September 21, 2021

COVID vaccine mandate

To Whom It May Concern,

I am not an "anti-vaxxer". I am not a conspiracy theorist. I agree with, and abide by public health measures that can reduce the COVID burden on the community and on health care. Furthermore, in my position as a hospital-based pediatrician for 11 plus years, I have consistently and successfully advocated for children to be vaccinated when their parents are hesitant to do so, often educating them about the risks and benefits of vaccines and correcting any misinformation they may have. That being said, I am strongly opposed to the vaccine mandate that AHS has put forth.

I am hospital-based pediatrician who consistently uses evidence to support my medical decision-making and provide the best care to the patients I care for. I am a father of four amazing boys. And every day, I work as hard as possible to be the best pediatrician and father I can be. These are my *raisons d'être.* I have received every vaccine available to me since birth, including influenza vaccines annually. My boys, aged 7-13, have also received every vaccine, including influenza annually, not because they're high risk, but because the science is clear that the benefit outweighs the risk. And this is how most of us practice medicine. We look to the gold standard if one exists, we search and critically analyze the evidence where it exists, and we balance the risks and benefits of every investigation and treatment we offer. I practice medicine this way, and teach my children to use this method in their lives to help guide their decision-making.

Once the various iterations of the COVID vaccine were announced, I was hopeful of a return to normalcy from the times pre-COVID, as did most people. However, I was reticent given the paucity of long-term data regarding the safety of these vaccines, especially in children. I was simultaneously weighing the risk of me getting COVID vs the risk of novel mRNA vaccines. This is why I hadn't been vaccinated at the outset of vaccine availability. The more I read the data, the more hesitant I was. Until I decided, based on my review of the literature, in a very informed way that I was taught throughout medical school and residency, that my risk from COVID was significantly less than the risk from the vaccines. That was my personal choice, and an informed and educated one. I work at Alberta Children's Hospital, and I would be remiss to not mention that the care of my patients obviously play a role in this decision-making also. Should we have seen a large volume of hospitalizations within the pediatric population, or if it had been obvious and supported by the evidence that being vaccinated reduced transmissibility to my patients, I would have adjusted my decision to reflect that. But the more I read the data, the more I realized that not to be the case, so I remained steadfast in my decision to not get this novel vaccine. When it was announced that COVID vaccines would be mandatory within Alberta, I was shocked. Nevertheless, the emergence of the DELTA variant resulting in increasing hospitalizations and severe disease, in conjunction with this mandate, provided me with the opportunity to further review the latest data. The data is clear in not supporting such a mandate and I will explain this below.

I recognize that this goes against public perception and more importantly, places me in the minority of physicians that have gone above and beyond listening to epidemiologists and other experts and have looked at the data myself. This stance risks my professional reputation among my colleagues

who think everyone should be vaccinated but have neither the time, nor the energy to review the evidence themselves. That I am risking being unable to work in what I have always thought of as a dream, with the population I'm caring for, being able to teach medical students and residents, in this hospital environment which I absolutely love for the people who make this institution truly amazing, should highlight the level of dedication I have to this cause and the emphasis I am placing on it.

I will demonstrate below that natural immunity is far superior to vaccine immunity in terms of future infection risk, discuss the risk of transmission between those vaccinated and unvaccinated, and then show vaccine effectiveness and adverse event data. I will then discuss 2 potential disastrous adverse consequences of the vaccine with respect to Antibody-Dependent Enhancement and biodistribution data. Lastly, because I am a hospital-based pediatrician and have always been an advocate for the pediatric population, I will demonstrate why this vaccine should not be administered to the pediatric population as the risks, including long-term risks, far outweigh any potential benefits.

Natural immunity vs vaccine coverage

In Israel, the largest real-world study looking at natural vs vaccine-induced immunity had over 32,000 participants, half of whom were unvaccinated, and compared their rates of re-infection vs the other half who were vaccinated and had breakthrough infections, adjusting for the time the infection/vaccine took place, ensuring all were in Jan/Feb 2021. After adjusting for comorbidities, there is a **13.06-fold increased risk** of breakthrough infection (vaccinated) vs re-infection (previous infection) in the asymptomatic group. When looking at symptomatic groups, the difference is even higher, demonstrating a **27.02-fold increased risk** of breakthrough infection vs re-infection. When not adjusting for time of first exposure to either vaccine or first infection (ie. infection occurring anytime between March 2020 and Feb 2021), the results still favored natural immunity, showing a 5.96-fold increased risk of breakthrough infection vs re-infection, and 7.13-fold increased risk in the symptomatic breakthrough group compared to the symptomatic re-infected group. Adding one dose of the vaccine after being infected, resulted in a meagre (and not statistically significant) 0.53-fold decreased risk of re-infection in the 1-dose vaccine group.[1]

This is why in Israel, one of the first countries to implement widespread immunizations, develop one of the most robust contact tracing systems, and implement vaccine passports, their passport includes those who are vaccinated and also those who have recovered from the virus, thereby demonstrating that natural immunity can be just as protective, if not more protective than the vaccine.[2] The European Union similarly accepts evidence of previous infection as immunity in its digital COVID certificate.[3]

Furthermore, in Qatar, a study following 43,000 antibody positive individuals over 35 weeks, documented that the efficacy of a previous natural COVID infection against re-infection is **between 93-99%**.[4]

The NIH and WHO both independently report that this protection from natural immunity last for at least 6-8 months (8 months is the longest period studied to date).[5-6]

Transmissibility

I cannot know for certain the impetus for the vaccine mandate within AHS. I would hope that the mandate was invoked to protect the patient population that we care for, with the notion that being vaccinated will prevent or reduce transmissibility. However, what I will demonstrate is the lack of scientific data to support it.

Previous studies have suggested that Ct values of ~30 or lower are consistent with the recovery of infectious virus in biological specimens, an indication of potential contagiousness and thus transmission to others. [7-9]

A study out of the University of Wisconsin studied 699 swabs between June 29 and July 31, 2021 when the Delta variant was the predominant strain, increasing from 69% to 95% of all swabs over that time period. Within their symptomatic subset, they found low Ct values (<25) in 212 of 310 fully vaccinated (68%) vs 246 of 389 (63%) of unvaccinated individuals. Within the asymptomatic subset, Ct values of <25 were found in 9 of 11 fully vaccinated (82%) vs 7 of 24 unvaccinated (29%) individuals.[10] The latter must be interpreted with caution given the low numbers, but the numbers are low because asymptomatic people are less likely to get tested at present. Nevertheless, this data clearly shows that the viral load of vaccinated vs unvaccinated is at the very least, not statistically significant in demonstrating that vaccinated people are less likely to transmit the virus.

A similar study out of a Massachusetts outbreak found 469 + COVID cases, 74% of whom were fully vaccinated, approximating local and national figures for immunization status. Within this study, Ct values for the fully vaccinated had a median of 22.77, not statistically different from those were unvaccinated where the median was 21.54.[11]

A multicenter trial in Singapore on hospitalized patients shows a similar lack of difference in Ct values between vaccinated (Ct mean 19.2) and non-vaccinated (Ct mean 18.8) symptomatic patients.[12]

In a large Johns Hopkins study, no significant differences were observed between vaccinated and unvaccinated Ct values in either the Alpha or Delta lineages.[13]

While there seems to be significant evidence to suggest that the current mRNA vaccines prevent serious outcomes in terms of morbidity and mortality (although at similar effectiveness to a previous COVID infection), it does not alter transmissibility, so the decision for a vaccine, especially from an informed educated healthcare worker, should rest within that individual and must not be mandated. And that doesn't even consider the waning immunity of the vaccine, or the decreased effectiveness of the vaccine against the Delta variant.

Vaccine effectiveness

Delta is clearly more transmissible than the previous variants. A Johns Hopkins study looked at over 200,000 COVID samples with 2,785 + samples tested for variants. When compared with Alpha variant, Delta has statistically significant increase in breakthrough infections (28% vs 12.4%). Most importantly, when vaccine breakthrough infection cases were compared to the unvaccinated patients in

the Alpha and Delta groups, no significant differences in the likelihood of COVID related hospital admissions were observed.[13]

Epidemiological analysis by Israel's public health services show marked decline in vaccine effectiveness in preventing infection (**39%**,[14] down from 64% just 2 weeks prior[15]) and symptomatic illness (**41%**,[14] down from 64% 2 weeks prior[15]) from Delta variant.

A large Mayo clinic study looking at over 25,000 vaccinated patients demonstrated that effectiveness of both Moderna and Pfizer waned, going from 86% and 76% respective effectiveness against COVID infection in January to 76% and **42%** effectiveness against infection in July.[16] It's important to note here that the FDA has set a 50% effectiveness threshold for approving a COVID vaccine.[17]

The CDC's own study of frontline workers similarly shows that vaccine effectiveness (65% got Pfizer and 33% Moderna of the 4200 participants) dropped from 91% pre-Delta predominance to 66% once Delta was the predominant variant.[18]

In summary, data from Israel and Mayo clinic show that the mRNA vaccines, especially Pfizer, wouldn't even be approved currently because its lack of effectiveness. And yet, shockingly, we've now moved into mandating it!!

Vaccine adverse events

Historically, vaccine adverse events are vastly underreported. Lazarus et. Al[19] demonstrated that less than 1% of vaccine adverse events are reported. The Public Health Agency of Canada's Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) and Health Canada's Canada Vigilance program have been providing surveillance in Canada for COVID vaccine related adverse events. Up to September 3, 2021, for all ages, there have been a total of 14,702 events (27.8 per 100,000 doses). Of the 14,702 reports, 3,967 were considered serious (7.5 per 100,000 doses).[20]

Specifically, a large multi-center trial involving 40 hospitals across 4 states demonstrated the risk of myocarditis or pericarditis post-vaccine is 2.8 per 100,000.[21] Although that number appears low, it is a statistically significant increase compared to pre-COVID vaccine rate, where the mean monthly number of myocarditis was 16.9 vs 27.3 during the vaccine period; the mean monthly number of pericarditis in the pre-vaccine period was 49.1 vs 78.8 during the vaccine period. [21]

Please consider the hospitalization risk from COVID infection among the pediatric population. The cumulative risk from the start of the pandemic is 49.7 per 100,000.[22]

The key points are that the adverse events reporting is significantly underreported, so the true serious adverse events are much higher than reported. Even if we suppose that reporting is higher than 1%, even if it was 10%, the true incidence of **serious adverse events** would be approximately 75 per 100,000, much higher than the hospitalization rates in the pediatric population. Furthermore, the cumulative hospitalization risk includes cases from February 2020, while adverse events after the vaccine were from after February 2021, a full year later.

It is very important to note that the adverse events being reported are obviously short-term and temporally related to the vaccine. Many of the adverse events in pediatrics can be mid- to long-term. It is obviously very difficult to follow long-term events from vaccines as this would be resource-intensive and there has historically been very little motivation from vaccine producers and regulators to make resources available for such studies.

An example of such a long-term event would be the thrombotic events that have been known to be an adverse event of these mRNA vaccines. Micro-clots that would be insufficient to cause observable symptoms could certainly raise the baseline for thrombotic disease and future significant events.[23]

Examples of long-term vaccine adverse events include HBV vaccine leading to increased development of multiple sclerosis up to and beyond 3 years later[24-25], HPV vaccine and development of primary ovarian failure within 2 years of the vaccine[26], and HiB vaccine and insulin-dependent diabetes occurring in clusters approximately 38 months after vaccination[27].

Lastly, in a recent Phase III study performed in the pediatric population, the Pfizer vaccine was tested on a group of 2,260 children, aged 12-15 years, with no prior clinical signs of COVID infection.[28] Within this study, only 1,005 children were given the vaccine, which would obviously miss any potential adverse events, even very serious ones, if the rate of such an event was less common than 1 in 1,000. So even if there was a 1 in 1,200 risk of severe outcome such as death, this Phase III study would not capture it!!

Antibody-Dependent Enhancement

Antibody-dependent enhancement (ADE) is a critical issue within the COVID vaccine. This is a phenomenon in which an antibody actually facilitates entry of the pathogen into a host allowing for higher virus production, while also suppressing cellular innate antiviral immune responses, and consequently exacerbating the disease from this pathogen.[29] We have seen real world evidence of this with Dengue virus[30-34], and in fact, we have seen that the dengue vaccine CYD-TDV was not approved in under 9 year-olds because immunization in the 2-5 year old group showed ADE and increased hospitalization in the **3rd year of follow-up**.[35-37] It is also seen in RSV with enhanced disease after administration of the first vaccine developed against it.[38-40]

Most importantly, ADE has been shown in the SARS-CoV immunization. SARS-CoV is approximately 80% genetically identical to SARS-CoV-2.[41] In vitro studies demonstrated ADE by observing that antibodies specific to the viral surface spike protein enhanced viral infection of immune cells.[41-45] In animals vaccinated with SARS-CoV, mouse studies have similarly shown enhanced immunopathology[41,46-48], as have cat studies[49-51]. Further, immunization of macaques enhanced pulmonary infiltration and resulted in more severe lung injury compared to unvaccinated animals.[52]

ADE has been demonstrated to occur in the virus most genetically similar to SARS-CoV-2 from a vaccine that utilizes the spike protein just like the mRNA vaccines we are using now! Moreover, the lesson learned from the preschool age group in Dengue demonstrates that long-term studies are required to identify ADE.

Biodistribution Data

The S1 antigen was found in the plasma in 11 of 13 participants who had received their first mRNA vaccine, while not identifying nucleocapsid antigen, thereby demonstrating that the S1 antigen of the vaccine is circulating throughout the body, and without evidence of prior natural infection.[53] S1 subunit of the spike protein was also found to cross the blood-brain barrier and was thus found in the brain parenchyma, as well as in the lung, spleen, kidney and liver of injected mice.[54]

An open letter from the European Medicines Agency (EMA), which is the agency of the European Union dedicated to the evaluation and supervision of medicinal products, notes that nonclinical pharmacokinetic studies such as biodistribution studies are not required to support the development and authorization of vaccines for infectious diseases.[55] I can understand this rationale as it would be more relevant to look at clinical outcomes, but when long-term outcomes do not exist in the setting of a novel vaccine, biodistribution can be used as a surrogate marker to understand potential long-term outcomes. For example, if we show biodistribution and accumulation in the brain or reproductive organs, it would obviously affect the risk-benefit ratio that many use to decide whether to get vaccinated.

Pfizer's own surrogate study of distribution in animals confirms biodistribution to the liver and plasma.[56] A Pfizer Confidential study also demonstrated accumulation in adrenal glands, liver, spleen, bone marrow, and ovaries.[57] Similarly, Moderna's own surrogate studies of distribution show inflammatory changes in the spleen and lymph nodes[58], as well as in subcutaneous tissue, dermis, epidermis, skeletal muscle, and perineural tissue.[59]

Most concerningly, within the EMA's Assessment Report on Moderna's COVID-19 vaccine, there is demonstration of decreased fertility in rats that were vaccinated, with **an overall pregnancy index that was lower** in mRNA-1273 vaccinated female rats (84.1%), compared to control animals (93.2%).[59]

So why are we not looking at biodistribution data as a marker until more time has elapsed and we can fully understand the impact on **reproduction**?? Especially in the adolescent population where the known risks of these vaccines already far outweigh the benefits!

Vaccine in the pediatric population

One of the most comprehensive early studies showed that the majority of the pediatric population suffers only mild disease (83%), while 13% are asymptomatic and only 3% presenting with severe disease.[60] Other studies have revealed the asymptomatic rate in children to be 26% in the US[61], 36% in Alberta[62], 22% in Korea[63].

During the period when the Delta variant became the predominant strain, the weekly hospitalization rate was only 1.4 per 100,000 children. When we look at cumulative COVID-associated hospitalizations, not mentioning anything about their reasons for admission, nor whether they had COVID-associated presentations, only COVID positivity, the cumulative risk for hospitalization is still only 49.7 per 100,000 from March 1, 2020 through August 14, 2021.[22] Looking deeper into hospitalization rates with COVID positivity, the CDC has shown that from Jan-March, 2021, only **54% were thought to**

be COVID related. Within that segment of presumed COVID-related admissions, **71% had ≥ 1 significant underlying medical condition**, and yet still, the median length of stay in hospital was only **2.4 days**.[64]

Adolescents (12-17) specifically have been described, by the CDC's data, to have a cumulative hospitalization rate associated with COVID of 63.7 per 100,000. When we break down this down into the weekly hospitalization rate rather than the rate since the pandemic started, we can then further examine the difference between the vaccinated and unvaccinated, and their weekly hospitalization rate is **0.1 vs 0.8 per 100,000 respectively**.[22]

Given the asymptomatic positive rates in pediatrics, and studies like the CDC looking at COVID-related vs COVID-associated admissions, we can see that most studies are clearly overreporting the hospitalization rates. The vaccination data becomes much less robust, because although adolescents still have a higher rate of hospitalization when unvaccinated, the weekly hospitalization rates for symptomatic patients who are hospitalized with COVID symptoms becomes somewhere in the range of 0.05 per 100,000 in the vaccinated to 0.4 per 100,000 in the unvaccinated.

Of note, severe disease has been relatively unaffected by the Delta variant in pediatrics, where approximately 23% of those hospitalization required ICU admission with Delta compared to 27% with previous variants.[65]

Hospitalization Rates of other viral RTIs

A German study looking at cumulative hospitalization rates over 1 season in all pediatric patients demonstrated the rates for Influenza A to be 53 per 100,000, Influenza B to be 16 per 100,000 and RSV to be 165 per 100,000.[66]

The CDC cumulative hospitalization rates (and average weekly rates, with 28 weeks in a reporting season) for influenza are 41.8 per 100,000 for the 2019-2020 season (1.5 per 100,000 average weekly rate), 33.8 per 100,000 for the 2018-2019 season (1.2 per 100,000 average weekly rate), 33.5 per 100,000 for the 2017-2018 season (1.2 per 100,000 average weekly rate).[67]

We are requiring adolescents to be vaccinated to go to restaurants, concerts, museums, movie theatres, and even playing hockey, among other restrictions, when their weekly rate of being hospitalized related to COVID while being unvaccinated is **0.4 per 100,000!!!** This is approximately **one third** of the risk of hospitalization from influenza!!! And it is likely an overestimation given what myself and all of us are seeing at Alberta Children's Hospital, that the burden of COVID-caused disease is much lower than for other respiratory viruses in years past.

Pediatric Transmissibility

The current mandates within the pediatric population certainly imply that those governing these mandates are attempting to protect children from severe disease, which I've described above as a very rare phenomenon above. Therefore, the only other plausible rationale for the mandates would be to limit transmissibility to the population at large. While children are certainly theoretically at risk of spreading respiratory viruses given their community contact during school or extra-curricular activities, the data does NOT support that.

A meta-analysis examining the role of children in COVID transmission revealed that only 3.8% of all transmission clusters were identified as having a pediatric index case.[68] This is similar to other household contact studies from China[69] and Geneva[70] demonstrating a child as the suspected index case transmitting COVID to the rest of the family in 4% and 8% of the cases respectively. When examining the percentage of households where the index case was a child, numerous studies demonstrate the same effect. The index case was a child in 7% of the households in Ontario[71], 8% in Switzerland[70], 9% in Greece[72], 5% in Denmark[73], 5% in 2 different regions in China[74,75], 3% in South Korea[76], 0.5% in another South Korean study[77], and 1% in Wuhan[78].

It is abundantly clear that children are **NOT** driving the transmission of COVID to the rest of the community.

Conclusion

In conclusion, the mRNA vaccines brought forward for the prevention of COVID have been shown to be significantly less effective than natural infection in preventing subsequent infection. Surrogate markers of transmissibility via Ct values demonstrate no difference between vaccinated and unvaccinated individuals. The vaccines are no longer as effective as they were during Pfizer and Moderna's trials, falling to as low as 39%, below the threshold required for FDA approval. Adverse events related to COVID have only been studied in the short term, despite evidence from other vaccines that significant events can occur months or years later. Antibody-dependent enhancement is a considerate risk within this vaccine, especially when comparing SARS-CoV-2 to its closest genetic virus SARS-CoV, which showed devastating injury in non-human primates, and can be driving more severe outcomes within the population at large with respect to later variants, on top of driving further variant evolution. Reporting of adverse events is historically severely underreported, and within the pediatric population, these events clearly exceed the burden of disease. The most severe outcomes within pediatrics have not been appropriately studied as the timeline after vaccination is too short, the biodistribution data is not expansive (and often not being done at all) and yet still concerning with respect to accumulation in various organs, and rat models showing decreased fertility. Finally, the pediatric population is **NOT** seeing significant severe outcomes in general, and certainly not when compared to other respiratory illnesses, and are **NOT** drivers of transmission either.

Throughout my professional career, I have always been an advocate for the pediatric population and now**, it is more important than ever that we all recognize that the risks of these vaccines in pediatrics outweigh the benefits**, as I have demonstrated above. Government decisions as well as the media have rendered those who look at the science as "anti-vaxxers", whereas that label couldn't be further from the truth.

I expect our leaders to stand up for our children and adolescents, and request that they remove the "safe and effective" label as it pertains to vaccinating our children with experimental vaccines.

They are NEITHER safe, NOR effective in this population.

I do not want to my nursing colleagues and friends to have any more on their plate than they already do. I would never wish anything but the best for those who truly are the glue in our health care system and the reason why our hospital is such an amazing place and so well-respected. I feel the stress for them as they are re-deployed through all this. I certainly do not want to see the adult intensive care units to be at or near capacity. But the message that the vaccine is the way out is WRONG, and this has been the case throughout the pandemic. We must listen to the science and recognize **NATURAL IMMUNITY**. It is the safest and best path forward. For ourselves, and especially for our children. Starting with that recognition like Israel and the European Union is a critical first step.

Thank you for reading my letter above and taking its contents with the utmost serious attention it deserves. I would welcome the opportunity to discuss any aspects of it further. Let us not forget what we've all been trained to do, and realize that good science requires dialogue and debate. Those of us who see the evidence as I have pointed out should not be ostracized, but welcomed.

Yours sincerely,

J. Michael Vila, M.D., F.R.C.P.C.
Pediatrician
Section of Pediatric Hospital Medicine
Alberta Children's Hospital
Clinical Assistant Professor of Pediatrics, University of Calgary
mike.vila@albertahealthservices.ca

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