An examination of COVID-19 vaccine mandates in Canada: The scientific and ethical argument against this ill-conceived move

BY: Dr. Shirin Kalyan (PhD)
Doctorate, Experimental Medicine/Immunology (UBC)
Adjunct Professor, Medicine (University of British Columbia)

Reasonable limits can be considered by governing bodies if these limits can be demonstrably justified in a free and democratic society.
- Canadian Charter of Rights & Freedoms

Within this framework, a vaccine mandate can be reasonably justified in a pandemic if:

1) The vaccines available to Canadians at this time can expect to significantly limit the spread of disease
2) The available vaccines have demonstrated to be reliably effective against the disease
3) The mandate is not overly broad or unreasonable, and is equitable
4) Those subjected to the vaccine mandate can make informed consent, which includes knowing the long-term safety and efficacy profile of the vaccines
5) There is a reasonable, if not rigorous, risk-benefit analysis performed such that those subjected to the mandate can expect to know their risk of severe disease from infection and the potential serious adverse events of the vaccine of someone of their age, sex, and physical health

The above points shall now be singularly considered with the latest evidence we have for guidance...

1) Efficacy against disease transmission

The nucleic acid delivery platform vaccines in use in Canada have not shown the ability to deter the spread of the dominant delta variant of SARS-CoV-2 in circulation across Canada. A study done by scientists at Oxford in the UK found **fully vaccinated individuals who experience "breakthrough" infections have viral loads as high as unvaccinated individuals** (reference: https://www.bmj.com/content/374/bmj.n2074). This is among the most basic arguments against the judicial imposition of a vaccine mandate. Not only do these vaccines not fulfill the objectives of the mandates according to the science; the imposition of these mandates provides a false sense of security. The delta variant was selected for and continues to spread in regions that are highly vaccinated using the mRNA vaccines (which are single antigen target vaccines).

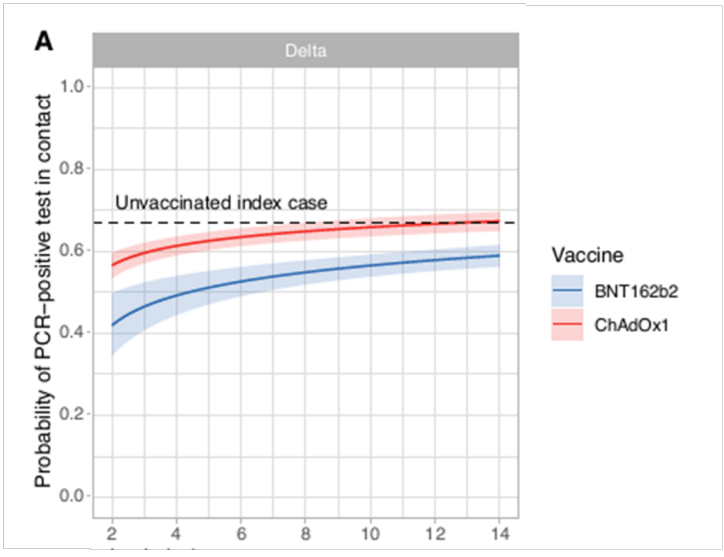
A study published in the New England Journal of Medicine describes the resurgence of SARS-CoV-2 infections in highly vaccinated healthcare workers (the majority of those infected were fully vaccinated; reference: https://www.nejm.org/doi/full/10.1056/NEJMc2112981#). Thus, the rational of a vaccine mandate stands on faulty ground on this basis alone. In the UK, cases are soaring, and the majority of cases in those over 30 years

old (as of October 2021) are in those fully vaccinated, according to the Vaccine Surveillance Report (week 41) put out by Public Health England. Closer to home, the misguided application of the vaccine mandates in Canada is in full display by the report of a COVID-19 outbreak in the N.W.T Legislative Assembly that was traced back to fully vaxxed MLA, Steve Norn, following his return from Alberta.

A well-designed study (https://www.medrxiv.org/content/10.1101/2021.09.28.21264260v1) that followed-up with contacts of infected individuals found that the likelihood of transmitting the disease increases in fully vaccinated individuals over time (in line with the "waning" immunity phenomenon noted in Point 2 below). As shown in Figure 1, a person fully vaccinated with the AstraZeneca viral vector vaccine is just as likely to pass on the infection two months post-vaccination, as an unvaccinated person. An individual fully vaccinated with the Pfizer-BioNTech mRNA vaccine is 60% likely to pass on the infection at 12 weeks post-last vaccination (compared to ~67% likelihood of transmission from a person with no immunity). A subsequent study that was reported on in *The Guardian* found **that fully vaccinated individuals are just as likely** as those with no previous immunity **to transmit the infection to members of their household**. As such, the vaccines in use in Canada currently are quite leaky and the durability of their immune protection is unknown (Point 2 below), which questions the rational of the absolutist mandates – especially in relation to those with infection-acquired immunity (now called "natural" immunity). The best study to date assessing natural immunity to vaccination, found **those with infection-acquired immunity (who are unvaccinated) are 27 times less likely to experience a re-infection and 8 times less likely to be hospitalized with COVID-19, compared to a fully vaccinated individual** (https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1). More discussion on the lack of recognition of natural immunity in Point 3 below.

Figure 1

Probability of infection in an unvaccinated contact by a fully vaccinated or unvaccinated case positive for SARS-CoV-2



Weeks following vaccination

Source: *"The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission"* by DW Eyre et al. https://www.medrxiv.org/content/10.1101/2021.09.28.21264260v1

In support of the above evidence regarding the poor ability of the current vaccines to prevent transmission, a study found "there appears to be no discernible relationship between percentage of population fully vaccinated and new COVID-19 cases... In fact, the trend line suggests a marginally positive association such that countries with higher percentage of population fully vaccinated have *higher* COVID-19 cases per 1 million people" (https://link.springer.com/article/10.1007/s10654-021-00808-7). This is reason to abandon the mandates, as many common-sense countries have. The transparent recognition of evidence has earned these countries, which include Singapore, Sweden, Norway and Denmark, the trust of the public – particularly in respect to the competence of their public health professionals. As such, these nations are now in the envious position of lifting most of their COVID-19 restrictions, while having similar or lower vaccination rates than Canada, without ever needing to implement heavy-handed mandates. Public trust thus continues to be placed in the competence of their government given their respect of personal boundaries while dealing with this infectious threat through evidence rather than politics.

Lastly, there is the additional issue of imperfect vaccination of a large population selecting for more virulent pathogens (https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002198). Experimentally it has been shown that "anti-disease vaccines that do not prevent transmission can create conditions that promote the emergence of pathogen strains that cause more severe disease in unvaccinated hosts."

2) Vaccine efficacy

In direct relation to the above, there has been a recognition of a precipitous drop of vaccine efficacy, defined as the ability to prevent COVID-19 infection, with the mRNA vaccines, over a relatively brief period (https://www.nejm.org/doi/full/10.1056/NEJMoa2114114). As noted in the large population-based study published in NEJM, vaccine efficacy decline accelerated "after the fourth month to reach approximately 20% in months 5 through 7 after the second dose." This same dramatic loss of efficacy has been independently verified in another population-based study that found vaccine efficacy dropped from **92% at day 15-30 to 47% at day 121-180; no effectiveness was detected day 211 onwards.** This is problematic given that transmission of disease is highly likely in those fully vaccinated who experience what has come to be called "breakthrough" infections, as covered in detail above. Although certain jurisdictions have decided to keep plunging on with 3rd and 4th booster shots in less than a year due to skyrocketing COVID-19 cases in highly vaccinated regions, **this not sustainable. Even more pertinent, no trials have shown the long-term safety and efficacy of giving multiple booster shots of these mRNA vaccines because we have never used mRNA delivery platform vaccines outside of emergency use authorization prior to this pandemic.** This has made making informed decisions about their use exceedingly difficult. Given this technology is relatively new in its clinical use, it poses a valid ethical issue in mandating their use without providing other options.

There is clear evidence that the risk of COVID-19 mortality and serious morbidity have been reduced to date *in at-risk individuals* with the vaccines we are using. This evidence should be used to strongly recommend vaccination without absolutist mandates particularly for those at moderate-to-high risk of serious disease. It is clear COVID-19 morbidity and mortality is significantly amplified by co-morbid conditions; 95% of those hospitalized with

COVID-19 have at least one co-morbid condition (https://www.cdc.gov/pcd/issues/2021/21_0123.htm). Age is by far the largest risk factor for COVID-19 related death. Apart from age, among those hospitalized for COVID-19, obesity and anxiety/fear-related disorders and diabetes were the strongest independent risk factors of dying. This data underscores the inappropriateness of mandating vaccines to everyone for access to services, being employed or having freedom of movement. Further, the irrational implementation of these mandates (e.g. different definitions for what constitutes "fully vaccinated" for federal government employees in Quebec vs. those in the rest of the Canada) underscores the political – and worse coercive - nature of these policies that have nothing to do with evidence-based health policy or equity.

3) "Natural immunity": the gold standard of immune protection

If the vaccine mandate was really based on ensuring immune protection, then there exists a **glaring oversight in not including equal access rights to those who have been previously infected and recovered from COVID-19.** Although it has long been recognized that natural infection typically provides more durable and comprehensive immunity than vaccines, there has been resistance in acknowledging this fact by our public health officials.

A UK study confirms, that **those who have been infected with SARS-CoV-2 once have better immunity than someone who has had 2 doses of the mRNA vaccine** (reference: https://www.science.org/content/article/having-sars-cov-2-once-confers-much-greater-immunity-vaccine-vaccination-remains-vital). It has been clearly shown that immunity from infection induces memory B cells (the cells that confer protective antibodies and long-lived memory to the virus) that "have a higher antigen-binding capacity per cell and are more efficient at producing plasmablasts and memory B cells during secondary immune responses than… memory B cells formed in response to mRNA vaccination." (https://www.cell.com/cell-reports/fulltext/S2211-1247(21)01287-0). An independent group found that those who had recovered from COVID-19 infection have long-lived antibody producing cells in the bone marrow that are likely to generate anti-SARS-CoV-2 antibodies for decades if not the rest of their lives (https://www.nature.com/articles/d41586-021-01442-9).

In addition to this more potent and long-lived immunity relative to the mRNA vaccines, past infection also appears to provide better protection against the delta variant (https://www.medpagetoday.com/infectiousdisease/covid19/94258). There are now over 100 studies (and counting) documenting the undeniable reliability of natural immunity. Given this, why would these individuals who have the "gold standard" of immunity to COVID-19 (which includes at least 1.7 million Canadians) not be given at least the same access to public life, as the vaccinated group under this mandate?

This question was explored by the British Medical Journal (BMJ), who consulted experts on this issue of the sudden lack of recognition of natural immunity by the US (and its follower, Canada). The silent consensus was that this stance was political and clearly not evidence based. Dr. Christine Stabell Benn, a vaccinologist and Professor in Global Health (University of Southern Denmark), said, "If natural immunity is strongly protective, as the evidence to date suggests it is, then vaccinating people who have had COVID-19 would seem to offer

nothing or very little to benefit, logically leaving only harms—both the harms we already know about as well as those still unknown…."

The failure of Canada in recognizing natural immunity is made even more questionable when considering the fact that infection-acquired immunity is typically sterilizing (i.e. would be better at preventing transmission), given long-lived memory T and B cells are generated specifically in the tissues, including the respiratory tract and lungs following infection (which does not occur following vaccination). This speaks to a profound lack of logic and equity in the rollout of vaccine mandates that seem to ignore immunity deliberately (and potentially dangerously) from previous infection. Many countries across the globe give immunological currency to natural infection. Ignoring this basic inclusion does nothing to inspire faith in the management of pandemic policies and can even be perceived as a means of coercing people into unnecessary procedures; thus incurring all of the potential risks (further elaborated upon below) and few if any of the benefits.

4) The evolving science: the unknowns and serious adverse events

As noted earlier, we have relatively limited experience using the nucleic acid delivery platform vaccines, and these are the only types of vaccines available to Canadians at this time. The mRNA vaccines in use in Canada were pre-emptively given full approval by Health Canada following the FDA's approval, a decision that has been questioned by one of the top medical journals, BMJ (https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/). There is a need to acknowledge that we are still relatively poorly informed about many aspects of this technology, as promising as it is.

For starters, there are **no publicly available biodistribution data** (i.e. where the drug product goes in the body after injection and where their encoded antigens are expressed and their mode of presentation to the immune system?); the **durability of their immune protection is at this time uncertain**; and there are non-trivial **safety signals,** which include (but are not limited to) **myocarditis/pericarditis** which is observed more frequently in young healthy males (reference: https://jamanetwork.com/journals/jama/fullarticle/2782900#), a number of hyperglycemic disorders including the onset of type2 diabetes, and **neurological disorders** which appear more commonly in women (reference: https://jnnp.bmj.com/content/early/2021/08/17/jnnp-2021-327000).

Furthermore, other than the pancreatic issues associated with hyperglycemia, most of these serious adverse events are observed to occur more frequently in those least likely to experience serious COVID-19. Given these issues, informed consent is challenging for a mandated drug for which the science is still evolving. To put in place such a policy seems ethically questionable given the poor scientific rational for its implementation (as outlined in points 1 & 2).

5) Risk-benefit analysis for informed consent

The collective points outlined above speak to the lack of efficacy in preventing the spread of the delta variant, short durability of immune protection against infection, non-trivial risks, and

insufficient data on long-term safety and efficacy with multiple boosters for the COVID-19 vaccines that are being mandated across Canada for the purpose of employment, freedom of movement, and access to public life. Given this evidence, not only are the vaccine mandates not sound as they stand, it may be argued that they are medically unethical. There is a clear need for a proper risk-benefit analysis that takes into account different risk profiles for serious disease and known serious adverse effects of these new nucleic acid delivery platforms so that a well-informed decision can be made. There is also a need to make transparent what we still don't know. For example, the risk of experiencing vaccine-induced myocarditis is increased with the 2nd shot – does this mean greater risk of heart injury, particularly in young vaccinated men following SARS-CoV-2 infection? These uncertainties make grounds for forcing vaccination in certain groups poor judgement at best given the gaps in our knowledge at this time.

Where do we go from here?

We should not politicize health. It is highly disappointing to see the Government of Canada forge this path. It is divisive and at worst dangerous because it turns away from logic and reduces us to dogma. Original modelling had put forth a target of having 70% of the population vaccinated to come close to herd immunity for SARS-CoV-2, and we have well surpassed this target – yet we have not succeeded in halting the number of growing cases. The rational for this is due to the new delta variant, which spread like rapid fire through highly vaccinated regions; but this is exactly how viral evolution and selection works. It seems disingenuous to blame this all on the unvaccinated, as the spread of the delta variant, across the globe, seems agnostic to mRNA vaccination status as noted. If going by the evidence, we ought to be re-evaluating our strategy at this time, specifically using risk-stratification, instead of just moving the goalpost and putting in broad over-reaching mandates that are not supported by any credible evidence and that serve to unnecessarily restrict and ostracize members of our society.

One immediate move would be to make available different types of vaccines to de-risk our response to the pandemic. Specifically, Canadians should have access to tried-and-true vaccines to protect specifically those at high risk of morbidity. We have had decades if not centuries of experience using whole inactivated adjuvanted vaccines [e.g. Covaxin and Valneva's vaccine] and adjuvanted subunit vaccines (e.g. Novavax). The whole inactivated vaccines would likely serve as better booster shots (if required or desired) for those who have already had COVID-19 and recovered, as it would stimulate a memory response to a larger repertoire of antigens (instead of the one under high selective pressure). A good segment of the "vaccine hesitant" are waiting for access to these traditional vaccines. Despite the picture painted that the vaccine hesitant are anti-science and anti-vaxx, a study by Carnegie Mellon University and the University of Pittsburgh found that those with a PhD are the most "vaccine hesitant" of all (reference: https://unherd.com/thepost/the-most-vaccine-hesitant-education-group-of-all-phds/); perhaps this is an attribute of their ability to more fully grasp what constitutes an effective vaccine and assess their risk/benefit profile.

We also need to make sure we now give due attention to the overall health of Canadians. As our population ages, sustainable health care needs to include a strong component that

focuses on disease prevention which goes beyond just vaccines. The benefit of vaccines is tempered in those with poor nutrition, with chronic metabolic and cardiovascular disease, and even in those who are under chronic stressors (be they infectious or non-infectious in nature). It is thus very unfortunate that our response to the pandemic resulted in an unprecedented increase in obesity in children (https://www.bmj.com/content/374/bmj.n2332) especially given the finding that obesity makes even "mild" COVID-19 worse (https://www.medpagetoday.com/infectiousdisease/covid19/95136). This is a failure of public health.

I hope some of the above can be used to put forth a reasoned science-based response to the pandemic and heal the divisions it has wrought.

I would be happy to discuss further if required,

Dr. Shirin Kalyan (PhD)

**All views expressed are the author's and not of her affiliated organizations.*

Background

Education:

- Doctorate, Experimental Medicine / Immunology (UBC)
  - Doctoral Scholarships from the Canadian Institutes of Health Research and the Michael Smith Foundation of Health Research
- Alexander von Humboldt Post-Doctoral Fellowship Awardee – Institute of Immunology (CAU, Germany)

Current Affiliations:

- Adjunct Professor, Medicine (University of British Columbia)
- Vice President, Scientific Innovation – Immunotherapeutics and Translational Research for Biotech company

Publications: https://www.researchgate.net/profile/Shirin-Kalyan/research

Some research updates are below for reference. These speak to the evidence that fully vaccinated people have unusually short-lived immunity against infection, are just as likely as unvaccinated people to pass on the infection to members of their household and are not protected against "long COVID".

Research Updates:

Research reveals fully vaccinated people are just as likely to pass virus on to those they share a home with
https://www.theguardian.com/world/2021/oct/28/covid-vaccinated-likely-unjabbed-infect-cohabiters-study-suggests

Effectiveness of Covid-19 Vaccination Against Risk of Symptomatic Infection, Hospitalization, and Death Up to 9 Months: A Swedish Total-Population Cohort Study
Findings: Vaccine effectiveness of BNT162b2 against infection waned progressively from 92% (95% CI, 92-93, P<0·001) at day 15-30 to 47% (95% CI, 39-55, P<0·001) at day

121-180, and from day 211 and onwards no effectiveness could be detected (23%; 95% CI, -2-41, P=0·07).
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3949410

Breakthrough infections in those fully vaccinated can lead to long COVID despite protecting against serious disease. "[The absence of protection] from long COVID is concerning given the high incidence and burden"
https://news.yahoo.com/breakthrough-infections-lead-long-covid-182622434.html

Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021
Among 4,899,447 hospitalized adults in PHD-SR, 540,667 (11.0%) were patients with COVID-19, of whom 94.9% had at least 1 underlying medical condition. Essential hypertension (50.4%), disorders of lipid metabolism (49.4%), and obesity (33.0%) were the most common. The strongest risk factors for death were obesity (adjusted risk ratio [aRR] = 1.30; 95% CI, 1.27–1.33), anxiety and fear-related disorders (aRR = 1.28; 95% CI, 1.25–1.31), and diabetes with complication (aRR = 1.26; 95% CI, 1.24–1.28), as well as the total number of conditions, with aRRs of death ranging from 1.53 (95% CI, 1.41–1.67) for patients with 1 condition to 3.82 (95% CI, 3.45–4.23) for patients with more than 10 conditions (compared with patients with no conditions).
https://www.cdc.gov/pcd/issues/2021/21_0123.htm