MRNA Covid Vaccines: A Risk-Benefit Analysis

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Written by Sadaf Gilani

Amidst the plethora of Covid-related issues, the Covid injections are the most imminent. Two formulations have received interim approval from the FDA, and Health Canada: Pfizer/BioNtech and Moderna.

Both these injections are employing the same technology, synthetic gene therapy (SGT), which is being dispensed to the populace for the first time in human history.

Medications are given to sick people to treat disease. Vaccines are given to healthy people to prevent an infection. Therefore consideration of risk-benefit analysis is paramount.

Covid is the umbrella label for PCR "positive" people regardless of clinical presentation. Most are "asymptomatic,"some have generic cold/flu symptoms, and a few present with moderate or severe respiratory distress. Unfortunately, the PCR assays being used for diagnosis, are not fit for purpose. Most PCR assays are constructed based on the German Drosten et al. protocol.

On November 27th 2020, 22 scientists submitted a request for retraction of this protocol which was published in the journal Eurosurveillance, citing a number of fatal design flaws.

It is also important to note, despite SarsCov2 virus and the syndrome labelled as Covid being used interchangeably, causation has not been proven as per Koch's postulates.

The first metric which every medical doctor must convey to a person is how deadly Covid actually is. This is context for the legal and ethical practice of informed consent.

Incidentally, all Covid death stats are inflated: under direction of the WHO, deaths 'from" and incidentally "with" Covid are not distinguished. Death coding has changed compared to Influenza/Pneumonia. According to one published analysis, this has resulted in over 16 times inflation of death stats, as supported by CDC data.

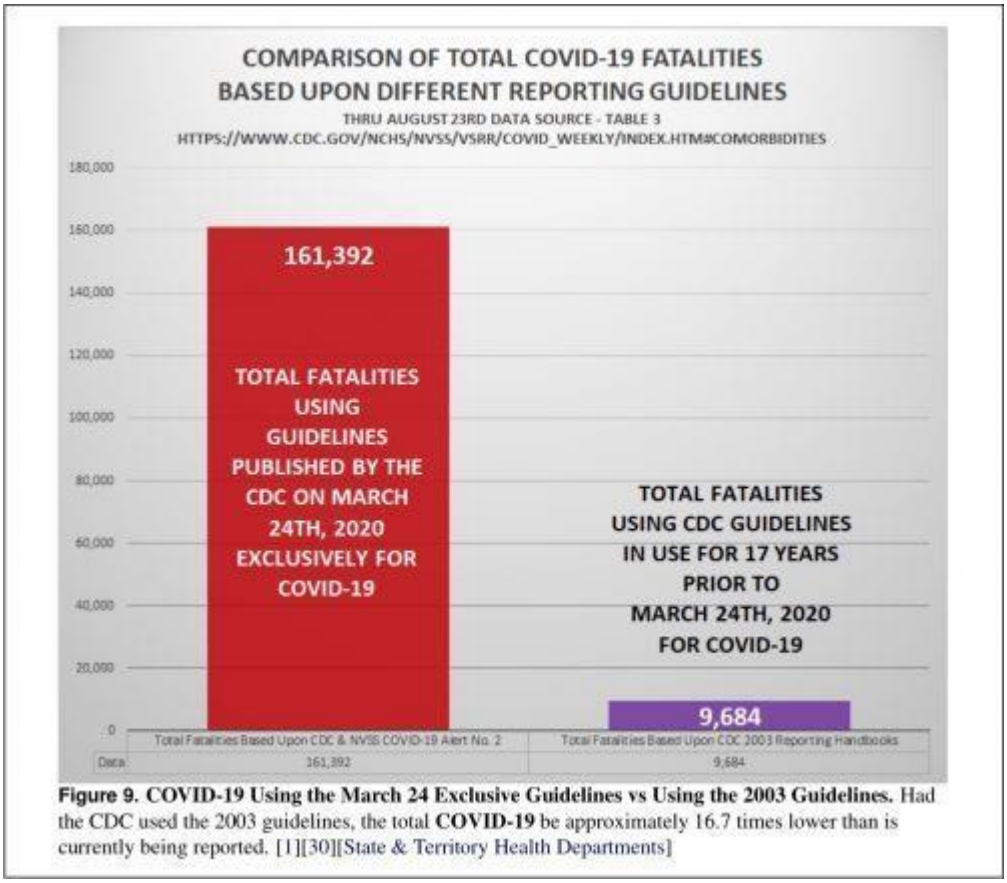


Figure 9. COVID-19 Using the March 24 Exclusive Guidelines vs Using the 2003 Guidelines. Had the CDC used the 2003 guidelines, the total **COVID-19** be approximately 16.7 times lower than is currently being reported. [1][30][State & Territory Health Departments]

Furthermore, Infection Fatality Rate (IFR) stats based on seroprevalence antibody studies are also inflated since T-cell immunity, is not measured in these studies. This may result in a 3-5X *lower* IFR for Covid. Regardless, the general IFR is on order of the seasonal influenza, approx. 0.2%.

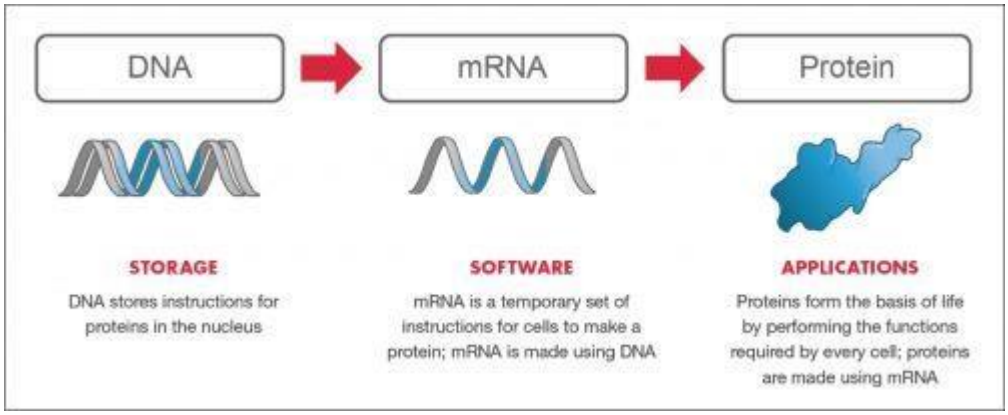
Covid mortality is a reflection of increased mortality with age, more so than influenza/pneumonia of previous years. The median age of Covid deaths (86) exceeds average life expectancy in Canada. Tragically, 70% of the deaths in the province of Ontario took place in care homes. The mortality rate from Covid in Canada under 59 years of age is 0.0017%.

According to the CDC, the survival from Covid (with inflated stats) is as follows: (under 20) 99.997%, (29-49) 99.98%, (50-69) 99.5% and (over 70), 94.6%.

The Covid synthetic gene therapy injections employ synthetic, thermostable nucleotide sequences which are wrapped in a PEG (polyethylene glycol)-lipid nanoparticles to protect from destruction in the bloodstream and facilitate entry into the cells. The claim is that the cellular machinery will engage with these synthetic sequences and produce segments which code for the SarsCov2 S1 spike protein. It is believed that the immune system will mount a sufficient antibody response.

Dr David Martin, emphasized that this technology does not meet the definition of a traditional vaccine as per the manufacturers' claims. The trials do not test for *reduction in transmission*. These therapies do not *prevent infection*, merely reduction in one or more symptoms.

Interestingly, Moderna describes its technology as the "software of life," not a vaccine.



Media outlets, politicians, and public health officials have blared the 95% efficacy for both formulations. To the casual observer, this would denote 95% reduction in hospitalizations or deaths. When in fact the 95% is calculated, based upon the "Primary Efficacy Endpoints."

In the trial literature these endpoints are described by both companies as non-severe cold/flu SYMPTOMS coupled with a positive PCR.

Pfizer has reported:

For the primary efficacy endpoint, the case definition for a confirmed COVID-19 case was the presence of at least one of the following symptoms and a positive SARS-CoV-2 NAAT within 4 days of the symptomatic period: Fever; New or increased cough; New or increased shortness of breath; Chills; New or increased muscle pain; New loss of taste or smell; Sore throat; Diarrhea; Vomiting."

Moderna reported in likeness:

*For the primary efficacy endpoint, the case definition for a confirmed COVID-19 case was defined as: At least **TWO** of the following systemic symptoms: Fever (≥38ºC), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s), **OR** At least **ONE** of the following respiratory signs/ symptoms: cough, shortness of breath or difficulty breathing, OR clinical or radiographical evidence of pneumonia; and NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR."*

To reiterate, in both trials, once one/two symptoms appeared in a participant, it was designated a "case" or "event" when coupled with a positive PCR "test". Once 170 "cases" occurred in Pfizer/BioNtech trial, and 196 "cases" occurred in Moderna trial, this data was used to calculate

efficacy. Shockingly, only under 200 cases for a novel therapy which is being deployed/subjected on millions of people around the world.

Furthermore, people are not being informed that "95%" or so efficacy, is calculated based on a useless metric of relative efficacy and is therefore very misleading.

Eg.Pfizer/BioNtech:

8 "cases" in vaccine group
162 "cases" in placebo group

8/162 = 5%
100%-5%= 95%

Therefore, they are claiming that the synthetic gene therapy injections are 95% efficacious. What they are not factoring in is the size of the denominator. If it is large, then with 8 vs 162, the difference becomes less significant. It matters how many people were in each group, for example, whether this be 200, 2,000, or 20,000.

This is the absolute risk reduction for Pfizer/BioNtech, each group had over 18,000 people!

Injection Group: 8/18,198 = 0.04%
Placebo Group: 162/18,325= 0.88%

Therefore, the absolute risk reduction for Primary Efficacy Endpoint is 0.84%. (ie. 0.88-0.04)

This means, that someone who takes the Pfizer/BioNtech injection, has less than 1% chance of reducing at least one symptom of non-severe "Covid" for a period of 2 months. This means that someone who takes this injection has over 99% chance that it won't work, regarding the efficacy. Over 100 people have to be injected for it to "work" in one person.

	Pfizer/BioNtech Placebo Group	Pfizer/BioNtech Injection Group	Absolute risk reduction
Non-severe "Covid"	**0.88%**	0.044%	0.84%
Severe "Covid"	0.04%	0.005%	0.035%

The actual efficacy of Pfizer/BioNtech Synthetic Gene Therapy

	Moderna Placebo Group	Moderna Injection Group	Absolute risk reduction
Non-severe "Covid"	1.33%	0.08%	1.25%
Severe "Covid"	**0.22%**	**0%**	**0.22%**

The actual efficacy of Moderna Synthetic Gene Therapy

There are many issues with the trial data, and design. It must be noted that PCR tests are not fit for purpose and without Sanger sequencing we have no idea how many of these people actually had "Covid" vs another respiratory virus or something else. This is a preeminent reason why Dr Yeadon and Dr Wodarg filed a Stay of Action on the vaccine trials.

As Dr Peter Doshi, Associate Editor of BMJ highlighted, access to the raw data is required to further elucidate the areas of concern:

With 20 times more suspected covid-19 than confirmed covid-19, and trials not designed to assess whether the vaccines can interrupt viral transmission, an analysis of severe disease irrespective of etiologic agent—namely, rates of hospitalizations, ICU cases, and deaths amongst trial participants—seems warranted, and is the only way to assess the vaccines' real ability to take the edge off the pandemic."

Approximately 5-6 symptoms listed as "side effects" are the same as Covid symptoms. Pfizer/BioNtech only started counting "cases" one week after the second dose, and Moderna, 2 weeks after the second dose. Therefore, if these side effects were labelled as "Covid" symptoms instead, even the paltry efficacy of about 1% would be relegated into the negative integers.

In others words, the injected group may have been sicker with "Covid" more than the placebo group.

There have been many critiques of the applicability of the limited data to the general populace, especially the vulnerable elderly. An important analysis of this was done by Dr James Lyons-Weiler who discovered the general population is dying at a rate 6.3 times the rate of participants in the Moderna trial (including placebo and injection groups).

If Moderna's on-vaccine death rate is so far below the national death rate and also simultaneously more than five times greater than Pfizer's on-vaccine death rate, then Pfizer's study sample appears even less representative of the entire population. This, too, requires due consideration."

An integral question as to whether Pfizer/BioNtech and Moderna recruited supermen and women for their trials, comes to mind. The incidence of "severe" Covid in Placebo groups which scrutinizing the details, wasn't necessarily severe presentation, is so low that trials of 30,000-

40,000 lacked statistical power to determine reductions in hospitalizations and deaths, according to Tal Zaks, CMO Moderna.

Zaks is correct, the incidence of severe "Covid" was only 0.04% in Pfizer/BioNtech and 0.22% in Moderna. Due to this very low attack rate of severe presentation in the population, the absolute risk reduction in severe presentation, even taking data at face value, is nominal.

Therefore, potential SGT recipients must be informed that to reduce "severe" presentation, chances are over 99.5% that these synthetic gene therapies will not work.

The British Medical Journal has reported:

Hospital admissions and deaths from covid-19 are simply too uncommon in the population being studied for an effective vaccine to demonstrate statistically significant differences in a trial of 30 000 people. The same is true of its ability to save lives or prevent transmission: the trials are not designed to find out."

To convey informed consent, the side effect profile must also be considered. Up to 80% of injected trial recipients experienced side effects, in a setting for a nebulous syndrome where 80% of people are asymptomatic.

The incidences of immediate side effects in both trials were significant and dwarfed the absolute risk reduction in both the primary efficacy endpoints, as well as for "severe" Covid.

For example, for Moderna 81.9% experienced any systemic reaction. Grade 3 reactions (considered severe) were experienced by 17.4%. This is 79X more likely than the incidence of severe Covid in the Moderna group. (17.4/.22=79X) Based on preliminary reports of adverse events [emphasis added]:

This is an injury rate of 1 in every 40 jabs. This means that ***the 150 shots necessary to avert one mild case of COVID will cause serious injury to at least three people.****"*

The safety data for both companies is approximately only two months before receiving emergency use authorization status. Therefore, there is no data for mid-long term side effects, as the trials are ongoing.

The estimated completion date for Pfizer/BioNtech trials is Jan 31, 2023. The estimate completion date for Moderna trials is October 27, 2022.

According to the data, and elaborated by Tal Zaks (CMO of Moderna) the trials *are not designed to demonstrate a reduction in transmission*, due to "operational realities". It is therefore baffling how medical doctors and public health officials are proclaiming these SGTs will promote herd immunity.

The manufacturers have also made it clear that efficacy beyond 2 months or so is unknown. Therefore, the 1% absolute risk reduction in mild/moderate, cold/flu symptoms **may not last more than a few months**.

Tragically, there is no pervasive data-centred discourse, only excessive fear-mongering. Without addressing the data people cannot make an informed choice about experimental SGTs.

Many are not aware any SGT recipient who participates in this therapy is now a part of an unprecedented experiment. When Health Canada shockingly agreed to interim authorization of the Pfizer/BioNtech injection, it came alongside a caveat: The company must submit 6 months of trial data *when it is available*.

To underscore: **Health Canada approved this experimental SGT on the populace without even 6 months of trial data.**

It is difficult to embark on a comprehensive risk-benefit analysis, as there is no safety data beyond a couple of months. New vaccines typically take about 7 to 20 years of research and trials before going to market. Pfizer/Moderna ran all of their trials simultaneously, including their animal trials, instead of sequentially. As retired Health Canada research scientist Dr Qureshi elaborated, it is during proper animal trials that meaningful toxicology data is obtained.

The anaphylactic reactions observed in some people is also worrisome, worthy of analysis. Children's Health Defense submitted a request to the FDA to address PEG allergies, as up to 70% of the populace has antibodies to these compounds. *PEG has never been a component in a vaccine before*.

It must also be noted that according to an internal Health Human Services and Harvard study, less than 1% of vaccine side effects are reported. At this juncture, based on: paltry efficacy, issues with data transparency and trial design, high level of immediate side effects, and low IFR for Covid, there is already enough reason for concern.

Yet, the more disconcerting side effects are the potential mid-long term effects.

Many doctors and researchers around the world have promulgated concerns about the well-documented phenomena referred to as Antibody Dependent Enhancement (ADE) seen in some viruses such as coronaviruses.

In previous SARS, MERS, Dengue fever and RSV virus vaccine trials the exposure of wild viruses to vaccine recipients resulted in severe disease, cytokine storms, and deaths in some animal and human trials. The phenomenon of ADE did not present initially in vaccine recipients, rather it presented after vaccine recipients were exposed to wild viruses.

This is the reason we do not have a vaccine for the common cold, MERS and SARS which is 78% homologous with SarsCov2 (based on analysis of the digital genome). Immunology Professor Dolores Cahill warned that this disease enhancement may cause many vaccine recipients to die months or years down the road. Esteemed German infectious disease specialist, Dr Sucharit Bhakdi opined:

This vaccine will lead you to your doom."

Researchers in The International Journal of Clinical Practice stated:

The absence of ADE evidence in COVID-19 vaccine data so far does not absolve investigators from disclosing the risk of enhanced disease to vaccine trial participants, and it remains a realistic, non-theoretical risk to the subjects. Unfortunately, no vaccines for any of the known human CoVs have been licensed, although several potential SARS-CoV and MERS-CoV vaccines have advanced into human clinical trials for years, suggesting the development of effective vaccines against human CoVs has always been challenging."

Traditional vaccines involve injection of the pathogen/toxin in whole/part to elicit an immune reaction. For the first time in history, the recipients' cells will manufacture the pathogen, the S1 spike protein of SarsCov2 virus.

In a presentation for Emergency Use Authorization to the FDA, Moderna reps explained that the mRNA stays in the cytoplasm of the cells, manufactures the S1 Spike Protein and then is destroyed. As Dr Sucharit Bhakdi and others have queried:

Where else do these packages go?"

Also, based on a couple of months of safety data, we do not know that these mRNAs last long enough to manufacture the protein but not long enough to exert deleterious effects. This nascent technology is risky.

Firstly, the RNA sequences are synthetic. Therefore, we do not know how long they will last in the cells. Dr Judy Mikovits has expressed concerns in that they may not be degraded immediately, and perhaps linger for days, months, years.

Moderna previously tried to use this same technology to treat Crigler-Najjar syndrome and was not able to strike the balance between therapeutic dose and toxic side effects.

It's encased in nanolipid to prevent it from degrading too rapidly, but what happens if the mRNA degrades too slowly, or not at all? What happens when you turn your body into a "viral protein factory", thus keeping antibody production activated on a continual basis with no ability to shut down?

So, taking a synthetic messenger RNA and making it thermostable — making it not break down — [is problematic]. We have lots of enzymes (RNAses and DNAses) that degrade free RNA and DNA because, again, those are danger signals to your immune system. They literally drive inflammatory diseases.

Moderna boldly claims that these synthetic mRNAs will not integrate with the host cell DNA. The discovery of epigenetics has revealed that DNA expression is in flux and constantly interacts with environmental signals. Dr Lanka explained that RNA-DNA is also a two-way process, dynamic.

There is the potential for this synthetic RNA to integrate into human DNA via the enzyme, reverse transcriptase. This may lead to mutagenesis, possibly cancer. It may lead to birth defects if it integrates into the germ cells of the injected. Reassurances cannot be made based on such limited safety data.

Therefore, it is important to clearly understand the potential risks of this type of mRNA-based vaccine, which include local and systemic inflammatory responses, the biodistribution and persistence of the induced immunogen expression, possible development of autoreactive antibodies and toxic effects of any non-native nucleotides and delivery system component"

It has been discovered that commonly transcribed mRNA sequences can integrate with DNA for form "R loop" patterns. Dysregulation of these sequences is implicated in different pathologies, including *"oncogenic stress."*

This finding was referred to as:

unexpected interplay between RNA modifications (the epitranscriptome) and the maintenance of genome integrity."

Clearly, we are in the nascent stages of understanding the complex field of epigenetics. The S1 SarsCov2 spike protein is highly homologous with HERV (human endogenous retrovirus) protein knowns as Syncytin-1. There is the potential for autoimmunity, as the Spike protein antibodies might attack Syncytin-1.

Whilst natural infections are benign and self-limiting for the vast majority of affected people, autoimmune diseases are mostly irreversible. This is even more terrifying with the mRNA treatment.

If the translation of SarsCov2 S1 spike protein persists there is potential to cause amplification of the expression of autoimmunity. As the SGT recipients' cells are now producing the viral spike proteins, there is the potential for explosion of auto-immune diseases in coming years.

Syncytin-1's primary function is in the placenta as well as sperm. Dr Wodarg and Yeadon's Stay of Action, included concerns that the potential for antibodies against Syncytin-1 proteins (part of the placenta) may result in permanent infertility in women and possibly men as well. The manufacturers give the caveat:

It is unknown whether COVID-19 mRNA Vaccine BNT162b2 has an impact on fertility. And women of childbearing age are advised to avoid pregnancy for at least two months after their second dose."

Pregnant women were not included in either of the trials. Trial recipients were instructed to use birth control.

The PEG-lipid nanoparticle is highly lipophilic, to cross cell membranes. Renowned aluminum and neurotoxicity expert Dr Chris Shaw, stated that these nanoparticles do cross the BBB (blood-brain barrier) and cited evidence from Moderna's previous animal trials.

On social media, there have been many documented cases of bizarre neurologic symptoms in the SGT recipients. Could one mechanism be dysregulation of Syncytin-1 in the brain?

Except for the normal physiologic function of Syncytin-1 in the development of placenta, the activity and expression of Syncytin-1 increase in several diseases, such as neuropsychiatric disorders, autoimmune diseases, and cancer […] Syncytin-1 participates in human placental morphogenesis and can activate a pro-inflammatory and autoimmune cascade […] A growing number of studies indicate that Syncytin-1 plays an important role in MS."

Bottom line: elevated levels of Syncytin-1 = brain inflammation.

We now have a therapy that uses the body's own cells to produce unknown (perhaps continuous) levels of a protein that is almost identical to Syncytin-1. This is potential for disaster, as Dr Mikovits elaborated:

Syncytin is the endogenous gammaretrovirus envelope that's encoded in the human genome…We know that if syncytin…is expressed aberrantly in the body, for instance in the brain, which these lipid nanoparticles will go into, then you've got multiple sclerosis […] The expression of that gene alone enrages microglia, literally inflames and dysregulates the communication between the brain microglia, which are critical for clearing toxins and pathogens in the brain and the communication with astrocytes that dysregulates not only the immune system but the endocannabinoid system…"

In the longer term, she suspects we'll see a significant uptick in migraines, tics, Parkinson's disease, microvascular disorders, different cancers, including prostate cancer, severe pain syndromes like fibromyalgia and rheumatoid arthritis, bladder problems, kidney disease, psychosis, neurodegenerative diseases such as Lou Gehrig's disease (ALS) and sleep disorders, including narcolepsy. In young children, autism-like symptoms are likely to develop as well, she thinks.

Heart attacks are another documented side effect. Loved ones of the deceased have shared on social media that these deaths are not considered vaccine reactions and are therefore not recorded as such.