVID-19 Vaccine. Each dose of this formulation contains 10 µg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 that is formulated in lipid particles and supplied as a frozen suspension in multiple dose vials.

To provide a vaccine with an improved stability profile, the Pfizer-BioNTech COVID-19 Vaccine for use in children 5-11 years of age uses tromethamine (Tris) buffer instead of the phosphate-buffered saline (PBS) as used in the previous formulation and excludes sodium chloride and potassium chloride. The packaged vials for the new formulation are stored frozen at -90°C to -60°C. The frozen vials may be thawed and stored at refrigerator at 2°C to 8°C for up to 10 weeks.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex. For the 10-µg RNA dose, each 1.3-mL filled via vial must be diluted with 1.3mL 0.9% sodium chloride for injection to provide 10 doses at 10 µg RNA / 0.2 mL Injection volume. After dilution, the vials should be stored at 2°C to 25°C and should be used within 12 hours.

6 EUA REQUIREMENTS, GUIDANCE AND CONSIDERATIONS PERTAINING TO COVID-19 VACCINES

6.1 U.S. requirements to support issuance of an EUA for a biological product

Based on the declaration by the Secretary of the U.S. Department of Health and Human Services (HHS) that the COVID-19 pandemic constitutes a public health emergency with a significant potential to affect national security or the health and security of United States citizens

living abroad, FDA may issue an EUA after determining that certain statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-3)).

- The chemical, biological, radiological, or nuclear (CBRN) agent referred to in the March 27, 2020 EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition.
- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2, or to mitigate a serious or life-threatening disease or condition caused by an FDA-regulated product used to diagnose, treat, or prevent a disease or condition caused by SARS-CoV-2.
- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

If these criteria are met, under an EUA, FDA can allow unapproved medical products (or unapproved uses of approved medical products) to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents. FDA has been providing regulatory advice to COVID-19 vaccine manufacturers regarding the data needed to determine that a vaccine's benefit outweigh its risks. This includes demonstrating that manufacturing information ensures product quality and consistency.

6.2 FDA guidance for industry related to COVID-19 vaccines

An EUA allowing for rapid and widespread deployment of the vaccine to millions of individuals, including healthy people, would need to be supported by clear and compelling evidence of effectiveness and adequate safety follow-up to make a determination of favorable benefit/risk (see guidance for industry "Emergency Use Authorization for Vaccines to Prevent COVID-19" February 2021, originally issued October 2020).[45] These expectations would apply to age-group specific data to support an EUA amendment for use of an unapproved COVID-19 vaccine in children 5-11 years of age. The timing, design, and appropriate endpoints for pediatric studies are discussed in the context of specific vaccine development programs as described in the guidance for industry "Development and Licensure of Vaccines to Prevent COVID-19" from June 2020.[46]

6.3 Regulatory considerations for clinical development of COVID-19 vaccines in children

The Vaccines and Related Biological Products Advisory Committee convened on June 21, 2021 to discuss, in general, the data needed to support authorization and/or licensure of COVID-19 vaccines for use in pediatric populations.

Effectiveness

Regulatory precedent with other preventive vaccines provides a basis for inference of vaccine effectiveness in pediatric populations based on immunobridging to a young adult population in which clinical disease endpoint vaccine efficacy has been demonstrated for the same prototype vaccine. The immune marker(s) used for immunobridging do not need to be scientifically established to predict protection but should be clinically relevant to the disease. Based on

available data in humans and animal models, FDA considers neutralizing antibody titers (a functional measure of the vaccine immune response against SARS-CoV-2) to be clinically relevant for immunobridging to infer effectiveness of COVID-19 vaccines in pediatric age groups. Because no specific neutralizing antibody titer has been established to predict protection against COVID-19, two immunogenicity endpoints (geometric mean titer [GMT] and seroresponse rate) are considered appropriate for comparing the range of neutralizing antibody responses elicited by the vaccine in pediatric vs. young adult populations.

Safety

The size of the safety database sufficient to assess risks of COVID-19 vaccines for EUA in pediatric age groups would generally be the same as for other preventive vaccines for infectious diseases, provided that no specific safety concern is identified that could reasonably be evaluated in pre-authorization clinical trials. These safety data would include characterization of common adverse reactions (reactogenicity, including injection site and systemic adverse reactions), and less common but medically important adverse reactions. Depending on prior experience with the vaccine in adults, and prior experience with licensed vaccines based on the same or similar platforms, FDA has accepted an overall pediatric safety database in the range of ~500 to ~3,000 trial participants exposed to the age-appropriate dose and regimen intended for licensure and have at least 6 months of follow-up evaluations after completion of the vaccination regimen. Since COVID-19 vaccines represent a new class of vaccines, with many of the lead candidates based on new platform technologies, an appropriate overall pediatric safety database would approach the upper end of this range, with adequate representation across all pediatric age groups, in particular younger age groups (e.g., <12 years) that are less physiologically similar to adults. A control group (ideally placebo control) would be important to inform interpretation of safety data and to comply with the expectation for adequate and well-controlled studies to support licensure. If another COVID-19 vaccine is licensed or authorized for use in the age group(s) enrolled in the trial, recommended by public health authorities, and widely available such that it is unethical to use a placebo control, the licensed or authorized COVID-19 vaccine could serve as a control.

Within the overall pre-licensure safety database, solicited reactogenicity could be adequately characterized among several hundred trial participants in each relevant age group. Additionally, safety evaluation in all trial participants would include collection of all AEs through at least 1 month after each study vaccination and collection of serious and other medically attended AEs for the duration of the trial. Although longer-term follow-up (through 1 year or longer post-vaccination) of trial participants would be important to ongoing assessment of both benefits and risks, completion of such longer-term follow-up would not be a prerequisite to licensure unless warranted by a specific safety concern. Post-licensure/post-authorization safety surveillance and observational studies in pediatric populations would be needed to evaluate for adverse reactions that occur too rarely to be detected in clinical trials.

7 FDA REVIEW OF CLINICAL SAFETY AND EFFECTIVENESS DATA

7.1 Overview of study C45910007

The EUA amendment request contains safety, immunogenicity, and descriptive efficacy data from children 5-11 years of age enrolled in C4591007, an ongoing Phase 1/2/3, randomized, placebo-controlled study. The comparator group for the immunobridging analyses to support vaccine effectiveness in this age group was a random subset of Phase 2/3 participants 16-25 years of age enrolled in study C4591001, the study in which vaccine efficacy against COVID-19 was established in individuals 16 years of age or older.

Data from study C4591007

- Phase 2/3: a total of 3,109 BNT162b2 (10 µg) recipients and 1528 placebo recipients 5-11 years of age

  - Cohort 1: 1,518 BNT162b2 (10 µg) recipients and 750 placebo recipients, of whom 1,444 (95.1%) and 714 (95.2%), respectively, had at least 2 months of safety follow-up after completing a 2-dose primary series (data cutoff September 6, 2021). Summary tables for solicited adverse reactions (ARs) and immunogenicity analyses are based on this cohort of subjects. A descriptive efficacy analysis was also based on this cohort; at the time of this Briefing Document was prepared, FDA has not fully verified the underlying data or Pfizer-BioNTech's conclusions from this analysis.

  - Cohort 2: A second cohort of 1,591 BNT162b2 (10 µg) recipients and 778 placebo recipients had a median duration of follow-up of 2.4 weeks post-Dose 2 at the time of data cutoff (October 8, 2021). Safety data from this cohort were provided for further assessment of SAEs and AEs of clinical interest. Data verification is in process, but not yet finished at the time this briefing book was completed.

- Phase 1 data to support dosage selection for Phase 2/3 portion of the study

Table 3. Study C4591007*: Participants 5-11 Years of Age (10 µg BNT162b2)

Study Number/ Countries	Description	BNT162b2 N	Placebo (Saline) N	Study Status
C4591007 United States, Finland, Poland, and Spain	Phase 1/2/3 randomized, placebo-controlled; to evaluate safety, immunogenicity and efficacy of COVID-19 vaccine	Phase 1: 16 Phase 2/3: 3,109	Phase 1:0 Phase 2/3: 1,528	Ongoing

N=Number of randomized participants as of data cutoff dates July 16, 2021 (all Phase 1 participants), September 6, 2021 (Phase 2/3 Cohort 1: 1,518 BNT162b2, 750 placebo; includes participants starting March 24, 2021) and October 8, 2021 (Phase 2/3 cohort 2: 1,591 BNT162b2, 788 placebo; first subject in this second cohort randomized August 15, 2021).
*First participant, first visit was March 24, 2021.

7.2 Study design

Study C4591007 is an ongoing Phase 1/2/3 randomized, observer-blinded, placebo-controlled safety, immunogenicity, and efficacy study. This section presents the design for the Phase 2/3 portion of the study in children 5-11 years of age. Please see Appendix 1 for Phase 1 study design.

Phase 2/3 is being conducted in the United States, Finland, Poland, and Spain. The Phase 2/3 portion of the study did not exclude children with a history of prior SARS-CoV-2 infection or clinical symptoms/signs of COVID-19, children with known HIV, hepatitis B or hepatitis C, or stable pre-existing disease (defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment).

Participants were randomized 2:1 to receive two doses of 10 µg BNT162b2 or placebo (saline), 3 weeks apart. Participants who turned 12 years of age during the study would have the opportunity to receive the EUA-authorized dose level of 30 µg (12-15 years of age) if they originally received placebo.

Immunogenicity evaluation

Immunobridging was based on SARS-CoV-2 neutralizing antibody responses in study C4591007 Phase 2/3 (Cohort 1) participants 5-11 years of age compared to neutralizing antibody responses in a random subset of study C4591001 participants 16-25 years of age, as measured by 50% neutralizing antibody titers (NT50, SARS-CoV-2 mNG microneutralization assay) against the reference strain (USA_WA1/2020) at 1 month after a primary series. The primary analysis is based on the evaluable immunogenicity population of participants without evidence of prior SARS-CoV-2 infection up to 1 month after Dose 2.

Primary endpoints and statistical success criteria

- Immunobridging success based on GMT was declared if the lower limit (LL) of the 95% CI for the GMT ratio (5-11 years of age / 16-25 years of age) was >0.67, and the point estimate of the GMT ratio was ≥1.0.
- Immunobridging success based on the seroresponse rate was declared if the LL of the 95% CI for the difference in seroresponse rates (5-11 years of age minus 16-25 years of age) was >-10%. Seroresponse was defined as a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers from before vaccination (pre-Dose 1) to 1 month after Dose 2.

Efficacy evaluation

A secondary objective is to evaluate efficacy of BNT162b2 against laboratory-confirmed symptomatic COVID-19 occurring from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection and in participants with or without evidence of prior SARS-CoV-2 infection. A descriptive analysis was conducted once 19 confirmed cases had accrued.

Safety evaluation

Reactogenicity (solicited local and systemic adverse reactions)

The participants' parents or participants themselves recorded reactogenicity assessments and antipyretic/pain medication use from Day 1 through Day 7 after each dose in an e-diary. Reactogenicity assessments included solicited injection site reactions (pain, redness, swelling) and systemic AEs (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain).

Unsolicited adverse events

Other safety assessments included: AEs occurring within 30 minutes after each dose, non-serious unsolicited AEs from Dose 1 through 1 month after Dose 2, and SAEs from Day 1 to 6 months after Dose 2, or the data cutoff date (Phase 1: of July 16, 2021; Phase 2/3: September 6, 2021). AEs were categorized by frequency and maximum severity according to system organ class (SOC) and preferred term (PT), according to MedDRA, and relationship to the study intervention was assessed. Deaths are recorded to the end of the study.

Adverse events of clinical interest

The occurrence of certain AEs including lymphadenopathy and myocarditis/pericarditis were assessed as part of the safety review, as well as additional AEs requested by FDA (including anaphylaxis, Bell's palsy, appendicitis, pregnancy exposures and outcomes, and MIS-C cases).

Analysis populations

Pertaining to participants 5-11 years of age

- Safety: All participants who receive at least 1 dose of the study intervention.

- All-available immunogenicity: All randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after vaccination.
- Evaluable immunogenicity: All eligible randomized participants who receive two doses of the vaccine to which they are randomized with Dose 2 received within the predefined window, have at least 1 valid and determinate immunogenicity result from the blood sample collected within an appropriate window, and have no other important protocol deviations as determined by the clinician.
- Evaluable efficacy: All randomized participants who receive all vaccinations as randomized, with Dose 2 received within the predefined window (within 19-42 days after Dose 1) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2.

Data analysis cutoff dates:

- All Phase 1 participants: July 16, 2021
- Phase 2/3 Cohort 1: September 6, 2021; includes participants starting March 24, 2021
- Phase 2/3 Cohort 2: October 8, 2021; first subject in this cohort was randomized August 15, 2021

7.3 Disposition of Phase 2/3 participants

Cohort 1

Cohort 1 was comprised 1,528 BNT162b2 10 µg participants and 757 placebo participants; 11 (0.7%) BNT162b2 and 6 (0.8%) placebo participants did not receive any study agent. Two BNT162b2 participants (0.1%) and two placebo participants (0.3%) discontinued vaccination before the 1 month post-Dose 2 follow-up; none resulted from an AE. Three participants turned 12 years of age during the course of the study and became eligible to receive 30 µg BNT162b2 under EUA; two of these participants received two doses of 10 µg BNT162b2 prior to being unblinded, and the other participant received both doses of placebo before being unblinded and withdrew to receive a COVID-19 vaccine outside of the study; data from these participants were included in endpoint analyses up to the point at which they were unblinded.

Safety population: solicited ARs, unsolicited AEs, SAEs and AEs of clinical interest were assessed in a total of 2,268 (1,518 10 µg BNT162b2, 750 placebo) participants 5-11 years of age; 95% of participants in each study group completed at least 2 months of safety follow-up after Dose 2. Five BNT162b2 recipients and six placebo recipients withdrew from the study, mainly due to voluntary withdrawal.

Comparator group for immunogenicity: The comparator group for immunobridging analyses consisted of 300 evaluable participants 16-25 years of age who received both doses of BNT162b2 30 µg and were randomly selected from study C4591001 Phase 2/3.

Table 4. Disposition of Immunogenicity Populations, Phase 2/3, Participants 5-11 Years of Age (Study C4591007 Cohort 1) and Participants 16-25 Years of Age (Study C4591001)

Disposition	5-11 years of age BNT162b2 (10 µg) n (%)	5-11 years of age Placebo n (%)	16-25 years of age BNT162b2 (30 µg) n (%)
Randomized to receive BNT162b2[a]	322 (100.0)	163 (100.0)	300 (100.0)
All-available immunogenicity population	311 (96.6)	156 (95.7)	286 (95.3)
Excluded because they did not have at least 1 valid and determinate immunogenicity result after vaccination	11 (3.4)	7 (4.3)	13 (4.3)
Evaluable immunogenicity population	294 (91.3)	147 (90.2)	273 (91.0)
Without evidence of infection up to 1 month after Dose 2[b]	264 (82.0)	130 (79.8)	253 (84.3)
Subjects excluded from evaluable immunogenicity population	28 (8.7)	16 (9.8)	27 (9.0)
Reason for exclusion (subjects may have been excluded for >1 reason)			
Did not receive 2 doses of the vaccine as randomized	3 (0.9)	1 (0.6)	0
Did not receive Dose 2 within 19 to 42 days after Dose 1	3 (0.9)	2 (1.2)	3 (1.0)
Did not have at least 1 valid and determinate immunogenicity result within 28 to 42 days after Dose 2	13 (4.0)	14 (8.6)	21 (7.0)
Did not have blood draw at 1 month after Dose 2 visit	7 (2.2)	6 (3.7)	8 (2.7)
1 Month after Dose 2 blood draw outside of window (28-42 days after Dose 2)	6 (1.9)	8 (4.9)	13 (4.3)
Had important protocol deviation(s) as determined by the clinician	10 (3.1)	0	4 (1.3)

%:n/N. n = number of participants with the specified characteristic. N = number of randomized participants in the specified group; this value is the denominator for the percentage calculations.

a. Participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding ant body [serum] negative at Visit 1 and Visit 4 (C4591007) or Visit 3 (C4591001), SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT [nasal swab] result at any unscheduled visit prior to the 1-month post-Dose 2 blood sample collection) and had no medical history of COVID-19 were included in the analysis.

b. Participants may have been excluded for more than 1 reason.

Cohort 2

In the Phase 2/3 safety expansion, 1,598 participants were randomized to receive BNT162b2 and 796 were randomized to placebo. At the time of the October 8, 2021 cutoff, most participants (98.7%) had received both Dose 1 and Dose 2. Seven participants in the BNT162b2 group did not receive vaccine, for a Safety Population of 1,591. One participant in the BNT162b2 group discontinued from the vaccination period due to AEs of pyrexia and neutropenia that worsened from baseline (see Section 7.6.7, AEs leading to withdrawal). Two participants (0.1%) in the BNT162b2 group withdrew from the study before the 1 month period. Neither withdrawal was due to an AE.

Comorbidities at baseline

Comorbidities were defined as described in Kim et al. MMWR 2020.[47] Participants with any comorbidity, including obesity, constituted 20.6% of the BNT162b2 group and 20.3% of placebo group. The most common comorbidities at baseline in the Cohort 1 BNT162b2 group were obesity (11.5%), asthma (7.8%), neurologic disorders (1.3%), and congenital heart disease

(1.0%). Other comorbidities included diabetes in 2 participants (0.2%), and one participant each (0.1%) for acute lymphocytic leukemia (immunocompromising conditions), cystic fibrosis, and sickle cell disease.

Demographic characteristics were similar in Cohort 2 as Cohort 1. Overall, 11.1% of participants were obese. Comorbidities including obesity were found in 19.9% of participants. As in Cohort 1, the most common comorbidities were asthma, neurologic disorders and congenital heart disease.

7.4 Demographic and baseline characteristics

Demographic characteristics for the safety population of participants who received BNT162b2 10 µg in Phase 2/3 study C4591007 Cohort 1 are summarized in Table 5 below. Participants were predominately White, with a mean age of approximately 8 years. Of the BNT162b2 recipients, 11.5% met the definition of obesity, 8.8% had evidence of prior SARS-CoV-2 infection and 20.6% had comorbidities placing them at increased risk of severe COVID-19. More than 70% of participants were enrolled in the United States.

Table 5. Demographic and Baseline Characteristics, Phase 2/3, Participants 5-11 Years, Safety Population, Study C4591007 Cohort 1

Characteristic	C4591007 BNT162b2 10 µg (N[a]=1518) n[b] (%)	C4591007 Placebo (N[a]=750) n[b] (%)
Sex: Male	799 (52.6)	383 (51.1)
Sex: Female	719 (47.4)	367 (48.9)
Race: White	1204 (79.3)	586 (78.1)
Race: Black or African American	89 (5.9)	58 (7.7)
Race: American Indian or Alaska Native	12 (0.8)	3 (0.4)
Race: Asian	90 (5.9)	47 (6.3)
Race: Multiracial	109 (7.2)	49 (6.5)
Race: Not reported	9 (0.6)	7 (0.9)
Ethnicity: Hispanic or Latino	319 (21.0)	159 (21.2)
Ethnicity: Not Hispanic or Latino	1196 (78.8)	591 (78.8)
Age: Mean years (SD)	8.2 (1.93)	8.1 (1.97)
Age: Median (years)	8.0	8.0
Obese[c]: Yes	174 (11.5)	92 (12.3)
Obese[c]: No	1343 (88.5)	658 (87.7)
Baseline Evidence of Prior SARS-CoV-2 Infection: Negative[e]	1385 (91.2)	685 (91.3)
Baseline Evidence of Prior SARS-CoV-2 Infection: Positive[f]	133 (8.8)	65 (8.7)
Comorbidities[d]: Yes	312 (20.6)	152 (20.3)
Comorbidities[d]: No	1206 (79.4)	598 (79.7)
Country: Finland	158 (10.4)	81 (10.8)
Country: Poland	125 (8.2)	60 (8.0)
Country: Spain	162 (10.7)	78 (10.4)
Country: United States	1073 (70.7)	531 (70.8)

Abbreviations: BMI = body mass index; COVID-19 = coronavirus disease 2019; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein-binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Demographic and baseline characteristic categories with 0 participants in any treatment group are not shown to avoid inadvertent unblinding through public disclosure.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Obese is defined as a body mass index (BMI) at or above the 95th percentile according to the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.
d. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least one of the prespecified comorbidities based on MMWR 69(32);1081-1088 and/or obesity (BMI ≥ 95th percentile).
e. Negative N-binding antibody result and negative NAAT result at Visit 1 and no medical history of COVID-19.
f. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.

Demographic characteristics in Cohort 2 were similar to Cohort 1.

Comparator group for immunogenicity: The 300 participants ages 16-25 years from study C4591001 were from sites in the United States (64%), Argentina (18%), Brazil (12%), and South Africa/Turkey/Germany (6% combined total).

Less than 0.8% of participants in either group received non-COVID-19 vaccines during the study; most were routine pediatric immunizations including diphtheria, pertussis, tetanus, human papillomavirus vaccine, and meningococcal vaccine.

7.5 Immunogenicity results

7.5.1 Primary immunogenicity objective

Immunogenicity of BNT162b2 was assessed based on analyses of GMTs and seroresponse rates for neutralizing antibody titers to the reference strain (USA_WA1/2020).

GMTs of neutralizing antibody titers to the reference strain

Among participants in the evaluable immunogenicity population without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 2, the ratio of SARS-CoV-2 50% neutralizing GMT in children 5-11 years (10 µg each dose) compared to individuals 16-25 years (30 µg each dose) was 1.04. (95% CI: 0.93, 1.18). The lower bound of the 2-sided 95%CI for GMR was >0.67 and the point estimate was ≥1, which met FDA's requested criteria; see Table 6, below.

Table 6. SARS-CoV-2 Neutralizing GMTs (NT50)[a] at 1 Month Post-Primary Series in Phase 2/3 BNT162b2 (10 µg) Recipients 5-11 Years of Age and Study C4591001 Phase 2/3 Cohort 1 BNT162b2 (30 µg) Recipients 16-25 Years of Age Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2, Evaluable Immunogenicity Population[b]

GMT (95% CI) 5-11 Years of Age Study C4591007 N[c] = 264	GMT (95% CI) 16-25 Years of Age Study C4591001 N[c] = 253	GMT Ratio (95% CI) (5-11 Years of Age / 16-25 Years of Age)[d]
1197.6 (1106.1, 1296.6)	1146.5 (1045.5, 1257.2)	1.04 (0.93, 1.18)

a. SARS-CoV-2 mNeonGreen virus microneutralization assay (SARS-CoV-2 mNG NT), reference strain: recombinant USA_WA1/2020. NT50= 50% neutralizing titer.
b. Evaluable immunogenicity population pertaining to Phase 2/3 BNT162b2 participants 5-11 years of age (study C4591007) and Phase 2/3 BNT162b2 participants 16-25 years of age (study C4591001).
c. N = Number of Phase 2/3 participants with valid and determinate assay results for the specified assay at the given dose/sampling time point within specified window.
d. Immunobridging statistical success is declared if the lower limit of the 2-sided 95% CI for the GMT ratio is greater than 0.67 and the point estimate of the GMT ratio is ≥1.0.

Rates of neutralizing antibody seroresponse to the reference strain

Seroresponse rates among participants without evidence of prior SARS-CoV-2 infection up to 1 month after Dose 2 are displayed in Table 7 below. Children 5-11 years of age had similar seroresponse (as measured from before vaccination to 1 month after Dose 2) rate as individuals 16-25 years of age. The difference between the two age groups was 0.0% (95% CI: -2.0%, 2.2%). The lower limit of the 95% CI for the difference in seroresponse rate was -2.0%, which was greater than the prespecified margin of -10% and thus immunobridging based on seroresponse rate was met, see Table 7 below.

Table 7. Seroresponse Rates[a,b] at 1 Month Post-Primary Series in Phase 2/3 BNT162b2 (10 µg) Recipients 5-11 Years of Age and Study C4591001 Phase 2/3 Cohort 1 BNT162b2 (30 µg) Recipients 16-25 Years of Age[b] Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2, Evaluable Immunogenicity Population[c]

Seroresponse 5-11 Years of Age Study C4591007 %[d] (95% CI) N= 264	Seroresponse 16-25 Years of Age Study C4591001 %[d] (95% CI) N= 253	% Difference in Seroresponse Rate (Age Group 5-11 Years minus Age Group 16-25 Years)[e] (95% CI)
99.2 (97.3, 99.9)	99.2 (97.2, 99.9)	0 (-2.0, 2.2)

a. SARS-CoV-2 mNeonGreen virus microneutralization assay-NT50, reference strain: recombinant USA_WA1/2020.
b. Seroresponse defined as at least 4-fold rise relative to pre-Dose 1; if the baseline measurement was below LLOQ, a postvaccination titer of ≥4 × LLOQ was considered a seroresponse.
c. Evaluable immunogenicity population pertaining to Phase 2/3 BNT162b2 participants 5-11 years of age (study C4591007) and Phase 2/3 BNT162b2 participants 16-25 years of age (study C4591001).
d. %: n/N. n = number of participants with seroresponse for the given assay at the given dose/sampling time point. N = Number of subjects with valid and determinate assay results for the specified assay within the specified window for blood samples collected at baseline (pre-Dose 1) and 1 month after primary series.
e. Immunobridging statistical success is declared if the lower limit of the 2-sided 95% CI for the difference in percentages of participants with seroresponse is >-10%.

Subgroup Analyses of Geometric Mean Titers

GMTs of SARS-CoV-2 neutralizing titers and seroresponse rates at 1 month after Dose 2 did not vary by demographic subgroup, although some subgroups were too small to evaluate by protocol-specified methods. Specifically, no notable differences in GMTs or seroresponse rates were observed by age (i.e., 5-6 year-old vs. 7-8 year-old vs. 9-11 year-old), sex, race, ethnicity, obesity (Y/N), or SARS-CoV-2 status.

In descriptive post hoc analyses of immunogenicity data based on the presence or absence of comorbidities (defined as described in Kim et al. MMWR 2020[47]), GMT and seroresponse rates among those with comorbidities were comparable to those without comorbidities.

7.5.2 Exploratory immunogenicity analyses against the Delta Variant

In response to FDA's request for immunogenicity data to support effectiveness of a 10 µg BNT162b2 primary series against the Delta variant, Pfizer submitted exploratory descriptive analyses of data from a randomly selected subset of participants (34 BNT162b2 recipients, 4 placebo recipients) with no evidence of infection up to 1 month post-Dose 2. These data were generated using non-validated SARS-CoV-2 plaque reduction neutralization assays with the

reference strain (USA-WA1/2020) and the Delta variant; the relative sensitivity of the two assays is not known.

Table 8. SARS-CoV-2 Neutralizing GMTs[a] at Pre-Dose 1 and 1 Month Post-Primary Series in C4591007 Phase 2/3 Cohort 1 Participants 5-11 Years of Age Without Evidence of SARS-CoV-2 Infection up to 1 Month After Primary Series, Evaluable Immunogenicity Population[b]

Assay Target	Time Point	BNT162b2 10 µg N=34 GMT (95% CI)	Placebo N=4 GMT (95% CI)
Reference strain	Pre-Dose 1	10.0 (10.0, 10.0)	10.0 (10.0, 10.0)
	1 month post-Dose 2	365.3 (279.0, 478.4)	10.0 (10.0, 10.0)
Delta variant	Pre-Dose 1	10.0 (10.0, 10.0)	10.0 (10.0, 10.0)
	1 month post-Dose 2	294.0 (214.6, 405.3)	10.0 (10.0, 10.0)

a. SARS-CoV-2 plaque reduction neutralization assay, SARS-CoV-2 strains: recombinant USA_WA1/2020 (reference), B.1.617.2 (Delta).
b. N = number of participants with valid and determinate assay results for the specified assays at the given dose/sampling time point. Participants with no serological or virological evidence of SARS-CoV-2 infection: defined as N-binding ant body [serum] negative from pre-Dose 1 to 1 month post-Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] prior to Dose 1 and Dose 2, and negative NAAT [nasal swab] result at any unscheduled visit prior to 1-month post-Dose 2, and no medical history of COVID-19.

7.5.3 Efficacy evaluation

Pfizer submitted supplemental, descriptive efficacy data for Phase 2/3 Cohort 1 participants 5-11 years of age, based on a total of 19 confirmed symptomatic COVID-19 cases occurring at least 7 days post-Dose 2, accrued up to the data cutoff of October 8, 2021. The evaluable efficacy population included 1,450 participants randomized to BNT162b2 and 736 participants randomized to placebo.

In participants 5-11 years of age without evidence of SARS-CoV-2 infection prior to Dose 2, the observed VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 90.7% (95% CI: 67.4%, 98.3%), with 3 COVID-19 cases in the BNT162b2 group compared to 16 in the placebo group (2:1 randomization BNT162b2 to placebo). All cases of COVID-19 occurred in children without prior history of infection. None of these cases met the criteria for severe infection. Most of the cases occurred in July-August 2021. Comorbidities at baseline (including obesity) were present in total of 20.1% of cases. No virus sequence analyses were available to determine whether these cases were caused by the Delta variant or another variant.

7.6 Safety results

Please see the Appendix for Phase 1 study results.

Overview of adverse events: Phase 2/3

In C4591007 Phase 2/3 Cohort 1, e-diary data were collected on 1,511 participants for reactogenicity (local and systemic reactions). Overall, injection site reactions occurring within 7 days of vaccination with BNT162b2 were common, occurring in approximately 75% of participants after either Dose 1 or Dose 2. Systemic AEs occurred in approximately 50% of BNT162b2 recipients.

No participants withdrew because of AEs, and there were no deaths reported. SAEs occurred in one participant each from the BNT162b2 and placebo groups, and neither were considered by the investigator or FDA to be related to the investigational agent. Immediate unsolicited AEswere rare in this study, occurring in 0.3% or less after either Dose 1 or Dose 2. See Table 9 below.

Table 9. Safety Overview, Phase 2/3 Cohorts 1 and 2, Participants 5-11 Years, Safety Population, Study C4591007

Event	BNT162b2 10 µg n/N (%)	Placebo n/N (%)
Immediate unsolicited AE within 30 minutes after vaccination		
Dose #1	3/1518 (0.2)	3/750 (0.4)
Dose #2	4/1515 (0.3)	2/746 (0.3)
Solicited injection site reaction within 7 days		
Dose #1	1150/1511 (76.1)	254/749 (33.9)
Dose #2	1096/1501 (73.0)	237/741 (32.0)
Solicited systemic AR within 7 days		
Dose #1	715/1511 (47.3)	334/749 (44.6)
Dose #2	771/1501 (51.4)	272/741 (36.7)
From Dose 1 through 1 month after Dose 2		
Any AE	166/1518 (10.9)	69/750 (9.2)
Unsolicited non-serious AE	166/1518 (10.9)	68/750 (9.1)
SAE	0/1518 (<0.1)	1/750 (0.1)
From Dose 1 through cutoff date[a] or participant unblinding[b]		
Withdrawal due to AEs	1/3109 (<0.1)	0/1538 (0.0)
SAE	4/3109 (0.1)	1/1538 (0.1)
Deaths	0/3109 (0.0)	0/1538 (0.0)

Note: MedDRA (v24.0) coding dictionary applied.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.
%:n/N. n = Number of participants with the specified characteristic. N = number of administered participants in the specified group; this value is the denominator for the percentage calculations.
a. Sept 13, 2021 for 1,518 BNT162b2 and 750 placebo; Oct 8, 2021 for the additional 1,591 BNT162b2 and 788 placebo.
b. Three participants (2 BNT162b2, 1 placebo) turned 12 years of age during the course of the study and elig ble to received 30 µg BNT162b2 under EUA; for this reason, the participants were unblinded to their treatment assignment.

7.6.1 Immediate AEs

Among the 1,518 Cohort 1 participants who received BNT162b2 Dose 1, a total of 3 reported any immediate AE, and all were injection site pain. Following Dose 2, 4 participants experienced an immediate AE, including 1 with nausea, 1 with injection site pain, 1 with injection site erythema, and 1 with erythema (skin and subcutaneous disorder).

7.6.2 Solicited adverse reactions

Solicited local adverse reactions generally occurred more commonly after Dose 2 and included pain at the injection site (71%), redness (18.5%) and swelling (15.3%). Systemic adverse reactions also occurred more frequently after Dose 2 and included fatigue (39.4%), headache (28%), and muscle pain (11.7%). Most local and systemic reactions were mild to moderate in severity, with median onset 2 days post-vaccination, and resolved within 1 to 2 days after onset. Adverse reactions in BNT162b2 recipients that were graded as severe included 4 local reactions (3 participants with redness, 1 participant with swelling) and 1 systemic reaction (1 participant with muscle pain).

Rates of local and systemic adverse reactions in children 5-11 years of age were generally similar to those in individuals 12 years of age or older enrolled in study C4591001, with pain at the injection site slightly lower in the 5-11 year-old group, but redness and swelling slightly higher. Systemic adverse reactions such as fever, fatigue, headache, chills, and muscle pain were generally reported less frequently and were milder in severity in the 5-11 year-old group compared to individuals 12 years of age or older.

The frequencies of local and systemic adverse reactions within 7 days after each vaccination in participants with evaluable e-diary data are summarized in Tables 10, 11, and 12 below.

Table 10. Frequency of Solicited Local Reactions Within 7 Days After Each Dose, by Severity, Phase 2/3 Cohort 1 Participants 5-11 Years of Age, Safety Population[a], Study C4591007

Event	BNT162b2 Dose 1 N=1,511 %	Placebo Dose 1 N=749 %	BNT162b2 Dose 2 N=1,501 %	Placebo Dose 2 N=741 %
Pain at the injection site[b]				
Any[d]	74.1	31.3	71.0	29.5
Mild	58.9	27.3	52.8	25.9
Moderate	14.9	4.0	17.8	3.5
Severe	0.3	0.0	0.3	0.0
Redness[c]				
Any[d]	14.7	5.7	18.5	5.4
Mild	9.5	4.9	9.5	4.2
Moderate	5.2	0.8	8.8	1.2
Severe	0.0	0.0	0.2	0.0
Swelling[c]				
Any[d]	10.5	2.7	15.3	2.7
Mild	5.6	1.7	7.8	2.0
Moderate	4.8	0.9	7.5	0.7
Severe	0.1	0.0	0.0	0.0

%:n/N. n=number of participants in the specified age group with the specified reaction. N=number of participants in the specified age group reporting at least 1 yes or no response for the specified reaction after the specified dose.
[a] All participants in the specified age group who received at least 1 dose of the study intervention.
[b] Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity.
[c] Mild: 0.5 to ≤2.0 cm; moderate: 2.0 to ≤7.0 cm; severe: >7.0 cm.
[d] Any local reaction: any redness >0.5 cm, any swelling >0.5 cm, or any pain at the injection site.

Table 11. Frequency of Solicited Systemic Reactions Within 7 Days After Dose 2 by Severity, Phase 2/3 Cohort 1 Participants 5-11 Years of Age, Safety Population, Study C4501007

Event	BNT162b2 Dose 1 N=1,511 %	Placebo Dose 1 N=749 %	BNT162b2 Dose 2 N=1,501 %	Placebo Dose 2 N=741 %
Fever				
≥38.0°C	2.5	1.3	6.5	1.2
≥38.0°C to 38.4°C	1.5	0.5	3.4	0.7
>38.4°C to 38.9°C	0.8	0.7	2.5	0.4
>38.9°C to 40.0°C	0.2	0.1	0.5	0.1
>40.0°C	0.0	0.0	0.1	0.0
Fatigue[b]				
Any[e]	33.6	31.3	39.4	24.3
Mild	22.0	20.1	21.4	13.0
Moderate	11.3	11.1	17.3	11.2
Severe	0.3	0.1	0.7	0.1

Event	BNT162b2 Dose 1 N=1,511 %	Placebo Dose 1 N=749 %	BNT162b2 Dose 2 N=1,501 %	Placebo Dose 2 N=741 %
Headache[b]				
Any[e]	22.4	24.1	28.0	18.6
Mild	16.5	17.5	18.7	12.6
Moderate	5.8	6.0	9.1	6.1
Severe	0.1	0.5	0.2	0.0
Chills[b]				
Any[e]	4.6	4.7	9.8	4.3
Mild	3.6	4.0	7.0	3.2
Moderate	1.1	0.7	2.7	0.9
Severe	0.0	0.0	0.1	0.1
Vomiting[c]				
Any[e]	2.2	1.5	1.9	0.8
Mild	1.7	1.5	1.8	0.8
Moderate	0.5	0.0	0.1	0.0
Severe	0.0	0.0	0.0	0.0
Diarrhea[d]				
Any[e]	5.9	4.1	5.3	4.7
Mild	5.2	4.1	4.8	4.3
Moderate	0.7	0.0	0.5	0.4
Severe	0.0	0.0	0.0	0.0
New or worsened muscle pain[b]				
Any[e]	9.1	6.8	11.7	7.4
Mild	6.4	4.7	7.7	5.1
Moderate	2.6	2.1	3.9	2.3
Severe	0.1	0.0	0.1	0.0
New or worsened joint pain[b]				
Any[e]	3.3	5.5	5.2	3.6
Mild	2.3	4.1	3.8	2.7
Moderate	1.1	1.3	1.4	0.9
Severe	0.0	0.0	0.0	0.0
Use of antipyretic or pain medication[f]	14.4	8.3	19.7	8.1

%: n/N. n = Number of participants with the specified reaction. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

[a] All participants in the specified age group who received at least 1 dose of the study intervention.

[b] Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

[c] Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

[d] Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

[e] Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.

f Severity was not collected for use of antipyretic or pain medication.

Table 12. Characteristics of Solicited Local and Systemic Adverse Reactions, Phase 2/3 Cohort 1, Participants 5-11 Years, Safety Population, Vaccine Group as Administered, Study C4591007

Event	BNT162b2 10 µg Dose 1 n[a]/N[b]	Placebo Dose 1 n[a]/N[b]	BNT162b2 10 µg Dose 2 n[a]/N[b]	Placebo Dose 2 n[a]/N[b]
Any solicited local reaction				
Day of onset: median (min, max)	1.0 (1, 6)	1.0 (1, 6)	1.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 10)	1.0 (1, 10)	2.0 (1, 11)	1.0 (1, 12)
Persisted beyond 7 days	11/1511	9/749	8/1501	5/741

	BNT162b2 10 µg Dose 1	Placebo Dose 1	BNT162b2 10 µg Dose 2	Placebo Dose 2
Redness				
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 5)	2.0 (1, 6)	1.0 (1, 5)
Duration: median (min, max)	1.0 (1, 10)	1.0 (1, 8)	2.0 (1, 10)	1.0 (1, 11)
Persisted beyond 7 days	4/1511	1/749	2/1501	1/741
Swelling				
Day of onset: median (min, max)	2.0 (1, 4)	1.0 (1, 7)	2.0 (1, 4)	1.0 (1, 5)
Duration: median (min, max)	1.0 (1, 8)	1.0 (1, 9)	2.0 (1, 10)	1.0 (1, 12)
Persisted beyond 7 days	1/1511	1/749	2/1501	2/741
Pain at injection site				
Day of onset: median (min, max)	1.0 (1, 6)	1.0 (1, 6)	1.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 10)	1.0 (1, 10)	2.0 (1, 11)	1.5 (1, 12)
Persisted beyond 7 days	7/1511	8/748	6/1501	5/740
Any solicited systemic reaction				
Day of onset: median (min, max)	2.0 (1, 7)	1.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 22)	1.0 (1, 19)	1.0 (1, 51)	1.0 (1, 10)
Persisted beyond 7 days	29/1511	15/749	30/1501	13/741
Fever				
Day of onset: median (min, max)	2.0 (2, 7)	2.5 (1, 7)	2.0 (1, 7)	6.0 (2, 7)
Duration: median (min, max)	1.0 (1, 3)	1.0 (1, 3)	1.0 (1, 5)	1.0 (1, 5)
Persisted beyond 7 days	0	0	0	0
Fatigue				
Day of onset: median (min, max)	2.0 (1, 7)	1.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 21)	2.0 (1, 9)	1.0 (1, 14)	1.0 (1, 10)
Persisted beyond 7 days	16/1511	7/748	17/1501	6/740
Headache				
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 22)	1.0 (1, 19)	1.0 (1, 51)	1.0 (1, 9)
Persisted beyond 7 days	12/1511	9/748	10/1501	6/740
Chills				
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 10)	1.0 (1, 7)	1.0 (1, 8)	1.0 (1, 8)
Persisted beyond 7 days	3/1511	0	1/1501	1/740
Vomiting				
Day of onset: median (min, max)	4.0 (1, 7)	4.0 (1, 6)	2.0 (1, 6)	3.0 (2, 6)
Duration: median (min, max)	1.0 (1, 5)	1.0 (1, 1)	1.0 (1, 2)	1.0 (1, 5)
Persisted beyond 7 days	0	0	0	0
Diarrhea				
Day of onset: median (min, max)	3.0 (1, 7)	3.0 (1, 7)	3.0 (1, 7)	4.0 (1, 7)
Duration: median (min, max)	1.0 (1, 8)	1.0 (1, 6)	1.0 (1, 28)	1.0 (1, 9)
Persisted beyond 7 days	1/1511	0	2/1501	2/740
New or worsened joint pain				
Day of onset: median (min, max)	2.0 (1, 6)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 7)	1.0 (1, 4)	1.0 (1, 18)	1.0 (1, 6)
Persisted beyond 7 days	0	0	1/1501	0

	BNT162b2 10 µg Dose 1	Placebo Dose 1	BNT162b2 10 µg Dose 2	Placebo Dose 2
New or worsened muscle pain				
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 9)	1.0 (1, 8)	1.0 (1, 9)	1.0 (1, 6)
Persisted beyond 7 days	1/1511	1/748	3/1501	0

a. n = Number of participants with the specified reaction persisted beyond 7 days.
b. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

7.6.3 Subgroup analyses of solicited adverse reactions

Subgroup analyses were performed for solicited adverse reactions, comparing BNT162b2 and placebo groups by sex, race, ethnicity, and baseline SARS-CoV-2 status at baseline. No notable differences were observed among the study groups, although certain subgroups such as Black or African American race and Hispanic/Latino ethnicity had too few participants to draw meaningful conclusions.

7.6.4 Unsolicited adverse events

Information about unsolicited AEs was collected from Dose 1 to 1 month post-Dose 2. No unsolicited AEs were reported by ≥1% of participants.

In Cohort 1, the most common unsolicited AE was lymphadenopathy, which was reported in 13 (0.9%) participants in the BNT162b2 group, and 1 participant in the placebo group (0.1%). Additional unsolicited AEs reported more commonly in the BNT162b2 group than in the placebo group included otitis externa in 7 participants (0.5%), arthropod bite, nasal congestion, oropharyngeal pain, and rash in 5 participants (0.3%), each. In BNT162b2 recipients, the following AEs were considered Grade 3 in severity: 1 tic, 1 rash (bilateral pleomorphic light eruption on arms). No Grade 4 (life-threatening AEs) were observed in the study. In Cohort 2, lymphadenopathy was reported in 6 (0.4%) vaccine recipients and 3 placebo recipients (0.4%).

7.6.5 SAEs

In Cohort 1, SAEs occurred at frequency of 0.1% in both BNT162b2 and placebo recipients. For BNT162b2 recipients, only one SAE was reported, an upper limb fracture. In Cohort 2, 3 BNT162b2 recipients (0.2%) reported a SAE: 1 infection of the knee, 1 foreign body ingestion, and 1 epiphyseal fracture. All SAEs reported in the study were considered by the study investigator to be unrelated to vaccination. FDA agrees with this assessment.

Deaths: No deaths have occurred during the study in either Cohort 1 or 2.

7.6.6 AEs of clinical interest

FDA conducted Standardized MedDRA Queries (SMQs) to evaluate for constellations of unsolicited AEs among recipients 5-11 years of age in study C4591007 Phase 2/3 Cohort 1 through the September 6, 2021 cutoff date. SMQs (narrow and broad in scope) were conducted on AE Preferred Terms (PTs) that could represent various conditions, including but not limited to angioedema, arthritis, cardiomyopathy, ischaemic heart disease, cardiac arrhythmia, cardiac failure, central nervous system (CNS) vascular disorders, convulsions, demyelination, embolic and thrombotic events, hearing and vestibular disorders, hematopoietic cytopenias, hypersensitivity, peripheral neuropathy, thrombophlebitis, and vasculitis. For example, the cardiomyopathy SMQ includes PTs that may be related to myocarditis and pericarditis, such as

chest pain, palpitations, dyspnea, syncope, troponin elevation, ECG with ST elevation or PR depression, pericardiac rub, or echocardiographic findings.

For Cohort 1, the SMQ analyses resulted in identification of 19 participants with AEs of interest in the SMQs (narrow and broad in scope) in the BNT162b2 group and 6 in the placebo group. The SMQ analyses revealed an imbalance of AEs potentially representing allergic reactions, with 14 participants in the vaccine group (0.92%) reporting hypersensitivity-related AEs (primarily skin and subcutaneous disorder including rash and dermatitis) compared with 4 participants in the placebo group (0.53%). See Table 13, below.

As in Cohort 1, SMQ analyses in Cohort 2 showed an imbalance of AEs in the BNT162b2 group compared to the placebo with respect to hypersensitivity, with 9 participants in the vaccine group (0.57%) and 4 in the placebo group (0.51%) reporting unsolicited AEs in this category, primarily skin and subcutaneous disorders of rash and dermatitis. Angioedema was reported in 3 (0.19%) in the vaccine group compared to 1 (0.13%) in the placebo group. These events included one participant with both angioedema and urticaria, and 3 participants with urticaria.

One participant, a 6-year-old female in the BNT162b2 group, had a non-serious AE of Henoch-Schonlein purpura which was diagnosed 21 days after Dose 1 and was considered non-serious.

No new or unexpected adverse reactions were identified based on these SMQ results.

Table 13. Standard MedDRA Query of Adverse Events by System Organ Class and Preferred Terms, Phase 2/3, Participants 5-11 Years, Safety Population, Vaccine Group as Administered, Cohort 1, Study C4591007

SMQ	Overall SMQ System Organ Class Preferred Term	BNT162b2 10 µg (N[a]=1,518) n[b] (%)	Placebo (N[a]=750) n[b] (%)
Any	Participants with any unsolicited AEs within SMQ	19 (1.25)	6 (0.80)
Angioedema (SMQ)	Any unsolicited AEs within Angioedema (SMQ)	4 (0.26)	3 (0.40)
	Eye disorders	0	1 (0.13)
	Periorbital oedema	0	1 (0.13)
	General disorders and administration site conditions	1 (0.07)	0
	Swelling face	1 (0.07)	0
	Skin and subcutaneous tissue disorders	3 (0.20)	3 (0.40)
	Urticaria	3 (0.20)	3 (0.40)
Arthritis (SMQ)	Any unsolicited AEs within Arthritis (SMQ)	1 (0.07)	0
	Musculoskeletal and connective tissue disorders	1 (0.07)	0
	Synovitis	1 (0.07)	0
Convulsions (SMQ)	Any unsolicited AEs within Convulsions (SMQ)	0	0
Demyelination (SMQ)	Any unsolicited AEs within Demyelination (SMQ)	0	0
Hypersensitivity (SMQ)	Any unsolicited AEs within Hypersensitivity (SMQ)	14 (0.92)	4 (0.53)
	Eye disorders	1 (0.07)	1 (0.13)
	Conjunctivitis allergic	1 (0.07)	1 (0.13)
	General disorders and administration site conditions	1 (0.07)	0
	Injection site rash	1 (0.07)	0
	Immune system disorders	0	1 (0.13)
	Hypersensitivity	0	1 (0.13)
	Skin and subcutaneous tissue disorders	12 (0.79)	2 (0.27)
	Dermatitis	1 (0.07)	0

SMQ	Overall SMQ System Organ Class Preferred Term	BNT162b2 10 µg (N^a=1,518) n^b (%)	Placebo (N^a=750) n^b (%)
	Dermatitis allergic	1 (0.07)	0
	Dermatitis contact	3 (0.20)	0
	Eczema	1 (0.07)	1 (0.13)
	Rash	5 (0.33)	0
	Rash erythematous	0	1 (0.13)
	Rash macular	1 (0.07)	0
	Rash pruritic	1 (0.07)	0
Peripheral neuropathy (SMQ)	Any unsolicited AEs within Peripheral neuropathy (SMQ)	0	0
Vasculitis (SMQ)	Any unsolicited AEs within Vasculitis (SMQ)	0	0

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any unsolicited AEs within SMQ," n = the number of participants reporting at least 1 occurrence of any unsolicited AEs within SMQ.

In Cohorts 1 and 2, "chest pain" was reported in a total of 12 participants: 6 assigned to the BNT162b2 group and 6 assigned to placebo. Chest pain resolved in all participants within 1-2 days of onset. No participants required a cardiac evaluation or ER visit, and none were hospitalized. In each case the AE was considered to be noncardiac in origin.

7.6.7 AEs leading to study withdrawal

In C4591007 Phase 2/3 Cohort 1, there were no AEs leading to withdrawal. In Cohort 2 with a follow-up cutoff of October 8, 2021, 1 participant was withdrawn due to AEs of fever 2 days after Dose 1 and worsening of neutropenia (previously diagnosed as benign transient neutropenia. Dose 2 was not administered.

7.7 Study C4591007 Phase 2/3 summary

This EUA request included safety data from 1,518 BNT162b2 recipients and 750 placebo (saline) recipients 5-11 years of age in the Phase 2/3 portion (Cohort 1) of an ongoing clinical trial, C4591007; Among Cohort 1 participants, 95.1% had safety follow-up ≥2 months after Dose 2 at the time of the September 6, 2021 data cutoff. Safety data from an additional 1,591 BNT162b2 recipients and 788 placebo recipients from the Phase 2/3 portion of the trial (Cohort 2) were provided for assessment of SAEs and other AEs of interest (e.g., myocarditis, pericarditis, anaphylaxis); the median duration of follow-up was 2.4 weeks post Dose 2 at the time of the October 8, 2021 data cutoff for Cohort 2.

Immunobridging success criteria were met for geometric mean neutralizing antibody titers and seroresponse rates at 1 month post-Dose 2 against the USA_WA1/2020 reference strain, as assessed by 50% mNG microneutralization assay, among children 5-11 years of age in study C4591007 Cohort 1 compared to study participants 16-25 years of age randomly selected from study C4591001. Subgroup immunogenicity analyses by age, gender, race and ethnicity, obesity and baseline SARS-CoV-2 status showed no notable differences compared to the overall study population, although some subgroups were too small to draw meaningful conclusions. Descriptive immunogenicity analyses, based on 50% plaque reduction neutralization test (PRNT), showed that a 10 µg BNT162b2 primary series elicited PRNT neutralizing titers against the reference strain and B.1.617.2 (Delta) strain in participants 5-11 years of age (34 BNT162b2, 4 placebo). Lastly, in a supplemental descriptive efficacy analysis,

VE against symptomatic COVID-19 after 7 days post Dose 2 as of the October 8, 2021 data cutoff was 90.7% (2-sided 95% CI: 67.4%, 98.3%) in participants 5-11 years of age without prior evidence of SARS-CoV-2 infection; 3 cases of COVID-19 occurred in the BNT162b2 group and 16 in the placebo group. All cases of COVID-19 occurred in participants 5-11 years of age without prior history of SARS-CoV-2 infection, and most occurred during July-August 2021. At the time of data cutoff, no cases met the criteria for severe COVID-19 infection.

Solicited local and systemic ARs generally occurred more frequently after Dose 2, and the most commonly reported solicited ARs were pain at the injection site (71%), fatigue (39.4%), and headache (28%). Most local and systemic reactions were mild to moderate in severity, with median onset 2 days post-vaccination, and resolved within 1 to 2 days after onset. The most frequently reported unsolicited AE in BNT162b2 recipients was lymphadenopathy (n=13; 0.9%). More BNT162b2 recipients (n=14; 0.92%) reported hypersensitivity-related AEs (primarily rash and dermatitis) than placebo recipients (n=4; 0.53%). Overall, from the combined safety database of 3,109 BNT162b2 participants, 4 BNT162b2 participants reported a SAE, and all of the SAEs were considered unrelated to vaccination. One BNT162b2 recipient withdrew from the study due to fever (40.1°C) that occurred 2 days after Dose 1 and neutropenia that had worsened from baseline; the neutropenia was related to a pre-existing condition. There were no reports of myocarditis/pericarditis or anaphylaxis, and no participant deaths. Subgroup safety analyses by gender, race and ethnicity, obesity and baseline SARS-CoV-2 status showed no notable differences compared to the overall study population, although some subgroups were too small to draw meaningful conclusions.

8 BENEFIT-RISK ASSESSMENT FOR CHILDREN 5-11 YEARS OF AGE

FDA conducted a benefit-risk assessment for use of a Pfizer-BioNTech COVID-19 Vaccine 2-dose primary series in children 5-11 years of age. The key benefits assessed include preventable COVID-19 cases, hospitalizations, intensive care unit (ICU) visits and deaths due to COVID-19. The key risks include excess myocarditis/pericarditis cases, and related hospitalizations, ICU admissions, and deaths attributable to myocarditis/pericarditis. The benefits and risks are assessed per million fully vaccinated individuals with and without stratification by sex, and with comparison to age groups 12-15 years and 16-17 years.

The model assesses the benefits of vaccine protection in a 6-month period after completion of the primary series. The model assumes vaccine efficacy of 70% against COVID-19 cases and 80% against COVID-19 associated hospitalization based on real-world data for ages 20+ years during circulation of the Delta variant.[48] The incidence rates of COVID-19 cases for the week of September 11, 2021 are obtained from COVID-NET for all sex/age groups. COVID-NET covers approximately 10 percent of the U.S. population. Four-week averages of incidence rate for hospitalizations (week ending on 8/21/2021 to week ending on 9/11/2021) are used due to the variability in rates given the small numbers of hospitalizations per age/sex group. Estimates for the percentage of hospitalizations resulting in ICU admission and the percentage of hospitalized patients who die are based on cumulative rates of hospitalizations, ICU admissions, and deaths for each sex/age groups reported in COVID-NET since March 2020. The death rate among 5-11 year-olds is lower in COVID-NET than in other national data sources such as the CDC COVID-19 Data Tracker. This could be due to geographic differences between COVID-NET's reporting areas and the recent trajectory of the pandemic. This difference will lead to a conservative estimate of benefits in the model. The model assumes the incidence rates of COVID-19 cases and hospitalizations remain constant over the assessment period of 6 months. The estimates for excess myocarditis/pericarditis among fully vaccinated individuals ages 12-15 years and ages 16-17 years are based on data from Optum health claim database for the period 12/10/2020 –

07/10/2021, which is a conservative approach that includes non-confirmed cases. For this analysis the estimate for ages 12-15 years is applied to ages 5-11 years because vaccine-associated myocarditis/pericarditis data is not available for this age group. The proportions of vaccine-attributable myocarditis/pericarditis hospitalizations and ICU admissions are obtained from Vaccine Safety Datalink (12-17 year-old group[49]). Some of these hospitalizations and ICU admissions may be precautionary and therefore not clinically equivalent to COVID-19 hospitalizations and ICU admissions. The dose intended for use in children 5-11 years of age (10 µg), is lower than the dose used under EUA in adolescents 12-15 years of age (30 µg), and the observed systemic reactogenicity associated with the respective antigen contents in clinical trials is lower for children 5-11 years of age as well. Thus, assuming the same rate of vaccine-associated myocarditis for children 5-11 years of age as has been observed for adolescents 12-15 years of age in Optum may be a conservative overestimate.

The model results indicate that the benefits of the vaccine are highly dependent on the incidence of COVID-19. To account for uncertain dynamics of the pandemic, the benefits and risks were assessed under six scenarios: Scenario 1 with COVID-19 incidence as of September 11, 2021, Scenario 2 with COVID-19 incidence close to the recent peak of the Delta variant surge at the end of August 2021, Scenario 3 with COVID-19 incidence close to the lowest recorded incidence in June 2021, Scenario 4 with the same COVID-19 incidence as Scenario 1 and an assumption of 90% vaccine efficacy against cases and 100% efficacy against hospitalizations based on the preliminary descriptive efficacy analysis from study C4591007 Phase 2/3 Cohort 1, Scenario 5 with a 3x multiple of the death rate to more closely match the cumulative death rate for 5-11 years old seen in CDC Data Tracker, and Scenario 6 with the same COVID-19 incidence and assumed vaccine efficacy as Scenario 1 but 50% of the myocarditis cases as Scenario 1.

The results of the benefit-risk assessment are summarized in Table 14 below. The results predict that under Scenarios 1 (Sept 11, 2021 Incidence), 2 (Delta surge peak incidence), 4 (high efficacy), and 5 (higher COVID-19 death rate, per the CDC COVID-19 Data Tracker), the benefits of the Pfizer-BioNTech COVID-19 Vaccine 2-dose primary series clearly outweigh the risks for ages 5-11 years. Under Scenario 3 (lowest incidence), the model predicts more excess hospitalizations due to vaccine-related myocarditis/pericarditis compared to prevented hospitalizations due to COVID-19 in males and in both sexes combined. However, in consideration of the different clinical implications of hospitalization for COVID-19 versus hospitalization for vaccine-associated myocarditis/pericarditis, and benefits related to prevention of non-hospitalized cases of COVID-19 with significant morbidity, the overall benefits of the vaccine may still outweigh the risks under this lowest incidence scenario. If the myocarditis/pericarditis risk in this age group is lower than the conservative assumption used in the model, the benefit-risk balance would be even more favorable.

Table 14. Model-Predicted Benefit-Risk Outcomes of Scenarios 1-6 per One Million Fully Vaccinated Children 5-11 Years Old

	Benefits				Risks			
Sex	Prevented COVID-19 Cases	Prevented COVID-19 Hospitalizations	Prevented COVID-19 ICU Admissions	Prevented COVID-19 Deaths	Excess Myocarditis Cases	Excess Myocarditis Hospitalizations	Excess Myocarditis ICU Admissions	Excess Myocarditis Deaths
Males & Females								
Scenario 1	45,773	192	62	1	106	58	34	0
Scenario 2	54,345	250	80	1	106	58	34	0
Scenario 3	2,639	21	7	0	106	58	34	0
Scenario 4	58,851	241	77	1	106	58	34	0
Scenario 5	45,773	192	62	3	106	58	34	0
Scenario 6	45,773	192	62	1	53	29	17	0
Males only								
Scenario 1	44,790	203	67	1	179	98	57	0
Scenario 2	54,345	250	82	1	179	98	57	0
Scenario 3	2,639	21	7	0	179	98	57	0
Scenario 4	57,857	254	83	1	179	98	57	0
Scenario 5	44,790	203	67	3	179	98	57	0
Scenario 6	44,790	203	67	1	89	49	29	0
Females only								
Scenario 1	45,063	172	54	1	32	18	10	0
Scenario 2	54,345	250	78	2	32	18	10	0
Scenario 3	2,639	21	7	0	32	18	10	0
Scenario 4	57,938	215	67	2	32	18	10	0
Scenario 5	45,063	172	54	4	32	18	10	0
Scenario 6	45,063	172	54	1	16	9	5	0

Scenario 1: COVID-19 incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
Scenario 2: COVID-19 incidence at peak of U.S. Delta variant surge at end of August 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
Scenario 3: COVID-19 incidence as of nadir in June 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
Scenario 4: COVID-19 incidence as of September 11, 2021, VE 90% vs. COVID-19 cases and 100% vs. COVID-19 hospitalization.
Scenario 5: COVID-19 case incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19. hospitalization, COVID-19 death rate 300% that of Scenario 1.
Scenario 6: COVID-19 incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization, excess myocarditis cases 50% of Scenario 1.

9 PHARMACOVIGILANCE ACTIVITIES

Pfizer submitted a revised Pharmacovigilance Plan (PVP) to monitor safety concerns that could be associated with BNT162b2 in individuals 5-11 years of age. The PVP includes the following safety concerns:

- Important Identified Risks: anaphylaxis, myocarditis, and pericarditis
- Important Potential Risks: Vaccine-associated enhanced disease (VAED), including vaccine-associated enhanced respiratory disease (VAERD).

Pfizer-BioNTech plans to conduct passive and active surveillance to monitor the post-authorization safety for the Pfizer-BioNTech COVID-19 Vaccine, including:

- Mandatory reporting by the Sponsor under the EUA for the following events to VAERS within 15 days: SAEs (irrespective of attribution to vaccination); COVID-19 disease resulting in hospitalization or death; multisystem inflammatory syndrome (MIS)
- Adverse event reporting in accordance with regulatory requirements for the licensed vaccine, COMIRNATY
- Additionally, following approval of COMIRNATY, the Sponsor was also asked to submit reports of myocarditis and pericarditis as 15-day reports to VAERS.
- Periodic safety reports containing an aggregate review of safety data including assessment of AEs; vaccine administration errors, whether or not associated with an AE; and newly identified safety concerns.
- Post-authorization observational studies, that would be modified to encompass the evaluation of children 5-11 years of age include active surveillance safety studies using large health insurance claims and/or electronic health record database(s):

  - Study C4591009: A non-interventional post-approval safety study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States

    Objective: To assess the occurrence of safety events of interest, including myocarditis and pericarditis, in the general U.S. population of all ages, pregnant women, the immunocompromised, and persons with a prior history of COVID-19 within selected data sources participating in the U.S. Sentinel System.

  - Study C4591021: Post-conditional approval active surveillance study among individuals in Europe receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

    Objective: To assess the potential increased risk of AESIs, including myocarditis/pericarditis, after being vaccinated with at least one dose of the Pfizer-BioNTech COVID-19 Vaccine.

  - Study C4591021 Substudy: Substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY

    Objective: To describe the natural history of post-vaccination myocarditis/pericarditis, including recovery status, risk factors, and/or identification of serious cardiovascular outcomes within one year of myocarditis/pericarditis diagnosis among individuals vaccinated with BNT162b2 as well as individuals not vaccinated with a COVID-19 vaccine.

  - Study C4591036: Prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network [PHN]). Working title: *Myocarditis/pericarditis follow-up study within the Pediatric Heart Network*

    Objective: To characterize the clinical course, risk factors, resolution, long-term sequelae, and quality of life in children and young adults <21 years with acute post-vaccine myocarditis/pericarditis.

Pfizer-BioNTech also plans to include vaccine effectiveness analyses among individuals 5-11 years of age in Study C4591014 entitled "Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study Kaiser Permanente Southern California."

10 TOPIC FOR VRBPAC DISCUSSION

The VRBPAC will convene on October 26, 2021, to discuss whether based on the totality of scientific evidence available, the benefits of the Pfizer-BioNTech COVID-19 Vaccine when administered as a 2-dose series (10 µg each dose, 3 weeks apart) outweigh its risks for use in children 5-11 years of age.

11 REFERENCES

[1] Irfan O, Muttalib F, Tang K, Jiang L, Lassi ZS, Bhutta Z. Clinical characteristics, treatment and outcomes of paediatric COVID-19: a systematic review and meta-analysis. Arch Dis Child. 2021 Feb 16;106(5):440–8. Epub ahead of print.

[2] Liguoro, I., Pilotto, C., Bonanni, M. et al. SARS-COV-2 infection in children and newborns: a systematic review. Eur J Pediatr 179, 1029–1046 (2020).

[3] Irfan O, Muttalib F, Tang K, Jiang L, Lassi ZS, Bhutta Z. Clinical characteristics, treatment and outcomes of paediatric COVID-19: a systematic review and meta-analysis. Arch Dis Child. 2021 Feb 16;106(5):440–8.

[4] Assaker R, Colas A-E, Julien-Marsollier F, et al. Presenting Symptoms of COVID-19 in Children: A Meta-Analysis of Published Studies. *Br J Anaesth*. 2020;125(3):e330-e332.

[5] Poline J, Gaschignard J, Leblanc C, et al. Systematic Severe Acute Respiratory Syndrome Coronavirus 2 Screening at Hospital Admission in Children: A French Prospective Multicenter Study. Clin Infect Dis. 2020;ciaa1044.

[6] Office of National Statistics. Updated estimates of the prevalence of ongoing symptoms following coronavirus (COVID-19) infection in the UK. https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/datasets/alldatarelatingtoprevalenceofongoingsymptomsfollowingcoronaviruscovid19infectionintheuk. Accessed October 9, 2021.

[7] Johns Hopkins Coronavirus Resource Center (website) https://coronavirus.jhu.edu/, Accessed October 17, 2021.

[8] Centers for Disease Control and Prevention, 2021. COVID Data Tracker (website) https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases, Accessed October 17, 2021.

[9] Link-Gelles, Ruth, COVID-19 Vaccine Effectiveness in the United States, the US CDC ACIP Meeting September 22, 2021. Retrieved from: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-22/04-COVID-Link-Gelles-508.pdf retrieved on October 15, 2021.Centers for Disease Control and Prevention, 2021. COVID Data Tracker (website) https://covid.cdc.gov/covid-data-tracker/#demographics. Accessed October 17, 2021.

[10] Centers for Disease Control and Prevention, 2021. COVID Data Tracker (website) https://covid.cdc.gov/covid-data-tracker/#demographics. Accessed October 17, 2021.

[11] Centers for Disease Control and Prevention. COVID Data Tracker (website) https://covid.cdc.gov/covid-data-tracker/#variant-proportions. Accessed September 26, 2021.

[12] Centers for Disease Control and Prevention, 2021. COVID Data Tracker (website) https://covid.cdc.gov/covid-data-tracker/#nowcasting. Accessed October 9, 2021.

[13] Centers for Disease Control and Prevention, 2021. COVID Data Tracker (website) https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases and CDC communication

[14]Centers for Disease Control and Prevention, 2021. COVID Data Tracker (website) https://covid.cdc.gov/covid-data-tracker/#demographics. Accessed October 17. 2021.

[15] Centers for Disease Control and Prevention. COVID Data Tracker (website).Counts of Hospitalizations by Age from the COVID-NET Network (data downloaded on October 17, 2021. https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network. Accessed October 9, 2021.

[16] Centers for Disease Control and Prevention. COVID Data Tracker (website) https://covid.cdc.gov/covid-data-tracker/#demographics. Accessed October 17, 2021.

[17]Centers for Disease Control and Prevention, 2021. COVID Data Tracker (website) https://covid.cdc.gov/covid-data-tracker/#pediatric-data. Accessed October 9, 2021.

[18] Kim L et al. Hospitalization Rates and Characteristics of Children Aged<18 Years Hospitalized with Laboratory-Confirmed COVID-19 - COVID-NET, 14 States, March 1-July 25, 2020. *MMWR* \2020;69(32):1081. Epub 2020 Aug 14.

[19] McCormick DW, Richardson LC, Young PR, et al. Deaths in children and adolescents associated with COVID-19 and MIS-C in the United States. *Pediatrics*. 2021; (preprint) doi: 10.1542/peds.2021-052273

[20] Diagnosis-wide analysis of COVID-19 complications: an exposure-crossover study William Murk, Monica Gierada, Michael Fralick, Andrew Weckstein, Reyna Klesh, Jeremy A. Rassen CMAJ Jan 2021, 193 (1) E10-E18.

[21] Daugherty S E, Guo Y, Heath K, DasmariÃ±as M C, Jubilo K G, Samranvedhya J et al. Risk of clinical sequelae after the acute phase of SARS-CoV-2 infection: retrospective cohort study BMJ 2021; 373:n1098.

[22] Boehmer, TK et al. Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data — United States, March 2020–January 2021 *MMWR* September 3, 2021.70(35);1228–1232

[23] Dufort EM et al. COVID-19: Multisystem inflammatory syndrome in children (MIS-C) clinical features, evaluation, and diagnosis. N Engl J Med. 2020;383(4):347. Epub 2020 Jun 29.

[24] Centers for Disease Control and Prevention. Information for Healthcare Providers about Multisystem Inflammatory Syndrome in Children (MIS-C). May 20, 2021. https://www.cdc.gov/mis-c/hcp/

[25] Centers for Disease Control and Prevention, 2021. COVID Data Tracker (website). https://covid.cdc.gov/covid-data-tracker/#mis-national-surveillance Graph - Daily MIS-C Cases and COVID-19 Cases Reported to CDC. Accessed October 17, 2021.

[26] Dufort EM et al. Multisystem Inflammatory Syndrome in Children in New York State. *N Engl J Med*. 2020;383:347-58

[27] Centers for Disease Control and Prevention. Health Department-Reported Cases of Multisystem Inflammatory Syndrome in Children (MIS-C) in the United States. October 17, 2021. https://covid.cdc.gov/covid-data-tracker/#mis-national-surveillance

[28] Feldstein et al. Characteristics and Outcomes of US Children and Adolescents with Mulitsystem Inflammatory Syndrome in Children (MIS-C) Compared with Severe Acute COVID-19. *JAMA* 2021;325(11):1074-1087.

[29] Farooqi et al. Longitudinal Outcomes for Multisystem Inflammatory Syndrome in Children. *Pediatrics.* 2021; 148(2):e2021051155

[30] Farooqi et al 2021.

[31] Viner RM, Mytton OT, Bonell C, et al. Susceptibility to SARS-CoV-2 Infection Among Children and Adolescents Compared With Adults: A Systematic Review and Meta-analysis. *JAMA Pediatr.* 2021;175(2):143-156.

[32] Leidman E, Duca LM, Omura JD, et al. COVID-19 Trends Among Persons Aged 0-24 Years - United States, March 1-December 12, 2020. *MMWR*. 2021;70(3):88-94.

[33] Sargent TH, Muller WJ, Zheng X, et al. Age-Related Differences in Nasopharyngeal Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Levels in Patients With Mild to Moderate Coronavirus Disease 2019 (COVID-19). *JAMA Pediatrics*. 2020;174(9):902-903.

[34] Yonker LM, Neilan AM, Bartsch Y, et al. Pediatric Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2): Clinical Presentation, Infectivity, and Immune Responses. *J Pediatr*. 2020;227:45-52.e5.

[35] Chu VT, Yousaf AR, Chang K, et al. Household Transmission of SARS-CoV-2 from Children and Adolescents. N Engl J Med. 2021;NEJMc2031915.

[36] Centers for Disease control and prevention. Science Brief: Transmission of SARS-CoV-2 in K-12 schools. https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission_k_12_schools.html. Accessed October 17, 2021.

[37] Ismail SA, Saliba V, Lopez Bernal J, et al. SARS-CoV-2 infection and transmission in educational settings: a prospective, cross-sectional analysis of infection clusters and outbreaks in England. Lancet Infect Dis 2021;21(3):344-353. doi:10.1016/s1473-3099(20)30882-3.

[38] Goldstein E, Lipsitch M, Cevik M. On the Effect of Age on the Transmission of SARS-CoV-2 in Households, Schools, and the Community. *J Infect Dis*. 2021 Feb 13;223(3):362-369.

[39] Larosa E, Djuric O, Cassinadri M, et al. Secondary transmission of COVID-19 in preschool and school settings in northern Italy after their reopening in September 2020: a population-based study. *Euro Surveill*. 2020;25(49):2001911.

[40] Tonzel JL, Sokol T. COVID-19 Outbreaks at Youth Summer Camps — Louisiana, June–July 2021. *MMWR* 2021;(70):1425–1426.

[41] Szablewski CM, Chang KT, Brown MM, et al. SARS-CoV-2 transmission and infection among attendees of an overnight camp—Georgia, June 2020. *MMWR* 2020;(69):1023–5.

[42] Gee J, Marquez P, Su J, et al. First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021. MMWR Morb Mortal Wkly Rep 2021;70:283–288. http://dx.doi.org/10.15585/mmwr.mm7008e3

[43] CDC COVID-19 Response Team et al. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020. MMWR Morb Mortal Wkly Rep 2021;70:46–51. DOI: http://dx.doi.org/10.15585/mmwr.mm7002e1

[44] FDA. Vaccine approval package: COMIRNATY (COVID-19 Vaccine, mRNA) (Application No 125742). August 23, 2021. https://www.fda.gov/media/151733/download

[45] FDA. Guidance for Industry: Emergency Use Authorization for Vaccines to Prevent COVID-19. February 2021. https://www.fda.gov/media/142749/download

[46] FDA. Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19. June 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19

[47] Kim L, Whitaker M, O'Halloran A, et al. Hospitalization Rates and Characteristics of Children Aged <18 Years Hospitalized with Laboratory-Confirmed COVID-19 - COVID-NET, 14 States, March 1-July 25, 2020. MMWR Morb Mortal Wkly Rep. 2020;69(32):1081-88.

[48] Link-Gelles, R. COVID-19 Vaccine Effectiveness in the United States, the US CDC ACIP Meeting September 22, 2021. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-22/04-COVID-Link-Gelles-508.pdf Accessed October 15, 2021.

[49] Klein, N. Rapid Cycle Analysis to Monitor the Safety of COVID-19 Vaccines in Near Real-Time within the Vaccine Safety Datalink: Myocarditis and Anaphylaxis, the US CDC ACIP Meeting August 30, 2021. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-30/04-COVID-Klein-508.pdf Accessed October 20, 2021.

12 APPENDIX: C4591007 PHASE 1 (DOSE RANGING) – SUMMARY OF SAFETY AND IMMUNOGENICITY

During study C4591007 Phase 1, BNT162b2 was evaluated in U.S. children who were not at high risk of SARS-CoV-2 exposure, did not have medical conditions that represented risk factors for severe COVID-19, and did not have serologic/virologic evidence of SARS-CoV-2 infection. BNT162b2 dosages of 10 µg, 20 µg, then 30 µg were evaluated sequentially (n=16 participants per dosage) based upon the safety evaluation and recommendation by the internal review committee (IRC) to either advance to the subsequent dosage or terminate a specific dosage. Safety evaluation was the same as for Phase 2/3. SARS-CoV-2 50% neutralizing GMTs (SARS-CoV-2 mNG microneutralization assay) were assessed at 7 days after Dose 2.

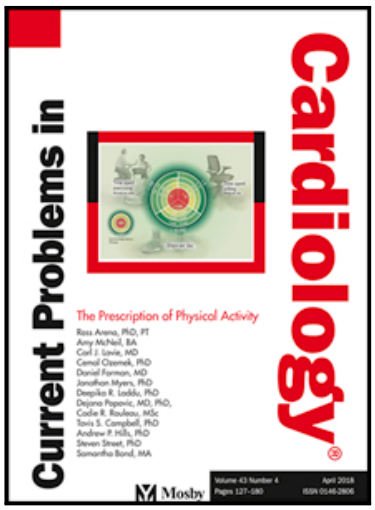
Altogether, 48/49 (98%) of participants (assigned to the 10 µg, 20 µg, or 30 µg dosage groups combined) received two doses of BNT162b2 and completed the 1 month follow-up visit after Dose 2. One BNT162b2 participant (20 µg dosage group) did not receive study vaccine. Following safety review of reactogenicity data from the initial 4 participants in the BNT162b2 30 µg dosage group, the IRC recommended to discontinue the 30 µg dosage, due to high frequencies of solicited ARs, and recommended that the remaining 12 participants receive the

dosage selected for Phase 2/3 (i.e., 10 μg) at Dose 2. No participants from Phase 1 withdrew or discontinued from the study.

The frequencies of local and systemic adverse reactions were generally dose number and dosage dependent. Across dosages, systemic adverse reactions were generally mild and moderate in severity and resolved within 1 day of onset. No SAEs, deaths or AEs leading to withdrawal occurred at the time of data cutoff on July 16, 2021, with approximately 3 months of follow-up. No participants reported anaphylaxis, myocarditis/pericarditis, or MIS-C. One BNT162b2 (30 μg) recipient reported Grade 1 axillary lymphadenopathy, which started 3 days after Dose 2 and resolved 17 days later; the AE was considered by the study investigator to be related to study intervention.

All four participants who received 30 μg for both doses developed mild-moderate redness and pain at the injection site, and 2 of the 4 participants developed swelling. In addition, all four subjects reported fevers to 38.9°C with mild to moderate fatigue, and 2 of the 4 developed muscle pain of moderate severity following the second dose. One participant in the 20 μg group reported Grade 3 pyrexia (temperature to 39.7° C, also reported as a systemic adverse reaction, on Day 2 post-Dose 2), which resolved by Day 3. Both 10 and 20 μg dosages elicited similar immune responses 7 days after Dose 2. In participants 5-11 years of age without evidence of SARS-CoV-2 infection up to 1 month post-Dose 2, the neutralizing antibody GMTs (NT50) at 1 month after Dose 2 were similar in the BNT162b2 10 μg and 20 μg groups (4163 and 4728, respectively).

The higher frequencies of solicited adverse reactions in participants receiving the 20 μg and 30 μg dosages, the favorable AE profile at the 10 μg dosage in participants 5-11 years of age followed for approximately 3 months after Dose 2, and the immunogenicity results demonstrating similar neutralizing antibody responses at the 10 and 20 μg dosages informed the Internal Review Committee's decision to discontinue the 30 μg dosage and proceed to Phase 2/3 at the 10 μg dosage.



A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products

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A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products

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Abstract

Following the global rollout and administration of the Pfizer Inc./BioNTech BNT162b2 and Moderna mRNA-1273 vaccines on December 17, 2020, in the United States, and of the Janssen Ad26.COV2.S product on April 1st, 2021, in an unprecedented manner, hundreds of thousands of individuals have reported adverse events (AEs) using the Vaccine Adverse Events Reports System (VAERS). We used VAERS data to examine cardiac AEs, primarily myocarditis, reported following injection of the first or second dose of the COVID-19 injectable products. Myocarditis rates reported in VAERS were significantly higher in youths between the ages of 13 to 23 ($p<0.0001$) with ~80% occurring in males. Within 8 weeks of the public offering of COVID-19 products to the 12-15-year-old age group, we found 19 times the expected number of myocarditis cases in the vaccination volunteers over background myocarditis rates for this age group. In addition, a 5-fold increase in myocarditis rate was observed subsequent to dose 2 as opposed to dose 1 in 15-year-old males. A total of 67% of all cases occurred with BNT162b2. Of the total myocarditis AE reports, 6 individuals died (1.1%) and of these, 2 were under 20 years of age - 1 was 13. These findings suggest a markedly higher risk for myocarditis subsequent to COVID-19 injectable product use than for other known vaccines, and this is well above

known background rates for myocarditis. COVID-19 injectable products are novel and have a genetic, pathogenic mechanism of action causing uncontrolled expression of SARS-CoV-2 spike protein within human cells. When you combine this fact with the temporal relationship of AE occurrence and reporting, biological plausibility of cause and effect, and the fact that these data are internally and externally consistent with emerging sources of clinical data, it supports a conclusion that the COVID-19 biological products are deterministic for the myocarditis cases observed after injection.

Keywords

SARS-CoV-2; COVID-19; myocarditis; VAERS; adverse events (AEs); COVID-19-Injection-Related Myocarditis (CIRM)

1. Background

Myocarditis is inflammation of the myocardium or 'musculature' of the heart. [1,2,3,4] The myocardium is made up of many cell types however the greatest mass of tissue is accounted for by cardiomyocytes. [4,5,6] Cardiomyocytes are the principal contractile cells and are supported by specialized conduction and stromal cell types. [4,5,6,7,8] Both systole and diastole are active processes that expend energetic resources of cardiomyocytes which are organized into myofibrils. [8,9,10] Myocarditis can manifest as sudden death, chest pain or heart failure. The symptoms of heart failure from myocarditis include effort intolerance, dyspnea, fatigue, and ankle swelling. [1,2,3,4,6,11,12,13] The cause is an inflammation of the heart muscle, often following a viral infection, but not exclusively so. The damaged muscle is prone to lethal cardiac arrythmias as well as having the potential to develop both right and left ventricular dysfunction (cardiomyopathy). [3,4,12,13]

Myocarditis is a major risk for cardiac death among the young. [11] The high-risk age population for myocarditis is from puberty through early 30s, and it is the third leading cause of sudden cardiac death in children and young adults. 1 per 100,000 children per year are affected by myocarditis and it has been reported that 0.05% of all pediatric hospitalizations are for myocarditis. Between 0.5 and 3.5% of heart failure hospitalizations are due to myocarditis. Most cases of myocarditis are identified in young adults with males affected more often than females. [12,13,14, 15,16]

In the context of COVID-19 respiratory illness, there are a significant number of patients who are otherwise healthy experiencing heart-related complications, including myocarditis, but the majority of clinical reports and diagnoses claim cardiac injury based on ICU-related-related injury to the heart. [17,18,19,20,21,22,23,24,25] This is relevant in terms of contextualizing the potential risk of myocarditis from the COVID-19 products against COVID-19 itself and establishing a background rate of myocarditis in specific contexts. Cardiac injuries associated with COVID-19 respiratory illness reveal a set of parameters based on a combination of measurements of troponin levels, electrocardiogram (ECG/EKG), echocardiogram readings, cardiac magnetic resonance imaging (MRI) and clinical symptoms that are different from the clinical picture of vaccine-induced myocarditis. COVID-19-Injection-Related Myocarditis (CIRM) can be defined as the onset of clinical myocarditis that is temporally associated with COVID-19 mRNA or adenoviral DNA vaccine administration and in the absence of another known cause. CIRM presents with clinical symptoms (chest pain, effort intolerance) combined with excessively

elevated troponin levels, EKG changes (diffuse ST segment elevation) and in some cases left and right ventricular dysfunction on echocardiography. In cases where the echocardiogram is unrevealing, cardiac MRI can detect changes in tissue characterization consistent with myocardial inflammation. [22,23,24,25,26,27]

The Vaccine Adverse Event Reporting System (VAERS) was created and implemented in 1990 by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to receive reports about adverse events that may be associated with vaccines. [28] The primary purpose for maintaining the database is to serve as an early warning or signaling system for adverse events not detected during pre-market testing. In addition, the National Childhood Vaccine Injury Act of 1986 (NCVIA) requires health care providers and vaccine manufacturers to report to the DHHS specific adverse events following the administration of those vaccines outlined in the Act.[1] Under-reporting is a known and serious disadvantage of the VAERS system. [28,29,30]

An Adverse Event (AE) is defined as any untoward or unfavorable medical occurrence in a human study participant, including any abnormal physical exam or laboratory finding, symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research. A serious or severe adverse event (SAE) is defined as any adverse event that results in death, is life threatening, or places the participant at immediate risk of death from the event as it occurred, requires, or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects or is another condition which investigators judge to represent significant hazards. [28,30,31] These classifications are based on the Code of Federal Regulations. The VAERS handbook states that approximately 15% of reported AEs are classified as severe.[28] Myocarditis qualifies as an SAE as it is often associated with hospitalization.

The BNT162b2, mRNA-1273, Ad26.COV2.S products have **not** been approved or licensed by the U.S. Food and Drug Administration (FDA), having been authorized instead for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older.[2] [32,33,34] Ultimately, the roll-out of COVID-19 injectable

[1] It must be noted that the reported adverse events as part of the VAERS represent a fraction of the actual number of incidents. Studies have shown that the percentage of incidents reported can be quite low (1-10%) but, for the purposes of this report, in order to do the necessary calculations, VAERS numbers were used, and the results should be considered to reveal trends. [23,24]

[2] mRNA biologicals are not true vaccines. True vaccines are a preparation of a weakened or killed pathogen, such as a bacterium or virus, or of a portion of the pathogen's structure that upon administration to an individual stimulates antibody production or cellular immunity against the

biologicals are actively being monitored, but all of the risks are not yet known. [16,17,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46]

2. Methods and results

To analyse the VAERS data set the Language and Environment for Statistical Computing, R, was used. The VAERS data set is available for download (https://vaers.hhs.gov/data/datasets) in three separate comma-separated values (csv) files representing i) general data for each report; ii) the reported AEs or 'symptoms', and iii) vaccine data including vaccine manufacturer and lot number, for each report. The VAERS dataset is updated approximately once a week and the uploaded set is approximately one week behind the reports. Upon individual reporting of vaccine side effects or adverse events, a VAERS ID number is provided to the individual to preserve confidentiality, and a detailed description of the side effects are transcribed along with the individual's age, residence by state, past medical history, allergies and gender and many other details. In addition, the vaccine lot number, place of vaccination and manufacturer details are included in the report. In order to maximize the input variables for my analysis, the three files were merged by VAERS ID that is included as a linking variable in all three files. The merged data set comprises data collected pertaining to all reported AEs associated with BNT162b2, mRNA-1273, and Ad26.COV2.S products: the three primary vaccine manufacturers responsible for nCoV-2019 products currently being administered in the U.S. Data was sorted according to vaccine type (data reported for COVID-19) and relevant variables were sorted including VAERS ID, AEs, age, gender, state, vaccination date, date of death, incident of death, dose series, treatment lot number, treatment manufacturer, hospitalizations, emergency department visits and onset date of AEs. Myocarditis as a standalone AE was extracted by keyword and cardiac events were grouped by extracting multiple keywords according to MedDRA nomenclature. Statistical analysis was done using the Student's t-Test to determine statistically significant differences between ages in the myocarditis AE. Skewing in distribution of data was tested using Pearson's Skewness Index, I, which is defined as I = (mean-mode)/standard deviation. The data set is significantly skewed if $|I| \geq 1$.

pathogen but is incapable of causing severe infection. Vaccines undergo an extremely rigorous testing time-dependent protocol to ensure safety and efficacy typically enduring between 10 and 15 years. The mRNA biologicals do not satisfy either these requirements and are thus more akin to experimental gene therapy.

2.1 Results: General information

To date, approximately 56% of the total US population has been 'fully vaccinated' against COVID-19. As of July 9th, 2021, 397,262 AEs have been reported in the VAERS system. This number is very atypical and large when compared to frequencies of AE reports from previous years. Figure 1 illustrates the stark contrast between what the count would be if the trend of past 30 years continued through to the end of 2021: ~65,000 for the entire 2021 year as opposed to ~400,000 over 6 months. There are almost 4,000 different AE types reported (to date) in the context of COVID-19 products and among them, many SAES. As previously stated, the VAERS handbook maintains that ~15% of all the AEs should classify as SAEs yet the percentage holds at 18% for COVID-19-related AEs.

Among these SAEs are cardiac AEs that include cardiac arrest, myocardial infarction, and myocarditis. Myocarditis reports in the context of the COVID-19 products are atypically high in the context of prior vaccine rollouts and in the context of baseline levels with respect to high-risk groups. The number of cases of myocarditis reported to the VAERS database dramatically outnumber case counts seen in previous years with 1 single case having been reported in 2019 and 1 single case being reported in 2020 (Refer to Section 1.4). Figure 2 shows the absolute numbers of myocarditis cases reported for 2021 as per Onset Date. It is clear from this bar plot that the frequency of myocarditis cases reported to VAERS has increased starting at the beginning of June. This is just shortly after the roll-out of injections into children aged 12-15 began. On May 10, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for BNT162b2 vaccine in children aged 12-15. Of note, 67% of myocarditis cases were in the context of administration of BNT162b2.

2.2 Incidence rates of myocarditis in youths

As of July 9th, 2021, a total of 559 myocarditis AEs (0.14% of all AEs) have been reported. Of the reports, 80% of the gender classification was male. In general, 71% of all VAERS reports are made by females so this statistic is particularly telling. The increase in myocarditis reports coincides with the COVID-19 injection rollouts in children aged 12-15, thus, we hypothesized that the increased cases of myocarditis were in fact occurring in children of these ages. Figure 3 shows the distribution of myocarditis cases by age grouped by decade. 41% of all myocarditis reports were made for children

aged 10 through 20 and 72% of all myocarditis reports were made for young adults aged 10-30 years of age. The distribution is right-skewed toward the younger age groups, and this is statistically significant (I=1.61). This provides strong evidence to support our hypothesis.

As of May 18th, 2021, 600,000 children aged 12-15 had been injected with COVID-19 products[3]. [14] The CDC estimated that 3,430,741 children aged 12-15 have received at least one dose of the COVID-19 products as of June 7th, 2021.[4] Since 1 per 100,000 children per year are affected by myocarditis[5] then, statistically, we would expect ~5 myocarditis cases if we calculate the expected number of cases using the June 7th CDC sample. To date (up to and including July 2nd, 2021), 97 children aged 12-15 have had reports submitted to VAERS representing 17.4% of all myocarditis reports – and these are merely the cases that we are aware of. Thus, after 8 weeks of roll-out into the 12-15 years-old age group, we are at ~19 times the expected number of cases within this sample. Thus, the number of VAERS-reported cases far outnumber what would typically be expected to date. It is important to note that of the 559 myocarditis VAERS reports, 6 died (1.1%) and 33% of these deaths were in individuals under 20 years of age: 1 individual was 13 and one was 19 years of age.

2.3 Data right-skewed in statistically significant way toward young males

In addition to very high rates of myocarditis cases in children aged 12-15, these rates are observed much more commonly in males. Figure 4 shows the distribution of myocarditis cases by age in males versus females. The distribution is right-skewed toward the younger age groups, and this is statistically significant (I=1.28), and males represent 80% of all cases. The most frequent occurrences were in 15-year-old boys (N= 44) and 18-year-old girls (N= 6).

2.4 Acute myocarditis following 2nd dose

The prevalence of myocarditis reports in the VAERS system is much higher in the context of dose 2 when comparing by age (t-test: p-value = 0.00092) and more highly associated with BNT162b2 (74% of all dose 2 reports are in the context of BNT162b2. It is also much higher in males when comparing by age (t-test: p-value = 0.000009). Dose 2 is generally administered 3 weeks following the first dose

[3] Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention
[4] VRBPAC-06.10.21-Meeting-Presentation-COVID-19-Adolescent-Vaccination.pdf
[5] Myocarditis in children: incidence, clinical characteristics, and outcomes. Jul 29, 2020. MYOCARDITIS FOUNDATION

assuming the individual survives dose 1 without any major complications, including death. The BNT162b2 maintains a 21-day interval between dose 1 and 2 while the mRNA-1273 maintains a 28-day interval.[6] Figure 5 reveals that myocarditis reports peak in frequency at 6X for dose 2 in 15-year-old males. It also reveals that regardless of age, myocarditis cases are more frequently reported following dose 2.

Since the high-risk age population for myocarditis is from puberty through early 30s, myocarditis should be considered diagnostically in any young adult who experiences shortness of breath, palpitations or chest pain following injection with dose 1 of any COVID-19 injectable product. It is notable that chest pain is a prevalent tandem AE (25% of individuals who filed myocarditis reports into VAERS also experienced chest pain following dose 1) and this may not be acknowledged by a teenager, or even a medical professional, as a warning sign of cardiac insult. The data is right-skewed toward the younger ages, and this is statistically significant (I=1.2).

2.5 COVID-19 products highly associated with myocarditis – a case for causation?

About 1.5 million cases of acute myocarditis occurred in 2013. In 1990, 294,000 individuals died from cardiomyopathy (including myocarditis) which increased to 354,000 deaths in 2015. Myocarditis is a rare disease and typically presents in males and younger individuals as previously stated. The trigger for myocarditis is considered idiopathic but generally thought to be the result of infection or toxin. [2] However, in the context of vaccine-induced myocarditis, report numbers have typically been very low. That is, however, until recently. Consider that 2021 is the only year we have been able to collect AE data for the COVID-19 products and prior years are exclusively non-COVID products, except for 2 weeks in December 2020.

The average number of myocarditis reports in VAERS in the context of all vaccines combined for the past 3 years is 4: 11 (0.02% of total) reports were made in 2018, and 1 report was made for 2019 (0.002% of total) and 2020 (0.002% of total), respectively. The number of myocarditis case reports for 2021 are at 559 (0.14%); far higher than last year for all vaccine products combined as shown in Figure 6. Myocarditis case rates for 2018-2021 reveal that the rates of myocarditis, when normalized to the

[6] FDA Statement on Following the Authorized Dosing Schedules for COVID-19 Vaccines

number of fully vaccinated/injected individuals, are exceedingly higher in 2021 than for previous years as shown in Table 1.

2.6 Cardiac events associated with COVID-19

There are 129,522 AEs to date (July 9th, 2021) that are directly related to clinical diagnosis of serious cardiac issues such as myocarditis. These AEs are shown Supplementary Tables 1 and 2 whereby Supplementary Table 1 shows clinical effects such as chest pain and pericarditis and Supplementary Table 2 shows clinical markers or diagnostic elements such as elevated Troponin and Fibrin D dimer levels. This number was calculated using a function that extracts field entries from the VAERS updated AE dataframe that match the list, and subsequently counts them. Figure 7 shows the distribution of cardiac events by age group generated just from this short list of keywords. The highest number of reports was made by individuals aged 30-40 but overall, the distribution is symmetric and unimodal with no statistically significant skewing toward any specific age group (I=0.32). This means that cardiac AEs are being heavily reported, regardless of age.

3. Discussion

In the context of COVID-19, and according to Dr. Leslie Cooper, there are a significant number of patients who present clinically as healthy who are experiencing heart-related complications, including myocarditis.[7] [2,17,18,19] There is a high risk of cardiac involvement both from COVID-19 infection and from COVID-19 injectable products and the risks of the latter must be further assessed and evaluated. Because of the spontaneous reporting of events to VAERS, we can assume that the cases reported thus far are not rare, but rather, just the tip of the iceberg. Again, under-reporting is a known and serious disadvantage of the VAERS system. [28,29,30] The only way to understand how common myocarditis is after COVID-19 vaccination, is to perform a prospective cohort study where all vaccinated individuals undergo clinical assessment, ECG, and troponin measurement at regular intervals post-administration.

The fact that the VAERS reporting of myocarditis is 6X higher in 15-year-olds following dose 2 may be indicative of a cause-effect relationship. If we assume that following dose 1, a certain percentage

[7] Dr. Leslie T. Cooper, Chair, Enterprise Department of Cardiovascular Medicine for Mayo Clinic and the Executive Medical Director and founder of the Myocarditis Foundation

of healthy young males who lack co-morbidities or co-factors experience cardiac-related AEs mild enough so as not to dissuade them from receiving dose 2 (ie: pallor, chest pain and shortness of breath, for example), then it is not difficult to imagine that they may have been experiencing symptoms of myocarditis. If a percentage of young males had experienced primary damage to the heart as a result of inflammation following dose 1, then dose 2 may have induced a much more noticeable clinical impact, or cardiac 'insult'. In other words, these young males may receive a definitive diagnosis of myocarditis only following dose 2. What this implies, based on these assumptions, is that if there is a causal relationship then it might manifest with overlooked/unreported AEs following dose 1 and a diagnosis of myocarditis following dose 2. It is noteworthy that 'Vaccine-induced myocarditis' was in fact used as the descriptor by medical professionals as the reason for the myocarditis in the VAERS database.

During phase III clinical trials for the mRNA COVID-19 products, safety was assessed based on a *maximum* observation period of 6 months. This is not adequate to assess long-term safety outcomes as it is a requirement, even in an accelerated timeline setting, to spend up to 9 months in Phase III trials.[8] The typical timeline is up to 10 years for safety and efficacy assessment. [47,48] There are many examples of biological product recalls historically. In 2010, rotavirus vaccines licensed in the U.S were found to contain Porcine circovirus (PCV) type 1 and were subsequently suspended. In 2009, an increased risk of narcolepsy was found following vaccination with a monovalent H1N1 influenza vaccine that was used in several European countries during the H1N1 influenza pandemic. Between 2005 and 2008, a meningococcal vaccine was suspected to cause Guillain-Barré Syndrome (GBS). In 1998, a vaccine designed to prevent rotavirus gastroenteritis was associated with childhood intussusception after being vaccinated. Also in 1998, a hepatitis B vaccine product was linked to multiple sclerosis (MS). [49] It is also vital to address that pregnant woman were in the exclusion criteria list for the Phase III trials (ref: NCT04368728) and thus it is unclear how a safety assessment can be made for pregnant women when the products were only tested for 6 months. [50] In this context, it is worth reiterating that BNT162b2, mRNA-1273, and the Ad26.COV2.S products have **not** been approved or licensed by the U.S. Food and Drug Administration (FDA), having been authorized instead for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19), and was originally meant for use in individuals 16 years of age and older. [32,33,34]

mRNA platforms have never before been implemented for use in human subjects on a global scale in the context of viruses and it has recently been shown that the spike protein itself systemically

[8] https://coronavirus.jhu.edu/vaccines/timeline

traffics inducing damage within cells, at the cell surface, and through circulation with endothelial damage and thrombosis. [44,45] It is unknown which cells and organs are seeded with mRNA, the cellular half-life of the products, duration of spike protein production, reverse transcription, future regulation, and ultimate disposal of mRNA technology. [51,52] Safety is always a point of relevance with regards to new biological agents and given these new findings, it would be prudent to pay particular attention to the AEs being reported to the VAERS system in the context of these experimental products with known dangerous mechanisms of action. When evidence of harm appears, we need to follow the evidence and immediately take steps to mitigate risks.

Based on this study, the risk of suffering myocarditis subsequent to injection with the mRNA-based products is low with an average of 4 individuals suffering myocarditis per million fully injected. However, the Israeli Ministry of Health recently announced that approximately 1 in 4,500 men ages 16 to 24 who received BNT162b2 developed myocarditis. [46] This rate is much higher than the rate estimated based on VAERS data and could reflect variation in reporting. Nonetheless, the risk is higher for the young with an average of 28 12-15-year-olds succumbing to myocarditis per million fully immunized. Discerning between ICU-related mild cardiac injury with SARS-CoV-2 respiratory infection and myocarditis in the context of COVID-19 and the injectable biologicals is important. In establishing background rates of myocarditis in the context of both COVID-19 and injection-associated cardiac injuries, it is vital to ensure that true myocarditis is ensuing for diagnostic purposes. This can be achieved by definitively quantifying the levels of markers for myocarditis such as troponin (I and T), EKG/echocardiograms, and detecting deviations in ST and T waves, PR and QT intervals and T wave inversion. Changes the overall area under the curve for cardiac troponin, reductions in left ventricular ejection fraction, and changes in tissue characterization by cardiac MRI can also be used as diagnostic quantifiers to aid in discerning between CIRM and ICU-related cardiac injuries. As a general rule, the ICU cardiac injury described in COVID-19 illness is subclinical and largely reflected by a minor elevation of cardiac troponin, whereas CIRM is characterized by a clinical syndrome often warranting hospitalization, dramatic ECG changes, and very large elevations of cardiac troponin that are sustained over time. [53,54,55,56,57,58,87]

It is vital to recall that children have a negligible risk for COVID-19 respiratory illness, and yet they are a high-risk group for myocarditis with vaccination. Newly-published evidence of Vaccine-Induced Autoimmune Myocarditis, [58] demonstrates the risks of myocarditis associated with

vaccination. [87,88,89,92,93,94,95] Despite this, a recent CDC report (May 31, 2021) claimed no danger signal was detectable from the VAERS AE data in the context of myocarditis and as such, they continue to support administration of these products into children 12 years of age and older despite reports of myocarditis and pericarditis in youth in temporal proximity to dose administration. [94]

It possible that vaccine-induced myocarditis is amplified by prior infection and pathogenic priming. Higher uptake of genetic material in some younger individuals who have been previously recovered from COVID-19 and were vaccinated, may partially explain why some individuals suffer from CIRM and others do not. Nevertheless, the background rate for children aged 12-15 has been established outside of the COVID-19 context and the rates in the context of CIRM are 19 times higher than the expected value.

A recent study shows increased myocardial ACE-2 expression in individuals with 'basic heart failure disease' indicating an intrinsic susceptibility of the heart to SARS-CoV-2 infection and worse prognosis. [55] Another study in *Hypertension* from 2008 claims that cardiac over-expression of ACE-2 exerts protective influence on the heart during myocardial infarction by preserving left ventricular wall motion and contractility, and by attenuating LV wall thinning. [56] However, we postulate the pathogenesis of CIRM must be much different with isolated production of spike protein over a sustained period of time and expression of the cell surface of cardiomyocytes, which would be considerably different than virion replication. The implications are the ACE-2 expression probably plays a smaller role in vaccine-induced myocardial injury and it has been noted by the co-author that the latter is more highly-associated with maintained elevated troponin levels. [unpublished clinical findings]

Additional information may be gleaned from routine EKG readings and cardiac troponin measurement in volunteers post-injection. It is unknown if in-situ production or perfusion with blood carrying spike protein are the major mechanisms by which CIRM is initiated. Once, damaged, inflammation in the myocardium may last for weeks or months after the original insult is removed. [55,58] The exact mechanisms of action for induction and progression of CIRM needs to be elucidated to ensure improved and safer products for the future.

The clinical implications of acute myocarditis in younger individuals as a result of uncontrolled production of the SARS-CoV-2 spike protein within cardiac myocytes and cardiac support cells is

unknown. If myocarditis has developed after the first injection, then second administrations and boosters should be avoided. Sustained elevations of cardiac troponin, reduction in left and right ventricular function, large areas of inflammation or scar on imaging, and cardiac arrhythmias all portend a poor prognosis for the development of heart failure and cardiac death. Because the duration of action of genetic material coding for spike protein is unknown, follow-up with cardiology consultation is advised in all cases and repeat imaging and biomarkers is wise. Empiric treatment with renin-angiotensin system inhibitors and evidence-based beta-blockers is advised for those at risk for or with manifest left ventricular dysfunction.

4. Conclusions

These data are derived from a rushed, non-FDA-approved, ongoing investigational product roll-out, and our conclusions are thus limited by the information at hand. In addition to the 12-15-year-old age group data being *very* early, it is vital to acknowledge that these reports represent a fraction of the actual total. Thus, due to both the problems of under-reporting and the known lag in report processing, this analysis reveals a strong signal from the VAERS data that the risk of suffering CIRM – especially males is unacceptably high. Again, children are not a high-risk group for COVID-19 respiratory illness, and yet they are the high-risk group for CIRM.

Efficacy of these products needs to be assessed by immunological assays and long-term studies are required, while safety needs to be evaluated by rigorous clinical, laboratory and imaging assessments of severe reported adverse events such as CIRM. Autopsies should be done in cases of cardiovascular-related deaths temporally associated with COVID-19 injectables. It is reasonable to use the precautionary principle in this particular setting since an alarming number of reports are coming from young males between the ages of 12 and 15. Boys of these ages should be carefully monitored for warning signs of myocarditis which many may pass off such as pallor, chest pain, shortness of breath or lethargy, following dose 1 with the aim of seeking prompt evaluation and avoiding dose 2.

Effective multidrug therapy is available for rare case of serious COVID-19 respiratory illness in the forms of antivirals, immunomodulators, and anthrombotics. [59,60,61,62,63,64,65,66,67,68,69,70,71,72] The combination of a low IFR in children indicating effective and robust immune responses

[73,74,75,76,77,78,79,80,81,82,83], and the ability to treat with medical therapy, should the need arise, bodes well for clinical outcomes in children [69,70,71,72].

As part of any risk/benefit analysis which must be completed in the context of experimental products, the points herein must be considered before a decision can be made pertaining to agreeing to 2-dose injections of these experimental COVID-19 products, especially into children and by no means, should parental consent be waived under any circumstances to avoid children volunteering for injections with products that do not have proven safety or efficacy.

Future work may include on-site clinical observations of Troponin, BNP, galectin-3, ST2, IL-6 and D-dimer levels to corroborate temporal effects of onset of myocarditis following injections with particular COVID-19 products. Delineation between COVID-19 respiratory infection with mild ICU-related cardiac injury and true CIRM using these and other clinical diagnostic markers would be incredibly useful for clinicians and should become the standard for differential diagnosis of suspected CIRM. Correcting the inherent limitations of the VAERS dataset must be a priority as part of future studies. Incomplete VAERS dataset field entries describing prior COVID-19 infection and diagnostic tests such as cardiac MRIs in individuals diagnosed with myocarditis, for example, would make this particular study even more potent. However, despite these limitations, and the limitation of using the VAERS dataset for studies like this one, the usable sample sizes have good statistical power. Ultimately, it remains vital to share the results herein to allow true pharmacovigilance to take place.

References

1. Cooper LT Jr. Myocarditis. N Engl J Med. 2009 Apr 9;360(15):1526-38. doi: 10.1056/NEJMra0800028. PMID: 19357408; PMCID: PMC5814110.
2. National Organization for Rare Disorders (NORD) https://rarediseases.org/rare-diseases/myocarditis/
3. Sinagra G, Merlo M, Pinamonti B, editors. Dilated Cardiomyopathy: From Genetics to Clinical Management [Internet]. Cham (CH): Springer; 2019.
4. ESC Textbook of Cardiovascular Medicine, 3rd edition
5. Libby P, Swirski FK, Nahrendorf M. The Myocardium: More Than Myocytes. J Am Coll Cardiol. 2019 Dec 24;74(25):3136-3138. doi: 10.1016/j.jacc.2019.10.031. PMID: 31856970.
6. Tran DB, Weber C, Lopez RA. Anatomy, Thorax, Heart Muscles. [Updated 2020 Sep 19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: https://www.ncbi.nlm.nih.gov/bookb/NBK545195/
7. Banerjee I, Fuseler JW, Price RL, Borg TK, Baudino TA. Determination of cell types and numbers during cardiac development in the neonatal and adult rat and mouse. Am J Physiol Heart Circ Physiol. 2007 Sep;293(3):H1883-91. doi: 10.1152/ajpheart.00514.2007. Epub 2007 Jun 29. PMID: 17604329.
8. M.F. Wendt-Gallitelli, G. Isenberg. Electrophysiology and Microinjection. Methods in Neurosciences, 1991.
9. https://www.britannica.com/science/myocyte
10. Weinhaus A.J., Roberts K.P. (2009) Anatomy of the Human Heart. In: Iaizzo P. (eds) Handbook of Cardiac Anatomy, Physiology, and Devices. Humana Press. https://doi.org/10.1007/978-1-60327-372-5_5.
11. Harris KM, Mackey-Bojack S, Bennett M, Nwaudo D, Duncanson E, Maron BJ. Sudden Unexpected Death Due to Myocarditis in Young People, Including Athletes. Am J Cardiol. 2021 Mar 15;143:131-134. doi: 10.1016/j.amjcard.2020.12.028. Epub 2020 Dec 19. PMID: 33347841.
12. https://www.mayoclinic.org/diseases-conditions/myocarditis/symptoms-causes/syc-20352539
13. Myocarditis Education Updates and How to Potentially Diagnose the Disease. Aug 4, 2020. Myocarditis Foundation
14. Myocarditis in children: incidence, clinical characteristics and outcomes. Jul 29, 2020. Myocarditis Foundation
15. https://www.cdc.gov/dhdsp/myocarditis.htm

16. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html
17. Siripanthong B, Nazarian S, Muser D, et al. Recognizing COVID-19-related myocarditis: The possible pathophysiology and proposed guideline for diagnosis and management. *Heart Rhythm*. 2020;17(9):1463-1471. doi:10.1016/j.hrthm.2020.05.001
18. Mele D, Flamigni F, Rapezzi C, Ferrari R. Myocarditis in COVID-19 patients: current problems. Intern Emerg Med. 2021 Jan 23:1–7. doi: 10.1007/s11739-021-02635-w. Epub ahead of print. PMID: 33484452; PMCID: PMC7823176.
19. Castiello T, Georgiopoulos G, Finocchiaro G, et al. COVID-19 and myocarditis: a systematic review and overview of current challenges [published online ahead of print, 2021 Mar 24]. *Heart Fail Rev*. 2021;1-11. doi:10.1007/s10741-021-10087-9.
20. Albert E, Aurigemma G, Saucedo J, Gerson DS. Myocarditis following COVID-19 vaccination. *Radiol Case Rep*. 2021;16(8):2142-2145. doi:10.1016/j.radcr.2021.05.033.
21. How Can COVID-19 Affect the Heart? Aug 18, 2020. Myocarditis Foundation
22. Montgomery J, Ryan M, Engler R, Hoffman D, McClenathan B, Collins L, Loran D, Hrncir D, Herring K, Platzer M, Adams N, Sanou A, Cooper LT Jr. Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military. JAMA Cardiol. 2021 Jun 29. doi: 10.1001/jamacardio.2021.2833. Epub ahead of print. PMID: 34185045.
23. Martinez MW, Tucker AM, Bloom OJ, Green G, DiFiori JP, Solomon G, Phelan D, Kim JH, Meeuwisse W, Sills AK, Rowe D, Bogoch II, Smith PT, Baggish AL, Putukian M, Engel DJ. Prevalence of Inflammatory Heart Disease Among Professional Athletes with Prior COVID-19 Infection Who Received Systematic Return-to-Play Cardiac Screening. JAMA Cardiol. 2021 Jul 1;6(7):745-752. doi: 10.1001/jamacardio.2021.0565. PMID: 33662103; PMCID: PMC7934073.
24. Puntmann VO, Carerj ML, Wieters I, Fahim M, Arendt C, Hoffmann J, Shchendrygina A, Escher F, Vasa-Nicotera M, Zeiher AM, Vehreschild M, Nagel E. Outcomes of Cardiovascular Magnetic Resonance Imaging in Patients Recently Recovered From Coronavirus Disease 2019 (COVID-19). JAMA Cardiol. 2020 Nov 1;5(11):1265-1273. doi: 10.1001/jamacardio.2020.3557. Erratum in: JAMA Cardiol. 2020 Nov 1;5(11):1308. PMID: 32730619; PMCID: PMC7385689.
25. Gregorio Tersalvi, MD, Marco Vicenzi, MD, Davide Calabretta, MD, Luigi Biasco, MD, PhD, Giovanni Pedrazzini, MD, Dario Winterton, MD. Elevated Troponin in Patients with Coronavirus Disease 2019: Possible Mechanisms. Review article| Volume 26, ISSUE 6, P470-475, June 01, 2020. Published:April 18, 2020DOI:https://doi.org/10.1016/j.cardfail.2020.04.009.

26. Nascimento JHP, Gomes BFO, Oliveira GMM. Cardiac Troponin as a Predictor of Myocardial Injury and Mortality from COVID-19. Arq Bras Cardiol. 2020 Oct;115(4):667-668. English, Portuguese. doi: 10.36660/abc.20200862. PMID: 33111867.
27. Ucar FM, Ozturk C, Yılmaztepe MA. Evaluation of Tp-e interval, Tp-e/QT ratio and Tp-e/QTc ratio in patients with acute myocarditis. BMC Cardiovasc Disord. 2019 Oct 22;19(1):232. doi: 10.1186/s12872-019-1207-z. PMID: 31640548; PMCID: PMC6805629.
28. VAERSDataUseGuide_November2020
29. https://vaxopedia.org/2017/08/26/underreporting-of-side-effects-to-vaers
30. NIA Adverse Event and Serious Adverse Event Guidelines
31. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?frexternal icon
32. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html
33. Temporary_Authorisation_Patient_Information_BNT162_7_0_UK.pdf
34. Fact Sheet for Vaccination Providers-Full EUA PI_Final_2.25.2021.pdf
35. Noa Dagan, M.D., *et al.* BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. New England Journal of Medicine. February 24, 2021, DOI: 10.1056/NEJMoa2101765
36. Walsh EE, Frenck RW Jr, Falsey AR, Kitchin N, Absalon J, Gurtman A, Lockhart S, Neuzil K, Mulligan MJ, Bailey R, Swanson KA, Li P, Koury K, Kalina W, Cooper D, Fontes-Garfias C, Shi PY, Türeci Ö, Tompkins KR, Lyke KE, Raabe V, Dormitzer PR, Jansen KU, Şahin U, Gruber WC. Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates. N Engl J Med. 2020 Dec 17;383(25):2439-2450. doi: 10.1056/NEJMoa2027906. Epub 2020 Oct 14. PMID: 33053279; PMCID: PMC7583697.
37. Polack FP, *et al*. C4591001 Clinical Trial Group. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020 Dec 31;383(27):2603-2615. doi: 10.1056/NEJMoa2034577. Epub 2020 Dec 10. PMID: 33301246; PMCID: PMC7745181.
38. Johns Hopkins University Coronavirus Resource Center. COVID-19 dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University. 2020, CDC, WHO, Khan T, Agnihotri K, Tripathi A, Mukherjee S, Agnihotri N, Gupta G. COVID-19: A Worldwide, Zoonotic, Pandemic Outbreak. Altern Ther Health Med. 2020 Aug;26(S2):56-64. PMID: 32412918
39. IPAK Report 2021-1. 2021. Post-vaccination Death Causality Likely Given Temporal Distribution of Deaths Following COVID19 Vaccinations. Interim results.
40. Tinari S. The EMA covid-19 data leak, and what it tells us about mRNA instability BMJ 2021; 372 :n627 doi:10.1136/bmj.n627

41. Corbett, K.S., Edwards, D.K., Leist, S.R. *et al.* SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness. *Nature* 586, 567–571 (2020). https://doi.org/10.1038/s41586-020-2622-0.
42. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups/allergies.html
43. https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-manufacturer%2Fpfizer%2Freactogenicity.html
44. https://www.docdroid.net/xq0Z8B0/pfizer-report-japanese-government-pdf#page=17
45. Yuyang Lei, *et al.*, SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE2. Circulation Research. April 30, 2021.
46. Gretchen Vogel, Jennifer Couzin-Frankel. Israel reports link between rare cases of heart inflammation and COVID-19 vaccination in young men. Jun. 1, 2021.
47. Johns Hopkins University of Medicine Coronavirus Resource Centre. Vaccine Research and Development. 2021
48. https://www.cdc.gov/vaccines/
49. https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html
50. https://clinicaltrials.gov/ct2/show/NCT04368728
51. RW Malone, PL Felgner, IM Verma. Cationic liposome-mediated RNA transfection. Proceedings of the National Academy of Sciences (PNAS) 86 (16), 6077-6081.
52. Wolff JA, Malone RW, et al. Direct gene transfer into mouse muscle in vivo. Science. 1990;247(4949 Pt 1):1465-8.
53. Siripanthong B, Nazarian S, Muser D, et al. Recognizing COVID-19-related myocarditis: The possible pathophysiology and proposed guideline for diagnosis and management. *Heart Rhythm*. 2020;17(9):1463-1471. doi:10.1016/j.hrthm.2020.05.001
54. Mele D, Flamigni F, Rapezzi C, Ferrari R. Myocarditis in COVID-19 patients: current problems. Intern Emerg Med. 2021 Jan 23:1–7. doi: 10.1007/s11739-021-02635-w. Epub ahead of print. PMID: 33484452; PMCID: PMC7823176.
55. Liang Chen, Xiangjie Li, Mingquan Chen, Yi Feng, Chenglong Xiong, The ACE2 expression in human heart indicates new potential mechanism of heart injury among patients infected with SARS-CoV-2, *Cardiovascular Research*, Volume 116, Issue 6, 1 May 2020, Pages 1097–1100, https://doi.org/10.1093/cvr/cvaa078.

56. Shant Der Sarkissian, Justin L. Grobe, Lihui Yuan, Dhruv R. Narielwala, Glenn A. Walter, Michael J. Katovich, Mohan K. Raizada. Cardiac Overexpression of Angiotensin Converting Enzyme 2 Protects the Heart From Ischemia-Induced Pathophysiology. Hypertension. 2008;51:712-718.
57. Peretto G, Sala S, Rizzo S, De Luca G, Campochiaro C, Sartorelli S, Benedetti G, Palmisano A, Esposito A, Tresoldi M, Thiene G, Basso C, Della Bella P. Arrhythmias in myocarditis: State of the art. Heart Rhythm. 2019 May;16(5):793-801. doi: 10.1016/j.hrthm.2018.11.024. Epub 2018 Nov 24. PMID: 30476544.
58. Bishwas Chamling, Volker Vehof, Stefanos Drakos, Mareike Weil, Philipp Stalling, Christian Vahlhaus, Patrick Mueller, Michael Bietenbeck, Holger Reinecke, Claudia Meier & Ali Yilmaz. Occurrence of acute infarct-like myocarditis following COVID-19 vaccination: just an accidental co-incidence or rather vaccination-associated autoimmune myocarditis? Clinical Research in Cardiology, Received: 25 June 2021 / Accepted: 28 July 2021. https://doi.org/10.1007/s00392-021-01916-w.
59. Colson P, Rolain JM, Lagier JC, Brouqui P, Raoult D. Chloroquine and hydroxychloroquine as available weapons to fight COVID-19. Int J Antimicrob Agents. 2020 Apr;55(4):105932. doi: 10.1016/j.ijantimicag.2020.105932. Epub 2020 Mar 4. PMID: 32145363; PMCID: PMC7135139.
60. Meo SA, Klonoff DC, Akram J. Efficacy of chloroquine and hydroxychloroquine in the treatment of COVID-19. Eur Rev Med Pharmacol Sci. 2020 Apr;24(8):4539-4547. doi: 10.26355/eurrev_202004_21038. PMID: 32373993.
61. Ibáñez S, Martínez O, Valenzuela F, Silva F, Valenzuela O. Hydroxychloroquine and chloroquine in COVID-19: should they be used as standard therapy? Clin Rheumatol. 2020 Aug;39(8):2461-2465. doi: 10.1007/s10067-020-05202-4. Epub 2020 Jun 3. PMID: 32495226; PMCID: PMC7267470.
62. N, Esposito S. Chloroquine or hydroxychloroquine for prophylaxis of COVID-19. Lancet Infect Dis. 2020 Oct;20(10):1118. doi: 10.1016/S1473-3099(20)30296-6. Epub 2020 Apr 17. PMID: 32311322; PMCID: PMC7164862.
63. Ferner RE, Aronson JK. Chloroquine and hydroxychloroquine in covid-19. BMJ. 2020 Apr 8;369:m1432. doi: 10.1136/bmj.m1432. PMID: 32269046.; Hernandez AV, Roman YM, Pasupuleti V, Barboza JJ, White CM. Hydroxychloroquine or Chloroquine for Treatment or Prophylaxis of COVID-19: A Living Systematic Review. Ann Intern Med. 2020 Aug 18;173(4):287-296. doi: 10.7326/M20-2496. Epub 2020 May 27. PMID: 32459529.;

64. Shah S, Das S, Jain A, Misra DP, Negi VS. A systematic review of the prophylactic role of chloroquine and hydroxychloroquine in coronavirus disease-19 (COVID-19). Int J Rheum Dis. 2020 May;23(5):613-619. doi: 10.1111/1756-185X.13842. Epub 2020 Apr 27. PMID: 32281213; PMCID: PMC7262257.
65. Rizzo E. Ivermectin, antiviral properties and COVID-19: a possible new mechanism of action. Naunyn Schmiedebergs Arch Pharmacol. 2020 Jul;393(7):1153-1156. doi: 10.1007/s00210-020-01902-5. Epub 2020 May 27. PMID: 32462282; PMCID: PMC7251046.
66. Heidary F, Gharebaghi R. Ivermectin: a systematic review from antiviral effects to COVID-19 complementary regimen. J Antibiot (Tokyo). 2020 Sep;73(9):593-602. doi: 10.1038/s41429-020-0336-z. Epub 2020 Jun 12. PMID: 32533071; PMCID: PMC7290143.
67. Sharun K, Dhama K, Patel SK, Pathak M, Tiwari R, Singh BR, Sah R, Bonilla-Aldana DK, Rodriguez-Morales AJ, Leblebicioglu H. Ivermectin, a new candidate therapeutic against SARS-CoV-2/COVID-19. Ann Clin Microbiol Antimicrob. 2020 May 30;19(1):23. doi: 10.1186/s12941-020-00368-w. PMID: 32473642; PMCID: PMC7261036.
68. Shih RD, Johnson HM, Maki DG, Hennekens CH. Hydroxychloroquine for Coronavirus: The Urgent Need for a Moratorium on Prescriptions. Am J Med. 2020 Sep;133(9):1007-1008. doi: 10.1016/j.amjmed.2020.05.005. Epub 2020 Jun 2. PMID: 32502485; PMCID: PMC7265864.
69. Lam S, Lombardi A, Ouanounou A. COVID-19: A review of the proposed pharmacological treatments. Eur J Pharmacol. 2020 Nov 5;886:173451. doi: 10.1016/j.ejphar.2020.173451. Epub 2020 Aug 6. PMID: 32768505; PMCID: PMC7406477.
70. McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2021 Jan;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. Epub 2020 Aug 7. PMID: 32771461; PMCID: PMC7410805.
71. McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin

JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020 Dec 30;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997.

72. McCullough PA, Vijay K. SARS-CoV-2 infection and the COVID-19 pandemic: a call to action for therapy and interventions to resolve the crisis of hospitalization, death, and handle the aftermath. Rev Cardiovasc Med. 2021 Mar 30;22(1):9-10. doi: 10.31083/j.rcm.2021.01.301. PMID: 33792243.
73. Ioannidis, J.P. (2021), Reconciling estimates of global spread and infection fatality rates of COVID-19: an overview of systematic evaluations. Eur J Clin Invest. Accepted Author Manuscript e13554. https://doi.org/10.1111/eci.13554
74. Noh J, Danuser G (2021) Estimation of the fraction of COVID-19 infected people in U.S. states and countries worldwide. PLoS ONE 16(2): e0246772. https://doi.org/10.1371/journal.pone.0246772
75. Toor SM, Saleh R, Sasidharan Nair V, Taha RZ, Elkord E. T-cell responses and therapies against SARS-CoV-2 infection. Immunology. 2021 Jan;162(1):30-43. doi: 10.1111/imm.13262. Epub 2020 Oct 27. PMID: 32935333; PMCID: PMC7730020.
76. Robbiani DF, *et al*. Convergent antibody responses to SARS-CoV-2 in convalescent individuals. Nature. 2020 Aug;584(7821):437-442. doi: 10.1038/s41586-020-2456-9. Epub 2020 Jun 18. PMID: 32555388; PMCID: PMC7442695.
77. Sun B, *et al*. Kinetics of SARS-CoV-2 specific IgM and IgG responses in COVID-19 patients. Emerg Microbes Infect. 2020 Dec;9(1):940-948. doi: 10.1080/22221751.2020.1762515. PMID: 32357808; PMCID: PMC7273175.
78. Le Bert N, *et al*. SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls. Nature. 2020 Aug;584(7821):457-462. doi: 10.1038/s41586-020-2550-z. Epub 2020 Jul 15. PMID: 32668444.
79. Mateus J, *et al*. Selective and cross-reactive SARS-CoV-2 T cell epitopes in unexposed humans. Science. 2020 Oct 2;370(6512):89-94. doi: 10.1126/science.abd3871. Epub 2020 Aug 4. PMID: 32753554; PMCID: PMC7574914.
80. Lipsitch M, Grad YH, Sette A, Crotty S. Cross-reactive memory T cells and herd immunity to SARS-CoV-2. Nat Rev Immunol. 2020 Nov;20(11):709-713. doi: 10.1038/s41577-020-00460-4. Epub 2020 Oct 6. PMID: 33024281; PMCID: PMC7537578.

81. Corbett, K.S., Edwards, D.K., Leist, S.R. *et al.* SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness. *Nature* 586, 567–571 (2020). https://doi.org/10.1038/s41586-020-2622-0.
82. Zimmermann P, Curtis N. Factors That Influence the Immune Response to Vaccination. Clin Microbiol Rev. 2019 Mar 13;32(2):e00084-18. doi: 10.1128/CMR.00084-18. PMID: 30867162; PMCID: PMC6431125.
83. Orenstein WA, Bernier RH, Dondero TJ, Hinman AR, Marks JS, Bart KJ, Sirotkin B. Field evaluation of vaccine efficacy. Bull World Health Organ. 1985;63(6):1055-68. PMID: 3879673; PMCID: PMC2536484.
84. Furman D, Davis MM. New approaches to understanding the immune response to vaccination and infection. Vaccine. 2015 Sep 29;33(40):5271-81. doi: 10.1016/j.vaccine.2015.06.117. Epub 2015 Jul 29. PMID: 26232539; PMCID: PMC4581990.
85. Vaidyanathan R, O'Connell RP, Deo M, et al. The ionic bases of the action potential in isolated mouse cardiac Purkinje cell. Heart Rhythm. 2013;10(1):80-87. doi:10.1016/j.hrthm.2012.10.002.
86. Singer ME, Taub IB, Kaelber DC. Risk of Myocarditis from COVID-19 Infection in People Under Age 20: A Population-Based Analysis. medRxiv [Preprint]. 2021 Jul 27:2021.07.23.21260998. doi: 10.1101/2021.07.23.21260998. PMID: 34341797; PMCID: PMC8328065.
87. Myocarditis and Pericarditis After Vaccination for COVID-19. JAMA Published online August 4, 2021. American Medical Association.
88. Kim HW, Jenista ER, Wendell DC, Azevedo CF, Campbell MJ, Darty SN, Parker MA, Kim RJ. Patients With Acute Myocarditis Following mRNA COVID-19 Vaccination. JAMA Cardiol. 2021 Jun 29:e212828. doi: 10.1001/jamacardio.2021.2828. Epub ahead of print. PMID: 34185046; PMCID: PMC8243258.
89. Shaw KE, Cavalcante JL, Han BK, Gössl M. Possible Association Between COVID-19 Vaccine and Myocarditis: Clinical and CMR Findings. JACC Cardiovasc Imaging. 2021 Jun 16:S1936-878X(21)00485-X. doi: 10.1016/j.jcmg.2021.06.002. Epub ahead of print. PMID: 34246586; PMCID: PMC8245050.
90. Mei R, Raschi E, Forcesi E, Diemberger I, De Ponti F, Poluzzi E. Myocarditis and pericarditis after immunization: Gaining insights through the Vaccine Adverse Event Reporting System. Int J Cardiol. 2018 Dec 15;273:183-186. doi: 10.1016/j.ijcard.2018.09.054. Epub 2018 Sep 14. PMID: 30236504.

91. Das BB, Moskowitz WB, Taylor MB, Palmer A. Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination: What Do We Know So Far? Children (Basel). 2021 Jul 18;8(7):607. doi: 10.3390/children8070607. PMID: 34356586; PMCID: PMC8305058.Hudson B, Mantooth R, DeLaney M. Myocarditis and pericarditis after vaccination for COVID-19. J Am Coll Emerg Physicians Open. 2021 Jul 26;2(4):e12498. doi: 10.1002/emp2.12498. PMID: 34337595; PMCID: PMC8313036.
92. Luk A, Clarke B, Dahdah N, Ducharme A, Krahn A, McCrindle B, Mizzi T, Naus M, Udell JA, Virani S, Zieroth S, McDonald M. Myocarditis and Pericarditis following COVID-19 mRNA Vaccination: Practical Considerations for Care Providers. Can J Cardiol. 2021 Aug 7:S0828-282X(21)00624-3. doi: 10.1016/j.cjca.2021.08.001. Epub ahead of print. PMID: 34375696; PMCID: PMC8349442
93. Vidula MK, Ambrose M, Glassberg H, Chokshi N, Chen T, Ferrari VA, Han Y. Myocarditis and Other Cardiovascular Complications of the mRNA-Based COVID-19 Vaccines. Cureus. 2021 Jun 10;13(6):e15576. doi: 10.7759/cureus.15576. PMID: 34277198; PMCID: PMC8270057
94. Dionne A, Sperotto F, Chamberlain S, Baker AL, Powell AJ, Prakash A, Castellanos DA, Saleeb SF, de Ferranti SD, Newburger JW, Friedman KG. Association of Myocarditis With BNT162b2 Messenger RNA COVID-19 Vaccine in a Case Series of Children. JAMA Cardiol. 2021 Aug 10:e213471. doi: 10.1001/jamacardio.2021.3471. Epub ahead of print. PMID: 34374740; PMCID: PMC8356143.
95. Montgomery J, Ryan M, Engler R, Hoffman D, McClenathan B, Collins L, Loran D, Hrncir D, Herring K, Platzer M, Adams N, Sanou A, Cooper LT Jr. Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military. JAMA Cardiol. 2021 Jun 29:e212833. doi: 10.1001/jamacardio.2021.2833. Epub ahead of print. PMID: 34185045; PMCID: PMC8243257.
96. Imazio M, Klingel K, Kindermann I, Brucato A, De Rosa FG, Adler Y, De Ferrari GM. COVID-19 pandemic and troponin: indirect myocardial injury, myocardial inflammation or myocarditis? Heart. 2020 Aug;106(15):1127-1131. doi: 10.1136/heartjnl-2020-317186. Epub 2020 Jun 4. PMID: 32499236.
97. Fatmi SS, Basso R, Liaqat A, Tariq F, Swamiappan R. COVID-19 Myocarditis: Rationale for Early Diagnosis and Intervention. Cureus. 2021 Jul 19;13(7):e16494. doi: 10.7759/cureus.16494. PMID: 34430109; PMCID: PMC8373509.

98. Salah HM, Mehta JL. COVID-19 Vaccine and Myocarditis. Am J Cardiol. 2021 Jul 12:S0002-9149(21)00639-1. doi: 10.1016/j.amjcard.2021.07.009. Epub ahead of print. PMID: 34399967; PMCID: PMC8272967.

99. Singh B, Kaur P, Cedeno L, Brahimi T, Patel P, Virk H, Shamoon F, Bikkina M. COVID-19 mRNA Vaccine and Myocarditis. Eur J Case Rep Intern Med. 2021 Jun 14;8(7):002681. doi: 10.12890/2021_002681. PMID: 34268277; PMCID: PMC8276934.

100. Bozkurt B, Kamat I, Hotez PJ. Myocarditis With COVID-19 mRNA Vaccines. Circulation. 2021 Aug 10;144(6):471-484. doi: 10.1161/CIRCULATIONAHA.121.056135. Epub 2021 Jul 20. PMID: 34281357; PMCID: PMC8340726.

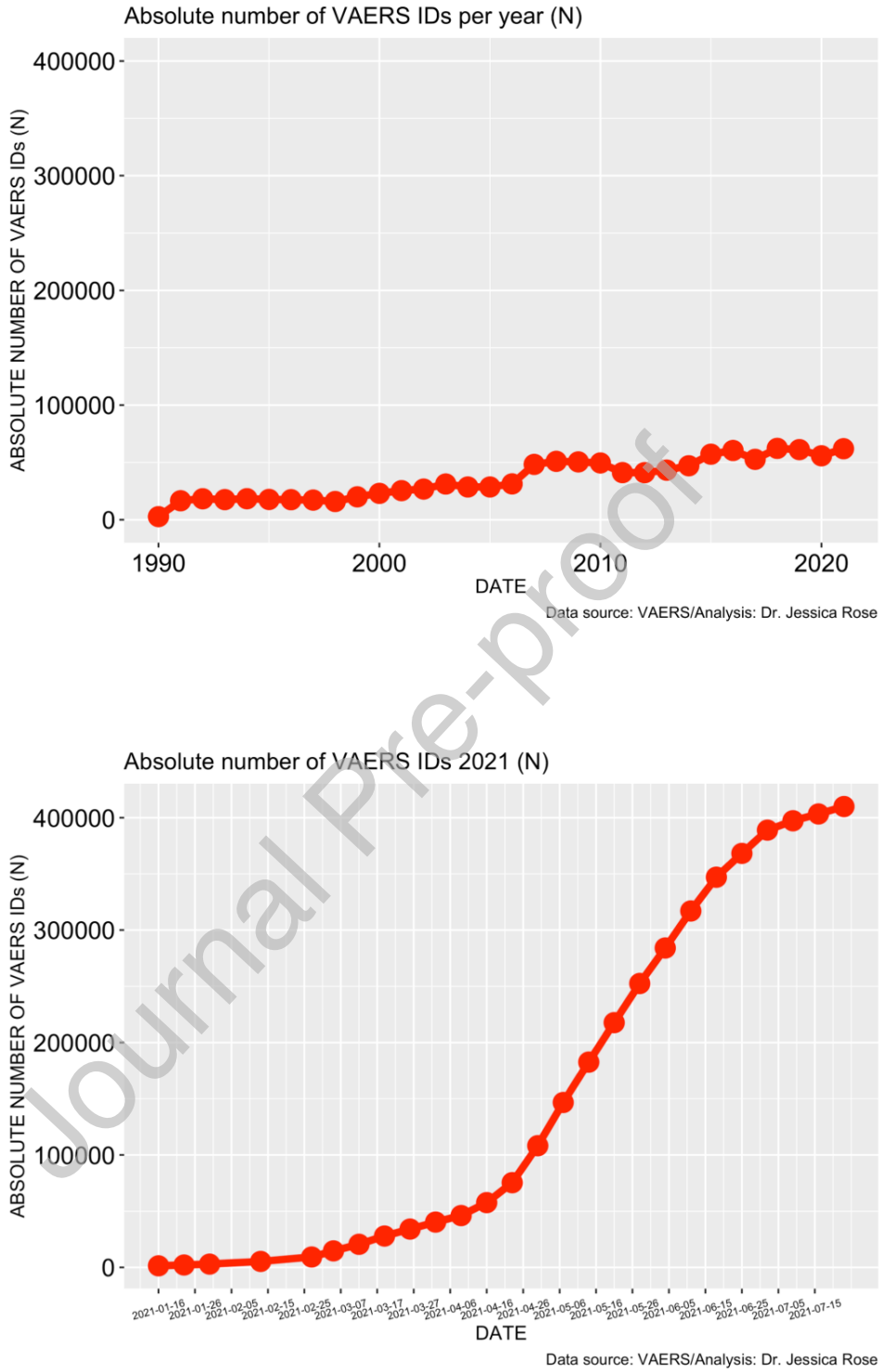

Figure 1: Time series plots – all VAERS reports in association with all vaccines administered to the U.S. population by year (left) and VAERS reports in association with COVID-19 products for 2021 (right).

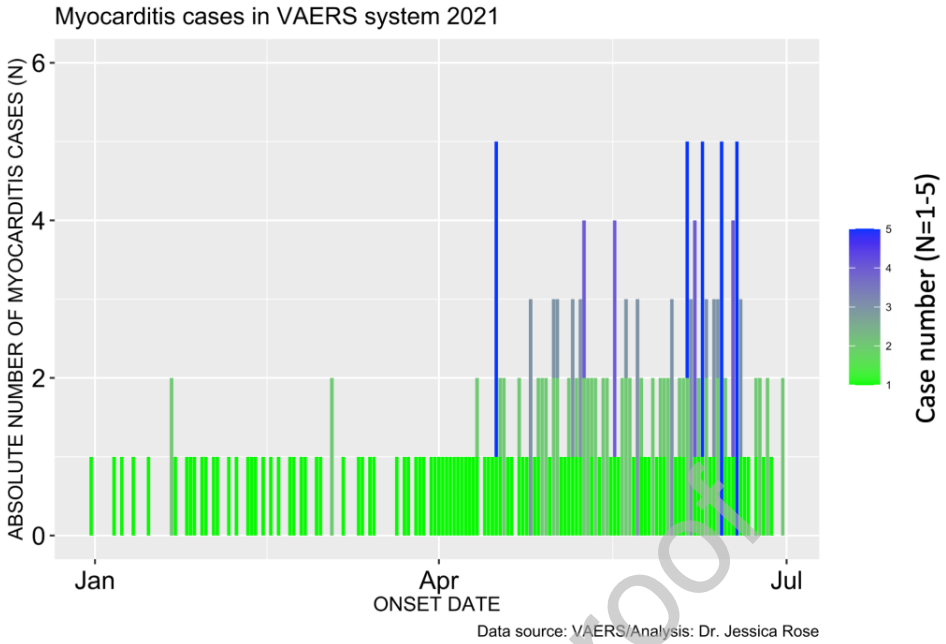

Figure 2: Bar plot showing the number myocarditis cases reported from January 1st to July 9th, 2021.

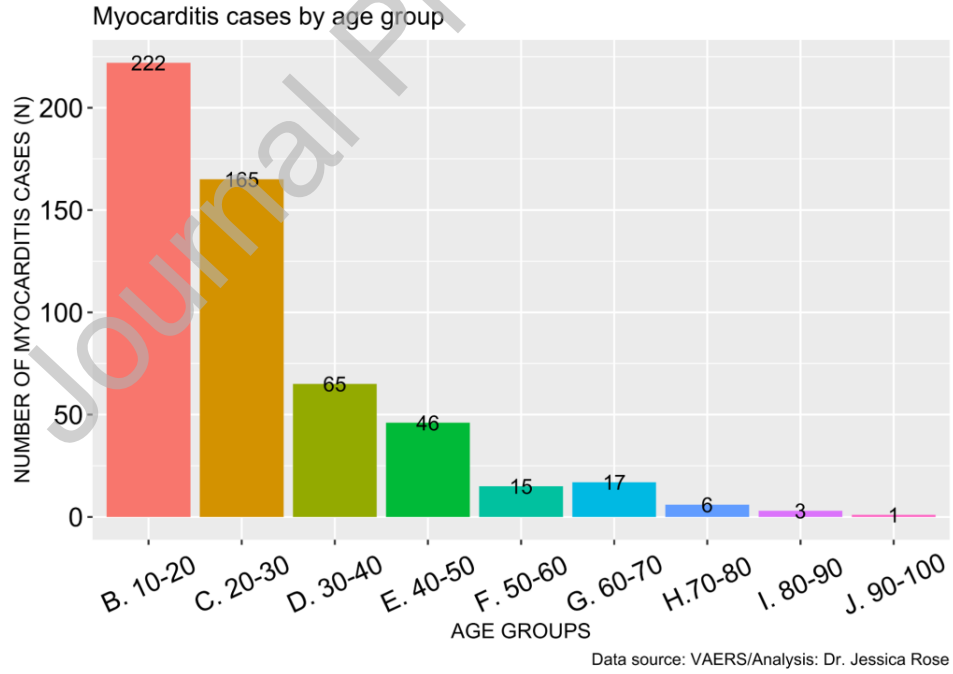

Figure 3: Histogram showing the number of reported VAERS cases of myocarditis by age group.

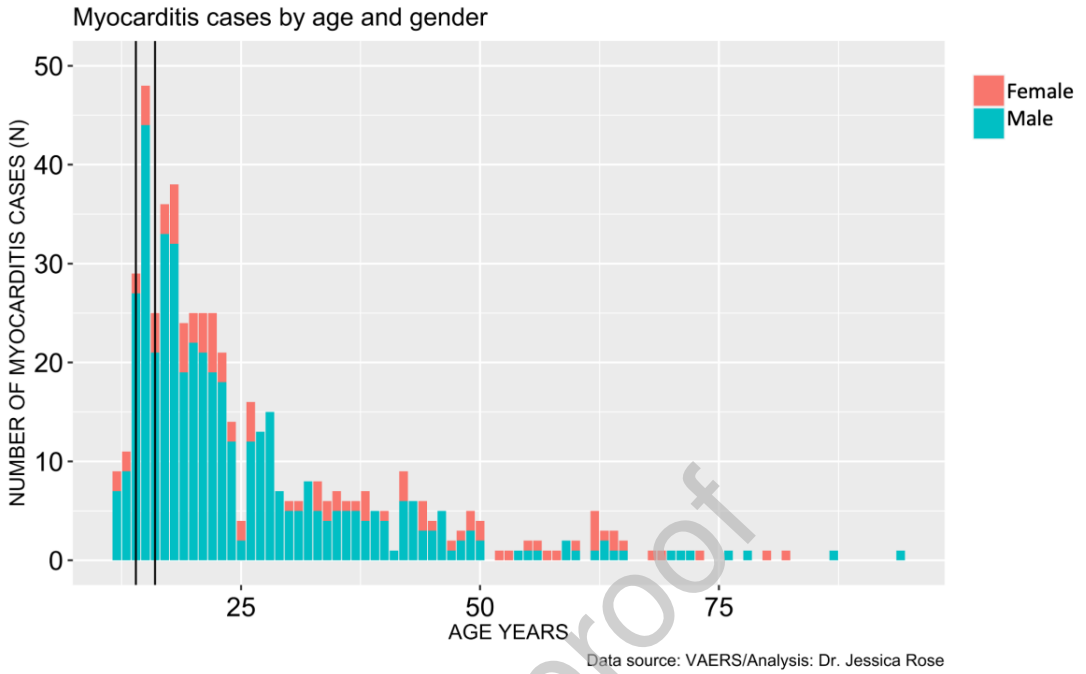

Figure 4: Histogram showing Myocarditis cases reported in VAERS following injection with COVID-19 products according to age and gender.

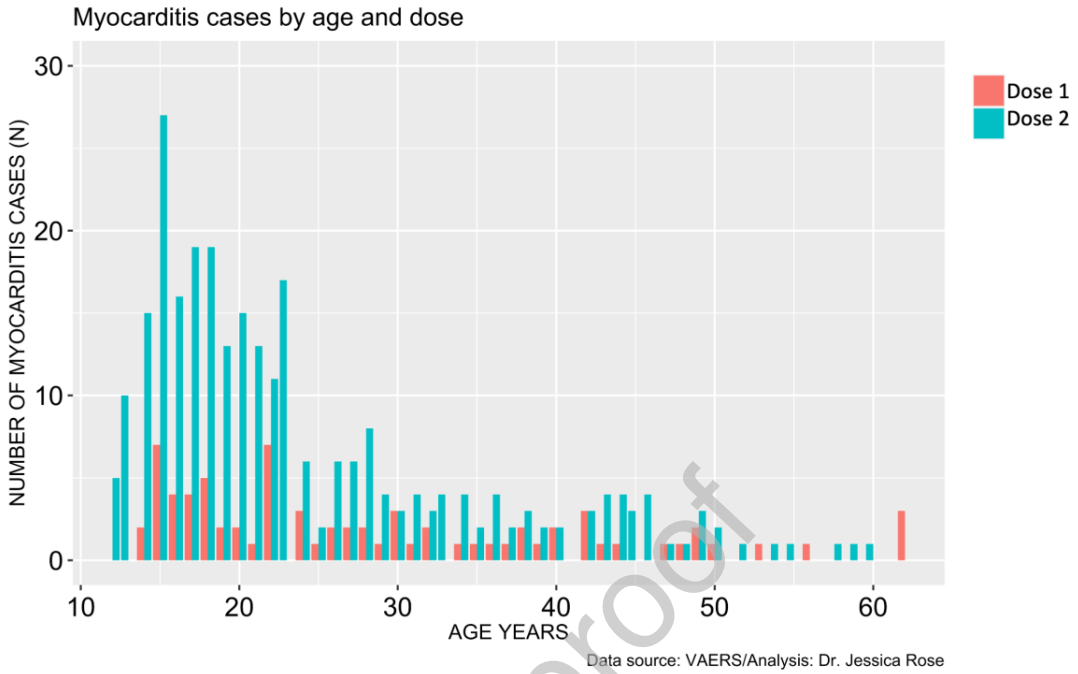

Figure 5: Histogram showing Myocarditis cases reported in VAERS following injection with COVID-19 products according to age and dose.

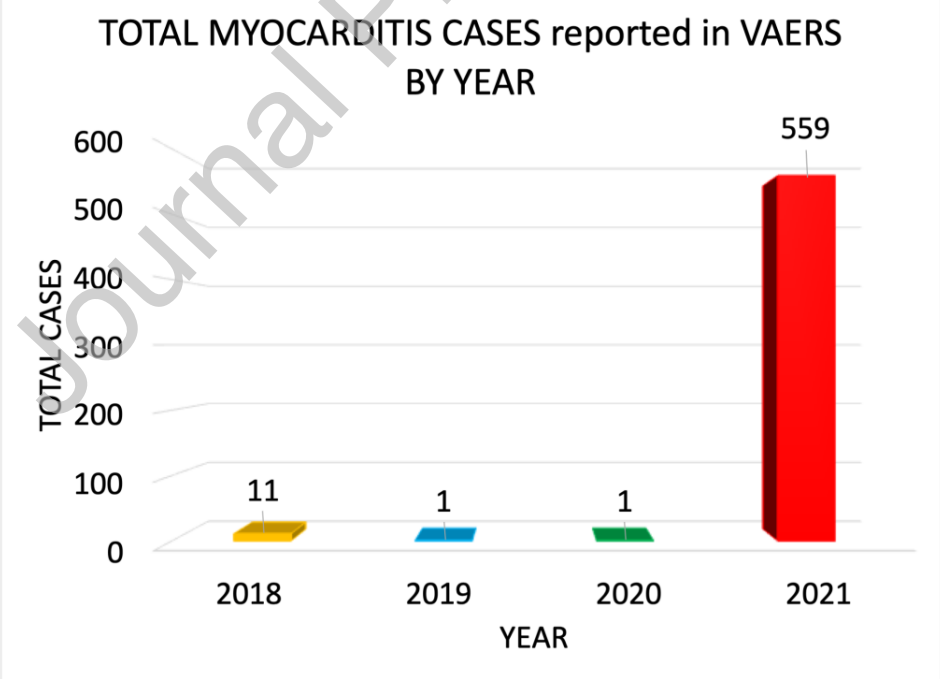

Figure 6: Bar plot showing Myocarditis cases reported in VAERS by year. *2021: up to and including July 9th, 2021.

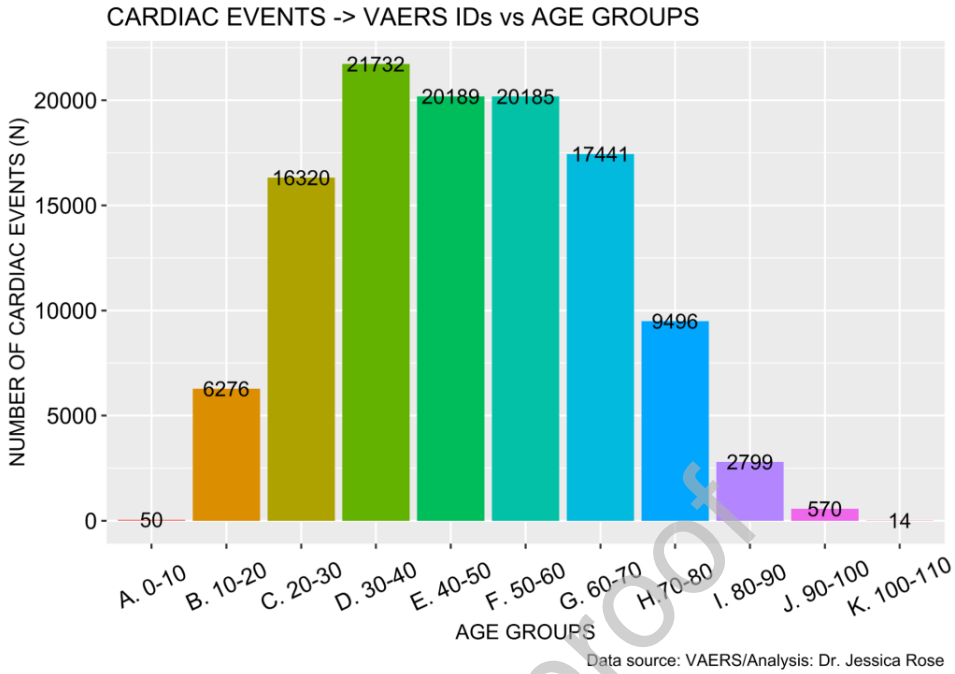

Figure 7: Histogram showing Cardiac cases reported in VAERS by year.

Table 1: Case rates of myocarditis per year based on estimated number of doses per year with respect to the population size for the season normalized to the number of doses administered per vaccine. *Population data extracted from Worldometer[9] and vaccine data extracted from Our World in Data[10] and CDC database[11]. [45,46,48]

Year	*Rate/million doses*
2018	0.067
2019	0.006
2020	0.024
2021	3.092

[9]https://www.worldometers.info
[10]https://ourworldindata.org/covid-vaccinations
[11] https://www.cdc.gov/vaccines/