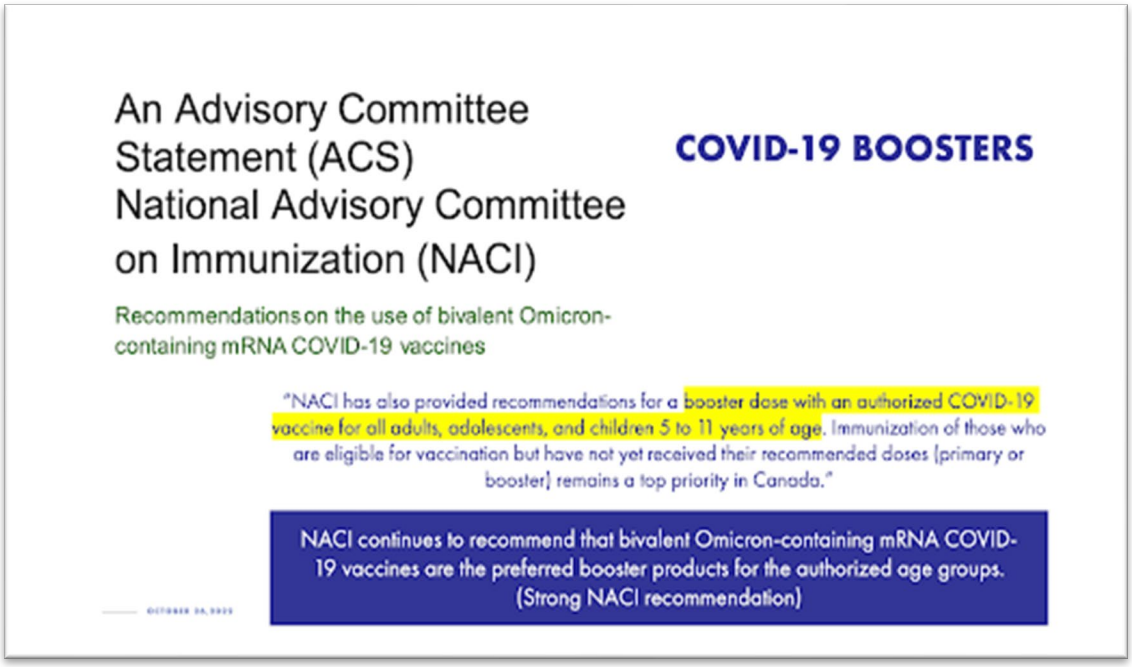
Canadian Covid Care Alliance
Alliance canadienne pour la prévention et prise-en-charge de la covid

April 2023

Dear Reader,

Last fall, the Public Health launched another COVID-19 vaccination campaign, this time focused on combating the more infectious and newly emerging Omicron BA.4/5 variants. Their new weapon? A new and improved bivalent booster with the reported additional capability to neutralize the BA.4/5 variant. While these highly touted, new, COVID-19 genetic vaccines are being rolled out nationally, newer SARS-CoV-2 variants have replaced BA.4 and BA.5, making these vaccines less effective.

Nevertheless, this push for the bivalent COVID-19 genetic vaccine boosters was backed by Canada's National Advisory Committee on Immunization (NACI), who **strongly recommended these Omicron bivalent boosters for anyone 5 years and older.** Such a strong recommendation came as a bit of a surprise given that updated guidance published by the CDC in August 2022 acknowledged that the primary series was unable to halt transmission or prevent infection and that additional protection afforded by boosters was short-lived.



When practicing evidence-based medicine, such strong recommendations would necessarily be backed by level 1 evidence: positive results from a randomized trial comparing the treatment against a current standard of care. Meeting this high threshold is even more important when working with genetic therapy, the technical classification for mRNA technology, especially as it is being given to healthy people.

This article will walk through available evidence supporting the use of these bivalent boosters to determine whether there is sufficient evidence to support Public Health claims of “safety and efficacy”.

Walking Through The Evidence

A quick review of the evidence supporting the NACI recommendations showed that their strong endorsement of the bivalent boosters was NOT based on level 1 evidence but rather on **NO EVIDENCE AT ALL**. In an unprecedented move, **NACI recommended these vaccines based on** preclinical data from 8 mice and **clinical data from a DIFFERENT vaccine, the BA.1 booster.**

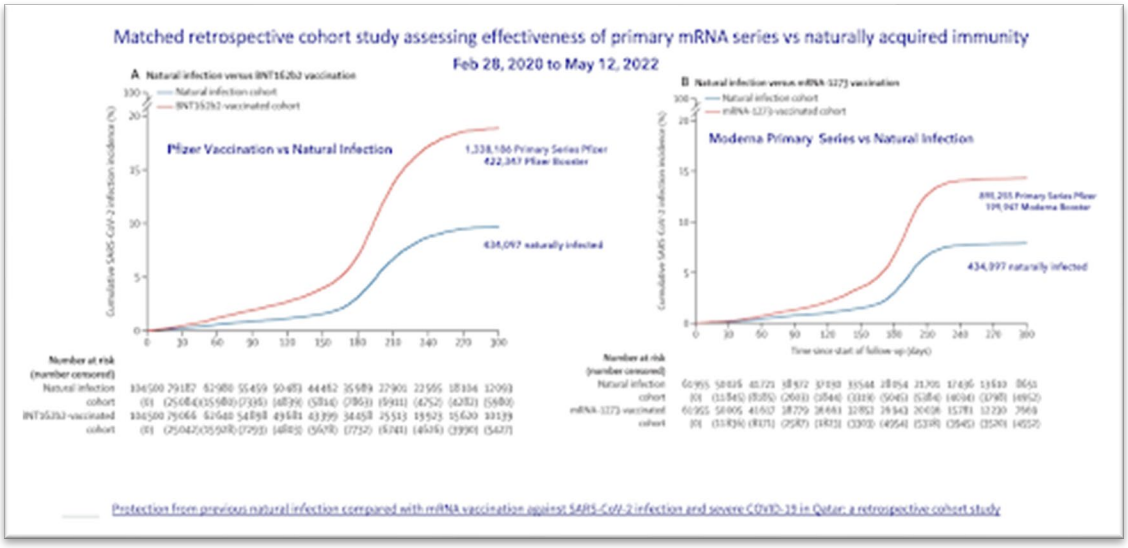
It is hard to fathom how the effectiveness and safety of one vaccine could be inferred based on the activity of another vaccine. The bivalent COVID-19 genetic vaccines incorporated genetic sequences from the original Wuhan strain and a synthetic version of Omicron that had mutations from both the BA.4 and BA.5 strains. Given the unpredictable side-effects profile of gene therapy and evidence that indicates adverse events increase with each dose of the vaccine, evaluation of the safety of such bivalent versions should be of paramount importance.

One would at least hope that the data on the BA.1 booster would provide the level 1 evidence that we would need to be assured of its safety. However, **a walk through the article published in the NEJM showed that the study was fatally flawed** - not only was it not a registered clinical trial (RCT), but it asked the wrong question, assessed the wrong endpoint, misinterpreted efficacy, misrepresented safety, and was biased from the start. We will explore these flaws in more detail below.

The Wrong Question

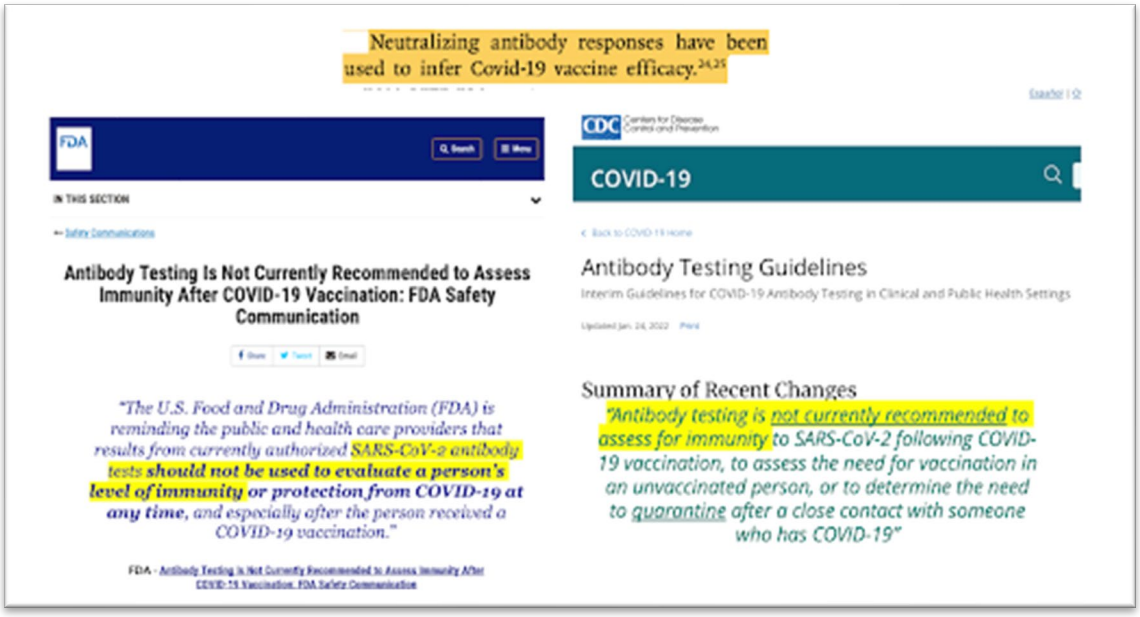
At this point in the COVID-19 crisis, most Canadians have strong naturally-acquired immunity through multiple exposures to the SARS-CoV-2 virus. Only 26% of Canadians have received boosters in the last 6 months. The BA.1 booster study compared the Omicron BA.1 booster to the original booster in adults who had received their primary series and at least one booster and had not been recently infected by SARS-CoV-2. Notably, no children were enrolled in the study. **As the people enrolled in the study do not represent the majority of Canadians, the results of this trial cannot reasonably be used as the basis for recommending these shots at this time in Canada.**

Even more, the study did not address the most important question, **which is how the BA.1 boosters compared to naturally acquired immunity.** A recent retrospective study published in The Lancet showed that those with naturally acquired immunity had an approximately 50% lower risk of contracting COVID-19 and a 76% lower risk of contracting severe, critical or fatal COVID-19 than those who had been vaccinated. **As the BA.1 study failed to provide information on how the Omicron booster compared to naturally acquired immunity, the clear standard of protection, these trial findings aren't really that helpful.**



Assessed the Wrong End-Point

Public health officials have claimed that the new boosters will prevent serious illness and death from COVID-19. Surprisingly, this efficacy was not even assessed in the study. What was assessed was the increase in neutralizing antibodies produced following an injection. These are antibodies that specifically bind to the receptor binding domain (RBD) of the spike protein, and block the ability of the viral protein to attach to the ACE2 protein on the surface of cells. Authors argue that this is important as it MAY be linked to lower rates of infection, even though both **the FDA and the CDC have clearly stated that antibody levels cannot be used as reliable measures of protection and that neutralizing antibody levels are not a correlate of prevention from COVID-19.**



Misinterpreted Effectiveness

Authors considered the study a success as more neutralizing antibodies were produced 28 days following the Omicron BA.1 booster compared to the Wuhan booster. The study also happened to explore the ability of each booster to prevent symptomatic infection **and found a 68% INCREASE in infection rate with the Omicron BA.1 booster compared to the original booster** in most participants. It is illogical **to think that higher rates of infection could lead to lower rates of hospitalization and death.**

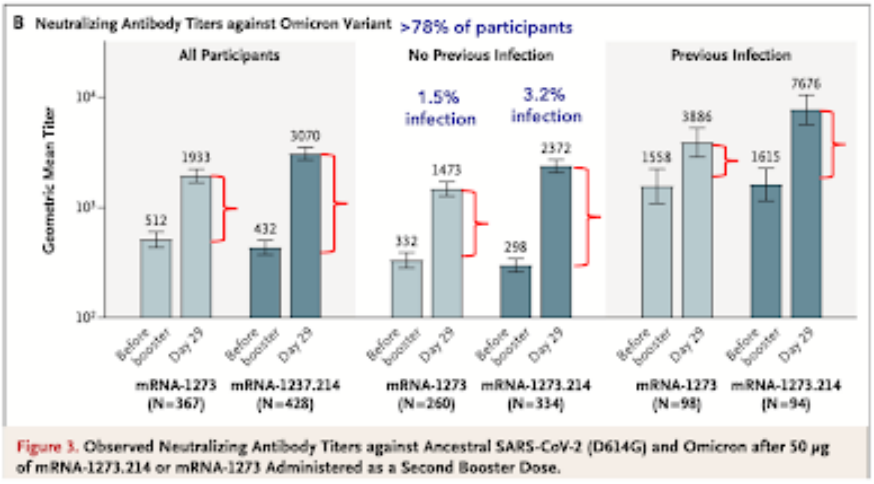
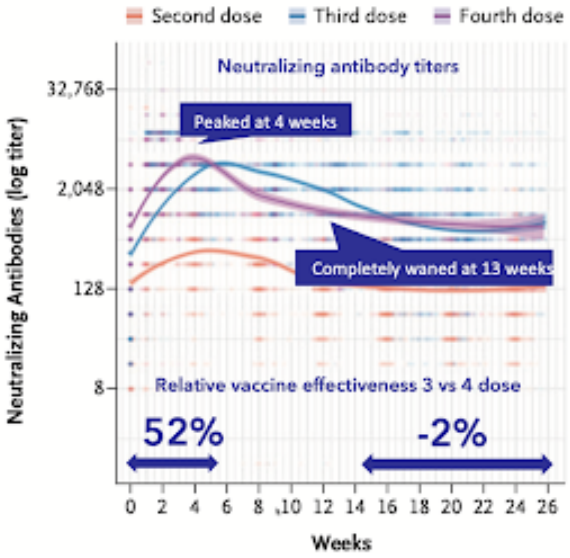


Figure 3. Observed Neutralizing Antibody Titers against Ancestral SARS-CoV-2 (D614G) and Omicron after 50 µg of mRNA-1273.214 or mRNA-1273 Administered as a Second Booster Dose.

Outcomes from this study suggest that neutralizing antibody levels are NOT a measure of immunity

Also, the study only assessed antibody levels for one month following the Omicron shot. A recent study published in NEJM reporting outcomes for a fourth Pfizer dose at six months showed that elevated antibody levels waned completely by 13 weeks. Alarmingly, there was **an increased risk of contracting COVID-19 (*i.e.*, negative vaccine effectiveness) from 15 to 26 weeks noted in this study.** If the Omicron booster increases the chance of infection at one month, we should assess what kind of effect it would have on one's immune system long-term before recommending it.



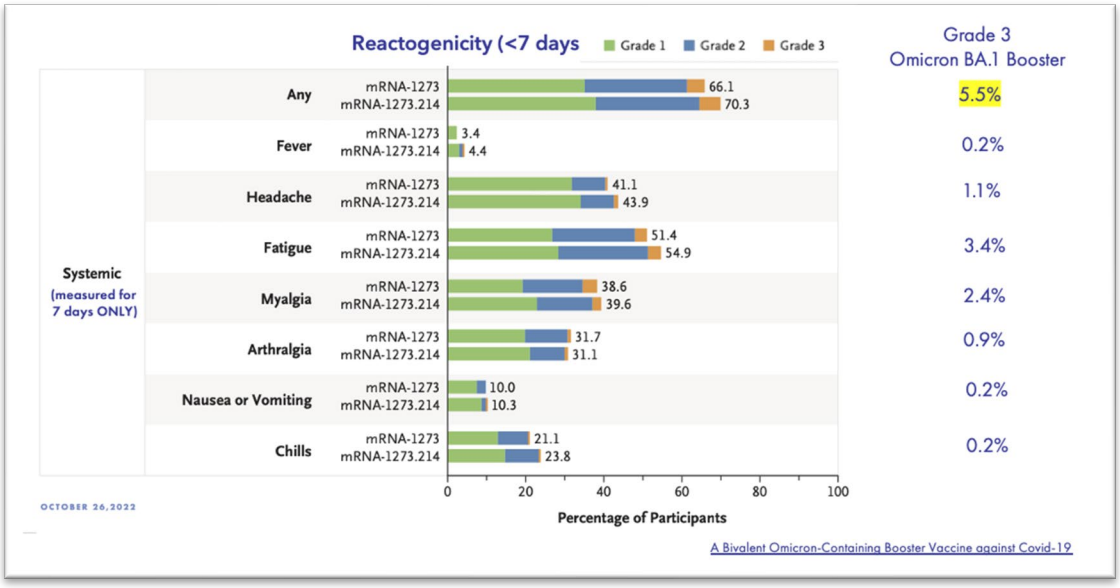
Antibody response peaked at approximately 4 weeks, waned to levels seen before the fourth dose by 13 weeks, and stabilized thereafter.

Time-specific vaccine effectiveness (which, in our analysis, compared infection rates among participants who had not yet been infected since vaccination) waned with time, decreasing from 52% (95% CI, 45 to 58) during the first 5 weeks after vaccination to −2% (95% CI, −27 to 17) at 15 to 26 weeks.

Six-Month Follow-up after a Fourth BNT162b2 Vaccine Dose

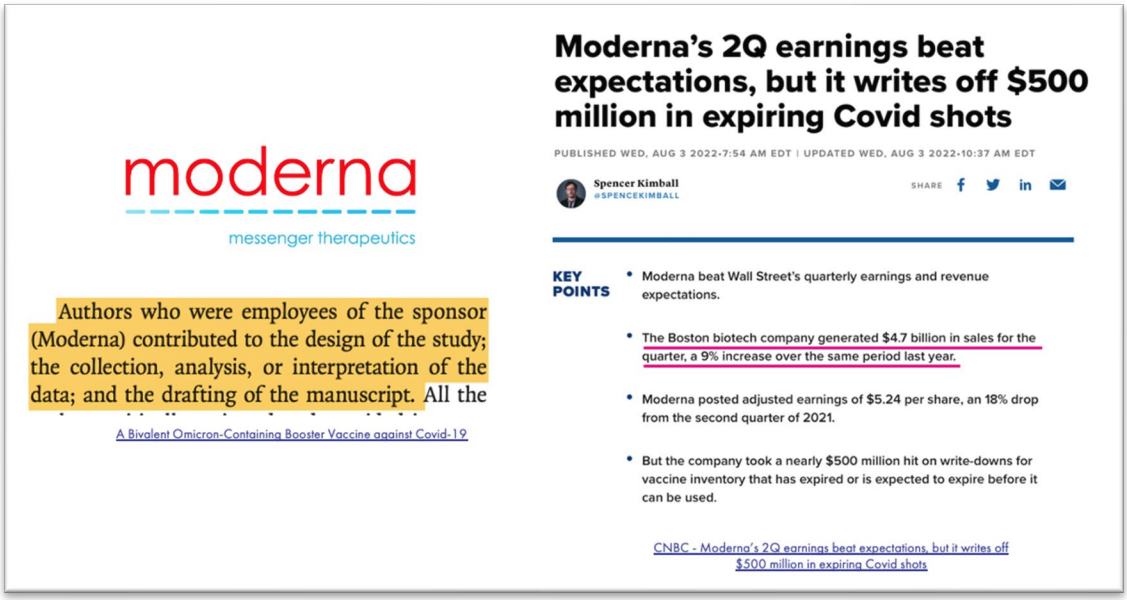
Misrepresented Safety

One of the main goals of the COVID-19 vaccines is to prevent symptomatic and severe COVID-19 infections. Although study authors report “no new safety concerns” with the Omicron booster relative to regular booster, their analysis fails to highlight that **the majority of people receiving the Omicron booster (>70%) experienced COVID-19-like symptoms** within 7 days of the injection.These systemic adverse events were **severe in 5% of recipients.** In other words, the bivalent boosters are actually causing 5 out of 100 people to get really sick shortly after receiving them.



Biased from the Start

When you see recommendations that are so disconnected from supporting evidence you need to ask if there are conflicted interests at play. Financial conflicts are where we usually start. A review of the disclosures section of BA.1 study revealed that Moderna employees were the ones who designed, executed, and published the study then went on to make a total of $4.7 billion in sales in the second quarter of 2022.



What about the "independent" advisors at NACI?

When considering conflicts of interest, you also need to consider the impact of research support for those involved in making the recommendations. A review of research funding for NACI chairs over the length of the COVID-19 crisis shows a concerning level of conflict.

Dr. Caroline Quach-Thanh, the NACI chair at the time that COVID-19 shots were approved, received a real career boost from the pandemic. Immediately following the declaration of the pandemic in March 2020, Dr. Quach personally received a $2.6 million grant from the CIHR to study various aspects of COVID-19, and went on to receive more than $10 million in grants for studies for which she was a principal investigator from the CIHR.

Dr. Shelley Deeks, the vice-chair of NACI at the time that the pandemic was declared and the chair of NACI when the Omicron booster was approved, benefited greatly from the COVID-19 vaccines. In July 2020, months before there was any data available on the COVID-19 vaccines, Deeks, as a named principal investigator of CIRN, was awarded a $3.5 million "COVID-19 Vaccine Readiness" grant.

Given how Tanh and Deeks' research careers have greatly profited from the COVID-19 crisis and the associated plan to vaccinate, it is hard to imagine how they could objectively evaluate the merits of the Omicron boosters.

Summing it All Up

This fall Public Health, under the counsel of NACI, promoted the Omicron BA.4/5 boosters to the general public as safe and effective. These recommendations were based on outcomes from a study of a different genetic injection, the BA.1 booster, that was rife with flaws. This non-RCT study asked the wrong question, assessed the wrong end-point, incorrectly interpreted effectiveness and misrepresented safety. There is also a concerning degree of conflicted interest at play in the COVID-19 guideline process.

Get Informed

One common question that people ask when they find out that Public Health is promoting untested vaccines is "If this were true, why are mainstream media and the medical establishment not picking up on it?" There are two reasonable answers to this question,-the first is that our team is wrong. To rule out this possibility, you are encouraged to thoroughly investigate the links to sources and watch Deanna McLeod's Open Mike interview on the Omicron Boosters for more information.

The other is that corporate interests have managed to suppress the truth through selective funding and extensive censorship of both the media and medical establishment. To further consider this possibility, please watch Deanna McLeod's Open Mike Interview on Vaccine Conflicts of Interest.

We thank you for taking the time to review this material, and encourage you to take responsibility for your health by making informed health choices.