COVID-19 Vaccines and Children:

A Scientist's Guide for Parents

by

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https://www.canadiancovidcarealliance.org/

EXECUTIVE SUMMARY

Pfizer BioNTech's COVID-19 mRNA vaccine has been *Authorized under an Interim Order* by Health Canada for use in Canadians as young as 12 years old, with mandatory commitments for the monitoring of long-term safety and efficacy. Authorization under an Interim Order means additional information is needed on the safety, efficacy, and quality of the vaccine, including in children and adolescents, to support the future full market approval and licensing of the vaccine.

There is some uncertainty regarding the long-term safety of Pfizer BioNTech's COVID-19 vaccine in all individuals, and especially in children, youth, and younger adults of child-bearing age. Indeed, some key safety studies appear to have been missed in the rush to roll out the vaccines, and more is being learned about the vaccines every day. For example, there was a previously wide-held assumption that vaccination with the mRNA vaccines is safe because it is a localized event in the body, with the vaccine remaining limited to the shoulder muscle following injection and triggering an immune response in the local lymph nodes. However, there is evidence that Pfizer's COVID-19 vaccine does not remain at the injection site. In fact, once injected, the vaccine contents appear to travel extensively throughout the body, to the brain and other sensitive tissues, such as bone marrow, spleen, liver, adrenal glands, ovaries *etc.* Whether these body sites are involved in producing the spike protein is not known, as this was never studied. Nonetheless, new data have been published that, following vaccination with the Moderna vaccine (an mRNA vaccine very similar to Pfizer's mRNA vaccine), the spike protein can enter the circulatory system. Presumably, this means the spike protein can travel extensively throughout the body. It is important to understand which organs are producing the spike protein, what factors result in the spike protein entering the circulation, how long the spike protein circulates, and in which body fluids (*e.g.*, semen, saliva, breast milk, urine) the spike protein is present. This information is incredibly important because recent data have come to light that the spike protein is "biologically active". This means that the spike protein is not just an antigen that is recognized by the immune system as being foreign. It means that the spike protein, itself, can interact with receptors throughout the body, called ACE2 receptors, potentially causing undesirable effects such as damage to the heart and cardiovascular system, blood clots, bleeding, and neurological effects. Although some might argue that the risk of the spike protein causing this type of damage is only a theoretical risk, when we are mass vaccinating a population of predominantly healthy people, including children, adolescents, and adults of child-bearing age, there is absolutely no room for avoidable error.

The current scientific uncertainties demand that the administration of Pfizer's COVID-19 vaccine to children, adolescents, and young adults of child-bearing age be paused until proper scientific studies that focus on the safety and pharmacokinetics and biodistribution of the vaccines and the vaccine-encoded spike protein can be conducted. Halting the vaccination can be done safely because:

- The risk of severe and potentially lethal COVID-19 in these specific populations is so low that we need to be very certain that risks associated with mass vaccination are not higher;
- Asymptomatic members of this population are not a substantial risk for passing COVID-19 to others; and

- There are effective early-treatment strategies for the very few children, adolescents, and young adults of child-bearing age who may be at risk of developing severe COVID-19, such as ivermectin, fluvoxamine, and budesonide.

It is not appropriate to use an "experimental" vaccine in a population group unless the benefit of vaccination exceeds the risk of vaccination in that population group. With risk of severe COVID-19 in children, adolescents, and young adults of child-bearing age already so low, the benefit of vaccinating these population groups with a vaccine for which neither the long-term safety nor efficacy is known cannot be concluded to exceed the risk. In other words, the risk of serious COVID-19 is so low in children, adolescents, and young adults of child-bearing age that the standards for safety must be set much higher for them.

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Who is Dr. Bridle?

I am an Associate Professor of Viral Immunology in the Department of Pathobiology at the University of Guelph in Canada. My research program focuses on the development of vaccines to prevent infectious diseases and treat cancers, as well as studying the body's immune response to viruses. I teach several courses at the undergraduate and graduate levels on the topics of immunology, virology, and cancer biology. The overall aim of my research efforts is to develop safe and effective new therapies for people. Indeed, one of my previous cancer therapies progressed into four human clinical trials. I am also involved in training Canada's next generation of multidisciplinary researchers, especially in vaccinology. I received funding from the Ontario Government (COVID-19 Rapid Research Fund, Ministry of Colleges and Universities) and Government of Canada (Pandemic Response Challenge Program, National Research Council of Canada) to develop vaccines against COVID-19. The scope of this research is limited to the pre-clinical realm and is years away from being ready for testing in a clinical trial. Since I do not hold any commercial interests, this is not considered a conflict of interest that would preclude me from publishing my research findings. If that were the case, most researchers could never comment on topics relevant to their area of expertise, because they receive funding in that area. Further, my laboratory's vaccine vectors also express the spike protein of SARS-CoV-2. As such, what I am presenting here affects my vaccines as much as anyone else's. I also hold numerous grants in support of my cancer research and basic viral immunology research programs, including, but not limited, to the Canadian Institutes for Health Research, Natural Sciences and Engineering Research Council of Canada, Canadian Cancer Society, and Cancer Research Society. Since the COVID-19 pandemic was declared, I have been actively involved in providing fact-based, balanced, scientific answers to questions posed by the public to help them make fully informed decisions. This has included ~150 media engagements ranging from radio shows, published articles, and appearances on televised news programs, spanning the local to international scope. I was also an invited keynote speaker for two international conferences that focused on COVID-19 and served as an invited member of several COVID-19-focused discussion panels. Vaccinology is a sub-discipline of immunology. I teach the value of high-quality, well-validated, robustly safety-tested vaccines and promote their use. I consider vaccines that have been developed on a foundation of sound science to be the most efficient type of medicine; they have cost-effectively saved millions of people from sickness and/or death. However, I am concerned that the risk-benefit profile of SARS-CoV-2 vaccines currently being used in Canada and elsewhere may not be appropriate for the mass immunization of children, youth, and young adults of child-bearing age. My scientific reasoning substantiated by the peer-reviewed literature is contained within this guide.

What is the Canadian COVID Care Alliance (CCCA)?

The CCCA is an alliance of independent Canadian scientists, physicians and other health professionals, committed to providing top-quality and balanced evidence-based information to

the Canadian public about COVID-19 so that hospitalizations can be reduced, lives can be saved, and our country can be safely restored as quickly as possible.

Disclaimer

The comments in this guide are mine alone and do not necessarily reflect the opinions held by my academic institution or the agencies funding my research program. Nevertheless, these comments have been vetted and supported by many like-minded researchers and physicians associated with the CCCA.

Preamble

Although I have tried to be reasonably comprehensive in my presentation of relevant facts about COVID-19 vaccines, I could have written much more; hundreds of pages, in fact. However, I feel that the current content represents the most important information that parents will need to make informed decisions about vaccinating their children. As children in Canada who are 12 and older can be vaccinated without parental consent, this guide also serves to share information and encourage open discussions between parents and their older children, so that the choice to consent or not consent is truly "informed". There will be many people who will challenge the content of this guide. I respect others' opinions and decisions. I simply ask for similar respect in return. I am a public servant providing information for which I have substantial expertise. It is being done from the perspective of having a genuine concern for the well-being of Canadian youth. I urge everyone to follow the weight of validated scientific data. I ask you to challenge information that is accompanied by loose claims of being 'data from on the ground' or 'data from the front lines', which often lack scientific rigor and a 'big picture' perspective, especially in an era of extensive social media censorship. Follow the weight of the validated data when deciding which evidence is relevant and reliable in your decision-making process.

Important note: many treasured colleagues from within and outside Canada have helped me piece together this story. Without them, we would not have made all the scientific links that are described in this guide. As such, **I can take only partial credit for this work**. Instead, I am fronting a larger group of physicians and researchers; consolidating our conversations and sharing of scientific articles into my own words. Sadly, many of these experts and professionals currently feel the need to remain anonymous to protect themselves from potentially career-ending reprisals when objective scientific evidence is presented publicly.

I have included some citations and links for important statements to show that they are backed by sound science. In many cases, there are other scientific articles that could have been referenced. However, the purpose of this document is not to provide an exhaustive list of references, but rather to provide sufficient evidence to support my concerns. My goal is not to prove that Canada's COVID-19 vaccines are unsafe, but to highlight the substantial uncertainties that exist in the current base of safety evidence and my consequent discomfort with the mass

vaccination of our youth. The proper scientific process dictates that the burden of proof of safety is on vaccine manufacturers and health protection agencies. Most importantly, a lack of proof of harm is not proof of safety.

I first presented some of the information that is in this guide during a radio interview on May 27, 2021. This was a truncated ~five-minute sound bite that triggered a public smear campaign, including a slanderous website, a fake Twitter account, and harassment in the workplace. Nobody involved in the establishment of the smear campaign reached out to me to respectfully discuss the science. As a result, I wrote, along with collaborators, a brief two-page 'guide' to provide some key scientific references. Here, I have assembled a much more comprehensive guide, written with the goal of trying to communicate complex scientific principles to a lay person, yet with sufficient scientific rigour to also address experts. As I have often done with presentations and articles over the past year, I have set up this guide to answer the most common questions that I have received from the public. It is with sincere concern, and with the best interests of my fellow Canadians in mind, that I present you with the information that follows.

The problem: COVID-19

"COVID-19" is a disease that develops in a subset of individuals infected with a virus that is known as 'severe acute respiratory syndrome-coronavirus-2' (SARS-CoV-2). In the vast majority of cases of SARS-CoV-2 infections, people remain healthy (*i.e.* they are 'asymptomatic') or develop only mild to moderate symptoms of illness. However, in some cases, severe, and potentially lethal pneumonia, occasionally accompanied by other inflammatory events causing bleeding, clotting and/or neurological impairment, can develop in people in high-risk demographics, which includes the frail elderly and individuals who are immunocompromised (*i.e.* their immune systems do not function properly). Many people who become infected with SARS-CoV-2 do not develop the disease called COVID-19.

What is 'herd immunity'?

The concept of 'herd immunity' means that a virus will stop spreading among a population once most of the people in that population acquire a protective immune response. Importantly, this does not require every person to become immune, just a large majority. There are two ways for people to acquire immunity to SARS-CoV-2 and thus avoid the debilitating effects of COVID-19:

1. Natural infection:

When infected with SARS-CoV-2, most people clear this virus from their body by mounting a robust, long-lasting immune response that targets multiple components of the virus[1]. These people will be protected from re-infection with the same variant of SARS-CoV-2 and, due to the breadth of a natural immune response, will also likely have some degree of protection against emerging new variants of SARS-CoV-2. Indeed, most people who have naturally acquired immunity should not be at risk of developing severe disease even if variants arise that can effectively bypass the narrower immunity conferred by COVID-19 vaccines that are focused on a single component of SARS-CoV-2, such as the spike protein[2]. Interestingly, a landmark study in Canada suggested that a majority of healthy adults in British Columbia have evidence of pre-existing or naturally acquired immunity to SARS-CoV-2[3].

2. Vaccination:

Vaccines that have undergone properly conducted preclinical studies and the full suite of clinical trials to ensure they are (i) effective; and (ii) have excellent short-term and long-term (*i.e.* a minimum of two years; preferably longer) safety profiles, can allow an individual to become immune to a virus without having to be naturally infected.

How do vaccines work?

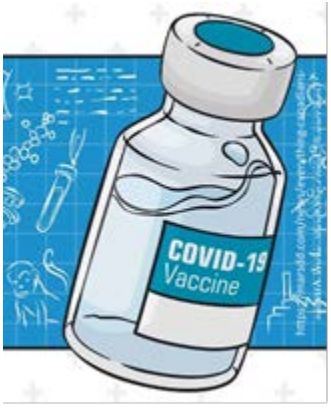
A successful vaccine must provide two things:

Thing 1: The virus or a piece(s) of the virus (*i.e.* a target for the immune system).

Thing 2: A danger signal (*i.e.* something that tells the person's immune system that the target it is seeing is dangerous and, therefore, worth responding to).

An effective vaccine simulates just enough of a natural infection, to trigger a person's body to develop an appropriate immune response without causing disease. Then, when the person becomes infected the first time by the natural virus, their body's immune system senses it is seeing the virus for the second time. This is because an immune response triggered by successful vaccination involves the body's development of 'immunological memory'. Therefore, the person's vaccine-primed immune response to the natural viral exposure will be faster and more robust, and the virus will be cleared without the person experiencing disease. Mass vaccination can accelerate progress of a population towards herd immunity.

How do Canada's COVID-19 vaccines work?



Canada currently has four COVID-19 vaccines that Health Canada has "Authorized by Interim Order". The Interim Orders enable the widespread deployment of the vaccines while the Phase 3 clinical studies (experiments in people) are being conducted. In the Phase 3 studies, all vaccine recipients must be followed for two years following the administration of the second vaccine dose. As long-term effects of the vaccine have yet to be understood, the vaccine is largely investigational. This is why the authorizations are "interim" and continued use is contingent on the collection of additional data from the Phase 3 studies, as well as other surveillance systems to assess the safety and effectiveness of the vaccines. Because the COVID-19 vaccines are being administered in Canada under experimental trial conditions, people receiving these vaccines should provide informed consent prior to being immunized. Informed consent demands that people be provided with all the known pros and cons, in an objective fashion and without undue pressure or coercion. This is a basic tenet of bioethics. Anyone administering a COVID-19 vaccine should be able to explain the benefits and risks based on the weight of the evidence provided in peer-reviewed, published scientific papers. Lay persons are encouraged to ask public health officials to explain the rationale for any statements made regarding COVID-19 vaccines and to have the sources of this information identified. Numbers in printed documents that do not contain citations do not necessarily reflect the robustness of the scientific literature.

The four COVID-19 vaccines currently being used in Canada include:

1. AstraZeneca/COVISHIELD vaccine (ChAdOx1-S):

These are two different names for the same vaccine (COVISHIELD is the brand name of AstraZeneca's vaccine that is manufactured by Verity Pharmaceuticals Inc. with the Serum Institute of India). Developed by AstraZeneca and Oxford University, the backbone of this vaccine is an adenovirus that does not cause disease in people. This adenovirus virus carries genetic material that provides instructions for a cell to manufacture a piece of SARS-CoV-2 (*i.e.,* the spike protein). When this adenovirus-based vaccine gets injected into the shoulder muscle, it is intended to infect cells and use the 'machinery' in these cells to manufacture small amounts of the SARS-CoV-2 spike protein. The SARS-CoV-2 spike protein and the adenovirus backbone provide the 'thing 1' and 'thing 2', respectively, that are needed to trigger an immune response.

Unfortunately, the rollout of the AstraZeneca vaccine in Canada proved to be a frustrating and complicated series of ever-changing, safety-triggered, recommendations given to a growing number of confused and distrusting members of the public. While many other countries paused their AstraZeneca vaccination programs to investigate safety issues related to potentially fatal blood clots, Canadians were told the AstraZeneca vaccine was safe for some population segments

and vaccinations with the AstraZeneca vaccine were initiated. After other countries practiced due diligence and confirmed that blood clotting was an adverse event associated with this vaccine, Canadians were then told that it was too unsafe for those under 55 years of age. Then Canadians between 40-55 years of age were told it was safe enough for them to use. Several weeks later, the message changed again, and the current messaging is that it is too unsafe to use as a first does in much of Canada. Millions of Canadians who received a single dose of this vaccine have since been wondering what to do. This highlights why the scientific method exists and why it should not be over-ridden by zealous public health officials. Safety testing should never be cut short. In many parts of Canada, the AstraZeneca vaccine is generally being used only for second doses for individuals who have had a first dose of the AstraZeneca vaccine and do not wish to have a second dose of another vaccine. The vaccine is irrelevant to Canadian children, youth, and young adults of child-bearing age, as it was never authorized for use in these population groups.

2. Janssen vaccine (Ad26.COV2.S):

This vaccine is made by Johnson & Johnson. Like the AstraZeneca vaccine, the Johnson & Johnson vaccine uses an adenovirus, albeit a different one. The way this vaccine works is similar to the AstraZeneca vaccine. After injection, cells infected with the adenovirus start to manufacture a spike protein that is very similar to that of the SARS-CoV-2 spike protein. There has been some public acknowledgement that this vaccine might also be associated with blood clots, and Health Canada has noted in their website notices of April 26th 2021 to healthcare professionals that "[v]ery rare cases of thrombosis in combination with thrombocytopenia, in some cases accompanied by bleeding, have been observed following vaccination with Janssen COVID-19 vaccine. A causal relationship with the vaccine is considered plausible." In considering the request for the Janssen vaccine to be Authorized Under Interim Order, Health Canada yet again acknowledged that "[i]mportant limitations of the data at this time include the lack of information on the long-term safety and effectiveness of the vaccine, interactions with other vaccines, and the lack of data in sub-populations (*e.g.* pregnant/breastfeeding women, pediatric population <18 years of age, patients with autoimmune or inflammatory disorders, immunocompromised patients and frail patients with comorbidities)." At the timing of writing this article, this vaccine has not been authorized for use in Canadian children, youth, and young adults of child-bearing age.

3. Pfizer BioNTech vaccine (BNT162b2):

This vaccine relies on technology that, prior to the COVID-19 pandemic, was not previously used in humans, except in small-scale clinical trials (such as a clinical trial of a rabies mRNA vaccine)[4]. The backbone of the Pfizer BioNTech vaccine is a lipid nanoparticle (a small bubble of fat). Inside the nanoparticle is a 'messenger ribonucleic acid' (mRNA). This is a tiny piece of genetic material that provides the instructions for a cell to manufacture a modified version of the SARS-CoV-2 spike protein. When these nanoparticles are injected into the body, they are

intended to fuse with cells with which they come into contact. When this happens, the mRNA migrates from the lipid nanoparticle and into the cell and the cell 'machinery' then uses this mRNA 'blueprint' to manufacture the modified version of the SARS-CoV-2 spike protein. This protein is the 'thing 1' that provides one of the two signals required for the immune system to become activated. It is not entirely clear what provides 'thing 2'. However, mRNA vaccines promote inflammation that can cause injury to normal tissue. When cells are injured, they release 'danger signals'. This might be what is providing the second signal ('thing 2') needed to induce an immune response.

Pfizer's vaccine has been associated with anaphylactic reactions in a small subset of individuals. These are serious allergic reactions that can be life-threatening. At the time of writing this guide, **the Pfizer vaccine is the only one that has received Authorization under Interim Order for Canadian children and adolescents 12 to 15 years of age.** In its decision-making process, Health Canada declared; "Health Canada has conducted a rigorous scientific review of the available medical evidence to assess the safety of the Pfizer-BioNTech COVID-19 vaccine. No major safety concerns have been identified in the data that we reviewed" [emphasis added]. Health Canada also acknowledged that "One limitation of the data at this time is the lack of information on the long-term safety and efficacy of the vaccine. The identified limitations are managed through labelling and the Risk Management Plan. The Phase 3 Study is ongoing and will continue to collect information on the long-term safety and efficacy of the vaccine. There are post-authorization commitments for monitoring the long-term safety and efficacy of Pfizer-BioNTech COVID-19 vaccine." Specifically related to the authorization for adolescents 12 to 15 years of age, "Health Canada declared, Health Canada has placed terms and conditions on this authorization requiring Pfizer-BioNTech to continue providing information to Health Canada on the safety, efficacy and quality of the vaccine in this younger age group to ensure its benefits continue to be demonstrated once it is on the market."

4. Moderna vaccine (mRNA 1273 SARS-CoV-2):

The Moderna vaccine also is an mRNA-based vaccine and, therefore, works the same way as Pfizer's COVID-19 vaccine. This vaccine has also been associated with anaphylactic reactions in a small subset of individuals. On June 7th 2021, Moderna had filed an application to extend the Authorization under an Interim Order to adolescents aged 12 to 17 years. At the time of writing this guide, Health Canada had not issued its decision.

None of Canada's COVID-19 vaccines can, in and of themselves, infect people with the SARS-CoV-2 virus, per se. Rather, these vaccines trigger the cells in a person's own body to manufacture one of the proteins that is a component part of SARS-CoV-2, and all the vaccines cause a person to make a modified version of the spike protein from SARS-CoV-2. The AstraZeneca vaccine contains the manufacturing blueprint for the exact same spike protein as is found on SARS-CoV-2. In contrast, the other three vaccines in use in Canada contain the manufacturing blueprint for a modified version that scientists refer to as the 'prefusion-stabilized spike'. All four vaccines are

designed to use the body's internal capability to manufacture the spike protein to then trigger the body's immune response.

What are the known serious adverse events that are associated with COVID-19 vaccines?

Using the United States Vaccine Adverse Event Reporting System (U.S. VAERS), as of June 11th 2021, the 20 most frequently reported adverse events (presented in descending order) were headache, pyrexia (fever), fatigue, chills, pain, nausea, dizziness, pain in extremity, injection site pain, myalgia (muscle pain), injection site erythema (redness), arthralgia (joint stiffness), pruritus (itching), rash, dyspnoea (difficulty breathing), injection site swelling, injection site pruritus (itching), vomiting, and asthenia (weakness). These side effects are common side effects and are similar to those reported in the Phase 3 clinical trials. Although these symptoms can be severe in some people and can result in an inability to perform daily activities, they usually subside over one to three days.

The mRNA vaccines (Pfizer and Moderna) can, in rare cases, cause anaphylaxis. Since this can be potentially fatal, these vaccines are often administered in special vaccine clinics that are staffed with personnel trained to treat people who may experience anaphylactic shock. The reason this problem is thought to be limited to the mRNA vaccines is likely due to a pre-existing allergy against something present in the liposome nanoparticles (the small bubble of fat) that are the part of the vaccine that envelopes the mRNA material. One of the liposome ingredients that might be the culprit is polyethylene glycol (PEG).

Based on data from international regulatory agencies (such as the Norwegian Medicines Agency), the adenovirus-based vaccines (*i.e.* AstraZeneca and Janssen) have been implicated in causing a very serious type of blood clot (a cerebral venous sinus thrombosis) that is simultaneously associated with a low platelet count and bleeding following vaccination. This is one of the reasons the AstraZeneca vaccine has largely been suspended for use in Canada, with the exception of use for second doses in those who received the AstraZeneca as their first dose and wish to stay with the same vaccine brand.

Are there other serious adverse events associated with COVID-19 vaccines that are being investigated?

Side effects that are rarer, including those that are serious or life-threatening, are still being learned about. For example, the United States Centers for Disease Control and Prevention (CDC) announced, only on June 11th 2021, that an Emergency Meeting would be held on June 18th 2021 to discuss reports of inflammation of the heart resulting from use of the Pfizer and Moderna vaccines in young males 16 to 24 years of age. It has been approximately six months since the vaccines were authorized under an emergency use in the U.S., and only now is this

association being recognized. There are many reasons why it is difficult to identify serious side effects that are rare or that occur only over a longer period of time or in a specific population group or sex. These difficulties are described below.

Difficulty #1: Too Soon to Tell for Sure

Pfizer and Moderna each initiated large, Phase 3 trials that were randomized, double-blind, and placebo-controlled. The placebo group is important because it serves as the reference group and helps in the interpretation of side effects experienced in the vaccine group. At the time that the vaccines were granted emergency use authorization, each company had safety and efficacy data for an average of only two months following the administration of the second vaccine dose; in the study in adolescents, most subjects had safety and efficacy data for either one or two months. According to the original protocols, every individual in the study is supposed to be followed for a total of two years following their second dose.

Difficulty #2: Abandoning the Control Group

The vaccines have been authorized under emergency use in many key countries, globally; and fear-based pressures imposed by public health agencies to vaccinate everyone has triggered study participants to want to know which study group they had been allocated to, so that those in the placebo group could be vaccinated. The studies have therefore been unblinded, meaning there is no longer a placebo group. This means that a rigorous assessment of safety in the context of a well-controlled clinical study is no longer possible, and there must be increased reliance on vaccine post-deployment, passive surveillance systems. Of course, this, itself, is challenging, given that there is uncertainty in both the numerator (the number of vaccine-related adverse events) and the denominator (the number that is typical for that event, otherwise referred to as the "background incidence" of the event). Moreover, it is extremely difficult to prove definitively that an event is caused by (and not just associated with) vaccination when using passive surveillance systems.

Difficulty #3: Under-Reporting of Adverse Events

The problem with passive adverse event reporting systems, which is the type of system that both Canada and the U.S. are relying on, is that there is a notorious problem of adverse event under-reporting. This is because reporting is voluntary; people may be unaware there are ways to report adverse events; people are often discouraged from reporting adverse events; people (including attending physicians) assume the condition is not related to vaccination; or people may not be able to report their adverse events (if they are severely disabled, ill, or deceased). Most disconcerting is the situation, as we see in Canada, where adverse event reports attempted to be submitted by medical professionals are pre-screened and sometimes rejected by pre-screening authorities. Consequently, adverse event databases can easily fail to identify potential concerns, or underestimate problems to an unknown degree and are, therefore, not a source of

accurate numbers to calculate true risk. For example, using the U.S. VAERS, it was estimated that the risk of anaphylaxis was 4.7 per million for the Pfizer vaccine and 2.5 per million for the Moderna vaccine[5]; however, in an active surveillance study of 64,900 healthcare workers who had been vaccinated, the rate was actually 216 per million[5], representing a potential rate of under-reporting of 46- to 86-fold. Despite these limitations, passive surveillance systems are useful for identifying potential risks that could then be investigated in properly designed safety studies.

Difficulty #4: Lack of Global Consistency and Thoroughness in Defining Events of Special Interest

Using the U.S. VAERS and similar adverse event reporting systems around the world, there is continuous monitoring of adverse events of special interest. But each jurisdiction is left to their own discretion to decide which, if any, particular adverse events of special interest will receive closer scrutiny. For example, the European Medicines Agency has compiled a list of important medical events (IMEs) which are always to be classified as serious (the IME list). The IMEs that are most frequently reported following COVID-19 vaccination (in descending order) are:

- Fainting (syncope)
- Blood clot(s) in the lungs
- Anaphylactic reaction
- Deep vein thrombosis
- Pneumonia
- Low blood platelet count (thrombocytopenia)
- Blood clot(s) or bleeding in the brain
- Hallucinations
- Cerebral stroke
- Loss of consciousness

Definitive cause-and-effect relationships for these events have not yet been established; it is hoped that with additional surveillance and time, clarity on the role of the vaccines in the cause of these events will be better understood. In the meantime, given that the spike protein is biologically active and there are mechanisms that could potentially explain some of these IMEs (discussed further below), there is good reason for genuine concern.

Why weren't serious adverse events identified before vaccines were rolled out?

Problems like anaphylactic shock (a severe allergic reaction) and potentially fatal blood clots were not identified until most of the experimental COVID-19 vaccines were used widely among the public[5, 6]. Janssen's study of the Johnson & Johnson vaccine did suggest some propensity for blood clotting. As for anaphylactic reactions, people with a history of allergies were excluded from the earlier clinical trials.

Another reason why some problems were not identified earlier is because short-cuts were taken with the traditional approach to vaccine research. Specifically, **the time taken to assess safety was too short**. Instead of taking the usual ~4-10 years to undergo thorough *in vitro* (*i.e.*, benchtop) tests, pre-clinical (*i.e.*, animal) studies, and then sequential clinical testing (*i.e.*, human Phase 1, 2 and 3 trials), COVID-19 vaccines were developed and assessed for safety and efficacy in less than one year. This meant that only very short-term safety scenarios could be evaluated. Of equal concern, **the number of people that were evaluated in clinical trials was too small** to capture rare but dangerous side-effects. This is unfortunate, because we have seen in Canada that rare but serious problems can lead to a vaccine program being suspended. Indeed, in Canada, a risk of blood clots for the AstraZeneca vaccine of 1 out of every 55,000 people vaccinated was deemed to be too dangerous, leading to its use being halted. Authorization under Interim Order for COVID-19 vaccines was granted after they were evaluated for a short duration in about 20,000 people. This means these studies could, at best, detect serious side effects that would occur in at least 1 out of every 20,000 people. In other words, the study design included a test population that was too small to identify vaccines that may be too dangerous for Canadians.

A clinical trial was conducted to justify using the Pfizer vaccine in Canadian children and adolescents; was it flawed as well?

Yes. First, it was far too short in duration to have any chance of assessing anything other than short-term harm. Also, in light of the information provided above, one needs to consider the following: only 1,131 adolescents between the ages of 12 and 15 received the vaccine in this study. This means that the study would have only been able to detect a serious side effect that occurs in 1 out of every 1,131 adolescents that are vaccinated; but a 1 in 55,000 risk was deemed to be too dangerous for adults for whom SARS-CoV-2 represents a greater risk. Furthermore, based on the recent observation of increased risk of heart inflammation following immunization with either the Pfizer or Moderna vaccine in young males, it appears serious side effects may be a function of both age and sex. In this regard, the Pfizer study of only 1,131 subjects provides even less robust data…enough to detect a serious gender-differentiating side effect that occurs in one out of approximately 565 (*i.e.*, 1,131÷2) males vaccinated and one out of approximately 565 females vaccinated.

But we have been told that adolescents and children can: (a) die from COVID-19, (b) suffer severe disease, and (c) be asymptomatic spreaders of SARS-CoV-2 and, therefore, kill others. Don't these risks suggest that children, youth, and young adults of child-bearing age should be vaccinated?

No, they don't. Let's break this down…

(a) Deaths due to COVID-19 are extremely rare in young Canadians. In sixteen months 13 Canadians under the age of 20 have died of 266,852 with confirmed SARS-CoV-2 infection (data from the Government of Canada, as of June 11, 2021). Because many children have asymptomatic infections, the true denominator is likely greater. This loss of 13 lives is indeed a tragedy, but no more so than the ~2,266 Canadians under the age of 20 who die from other causes every 16 months. Basic cost-benefit analyses have been largely ignored during the pandemic. The fear of young people dying from SARS-CoV-2 has reached a point where we seem to have placed a much higher value on lives lost due to COVID-19 than lives lost to any other causes.

SARS-CoV-2 is not a problem of pandemic proportions for all demographics. Infection fatality rate (IFR) is a way to assess how dangerous a pathogen is. The IFR is calculated based on the number of people who die, from among the total number infected. Early in the declared COVID-19 pandemic, it was estimated that the IFR for SARS-CoV-2 was ~10-fold higher than for a serious outbreak of an influenza virus, or ~1%; maybe even as high as 10%. Indeed, the IFR for a bad 'flu' season can be as high as ~0.1%[7]. This IFR for influenza is calculated despite the high use of influenza vaccines that are commonly given seasonally to target populations. It is important to note that calculating an accurate IFR requires having accurate data for the denominator in the equation, which is the total number of people that have been infected.

Exacerbated by Canada's lack of testing for evidence of seroconversion (*i.e.* when virus-specific antibodies are present in an individual, which indicates they were infected) against SARS-CoV-2, it has been impossible to ascertain how many Canadians have been infected. However, as data have accumulated in countries that did practice due diligence in this area, the total number of infections that have occurred keeps getting re-adjusted to higher numbers. This is due to phenomena such as the large number of people who were infected but did not realize it, because they never became ill (they never developed COVID-19). As a result, the actual calculated IFR for SARS-CoV-2 has been steadily declining. Remarkably, as the data regarding total infections have become more accurate, the IFR for SARS-CoV-2 has most recently been estimated to be only ~0.15%[8]. It is likely that this IFR will drop even further as the extent of unnoticed infections is further elucidated.

Indeed, a recent study found that ~90% of randomly tested healthy adults in British Columbia had evidence of natural immunity to SARS-CoV-2[9]. This indicates that the denominator for determining the true IFR is likely substantially higher than previously appreciated, which would mean the IFR is less than 0.15%[9]. Further, this IFR includes the high-risk frail elderly, immunocompromised, smokers, highly obese people, and those with diabetes, pulmonary and cardiovascular disease. For Canadians who are outside of these high-risk demographics, the IFR would be much less than 0.15%, especially for children. Therefore, COVID-19 does not represent a substantial risk to children, youth, and young adults of child-bearing age[10].

(b) Very few children are at risk of developing severe COVID-19. It is challenging to know how small this risk is because public health officials have refused to differentiate the nature of the 'cases' of COVID-19 that have been reported. Many estimates of children in hospital with COVID-19 include children who were admitted for other reasons but had tested positive with SARS-CoV-2. The reality is that most cases in children and adolescents are mild. In fact, most children do not get sick at all after being infected with SARS-CoV-2. Children have a lower risk of developing disease, especially severe forms, compared to adults. This is in large part because they express in their lungs and airways lower concentrations of the "ACE2 receptor", a protein on the surface of various cells in the body that serves as a point of attachment for the SARS-CoV2 spike protein, and that when "docked" enables entry of the virus into the cell for subsequent replication and spread of infection.

(c) Asymptomatic transmission of SARS-CoV-2 is negligible. The definition of an asymptomatic individual is a person who is known to be infected with a microorganism but fails to develop symptoms associated with a disease. Indeed, we are all 'asymptomatic carriers' in the sense that we harbor trillions of bacteria and viruses in and on our bodies. However, these normal microbiomes usually do not cause us any disease, unless we become immunosuppressed or unless 'safe' microbes get transferred to anatomical locations where they can potentiate disease (*e.g.* fecal-to-oral transfer of some strains of *Escherichia coli*). So, in the context of SARS-CoV-2, an asymptomatic carrier would be defined as an individual who is infected with the virus but fails to develop COVID-19. A colleague of mine recently asked this rhetorical question: "didn't we previously call an asymptomatic person 'healthy'?"

A study of the prevalence of SARS-CoV-2 in ~10 million people in Wuhan, China found no evidence of asymptomatic transmission[11]. In the United Kingdom, the 'Scientific Advisory Group for Emergencies' recommended that "Prioritising rapid testing of symptomatic people is likely to have a greater impact on identifying positive cases and reducing transmission than frequent testing of asymptomatic people in an outbreak area"[12]. Consequently, they have asked their government to change their testing policy by moving away from asymptomatic testing. The World Health Organization notes that "Most PCR assays are indicated as an aid for diagnosis, therefore, health care providers must 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"[13].

On its own, a positive result on a PCR test to detect SARS-CoV-2 is insufficient to diagnose COVID-19, yet this has become routine in Canada. In addition to the potential for false positive tests, true positive results can also be obtained from genomes of SARS-CoV-2 particles that are no longer infectious. An example of the latter would be an individual who has mounted an effective immune response and may have remnant replication-incompetent viral particles or partially degraded viral genetic material. Indeed, following clearance of SARS-CoV-2 from the body, full and/or partial genomes of SARS-CoV-2 can remain for up to several weeks. One key reason for this is that some phagocytic cells, which are a component of the innate immune

system, can be long-lived. Phagocytosis, which is the engulfment and digestion of SARS-CoV-2, is a mechanism to kill and remove the virus from the body and to activate other white blood cells. As such, these can be a source of SARS-CoV-2 genetic material that could be amplified by a PCR test. However, this genetic material would not have the potential to cause COVID-19. Persistence of whole or partial genetic material that is not associated with infectious particles is well-documented for a variety of other viruses, including measles[14], Middle East Respiratory Syndrome (MERS)-coronavirus[15], and other coronaviruses[16].

Too often, a positive PCR test for the presence of SARS-CoV-2, is being used, on its own, to define positive cases of COVID-19. However, the presence of a portion of the viral genome in an individual, on its own, does not necessarily equate with disease (*i.e.* COVID-19). To be declared a COVID-19 "case", the infection would also have to be associated with expected signs such as antibody development and/or symptoms of disease. This is known as a clinical diagnosis and would be based on evaluation by a physician, in conjunction with test results. A gold-standard test for infectivity of a virus is a cell-based functional assay that determines the potential for the virus sample to cause cell death. However, such an assay is not in routine use in Canada. Absence of such an assay further confounds any meaningful interpretation of positive results in asymptomatic people. Drawing conclusions based solely on the results of laboratory tests, would take the diagnosis of diseases out of the hands of physicians, and place the onus for this on technicians employed by testing laboratories. Further confounding this issue is the fact that cases of COVID-19 can be claimed in the absence of confirming infection with SARS-CoV-2 (this is known as "ICD code U07.2 COVID-19, virus not identified")[17]. Worse, the definition of a case of COVID-19 has changed over time in Canada. Indeed, the government of Canada has stated the following on their website: "Previous versions of the COVID-19 case definition are available upon request. Please email COVID19Surveillance@canada.ca to request a copy or for more information."[17]

Positive PCR tests for SARS-CoV-2 in asymptomatic people are often based on what scientists call 'high cycle numbers' (also called "cycle thresholds" or Ct"). PCR tests that only yield a positive result at high cycle numbers brings into question whether or not these individuals actually harbor infectious viral particles. This, combined with the absence of a functional cell-based assay to prove infectivity, renders results of asymptomatic testing nearly impossible to interpret accurately. Indeed, the World Health Organization, agreeing with many health professionals around the world, has emphasized that spreading of SARS-CoV-2 by asymptomatic individuals is rare and an emphasis should be placed, therefore, on testing people with signs or symptoms of illness, not those who are apparently healthy[18]. Of particular concern is the high cycle numbers being used by labs in Ontario (*i.e*. up to 38 cycles being defined as 'positive' by Public Health Ontario[19]), to define a COVID-19 positive "case." Several studies have been conducted to determine the highest number of PCR cycles at which live SARS-CoV-2 from a sample could be successfully cultured in cells. These studies suggest that appropriate cycle thresholds were 25[20], 22-27[21], and 30[22] cycles. This indicates that tests with positive results obtained above 22-30 cycles are not clearly supportive of the presence of live (*i.e.* replication-competent) SARS-CoV-2. The logical conclusion is that it is erroneous to declare samples that test

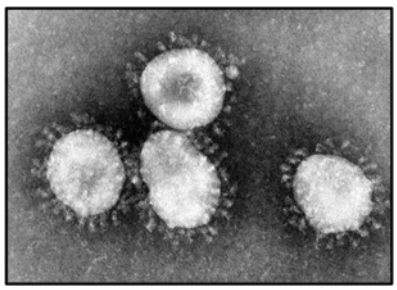
positive at high cycle numbers, especially those above 30, as being "positive" for infectious SARS-CoV-2. Appendix 1 shows results of a published study that depicts the numbers of PCR cycles at which asymptomatic people tested positive for SARS-CoV-2 relative to that observed for people with symptomatic infections[23]. Remarkably, if the cut-off for positive test results was set to Ct values of 22 or 30 (*i.e.* the point beyond which samples fail to yield potentially infectious virus particles), the vast majority of 'positive test results' would be rendered negative. It was even concluded in a study by La Scola B, *et al*., that patients testing 'positive' at cycle numbers above 33 could likely be discharged from hospitals[24]. This means that an unknown number of positive cases reported in Ontario were likely not true positives of COVID-19. This is further supported by evidence that asymptomatic people have detectable SARS-CoV-2-specific memory T immune cells after exposure to the virus, which would be inconsistent with a risk of them harboring and spreading the virus to others[25].

Importantly, false positive test results, which have a greater risk of happening among asymptomatic people, have been shown to have numerous negative consequences in terms of physical and mental health, and causes financial losses[26]. Testing of asymptomatic people for the presence of portions of the SARS-CoV-2 genome makes neither medical nor economic sense. Positive test results from asymptomatic individuals cannot be interpreted in a clinically meaningful way. Although asymptomatic transmission is theoretically possible, it is improbable that it is occurring in substantial numbers and does not represent a significant risk of causing COVID-19-related hospitalizations or deaths in others.

For all the aforementioned reasons, **it is wrong to label children as being asymptomatic spreaders of SARS-CoV-2** that will sicken and kill others. Indeed, as reported by L. T. Brandal *et al*., "under 14 year olds are not the drivers of SARS-CoV-2 transmission"[27]. A study in England concluded "SARS-CoV-2 infections and outbreaks were uncommon in educational settings", with staff (adults), not students (children) being the primary source of infections[28].

Now that the reasons that were used to justify using an experimental COVID-19 vaccine in children have been put into a reasonable perspective, let's continue talking about the vaccine technology.

Why was the spike protein from SARS-CoV-2 chosen as a target for the immune system?



Electron micrograph of a coronavirus
https://starfishmedical.com/blog/covid-19-point-of-care-diagnostic/

The spike protein gives SARS-CoV-2 its 'crown-like' appearance, which means it looks like it has a 'corona'. This protein allows the virus to attach to our cells and then infect them. If antibodies can bind to and 'block' all the spike proteins on the surface of the virus, then it could not infect our cells. Moreover, the binding of antibodies to even a part of the virus can tag it for attack by cells of our immune system. As such, COVID-19

vaccines currently being used in Canada instruct our cells to manufacture the spike protein in order to trigger our bodies to mount an immune response against this protein with the hope that the ensuing antibodies will get into our lungs and airways and block the virus, should we be infected in the future.

What should we know about the SARS-CoV2 spike protein?

Before we go any further with the story about COVID-19 vaccines, there is important information that you need to know about the spike protein from SARS-CoV-2.

The spike protein from SARS-CoV-2 has the potential to damage cells in the body

In cases of severe COVID-19, problems can extend well beyond pneumonia and the associated inflammation in the lungs. The disease can progress beyond the lungs and into other parts of the body. In severe infections, SARS-CoV-2 can cause damage to the cardiovascular system (*i.e.* heart and blood vessels). In fact, some have referred to severe COVID-19 as largely being a vascular disease[29, 30, 31]. Blood clots, bleeding and/or damage to the heart have all been linked to severe COVID-19. Severe COVID-19 can also cause neurological problems (*i.e.* damage in the brain). A series of recent scientific publications provide some evidence that this damage throughout the body may not require an intact SARS-CoV-2 particle. Instead, the spike protein from SARS-CoV-2 might be responsible for at least some of the damage that occurs in severe cases of COVID-19[32]. This is because there are many cells other than those in the lungs and airways that feature the receptor for the spike protein, known as the ACE2 receptor. Most notably, platelets and cells lining blood vessels can express high concentrations of this receptor. Importantly, autopsies performed on patients who died from severe COVID-19 revealed that free spike protein from SARS-CoV-2, not the intact virus, was responsible for substantial damage throughout the body. Notably, blood vessels in the skin, fat, and the brain were found to express high concentrations of the ACE2 receptor that the spike protein binds to. There was a lot of spike protein found in these tissues, with little to no evidence of the intact virus being present. Indeed, the authors of the study that described these autopsies concluded "COVID-19 represents a viral infection with limited sites of infectious virions but deadly sequelae due to the effective manner in which pseudovirions in the context of released viral proteins activate synergistic microvascular pathways of tissue destruction throughout the body."[33] In lay language, proteins like the spike protein, not the intact virus, appear to mediate

much of the damage in the body in people who suffer from severe COVID-19. When the spike protein binds to these receptors, there are several events that can take place:

1. Proteins (called 'complement proteins') that are part of our innate immune system can get activated, causing inflammation that can damage or destroy the cells lining blood vessels and/or platelets[34]. Platelets that are required for clotting of blood also express ACE2 receptors that can bind with spike protein with dire consequences. Damage and destruction of platelets can cause their numbers to go down (a condition known as "thrombocytopenia"), and if platelet counts get too low and blood vessels are damaged, bleeding cannot be stopped. Therefore, the spike protein can potentiate bleeding.

2. Binding of the spike protein to platelets can also cause the platelets to become activated[35]. Activated platelets tend to clump, which can lead to the formation of clots. There is evidence that the spike protein can interact with other proteins in the blood to promote clotting[36]. As such, the spike protein can promote blood clotting.

3. Spike proteins binding to the cells that line our blood vessels can cause these cells to express proteins (known as 'caspases') that can cause the cells to die[33]. This is similar to findings from the 2002-2004 SARS outbreak where the spike protein from the original SARS-CoV could cause cells to die when it was being manufactured inside of them[37]. Dying cells that have been manufacturing the vaccine-encoded spike protein would release free spike protein or portions thereof.

4. Spike proteins binding to the cells that line our blood vessels can cause these cells to over-produce cell-signalling cytokines that can potentially contribute to dangerous 'cytokine storms' (overly robust and severe inflammation)[33, 38].

Of additional concern is the knowledge that the spike protein is capable of dissociating into two parts and these smaller subunits (S1 and S2) can cross the blood-brain barrier where they can potentially cause damage in the brain[39]. Indeed, people who have died from severe COVID-19 with neurological signs were found to have the spike proteins but not the intact virus in their brains[40]. These neurological signs could be seen in laboratory studies when spike proteins were injected into the blood of mice.

Conclusion: The spike protein, if it gets into circulation, has the potential to cause damage to the cardiovascular system and other tissues.

Back to the vaccines

Now that there is a clear understanding that the spike protein from SARS-CoV-2 is a dangerous toxin when it gets into the blood and is distributed throughout the body, we can continue with the story about COVID-19 vaccines.

Evidence that mRNA-based COVID-19 vaccines can get distributed throughout the body

When the COVID-19 vaccines were designed, it was not appreciated that the spike protein could potentially damage cells in the body. As a consequence, administration of the current COVID-19 vaccines can put people at risk of damaging their cells, especially if expression of the spike protein is not limited to the vaccine injection site. An assumption was made with these vaccines that has proven to be incorrect. The assumption was that mRNA vaccines, which are a new technology, would behave the same as traditional vaccines. It was thought by many that mRNA vaccines would stay at the injection site and the only other place they would go is to the draining lymph nodes in the immediate vicinity of the injection site. More specifically, it was thought that cells of the immune system would come to the site of injection and create pieces of the virus and take these pieces to the lymph nodes where they would be shown to B and T cells (*i.e.*, B and T lymphocytes). The B and T cells would then get activated, multiply to large numbers (this is why lymph nodes swell when a person is mounting an immune response) and then head out into the body to search for the pathogen. Notably, B cells are the source of antibodies. Unfortunately, researchers have come to learn that **the mRNA vaccines do not stay in the shoulder muscle**. In fact, **they have the potential to spread far and wide throughout the body via the blood**. Obviously, this is a very serious conclusion to draw, so let's walk through the solid scientific evidence that demonstrates this potential for biodistribution.

A report that Pfizer provided to the Japanese government (see Appendix 2) was published as reference #25 in an article[41] published in *BMJ* that can be found at this link. In section 2.6.5.5B of the report to the Japanese government there is a table containing lipid nanoparticle biodistribution data. This table shows where their surrogate "vaccine" (*i.e.* represented in the laboratory test by little bubbles of surrogate fat containing an analytical detection marker) ended up in the body of immunized rats, used in the laboratory as surrogates for humans. A portion of the table is reproduced below. Please review the data so you can get the full picture. I would like to highlight some observations. First, as shown in the blue rectangle that I added to the table, a lot of the surrogate vaccine dose remained at the injection site, as one would expect. Remarkably, however, most of the vaccine dose had gone elsewhere. The right side of the table (shown in the report to the Japanese government but not below) shows that 50-75% of the vaccine dose failed to remain the site of injection. The big question is, where did it go? Looking at the other tissues shows some of the places it went and accumulated. The red rectangle shows that **the surrogate vaccine was circulating in the blood**. There is also evidence that a substantial amount of the vaccine went to places like the spleen (green rectangle), liver (brown rectangle), ovaries (yellow

rectangle), adrenal glands (purple rectangle), and bone marrow (orange rectangle). The vaccine went to other places as well, such as testes, lungs, intestines, kidneys, thyroid gland, pituitary gland, uterus, *etc*. **The surrogate vaccine tested in a laboratory setting was widely distributed throughout the laboratory animals' bodies**.

Species (Strain):
Sex/Number of Animals: Male and female/3 animals/sex
Feeding Condition:
Method of Administration: I
Dose: 50 µg [^{3}H]
Number of Doses:
Detection: Radioactivity quant
Sampling Time (hour): 0.25, 1, 2, 4,

Sample	Mean total lipid concentration (µg lipid equivalent/g (or mL) (males and females combined)						
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h
Adipose tissue	0.057	0.100	0.126	0.128	0.093	0.084	0.181
Adrenal glands	0.271	1.48	2.72	2.89	6.80	13.8	18.2
Bladder	0.041	0.130	0.146	0.167	0.148	0.247	0.365
Bone (femur)	0.091	0.195	0.266	0.276	0.340	0.342	0.687
Bone marrow (femur)	0.479	0.960	1.24	1.24	1.84	2.49	3.77
Brain	0.045	0.100	0.138	0.115	0.073	0.069	0.068
Eyes	0.010	0.035	0.052	0.067	0.059	0.091	0.112
Heart	0.282	1.03	1.40	0.987	0.790	0.451	0.546
Injection site	128	394	311	338	213	195	165
Kidneys	0.391	1.16	2.05	0.924	0.590	0.426	0.425
Large intestine	0.013	0.048	0.093	0.287	0.649	1.10	1.34
Liver	0.737	4.63	11.0	16.5	26.5	19.2	24.3
Lung	0.492	1.21	1.83	1.50	1.15	1.04	1.09

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED **Test A**

Sample	Total Lipid concentration (µg lipid equivalent/g [or mL]) (males and females combined)						
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253
Small intestine	0.030	0.221	0.476	0.879	1.28	1.30	1.47
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112
Spleen	0.334	2.47	7.73	10.3	22.1	20.1	23.4
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.00
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456
Whole blood	1.97	4.37	5.40	3.05	1.31	0.909	0.420
Plasma	3.97	8.13	8.90	6.50	2.36	1.78	0.805
Blood:Plasma ratio[a]	0.815	0.515	0.550	0.510	0.555	0.530	0.540

Based on the results of this biodistribution test, further tests should have been required in order to assess the impacts on more tissues and for a longer time before the vaccine was authorized for use, especially in growing children, adolescents, and young adults of child-bearing age. The vaccine manufacturer, researchers and regulatory authorities alike should have also looked more comprehensively at the potential for the test animals to shed the vaccine by assessing saliva, urine, and feces. Note that there was evidence of some trafficking of the vaccine to the salivary gland and bladder, which indicates there is potential for some degree of shedding of the vaccine from the body. Further, the biodistribution of the spike protein that is created by the body after vaccination should be carefully mapped. Studies such as these should be performed in at least two animal models, with one of these not being a rodent model since rodents have levels of ACE2 receptor binding affinity that is far less than that of humans and may, as a result, underestimate the impact of spike protein on humans. There should also have been an evaluation of where the vaccine and the spike protein were going in humans in a very limited Phase 1 clinical safety trial. **This may not have mattered as much if the protein encoded by the mRNA was inert, although the risks of autoimmunity with the deposition of the lipid nanomaterials at different organs are certainly worthy of consideration. But now that we know the spike protein encoded by the mRNA has**

its own biological activities of concern, there is even greater potential for damage to organs and tissues arising from circulating vaccine material.

Although not as detailed as the data in the report to the Japanese government, Pfizer's report to the European Medicines Agency states similar findings regarding the broad distribution of their vaccine platform throughout the body. The report is in Appendix 3. Of great concern is the following excerpt from section 2.3.2 on page 45: "**No traditional pharmacokinetic or biodistribution studies have been performed with the [Pfizer-BioNTech] vaccine candidate BNT162b2**". If this is the first time this vaccine technology platform has been rolled out for wide distribution to humans, and if the Japanese biodistribution data showed evidence of spread of the surrogate vaccine material, one must ask w**hy was this experimental vaccine allowed to be used in people without it having undergone a crucial biodistribution study first?** This would have told us where the vaccine was going in the body before its use in people.

Supporting the need to address uncertainties and concerns regarding the biodistribution of the vaccine and the resulting spike protein is a peer-reviewed scientific paper that has just been accepted for publication. It describes a study in which 13 healthcare workers were assessed for the presence of the spike protein in their blood after receiving Moderna's vaccine (an mRNA vaccine with essentially identical platform technology as the Pfizer-BioNTech vaccine). Notably, the spike protein, (or the portion of it that binds to ACE2 receptor), could be found in the circulation in 3 out of the 13 people (and in 11 out of the 13 people), respectively[42]. The spike protein could be detected in the blood up to two weeks post-vaccination in most individuals and at 28 days post-vaccination in one individual. Some may argue that the concentration of the protein was low in most of the people studied. However, a protein circulating at a low concentration for up to two or more weeks could accumulate on cells over time as the blood constantly perfuses *(i.e.*, flows through) bodily tissues. Further, the biodistribution studies in the appendices suggest the spike protein could potentially be concentrated in many tissues that would not be evident by looking in blood alone. The possibility also exists that there were spike proteins already bound to ACE2 on the cells lining the blood vessels, but this was not investigated. Regardless, low concentrations of the spike protein in circulation would be expected in this small-scale study. High concentrations of a protein that can cause damage to blood vessels in a large number of people would not be consistent with a low incidence of severe adverse events. Remember, the AstraZeneca vaccination program was suspended in Canada due to a 1:55,000 incidence of blood clots. If spike proteins in blood were responsible for a severe side-effect, one would expect to see high concentrations of this protein in only one out of many thousands of people; a phenomenon that would likely not be detected in an analysis of only 13 people. Clearly, more work is needed here to assess the biodistribution of spike proteins in the human body after vaccination.

In a pre-print article (note: this means the paper has not yet undergone independent scientific peer review), there are data that indicate mRNA can even be detected in breast milk post-vaccination. This aspect of the study was downplayed but provides proof-of-principle that

this can happen. Knowing what we now know, it would not be surprising to have the spike protein in the breast milk of some lactating women if they were to be vaccinated. Proteins circulating in the blood usually get concentrated in breast milk. Notably, there have been some adverse events reported of infants experiencing bleeding in their gastrointestinal tracts after suckling from mothers who had received a COVID-19 vaccine. Here are some examples from the U.S. VAERS (I haven't checked for more since May 2021):

Serious Adverse Events Related to Breastfeeding After Receiving a COVID-19 Vaccine

- VAERS ID #945282; a 32-year-old mother had her 2-month-old breastfeeding daughter die 7 days after the mother had received the Pfizer-BioNTech vaccine
- VAERS ID #949926; a 34-year-old mother had her 4-month-old breastfeeding boy pass blood and mucous in the stools starting 2 days after the mother had received the Moderna vaccine
- VAERS ID #992676; a 30-year-old mother had her 2-month-old breastfeeding boy experience anorexia, spitting up, discoloured bloody feces, vomiting of blood, ulceration of the stomach, and bleeding in the gastrointestinal tract starting 2 days after the mother had received the Moderna vaccine

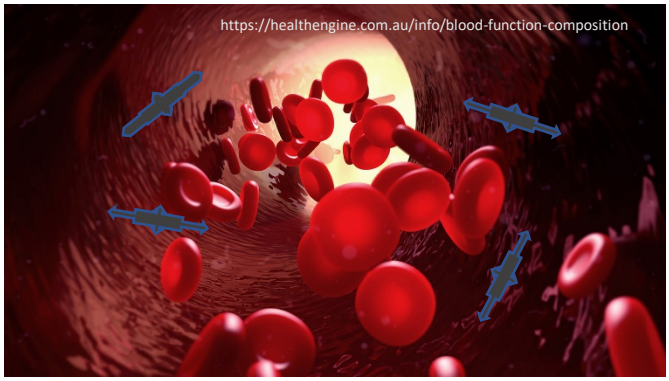
There were also other types of adverse events in infants associated with breastfeeding from mothers who had recently received a COVID-19 vaccine. For the sake of brevity, I have listed the VAERS ID #s here; anyone can look them up in the publicly available VAERS database.

- VAERS ID #s: 903355, 911226, 913968, 913971, 918972, 921052, 927664, 936865, 939409, 974519, 978085, 978485, 984448 (mother) - 984602 (infant), 1049482, 1105816, 1168901, 1171284

There is also a pre-print article that describes how an adenovirus-based vaccine can result in spike proteins damaging the vascular system. These types of vaccines are currently not being given to children in Canada. The mechanism is different from the mRNA-based vaccines, but the outcome is similar. The authors of this paper have coined an interesting term to describe the effect of a COVID-19 vaccine causing the same damage to the body that SARS-CoV-2 does; they called it "vaccine-induced COVID-19 mimicry syndrome".

It turns out that the suggested wide distribution of mRNA vaccines throughout the body has a historical precedent, such as for immunizing against influenza for example[43]. However, many people do not realize that lipid nanoparticles were not designed to function as vaccines. They were designed to serve as gene therapies or carry drug cargo throughout the body[44], including into the brain where attempts could be made to treat diseases such as Alzheimer's disease, Parkinson's disease, and brain cancers. Of substantial concern is the use of PEG, which has been associated with anaphylactic shock in some people after receiving a mRNA vaccine. PEG was added to lipid nanoparticles in the early days of drug development to promote much wider distribution throughout the body. Specifically, when PEG is added to lipid nanoparticles, it helps

the particles avoid being consumed by cells throughout the body, especially cells of the immune system, that would limit the distribution of the mRNA cargo[45, 46]. Indeed, addition of PEG to lipid nanoparticles was hailed as a breakthrough because "This effect is substantially greater than that observed previously with conventional liposomes and is associated with a more than 5-fold prolongation of liposome circulation time in blood"[45]. In retrospect, it seems that another mistake may have been made in the rush to get these vaccines into people: Arguably, the PEG component should have been removed from the lipid nanoparticle formulation. This likely would have resulted in lipid nanoparticles with a greater tendency to remain at the injection site and be picked up by the very cells of the immune system that we want to induce an immune response.



Conclusion: The assumption that COVID-19 vaccines remain at the injection site (*i.e.* the shoulder muscle) is not borne by the evidence. Laboratory studies have shown that the vaccine itself, and the spike protein that it encodes, may get into the blood, and be distributed widely throughout the body. Vaccines targeting the spike protein from SARS-CoV-2 were designed to induce antibodies that would bind to this protein to prevent the virus from being able to infect our bodies. The spike protein was supposed to be the 'first thing' that a vaccine must provide; a target for the immune system. We did not appreciate the potential for the spike protein alone to cause damage to cells in the body. We now understand that the current COVID-19 mRNA vaccines have the potential to be distributed throughout the body, thereby potentially and inadvertently inoculating many tissues with a protein that is possibly harmful. If unknown damage is being caused in some organs, this might not be clearly evident until years after vaccination. The data presented here do not provide proof of long-term harm. However, it provides the rationale for asking a number of safety questions. These questions should be thoroughly investigated in safety studies prior to using COVID-19 vaccines in children, adolescents, and young adults of child-bearing age.

A concern beyond circulating spike proteins: the potential for induction of autoimmunity

Some scientists have proposed that the spike protein from SARS-CoV-2 might have portions that are very similar to proteins in our own bodies[47]. If true, inducing immunity against the spike protein could theoretically promote autoimmune disorders. Indeed, two researchers found there was cross-reactivity between antibodies induced against the spike protein and several 'self' proteins[48]. This led to the recommendation almost one year ago to avoid targeting the entire spike protein in vaccines and instead target only portions of the protein that are not

similar to proteins in our own bodies. Unfortunately, autoimmune diseases can be insidious and take years for symptoms to become apparent.

The broad distribution of an mRNA vaccine throughout the body implicates other mechanisms that could lead to autoimmune disease. First, the mRNA vaccines promote robust inflammation. This is why many people have sore shoulders after being immunized. Promotion of inflammation in critical tissues, such as the ovaries, after being seeded with the vaccine could have dire consequences. Tissues like the ovaries are not supposed to become inflamed. This is because inflammation causes a lot of bystander damage to normal tissues, which is unwanted in an organ designed for reproduction. Also, the vaccine-encoded spike protein is designed to remain anchored on the surface of the cell that has manufactured it. If antibodies are present, such as would be the case several days after vaccination or natural infection, they could bind to the spike proteins on cells throughout our body, resulting in their destruction. Let's take the ovaries, again, as a theoretical scenario. If they were to undergo any type of tissue destruction, there is the possibility of proteins being released that the immune system has never seen before. This is because our immune systems learn to tolerate 'self' at a very young age. However, organs like the ovaries and testes start to express new proteins during puberty that the immune system has not been tolerized against. If these get released due to tissue damage, this could provide the same two signals that a vaccine needs to activate the immune system; signal 1 (target protein) and signal 2 (damage-associated danger signals). This could result in an autoimmune response against the organ. In this example (ovaries), such damage might not become apparent until years later when attempting to have a baby. This is speculation but is based on a huge body of scientific literature looking at how autoimmune diseases get started. Notably, this could potentially happen in any of the tissues seeded with the vaccine if they start to express the spike protein. This is certainly worthy of investigation before the mass vaccination of children, adolescents, and young adults of child-bearing age.

Even the fact that the current COVID-19 vaccines cause muscle cells in the shoulder to express the spike protein, is a potential problem. This could potentially result in immune responses being mounted against muscle tissue. This is of particular concern, because Israel has started to suspect a link between COVID-19 vaccines and inflammation in the heart muscle (a condition known as myocarditis). Indeed, this potential link is being actively investigated by the European Medicines Agency, as well as by the U.S. CDC. Again, with these kinds of concerns being raised in the global community, one must wonder why these vaccines are pushed so hard upon Canadian youth who are not at high risk of severe COVID-19. It will be a tragedy if we repeat something similar to or even worse than the AstraZeneca vaccine fiasco with our young people.

Why doesn't everyone who gets vaccinated experience a severe side-effect?

The spike protein likely does not get into circulation in every person. Indeed, in the study of 13 people vaccinated with the Moderna vaccine, ten had no evidence of the spike protein and

two had no evidence of the S1 subunit (a fragment of the spike protein) in their blood[42]. Also, it is important to remember that following vaccination, people manufacture the spike protein in their own cells. The amount and quality of mRNA in each dose of the vaccine can vary from batch to batch. The stability of the mRNA is also dependent on its handling as it is very temperature sensitive. So different people will receive different amounts of the active mRNA. People that receive the same amount of mRNA can produce different amounts of the spike protein depending on how metabolically active their cells are. And there are likely numerous other factors, including body size, *etc*. All of this could contribute to substantial variability in the concentration of spike proteins that a person produces. Notably, a standard vaccine injection might be expected to have a different impact in a 75-pound youth than in a 200-pound adult. The adverse events that we know about seem relatively rare. Some adverse events may go undetected. For example, knowing that the spike protein gets into circulation and knowing that it can kill platelets, it would not be surprising if most people have some loss of platelets after getting vaccinated. Also, platelets could pick up the mRNA from the circulating lipid nanoparticles and then display the spike protein on their surface, which would tag them for destruction by the ensuing antibody response. However, platelet counts are not being routinely monitored after people leave vaccination clinics, nor have the vaccine companies publicly released their data showing platelet counts post-immunization. Indeed, in a first-in-human study of BNT162b1, an earlier prototype of the Pfizer BioNTech BNT162b2 vaccine in use today, that encoded the S1 subunit of the spike protein (which contains the portion of the spike protein that binds to ACE2 receptors, called the receptor binding domain), platelet numbers dropped following vaccination in both the young and older adults studied[49]. Unfortunately, clinical chemistry and haematology values following vaccination with the BNT162b2 vaccine, which is the one currently being used to vaccinate people, were not published in Pfizer's first-in-human study[50].

One would be unaware if they were experiencing a loss of platelets unless their platelet count became dangerously low and they suffered trauma that would cause bleeding. Of greater concern is the potential for serious adverse events that we may not know about for quite some time. For example, damage to the ovaries or testicles might result in infertility that would not become apparent until attempting to have children. The oocytes that are present in the ovaries of newborn baby girls represent that female's life-long fixed supply of oocytes, which are the precursor of eggs. These oocytes cannot reproduce or regenerate if damaged or destroyed. Damage to the uterus could potentiate spontaneous abortions or miscarriages during pregnancy. The fact is, there is a clearly established set of biological mechanisms that raise numerous legitimate scientific concerns about COVID-19 vaccines. **We can't simply hope that none of these concerns end up being realized**. Instead, we must return to following the scientific method. We should stop the roll-out of the vaccination program for children, youth and young adults of child-bearing age, and ask the manufacturers of COVID-19 vaccines to take the time to conduct the proper biodistribution and safety studies to answer these emerging questions, and then conduct an accurate re-evaluation of the risk of COVID-19 versus the risks associated with the experimental COVID-19 vaccines.

Is the Pfizer BioNTech vaccine losing its effectiveness?

The stated purpose of vaccinating children, youth, and young adults of child-bearing age is to protect them from infection and reduce the risk of them transmitting SARS-CoV-2 to older adults. Therefore, it is important to note that the current COVID-19 vaccines fail to induce what we call 'sterilizing immunity'. This means that vaccinated individuals can still get infected with SARS-CoV-2, potentially become ill, and potentially transmit the virus to others. This is why vaccinated individuals are not exempt from lockdown policies and are still encouraged to wear masks. Importantly, there is evidence that the 'Delta variant' of SARS-CoV-2 has changed enough to be able to start evading the immunity conferred by the Pfizer BioNTech vaccine[51]. Indeed, the earlier 'South African' variant rendered AstraZeneca's vaccine only 10% effective[52]. With new variants on the horizon that will almost inevitably be able to bypass vaccine-induced immunity, this raises another question about whether the potential risks associated with the current vaccines are worth the minimal protection they will confer in the long-term to children, youth, and young adults of child-bearing age.

The Pfizer BioNTech vaccine might cause an excessive number of serious side-effects in young Canadians

As noted previously, Pfizer conducted an extremely small and very short-term clinical trial to test their vaccine in adolescents between the ages of 12-15 years. The results were reported in a fact sheet to the U.S. Food and Drug Administration. In this document, Pfizer defined severe adverse events as follows:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

No deaths occurred in this small study, but Pfizer did note the following on page 27 of their fact sheet: "Serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.1% of placebo recipients." Much larger numbers of adolescents would have to be studied to provide conclusive evidence, but these limited data suggest the risk of serious adverse events

may have been 0.3% higher in the vaccinated group (not statistically significant in this small study).

As discussed previously, adverse events of special interest are being monitored, although the thoroughness is questionable, and the transparency of such activity is spotty at best. For example, the European Medicines Agency has compiled a list of important medical events (IMEs) which are always to be classified as serious (the IME list). The IMEs that are most frequently reported following COVID-19 vaccination include (in descending order):

- Fainting (syncope)
- Blood clot in the lungs
- Anaphylactic reaction
- Deep vein thrombosis
- Pneumonia
- Low blood platelet count (thrombocytopenia)
- Blood clots or bleeding in the brain
- Hallucinations
- Cerebral stroke
- Loss of consciousness

As the number of adolescents studied in the Pfizer trial was so small, it remains unclear whether adolescents also will experience these IMEs. It is not appropriate or ethical to experiment with youth, especially when their risk of severe COVID-19 is so low.

A side note about blood donations

Although not directly related to vaccinating children, adolescents, and young adults of child-bearing age, it is important to recognize that if the spike protein, which can cause substantial damage, gets into the blood after vaccination, this could have implications for donating blood. It would be unwise to infuse a blood product into a potentially fragile patient if it is contaminated with the spike protein. Worse, Pfizer's own biodistribution data demonstrate that the vaccine itself, not the spike protein, circulates in blood for at least two days post-immunization. Intravenous infusion of mRNA that can produce the spike protein in cells of the recipient should not be infused into patients who require blood. Remember, not only is there a risk of free-floating and cell-expressed spike proteins, but the lipid nanoparticles themselves can promote anaphylactic shock in a small subset of people. Of concern, Canadian Blood Services currently states their approval for receiving blood donations from people who have received a COVID-19 vaccine, without deferral. This is based on assumptions made using traditional vaccines that remain at the injection site, not novel mRNA-based vaccines that have been shown in laboratory studies to travel throughout the body. **This practice should be halted immediately** until it can be determined how long it takes for the lipid nanoparticles, and spike proteins to disappear from the blood. Canadian Blood Services should then recommend deferring blood

donations from vaccinated individuals until there is no risk of transferring lipid nanoparticles, mRNA, or spike proteins. The small-scale study that has looked at circulating levels of spike proteins suggests that it might not be safe to use blood products from a vaccinated individual for at least 4-5 weeks post-immunization[42]. In the United Kingdom, the National Health Service Blood and Transplant has recommended that, "COVID-19 vaccine – please wait 7 full days from your vaccine before donating on the 8th day. If you had side effects from the vaccine such as headache, temperature, aches, and chills, please wait 28 days from your recovery". It is unfortunate that there is not international collaboration with regards to recommendations for the donation of blood after COVID-19 vaccination.

What options are we left with if we pause the vaccination roll-out for children, adolescents, and young adults of child-bearing age?

Canada abandoned the original goal of learning to live with SARS-CoV-2 after the initial 2-3-week 'flattening of the curve' of daily cases of COVID-19 early in the year 2020. A massive amount of scientific data about COVID-19 has been compiled over the past 16 months. But we have not been following the accumulating science. It can direct us towards what one of my colleagues likes to call a 'rapid but soft landing.' The purpose of this guide was not to build a detailed exit strategy. However, I have also been closely following the scientific literature about strategies that can be used to effectively treat COVID-19, especially if they are implemented as an early out-patient, at-home treatment before the disease progresses to a level requiring hospitalization. Some, but all too few Canadian physicians, are aware of, or using, these early at-home treatment protocols. These protocols include safe and highly effective drugs like ivermectin, fluvoxamine, budesonide, zinc, melatonin, vitamin C, vitamin D, and many others. Several cocktails of approved drugs have proven to be particularly effective and are described in a variety of websites including TreatEarly.org, c19protocols.com, and FLCCC.net. There is now an avalanche of scientific data in support of these treatment options, but this digresses into an area beyond the scope of this guide. Unfortunately, the use of these effective therapies has never been promoted in Canada even though they could have prevented a lot of sickness and deaths and would have reduced the burden on intensive care units. Many people do not realize that the Interim Order or emergency use authorization of COVID-19 vaccines would have been contraindicated if there was acknowledgement of effective treatment strategies. This rule is in place to protect Canadians from being experimented on when there are viable alternatives that are known to be safe. However, it is never too late to do the right thing. Canada panicked and threw out pandemic preparedness plans at all its public institutions. Sometimes poor decisions occur when being made during a crisis and in the absence of established guidelines. It is time to move on. By promoting widespread use of effective treatments for COVID-19, Canada can safely narrow its experimental vaccination program and call for the science to catch up before subjecting our children, adolescents, and young adults of child-bearing age to potential harm.

Concluding remarks

Looking back through this report, it is clear that there are too many warning signals to ignore. Each individual signal may present a particular level of uncertainty, but when all the signals are considered together, the alert is deafening and must not be ignored. We must halt the vaccination of our children, adolescents, and young adults of child-bearing age. This can be done safely and expeditiously because:

- The risk of severe and potentially lethal COVID-19 in these specific populations is so low that we need to be very certain that risks associated with mass vaccination are not higher;
- Asymptomatic members of this population are not a substantial risk for passing COVID-19 to others; and
- There are effective early-treatment strategies and considerations for the very few children, adolescents, and young adults of child-bearing age who may be at risk of developing severe COVID-19.

Our younger generations of Canadians are our treasures and our future. Let's not put their futures at unnecessary risk by forcing upon them experimental vaccines that present newly identified and still-to-be-clarified dangers. Proof-of-principle now exists to demonstrate the current crop of vaccines may be dangerous. This risk, no matter how theoretical, must be further investigated and all concerns put to rest prior to the vaccination of our youth. It's time to sort out the science and reduce the pressures on parents and their children so they can make truly informed decisions. It is time to pass the torch from the pharmaceutical companies and hand it to the leaders and innovators among our community of physicians and researchers who have the skills, knowledge and experience to optimize excellent treatment strategies encompassing repurposed drugs that can be deployed to reduce the future casualties of this war against COVID-19.

What to do next?

If interested in obtaining more information relevant to COVID-19, please go to the Canadian COVID Care Alliance (CCCA) website at https://www.canadiancovidcarealliance.org/. There is an option to join an e-mail list if you are interested in receiving news from the CCCA.

An example of the expertise represented within CCCA's membership and their balanced scientific messaging with an emphasis on charting a safe but rapid exit from the cycles of lockdowns can be found here: https://trialsitenews.com/covid-19-expert-panel-the-path-forward-for-canadians-trialsite-webinar/. This discussion panel was set-up after the governments of Alberta, Saskatchewan, and Ontario failed to respond to invitations to engage scientists and physicians in respectful public discussions of the scientific knowledge that has accumulated about COVID-19.

Interviews that include one of the original inventors of mRNA vaccine technology (Dr. Robert Malone) opining on findings described in this guide can be found here and here.

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Appendix 1

Most 'positive' results for the SARS-CoV-2 PCR test are negative based on the gold standard virology assay. Shown are graphs from Figure 2 of a paper published in the *Journal of the American Medical Association* (*JAMA Intern Med*. 2020; 180(11): 1447-1452. doi:10.1001/jamainternmed.2020.3862). The argument being made was that the frequency at which asymptomatic people tested positive for SARS-CoV-2 was like that observed for people with symptomatic infections. However, new cut-offs for a positive test result were placed at 22 (orange line) and 30 (red line) PCR cycles. These are the limits (depending on the laboratory) at which replication-competent SARS-CoV-2 can no longer be recovered from samples according to the gold standard functional virology assay. When this is done, it is apparent that most of the results would be negative (*i.e.* these samples would fail to transmit infectious SARS-CoV-2).