Dispelling the Myth of a Pandemic of the Unvaccinated

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Abstract

We have reanalyzed the Ontario Science Table data on hospitalizations for COVID-19 in COVID-19 vaccinated versus unvaccinated patients admitted to hospital during various waves of the pandemic. In spite of the Ontario Science Table and the mass media claims that the unvaccinated were the dominant population being hospitalized, a more rigorous evaluation of the existing data shows that this narrative is not correct for the latter waves of COVID-19. We identify a series of methodological issues that may have lead the Ontario Science Table to reach their conclusions and explain why such issues may have led to policies that have been largely ineffective.

Key words:

Ontario Science Table, hospitalizations due to COVID-19, pandemic of the unvaccinated, methodological errors

Introduction

According to various reports in the mainstream media, Ontario health data show that those unvaccinated against COVID-19 are up to 60-times more likely to end up in intensive care units (ICUs) with COVID-19 than the vaccinated (Young, 2021; Dunham, 2021; Morgan, 2021). With alarming headlines, the media promoted a narrative that the unvaccinated are driving the pandemic and increasing the burden on ICUs in Ontario at the expense of other people. These headlines typically depict the unvaccinated as careless vectors of disease and thus potentially dangerous and hence responsible for society's current COVID-19 plight. These headlines and the ensuing health policy, fails to recognize that at this stage of the COVID-19 pandemic, at least 22% and like more than 50% of the Canadian public appear to have been exposed to SARS-CoV-2, recovered, and developed natural immunity(Canadian Blood Service, 2022; Parsons, 2022; Michael Kuzmickas, personal communication; S.P., personal communication).

The vaccines in question are those currently in use in Canada where two of six use mRNA platforms, and two of the others use adenovirus-based delivery of DNA, from which mRNA is generated. Each of these four vaccines ultimately produce the spike protein of SARS-CoV-2, which is presented on the surfaces of cells near the injection site. Emerging bio-distribution data clearly show that both the spike protein produced and even some of the mRNA construct may migrate to sites far from the injection site (Comirnaty. European Medicne Agency Assessmentt, February 19, 2021; https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf**)**.

Because such assertions about the COVID-19 unvaccinated have far-reaching consequences, for both medical treatments *as well as* civil rights, there is a growing need for a critical evaluation of the accuracy of the various claims, particularly given that they can lead to increasing stigmatization from both the public and various levels of government against those who have chosen to not undergo vaccination against COVID-19. This analysis of the Public Health Ontario and Government of Ontario, Ministry of Health COVID-19 databases will focus on four areas of concern: the questionable basis for mass vaccination, the methodology of the studies used to support current vaccination policies, the lack of effectiveness of those same policies, and how these have failed to actually to consider vaccine safety with the hopes of supporting informed decision making at both individual and health policy levels.

Methods

Total and daily COVID-19 cases, total hospitalizations and deaths data were obtained from the "Full COVID-19 Summary Data for Ontario" datasheet available at the Public Health Ontario (PHO) COVID-19 Data Tool webpage (Public Health Ontario, 2022b) on January 5, 2022. In this dataset, hospitalization numbers included all cases reported as ever being hospitalized during their infection. Daily hospitalizations were calculated from the difference between total hospitalizations for the index date and the previous day. Similarly, the number of daily deaths were calculated from the difference between total deaths reported for the index date and the previous day. The number of daily COVID-19 cases, case rates (per 100,000, 7-day average), individuals in intensive care units (ICU) and in hospital (excluding ICU) due to COVID-19 by vaccination status, and individuals with at least one, two (considered fully vaccinated at the time) or three (boosters) vaccine doses were obtained from the "COVID-19 Vaccine Data in Ontario" datasheets as cited above.

The number of individuals in ICU's and in hospitals excluding ICU's were combined in order to obtain the total number of individuals in hospital due to COVID-19 by vaccination status. Daily mean temperature at Toronto International Airport was obtained from the Government of Canada, Historical Weather and Climate Data(webpage for the TORONTO INTL A, ONTARIO station; Government of Canada, 2022) on January 5, 2022).

Data from all sources were combined, organized, processed, and plotted in MS-Excel. While index dates for the Government of Ontario Data Catalogue were reporting dates with numbers indexed to the day in which numbers were released, PHO data were indexed to the day prior (of data collection). This caused a one-day shift between datasets that became apparent when trying to use them together. To harmonize the datasets, data collection dates were used as index dates for both datasets.

Results

Some potentially invalid assumptions driving vaccine policy

1. Antibody Efficacy

Most tests of antibody efficacy are based on assessing the extent to which vaccinal antibodies interfere with the binding of the SARS-CoV-2 spike protein to the host cell ACE2 receptor. In the rapidly emerging COVID-19 variants, mutations within the receptor binding domain may enhance the binding to ACE2, but reduce recognition by specific antibodies that target this region. However, immune responses are directed against many different regions of the spike protein, and binding of antibodies to these regions can also confer significant immune protection. This may include facilitating recognition of the spike protein and virus by immune cells that feature Fc receptors for the constant region of immunoglobulins as well as by the complement system. In any event, it is misleading to insist, as often the media or the OST do, that mass vaccination with COVID-19 vaccines will be effective over the long term or that they will be a means of achieving herd immunity. This becomes even more problematic when failure of the vaccines to block transmission is blamed on the unvaccinated.

2. Mass Vaccination

The practice of mass vaccination is based on the notion of "herd immunity", that is when a high percentage of the population has either contracted and recovered from any particular disease, thus gaining natural immunity, or has gained sterilizing immunity through specific vaccinations. At herd immunity, modeling data indicates that the disease cannot spread further and should not be transmittable to those who have neither form of immunity (e.g., unexposed or immunocompromised persons) (Shaw, 2021). The thresholds for attainment of herd immunity vary depending on many factors including characteristics of the virus, population, and vaccines. Early modelling of COVID-19 vaccine impact showed that herd immunity should be achievable when only 55% of the population has been vaccinated under reasonably favorable conditions (Hogan & Winskil *et al.*, 2020; Phillips, 2021). It should be noted that although the traditional definition of herd immunity included both natural and vaccine-derived immunity, at the outset of the COVID-19 pandemic the World Health Organization changed the definition of herd immunity to something that is achieved almost entirely through vaccination (WHO, 2020).

It is also worth noting that historically, vaccination alone has not been routinely successful in providing long lasting herd immunity for some diseases, due to secondary vaccine failure (Mathias & Meekison *et al*., 1989; Edmonson & Addiss *et al*., 1990; Zhang & Chen *et al*., 2018; Connell & Connell *et al*., 2020. The latter may occur as immune responses in terms of levels of antibody levels, T cells, and even memory cells decline over time (Heffernan & Keeling, 2008; Duintjer Tebbens & Pallansch *et al*., 2013; Vygen & Fischer *et al*., 2013; Koopman & Henry *et al*., 2017; Burdin & Handy *et al.* 2017; Lewnard & Grad, 2018). In addition, the infectious pathogen may undergo extensive mutation that may compromise immune recognition.

The long-lasting success of any vaccination campaign in halting disease is almost exclusively dependent on the use of vaccines that confer sterilizing immunity and do not suffer rapid secondary vaccine failure (Hellerstein, 2020; Pollard & Bijker, 2021; Yewdell, 2021; Focosi & Maggi *et al*., 2022). In contrast, the two doses of novel mRNA COVID-19 vaccines by Pfizer or Moderna or the viral vector vaccine of AstraZeneca, in contrast to those derived from conventional vaccine platforms, seem to exhibit a relatively rapid decline in efficacy, and as such can be characterized as "leaky", with outbreaks occurring over short time periods even in those with boosted vaccinations (Scott & Richterman *et al*., 2021). In addition, it is increasingly clear that individuals receiving COVID-19 vaccines can become re-infected or experience breakthroughs, as well as transmit the virus to others (Read & Mackinnon, 2008; Keeling & Tildesley *et al*., 2013; Read & Baigent *et al*., 2015; Brown & Vostok *et al*., 2021). Moreover, any efficacy initially promoted for these vaccines was based on PCR-confirmed symptomatic infection against the original Wuhan strain, and we currently lack proper assessment of transmission-blocking efficacy of the vaccine against emerging COVID-19 variants (Collie & Champion *et al*., 2021; Dejnirattisai *et al*.; Shaw *et al*., 2021; Keegan & Truelove *et al*., 2021; Lopez Bernal & Andrews *et al*., 2021; Reis & Barda *et al*., 2021; Singanayagam & Hakki *et al*. 2021; Thiruvengadam & Awasthi *et al*., 2021; Torgovnick, 2021).

Concerns Regarding Study Methodology of Supporting Evidence

The strength of a medical recommendation should rest on the level of evidence on which it is based. The highest level of evidence comes from a double-blinded, randomized Phase III trial showing benefits against a standard of care in a specific population (Misra, 2012). In contrast, retrospective analyses are unable to control for the influence of confounding variables and thus are more effectively used to generate hypotheses that can later be validated in prospective controlled trials. Such analyses are not sufficiently reliable to support mandatory treatment recommendations (Talari & Goyal, 2020). For example, retrospective analyses must be appropriately interpreted by considering the completeness of the data set, the terminology used, and the monitoring protocols, as well as the methods employed and verifiable assumptions.

Data Completeness

Population based COVID-19 registries are designed to collect data on COVID status, but not data on hospitalization events (Government of Ontario, 2022; Government of Ontario, 2021). Presently we know that the Canadian COVID-19 database preferentially captures data on symptomatic individuals and inevitably underrepresents those who refuse or are not required to undergo testing as well as those who are asymptomatic (Public Health Ontario, 2022b). For this reason, any such results should be extrapolated with caution when considering mildly symptomatic or asymptomatic individuals.

Conducting an analysis on COVID-19 hospitalization outcomes would require merging the COVID-19 database with one that is able to capture hospital level events, and as such the completeness of hospital data captured would need to be taken into consideration to ensure the reliability of the outcomes. Likewise, data would need to be interpreted in light of differences in monitoring or sampling across vaccination groups. Comparing outcomes across vaccination groups, however, assumes these groups are homogeneous which is unlikely. For example, it would not be unexpected for the groups to differ in terms of natural immunity status, virus exposure, and risk of severe disease. In Toronto, from January 1st to July 31st 2020, there were just under 1,000 hospitalized COVID-19 cases in the 70+ age group and just over 600 hospitalizations in the 50-69 age group (City of Toronto, 2022). Aside from age, underlying medical conditions such as "obesity, diabetes with complication and anxiety disorders were the strongest risk factors for severe COVID-19 illness"(Kompaniyets & Pennington *et al.*, 2021). Since details about other potentially relevant variables were not

provided by Public Health Ontario, these omissions reinforce the view that caution should be used when ascribing differences in observed outcomes to vaccination status alone.

Terminology

Another factor to consider is the definitions used to describe vaccination status. Public Health Ontario defines vaccination status based on immunity achieved 14 days after any second dose (Ontario Ministry of Health, 2021), contradicting at least one company using an mRNA platform, Pfizer, that in the Phase III trial asserted that immunity can be established after 7 days (Thomas & Moreira *et al.*, 2021). From such discrepancies, it seems likely that fully vaccinated individuals will be considered partially vaccinated up to 14 days after their vaccine, and individuals receiving their first dose will typically be categorized as unvaccinated up to 14 and even 21 days later. These overlapping definitions confound interpretation of outcomes as many vaccinated individuals will be classified as unvaccinated, thus inflating the numbers of the latter and making it difficult to distinguish differences in disease status and health outcomes (*e.g.*, infection, hospitalization, deaths) among vaccinated and unvaccinated. It would have been better if the unvaccinated category had excluded those who have been vaccinated.

Monitoring

The main test used to date in Ontario and elsewhere in Canada is the PCR (Polymer Chain Reaction) assay, a test which detects genetic fragments of the SARS-CoV-2 virus in tested individuals. Of note, with a cycle threshold (Ct) (the number of times the sample is amplified) typically used in Covid-19 testing (35 and above), the possibility of false positivity and thus actual infectivity becomes highly problematic (Mina & Peto *et al.*, 2021). This limitation is now acknowledged by the Centers for Disease Control and Prevention (CDC) (Centers for Disease Control and Prevention, 2021). For example, a Ct cut-off for positivity over 35 (Public Health Ontario officially uses a Ct of 35) (Public Health Ontario, 2021a) may result in up to an 85% false positive rate (Public Health Ontario, 2020). If these Ct levels are then used to describe “cases”, and asymptomatic low probability persons comprise most of tests conducted, the resulting data will inevitably generate inflated case numbers in that population. Moreover, someone with COVID-19 may only be infectious between 4 and 8 days, but may test “positive” between 22 and 33 days, introducing the possibility that a single infection may be recorded as more than one case (Mina & Peto *et al.*, 2021).

Given our current vaccine mandate environment, unvaccinated individuals often have to undergo systematic asymptomatic testing by their employers (CBC News, 2021; Government of Ontario Ministry of Health, 2021; Herhalt, 2021; Pringle, 2021). This increase in sampling is likely to result in higher case counts in this population where Ct levels are likely to generate greater false positives. In addition, as cited above, data collection systems may not be able to eliminate multiple counts of the same infection (Goodfield, 2021; Public Health Ontario, 2021b). Further, it remains unclear whether there are differences in testing requirements between hospitalized individuals based on vaccination status. Added to these constraints, it is well established that SARS CoV-2 is transmitted more readily in communal living environments such as hospitals (Morawska & Tang *et al.*, 2020). Thus, when interpreting the data, it is important to distinguish between individuals who were in the hospital for some non-COVID-19 related reason and then test positive for SARS CoV-2, compared to those who are in the hospital due to a COVID-19 infection. Furthermore, as it is often unclear what Ct was used and whether there were differences in monitoring based on vaccination status, the Ontario COVID-19 data showing differences between the vaccinated and unvaccinated is likely to be unreliable.

Study Design and Analysis

Retrospective reviews of the COVID-19 database are helpful for identifying potential associations between various events, but as they cannot control for differences in baseline factors, monitoring, or exposure, they are unreliable (Mann, 2003; Ranstam, 2019). Most importantly, the ability of retrospective analyses to infer causality is limited, and therefore should not be used to support major health policy decisions.

COVID-19 Risk Factors

There are some well-established factors that increase the risk of severe COVID-19 outcomes. These include older age, obesity, diabetes co-morbidities (Kompaniyets & Pennington *et al.*, 2021; Kompaniyets & Goodman *et al.*, 2021). Factors that lower the risk of severe disease includes naturally acquired prior immunity (Cohen & Linderman *et al.*, 2021) and younger age (Woolf & Champman *et al.*, 2021), as well as access to pharmacological interventions. As analyses are not always randomized and do not control for baseline factors, differences in such factors in vaccinated and unvaccinated populations could be partially, or fully, driving the claimed effects of higher unvaccinated cases

being causal to hospitalizations and deaths. For instance, frail elderly individuals are often not vaccinated due to a risk of vaccine injury. However, it would not be unreasonable, given the higher levels of co-morbidities associated with this group, to see a greater proportion of these individual in hospitals or ICU units, which may be misinterpreted as the unvaccinated being at greater risk of severe COVID-19 outcomes.

Concerns Regarding Effectiveness of Current Vaccination Policy

There has been some discrepancy concerning how many COVID-19 "waves" have occurred since the onset of the pandemic in early 2020. For the purposes of this article, while there has been five distinct waves starting with the initial wave in the spring of 2020, we have focused on the latter four waves. The second wave transpired from Nov 1, 2020 to January 4, 2022 (Figure 1. The second and third waves peaked above 4,000 cases per day in Ontario and occurred over the colder months beginning in November 2020, declining with warmer summer weather. Unlike the second and third waves, the fourth wave began at the height of the warmer summer weather in August, with an initial rise up to 1,000 cases per day in early September 2021, before dramatically shooting up in a fifth wave to an unprecedented 18,000 cases per day by early January 2022, the latter with a more than 4-fold increase over prior peaks. Whether the Omicron B.2 variant is emerging a sixth wave is presently unclear and not essential to the analysis below.

As noted above, herd immunity should be achieved with a highly effective vaccine once some 50% of the population is immune from prior infection or vaccination. In this regard, it should be noted that the third wave was clearly receding before the 50% vaccination threshold had been reached for the first shot in early May 2021. Further, the shape of the decline of the curve did not change after this threshold was achieved. Such data indicates that natural immunity rather than vaccine-induced immunity was the main driving factor in the decline of the third wave.

By early August 2021 at least 65% of the population had been fully vaccinated by the definition of the time, and by mid-November 2021 the number was as high as 75% and slowly increased to 78% by early January 2022. Administration of booster (third) doses started in September 2021, with an uptake of about 28% by January 4, 2022. While such high rates of full vaccination could explain the minimal rise in daily cases seen from August to September, the rise in cases could more parsimonious be explained by a shift in monitoring and sampling resulting from back-to-work and school policies requiring increased systematic testing of asymptomatic

unvaccinated individuals (Government of Ontario Ministry of Health, 2021). It is notable that analyses justifying vaccine mandates conducted by the Ontario Science Table were conducted within this time window and were likely heavily influenced by the differential testing policies. It should be noted that daily case counts began to sharply increase with the drop in temperature in November and December 2021, similar to the seasonal shifts in respiratory disease observed in the previous year and seemingly at variance with increasing levels of vaccination for the overall population. It is precisely these sorts of outcomes that led to claims, in late August and early September, that the unvaccinated were driving the bulk of new infections and threatening ICU capacities and that vaccine passports were required to limit the unvaccinated individuals from entering public spaces to halt further disease spread.

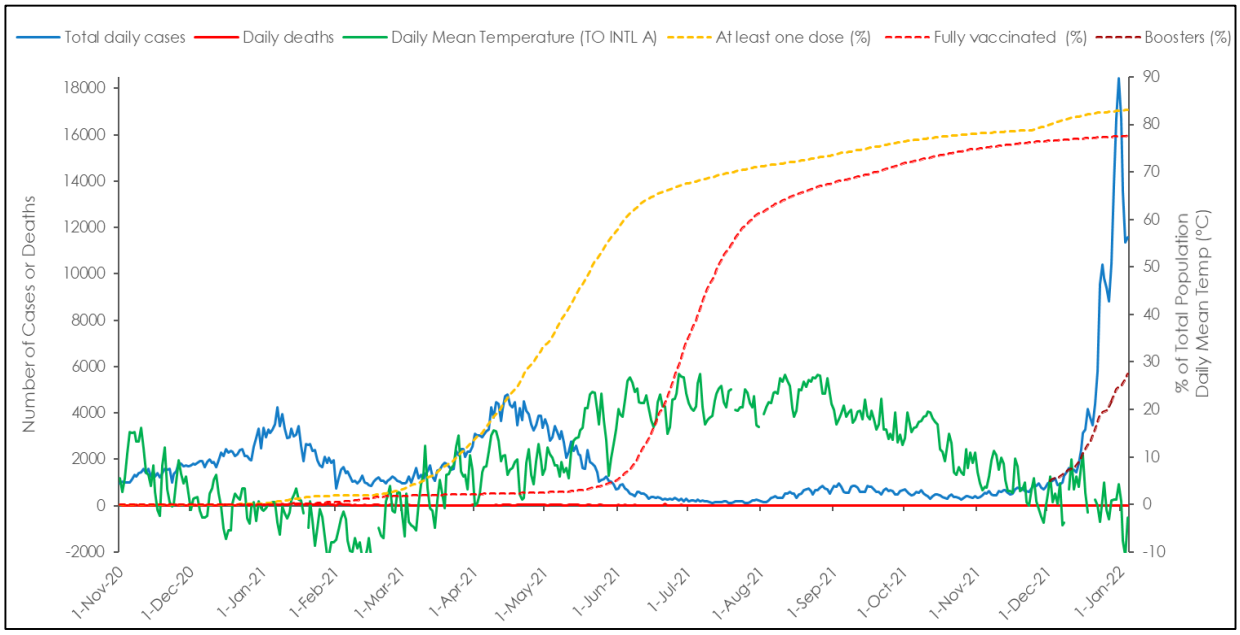

Figure 1: COVID-19 cases and deaths (data source: Public Health Ontario) (Public Health Ontario, 2022b), vaccination status in Ontario (Government of Ontario, 2022) and the mean temperatures at Toronto International Airport (Government of Canada, 2022) from November 1, 2020 to January 4, 2022.

In Figure 2A, daily COVID-19 case counts by vaccination status are plotted from Aug 8, 2021 to January 4, 2022. These data also lead to reports, as cited above, that this was a pandemic of the unvaccinated. However, when cases in the unvaccinated were compared to those who had received the vaccines, the differences in case counts and rates were low and steady leading up to early October 2021, at which point case counts in the two groups began

to overlap; by early December 2021, a surge in daily cases in the fully vaccinated typical of the infectious peaks of earlier waves was clearly apparent. By early January 2022, at the peak of the time period studied, the number of cases in the vaccinated were 6-fold higher than in unvaccinated.

It is important to note that unvaccinated individuals represent 20% of the population and that, children 11 years or younger, representing 15% of the population, are the largest demographic in the unvaccinated group. As COVID-19 vaccines were approved in Canada on November 19, 2021 for children 5 – 11 years old for most of the time period studied, this group was then ineligible for vaccination (Government of Canada, 2021b).

As case counts were 6-fold higher in the fully vaccinated group compared to the unvaccinated group by mid to late December 2021, the Ontario data does not provide compelling support for policy decisions recommending the vaccination of children younger than 11 years. At that time, the proportion of cases in the fully vaccinated had surpassed those of unvaccinated (7-day average: 87.89 per 100,000 vs 66.15 per 100,000, respectively), reflecting a higher degree of infectivity (Figure 2B). As currently the vast majority of the cases are estimated to be caused by the new Omicron variant, for the week of December 12th-18th 2021, Omicron was estimated to make up 66.1% of Ontario cases, rising to an estimate of 97.5% of positive Ontario cases the week of December 26th 2021–January 1, 2022 (Public Health Ontario, 2022a). It thus seemed that the vaccines designed to combat the wild-type strain have become largely obsolete. However, a third dose (the first "booster") of these vaccines may provide some initial protection in the face of secondary vaccine failure from the initial two vaccination schedule. Although increased infection rates in the vaccinated group could be due to them engaging in higher risk activities than the unvaccinated, it is also highly possible that these data show vaccine enhanced disease, a concern raised in the Pfizer Safety Report (Nevada Division of Public and Behavioral Health, 2021).

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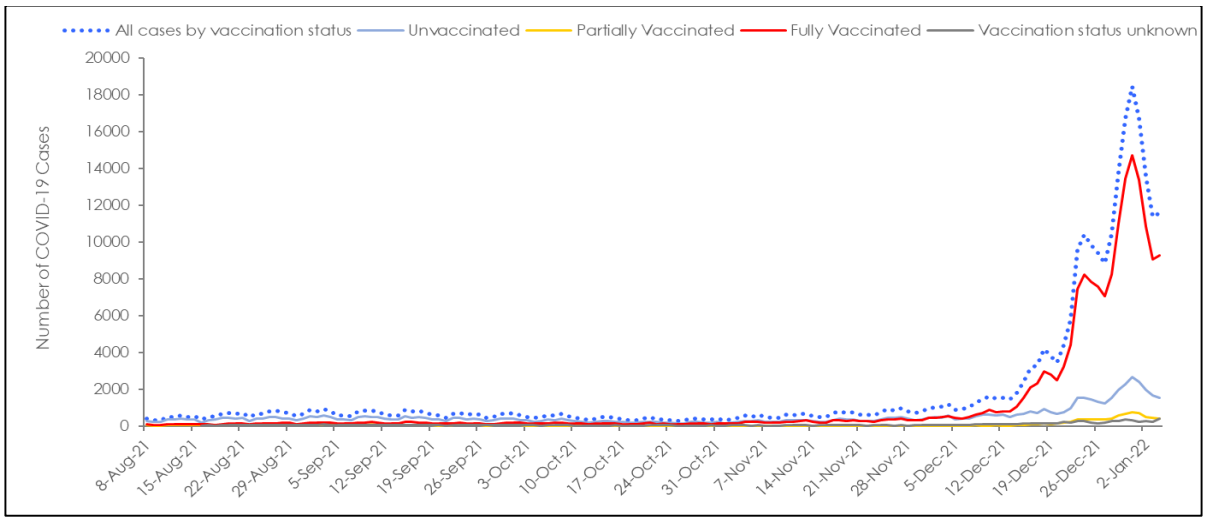

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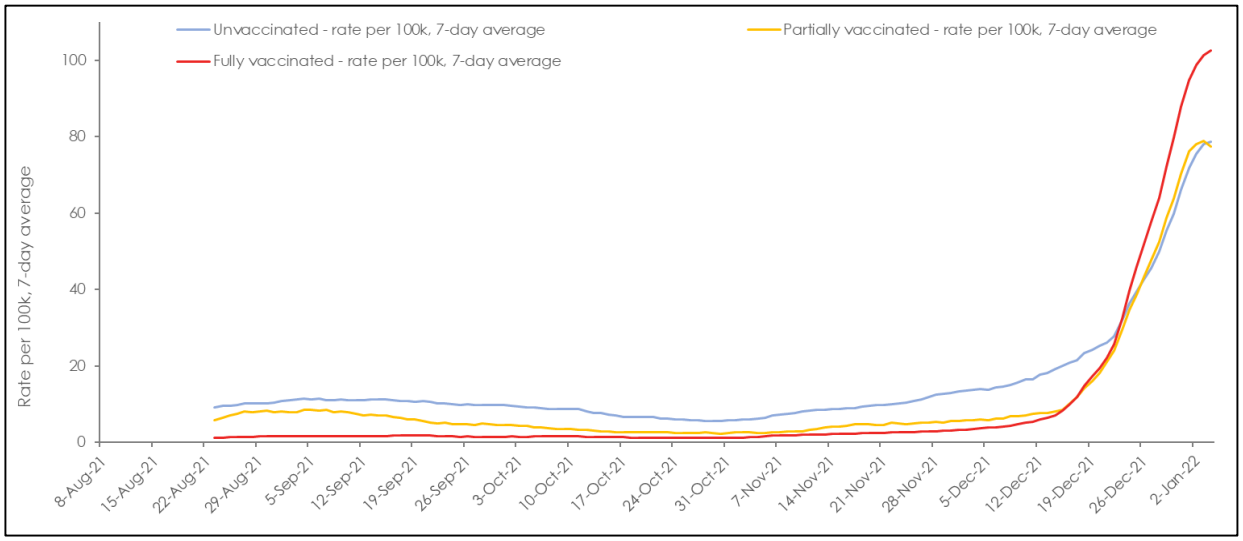

Figure 2: (A) Number of cases and (B) 7-day averaged case rates by vaccination status in Ontario from Aug 8, 2021 to Jan 4, 2022. (Government of Ontario, 2022).

Hospitalization Admissions and Death

Daily COVID-19 hospitalizations and deaths are plotted from November 1, 2020 to January 4, 2022 in Figure 3. Hospitalization admissions peaked at 200 admissions during the second wave, between 300 and 400 admissions for the third wave and were lowest for the fourth wave, and a potential fifth wave peaking at 148 cases on Jan 4, 2022. Likewise, COVID-19 deaths peaked at 100 deaths per day during the second wave, were as low as 50 deaths per day in the third wave, rarely exceeded 8 deaths per day in fourth wave, and as of January 4, 2022, deaths for the potential fifth wave

have not reached more than 13 deaths per day despite the dramatic surge in cases in December 2021 that are linked to the Omicron variant.

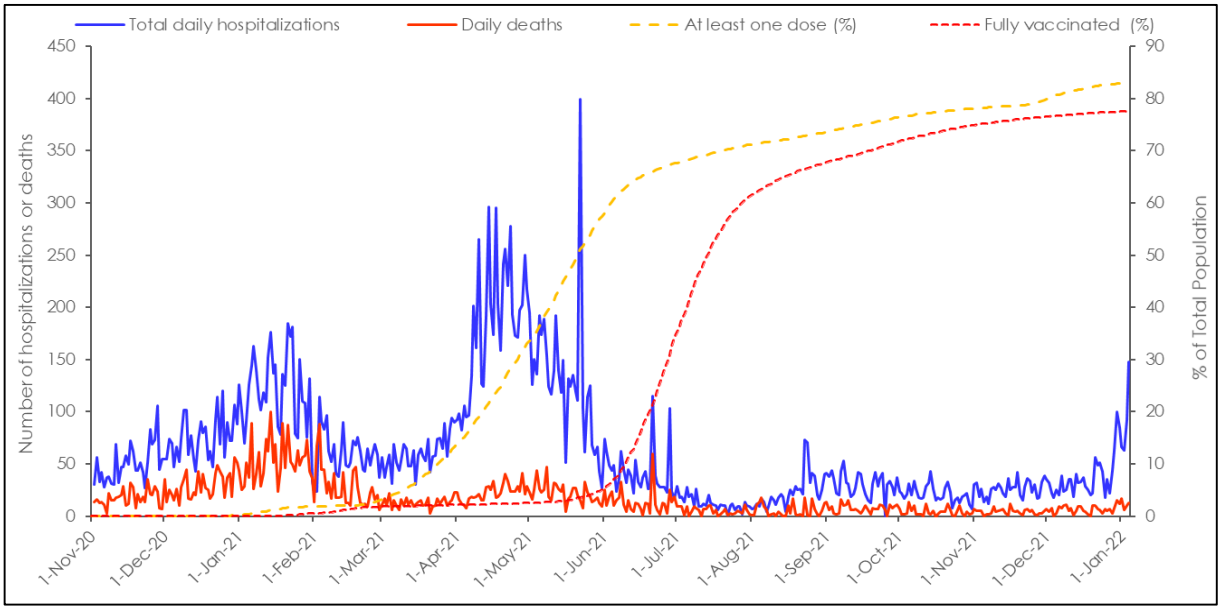

Figure 3: COVID-19 hospitalizations and deaths (Public Health Ontario, 2022b) and vaccination status (Government of Ontario, 2022) in Ontario from November 1, 2020 to January 4, 2022). Colour codes as in Fig. 1.

As noted above, it is possible that the lower death rates could be attributed to increasing rates of partial vaccination of high-risk populations from March to July 2021, serving to prevent more severe COVID-19 outcomes, including deaths. We find this interpretation unlikely, as only 35% of the population were vaccinated at that point and many were the elderly who are known to be immunosenescent, that is that they have a dysregulated immune system that makes it more difficult for them to develop sterilizing immunity leaving them more susceptible to infection (Crooke & Ovsyannikova *et al.*, 2019). However, such an uncoupling could also be attributed to a lower net number of individuals who might have been at risk of death from the disease: During the first and second waves, as the majority of deaths due to COVID-19 were in long-term care facilities (Marrocco & Coke, 2021; Canadian Institute for Health Information, 2021). Death rates were high in these facilities largely because many facilities were under resourced and ill-equipped to stop aerosol transmission of SARS-CoV-2 among residents (Tang & Mao *et al.*, 2020; Thompson & Barbu *et al.*, 2020; World Health Organization, 2021; Dykgraaf & Matenge *et al.*, 2021;

Brown & Jones *et al.*, 2021). These aspects, coupled with the fact that many individuals within these facilities were already at risk of severe disease (Thompson & Barbu *et al.*, 2020; World Health Organization, 2021; Dykraaf & Matenge *et al.*, 2021; Akhtar-Danesh & Baumann *et al.*, 2022), that early treatment was not routinely provided (Sundraram & Nasreen *et al.*, 2021), and that "35% of residents had no hospitalization orders and 80% had do not resuscitate" orders in place, made outbreaks in these facilities more likely to be fatal (Canadian Institute for Health Information, 2021; Morrocco & Coke, 2021).

By the beginning of the third wave many of those who were at risk of death from COVID-19 had either developed immunity or had died, limiting the number of those vulnerable to infection. While many vulnerable residents died due COVID-19 infections, others died due to failure to thrive from being isolated for a full year. Another contingent may have died due to vaccine-related injury (Wyller & Kittang *et al.*, 2021). In this regard, it is likely relevant that a CDC report using the VAERS system that was published in early 2021 reported that 69% of all reported possible vaccine deaths were in people living in long-term care facilities and occurred a median of 2 days after vaccination (Gee & Marquez *et al.*, 2021).

Hospitalizations and ICU due to COVID-19 by Vaccination Status

Total in hospital and ICU cases presumed to be due to COVID-19 vaccination status were plotted from Aug 8, 2021 to January 4, 2022 (Figure 4). The number of patients in hospital peaked at 526 during the early part of the time period studied, but by January 4, 2022 the number COVID-19 hospitalizations had reached up to 2,000. Although it had increased by at least 3-fold, it remained considerably below the 21,000 total number of acute care beds available in Ontario (Ontario Hospital Association, 2021). The number of people in ICU remained low and did not surpass more than 200 beds during the time period studied and thus did not come close to approaching the ICU capacity for Ontario of 2,343 beds (Government of Ontario, 2021). Although there were more unvaccinated compared to vaccinated people in the ICU throughout the initial time period studied, the number of admissions in the vaccinated rose progressively, to the point that on January 4, 2022, the number of vaccinated in ICU was very similar to that of unvaccinated (N= 109 vs 100) with ICU admissions still on the rise.

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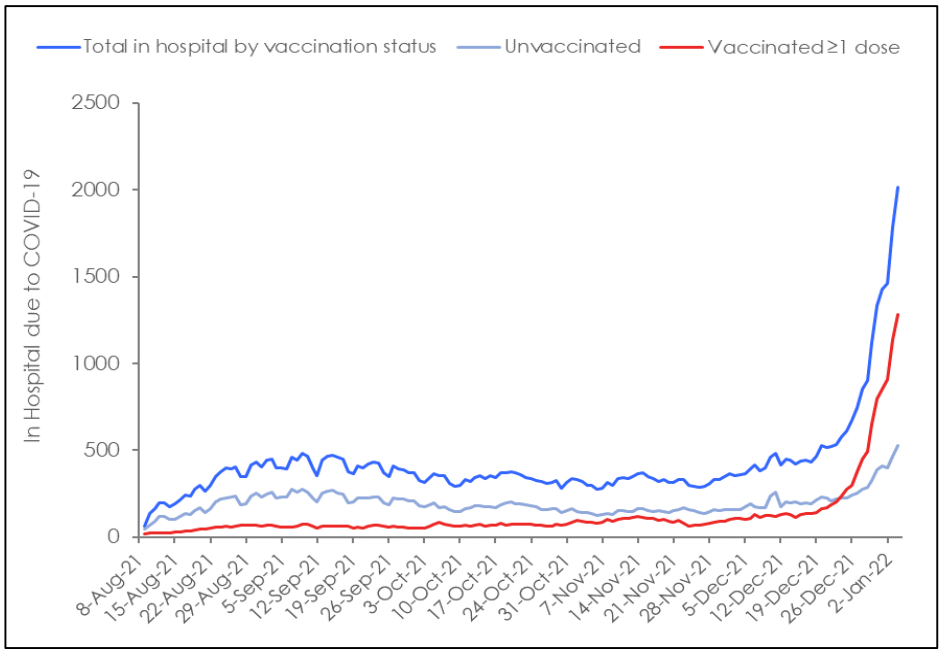

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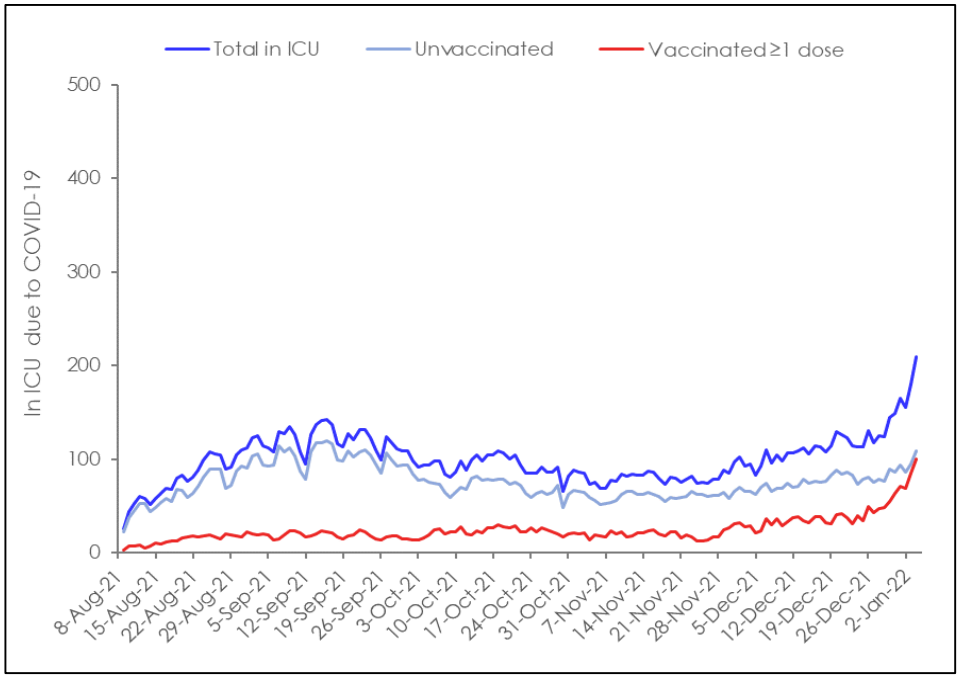

Figure 4: COVID-19 (A) Total hospitalized and (B) in ICU due to COVID-19 by vaccination status in Ontario from August 8, 2021 to Jan 4, 2022. (Government of Ontario, 2022)

The application of vaccines, as noted above, may have had a role in conferring some protection from severe disease and death from August through to the end of October 2021. However, such an interpretation does not explain why counts among the vaccinated and unvaccinated were comparably low even with counts only increasing in early November. An alternative, and to us a more likely explanation is that that differences seen in this time period are instead reflective of changes in vaccination policies requiring systematic testing of asymptomatic unvaccinated individuals. Such differences would be particularly apparent in settings such as hospitals where patients are closely monitored and may have heavily influenced the number of counts seen in this population. Additionally, as COVID-19 is transmitted in shared community living situations such as hospitals, events among the unvaccinated may be a by-product of hospital admission status. In fact, the ministry of health recently indicated that almost half of the COVID-19 hospitalizations were people who were admitted to the hospital with another condition and tested positive with COVID-19 rather than people in the hospital due to COVID-19 (Public Health Ontario, 2022c). The consistently low and comparable rates among the vaccinated and unvaccinated may strongly reflect differences in monitoring and sampling more than differences in actual infectivity.

Another notable observation from these data is that despite surges in total COVID-19 cases, the total number people in hospital and ICU remained relatively low, indicating that the COVID-19 variants are either less virulent, or that a clinically meaningful population level of vaccine and natural-induced immunity has now been achieved, or that there are fewer people at risk of severe disease either due to death or immunity.

Concerns Regarding the Safety of COVID-19 Vaccines and Current Vaccine Policies

The most significant limitation of retrospective analyses of real-world COVID-19 events is that they fail to weigh the benefits of vaccination against potential risks of vaccination. Randomized placebo controlled trials are the most reliable source of safety and efficacy data available. The 6-month data from the Pfizer phase III trial (Table 1) showed that receipt of the BNT1626b2 vaccine increased both the absolute (17.9%) and relative (299.7%) risk of experiencing a vaccine-related adverse event in fully vaccinated adults (Thomas & Moreira *et al.*, 2021). This study also reported relative (74.6%) and absolute (0.5%) increases in severe adverse events, events that affect daily activity, require medical intervention, or require hospitalization. Likewise, there were also relative (9.5%) and absolute (0.05%) risk increases in serious

adverse event, events that require hospitalization, were life-threatening, or resulted in persistent disability or death.

When deaths were considered for both the blinded and open-label periods of the study, there was an increase in deaths on the vaccine arm compared to the placebo arm (20 deaths vs 14 deaths), many of which were cardiovascular in nature (9 deaths vs 5 deaths). Although the Pfizer phase trials reported relative risk reductions in symptomatic COVID-19 cases (90.9%) and severe COVID-19 cases (95.7%) with BNT1626b2 compared to placebo, the absolute risk reductions were modest (mild to moderate 3.7% and severe 0.1%) and lower than the absolute risk increases in adverse events (any 17.8%, severe 0.05%). When the absolute benefit of the vaccine is compared to the absolute risk, it appears that the vaccine, and by extension current vaccine policy, may be doing more harm than good.

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Event	**BNT162b2 (n)**	**Placebo (n)**	**Absolute Difference (p-value)[?]**	**Absolute Risk Change* (%)**	**Relative Risk Change* (%)**
Cases in Fully Vaccinated Adults and Adolescents 7 days after 2nd dose[$]	77	850	-773 (p<0.00001)	-3.7	-90.9
Any Unsolicited Treatment-Related Adverse Event Adults[#]	5,241	1,311	+3,930 (p<0.00001)	+17.9	+299.7
Any Severe Event Adults[/]	390	289	+101 (p=0.0001)	+0.5	+34.9
Severe Cases in Fully Vaccinated Adults 7 days after 2nd dose[&]	1	23	-22 (p<0.00001)	-0.1	-95.7

Unsolicited Severe Adverse Events~ Adults	262	150	+112 (p<0.00001)	+0.5	+74.6
Serious Adverse Event Adults[$]	127	116	+11 (p=0.5)	+0.05	+9.5
Deaths Blinded Period [additional deaths during open-label period in vaccine recipients or placebo-only][%]	15 [+5]	14 [NR]	+1 [+5] (p=0.9)	+0.005	+7.1
Deaths Due to Cardiovascular Events^	9	5	+4		

Table 1.

[¥] For the purpose of this table and according to the terminology used in the study report, adult and adolescent populations are defined as ≥16 years old and 12-15 years old, respectively.

[?] Significance figures (p-values) estimated using chi-square calculator available at https://www.socscistatistics.com/tests/chisquare. P-values are without the Yates correction. This procedure was applied following the framework used by Classen (2021) in his analysis of "All Cause Severe Morbidity" based on data from the initial reports of the vaccine Phase III trials.[15]

* Authors estimated vaccine efficacy using total surveillance time as denominator, however, as this value was unavailable for all the events analyzed, our calculations used the common statistical definition, *i.e.*, number of events relative to total number of eligible patients for each event analysis reported[16] similar to previous analyses of this nature.[15,17]

[$] ≥7 Days after dose 2 among participants without evidence of previous infection.

[#] Adverse events reported outside of the reactogenicity subgroup and assessed by the investigator as related to investigational product.

In calculations combining efficacy and safety events, the number of patients randomized that received any dose of vaccine or placebo was used as the study population in the statistical calculations, following the framework used by Classen(2021) in his analysis of "All Cause Severe Morbidity". Differences in the total (event-incident) population (randomized vs efficacy vs safety) used as denominator are relatively small and are expected to have minimal impact on the relative differences between groups. Without access to individual patient data, these calculations were performed under the assumption that efficacy and safety events were non-overlapping.

[&] ≥7 Days after dose 2; confirmed severe COVID-19 defined as PCR-positivity and "presence of at least 1 of the following: • Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO2 ≤93% on room air at sea level, or PaO2/FiO2 <300 mm Hg); • Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO); • Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors); • Significant acute renal, hepatic, or neurologic dysfunction;• Admission to an ICU; • Death."

~ Severe (grade ≥3) adverse events were generally defined as those that interfere significantly with participant's usual function, those that affect daily living or require medical care; grade 4 events were generally defined as those that required emergency room visit or hospitalization.

[§] Serious adverse events were defined as any untoward medical occurrence that, at any dose: a. Results in death; b. Is life-threatening; c. Requires inpatient hospitalization or prolongation of existing hospitalization; d. Results in persistent disability/incapacity.

[%] Deaths during the open-label period were reported only in vaccine recipients, 3 participants in the BNT162b2 group and 2 in the original placebo group who received BNT162b2 after unblinding.

^Those with reported cause of death due to: aortic rupture, arteriosclerosis, cardiac arrest, cardiac failure congestive, cardiorespiratory arrest, hypertensive heart disease, or myocardial infarction.

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Although there is a sophisticated system in place for monitoring and tracking COVID-19 events, COVID-19 Ontario relies on a national passive surveillance system to monitor adverse events. This system launched decades ago, is burdensome, heavily audited, and provides no financial compensation to clinicians for the considerable time required to complete the reports. Moreover, assertions on the part of public health officials claiming vaccine safety may make clinicians and vaccine recipients alike less likely to attribute an injury to the vaccine and thus make them less likely to report adverse events.

The phase III trials report a solicited adverse event rate of up to 78% and a severe adverse event rate of 5% within 7 days of a given dose (Figure 5). However, Health Canada's passive surveillance system reports an event rate of 0.1% for vaccine recipients (Government of Canada, 2021a). This indicates that the passive reporting system is largely inadequate for monitoring COVID-19 vaccine safety and that there are likely a significant number of Canadians experiencing adverse effects from these vaccines that are not being captured by this system and that are not being factored into our policy decision-making.

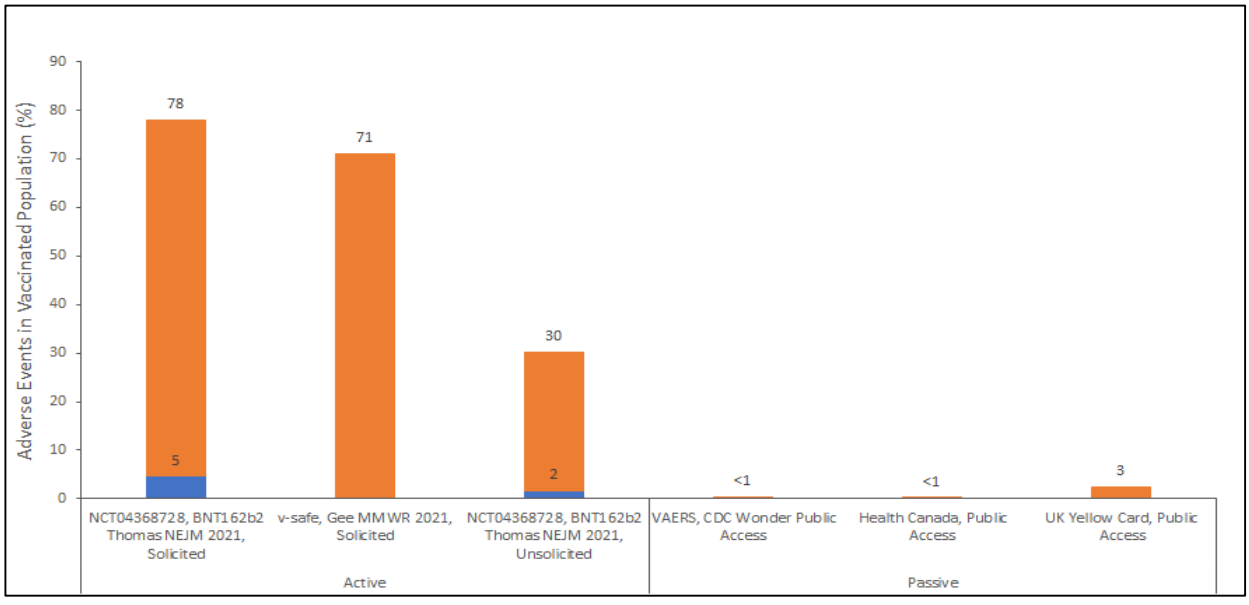

Figure 5: The rate of solicited and unsolicited adverse events in active surveillance studies of COVID-19 vaccines (NCT04368728 and v-safe) and proportion of adverse events following COVID-19 vaccination reported to passive surveillance systems (VAERS (U.S. Department of Health and Human Services, 2021), Health Canada

(Government of Canada, 2021a) and UK Yellow Card (UK Government, 2021)) relative to total vaccinated (≥1 dose) population.

Conclusions

Health officials claim that the unvaccinated are driving infection rates and that mandates are necessary to preserve hospital capacity. However, a careful inspection of the data indicates not only were these policies are based low quality evidence that was highly subject to bias, the actual data demonstrated the opposite trend. Although there was a slight increase in cases among the unvaccinated from August through to mid-October 2021, reflective on increased testing rates, by early December 2021 the majority of cases were among the vaccinated. Moreover, this surge in cases resulted in a higher proportion of vaccinated compared to unvaccinated individuals in the hospital or ICU admissions despite vaccine mandates and high vaccine uptake. Finally, the policy did not adequately weigh the benefits of vaccination against potential risks, which outweigh (adverse events, ARI of 17.9% and 0.5%) any benefits derived from the vaccines (symptomatic cases, ARR of 3.7% and 0.1%) (Thomas & Moreira *et al.*, 2021).

Optimal care should be characterized by, scientific discourse and inquiry, reliance on the highest levels of evidence, individualized care, and informed consent (Chow & Gallo *et al.*, 2018; Madden & Bhandari, 2020; Shah & Turrin *et al.*, 2021. As COVID-19 is no longer a risk to the population at large due to the arrival of less virulent strains like Omicron, or the latest B.2 variant, and the widespread population-based immunity, it is time to abandon these outdated vaccines and mandates and return to good medical practice and established standards of care.

Conflicts of interest

DMc, SP, and CAS are all members of the Science and Medical Advisory Committee for the Canada Covid Care Alliance. No other conflicts of interest are declared.

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