Dispelling the Myth of a Pandemic of the Unvaccinated

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https://www.canadiancovidcarealliance.org/

Introduction

According to mainstream media, Ontario health data show that the unvaccinated are up to 60-times more likely to end up in intensive care units (ICUs) with COVID-19 than the vaccinated .[1-3] With alarming headlines, the media promoted a narrative that the unvaccinated are driving the pandemic and increasing the burden on ICUs in Ontario. These headlines typically depict the unvaccinated as careless vectors of disease, potentially dangerous and thus essentially responsible for society's current COVID-19 plight. In this environment, vaccine mandates and other public and private policies have been issued to the detriment of the unvaccinated that are often based on real world cohort analyses of COVID-19 database such as the retrospective review conducted by the Ontario Science Table (OST).[4]

Because such assertions have far-reaching consequences for both medical treatments *as well as* civil rights, there is a need for a critical evaluation of the accuracy of the various claims, 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. The vaccines in question are those currently in use in Canada where two of four use mRNA platforms, and the others use adenovirus-based delivery of DNA, from which mRNA is generated. Each of these vaccines ultimately produce the spike protein of SARS-CoV-2, which is presented on the surfaces of vaccinated cells. The following analysis will put the assumed versus actual data into a more rigorous context with the goal of supporting informed decision making at both an individual and health policy level.

The practice of mass vaccination is based on the notion of “herd immunity”, in that 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, the disease cannot spread further and should not be transmittable to those who have neither form of immunity (e.g., unexposed or immunocompromised persons). 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.[5,6] 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 conveniently changed the definition of herd immunity to something that is achieved almost entirely through vaccination.[7]

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.[8-11] The latter may occur as immune responses in terms of levels of antibody levels, T cells, and even memory cells decline over time.[12-17] Long-lasting success of a 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.[18-21] 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 the fully vaccinated.[22] 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.[23-26] 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.[27-34] 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 receptor ACE2. In the 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. In any event, it is misleading to insist, as often do the media or the OST, 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.

The following analysis of the Public Health Ontario and Government of Ontario, Ministry of Health COVID-19 databases demonstrate that the current vaccine strategy is ineffective and even harmful, and that Health Care Officials in Ontario and elsewhere must stop blaming the unvaccinated and focus instead on more effective policies to help navigate the pandemic. It will focus on three areas of concern: the methodology of the studies used to support current policy, the lack of effectiveness of current vaccination policy, and how current policy has neglected to consider vaccine safety.

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[35] on January 5, 2022. In this dataset, hospitalization numbers include 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 (fully vaccinated) or three (boosters) vaccine doses were obtained from the "COVID-19 Vaccine Data in Ontario" datasheets available at the Government of Ontario Data Catalogue[36] on January 5, 2022. Number of individuals in ICU and in hospital excluding ICU 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[37] on January 5, 2022. Data from all sources where combined, organized, processed, and plotted in 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.

Findings

1) 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.[38] 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 should not be used to support mandatory treatment recommendations.[39] 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.[36,40] Presently we know that the Canadian COVID-19 database preferentially captures data on symptomatic individuals and almost certainly underrepresents those who refuse or are not required to undergo testing or those who are asymptomatic.[41] 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 reliability of the outcomes. Likewise, data would need to be interpreted in light of differences in monitoring or sampling across vaccination groups. Comparing outcomes by vaccination groups assumes these groups are homogeneous. However, there may have been multiple differences between groups, including natural immunity, disease 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.[42] 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”.[43] As details

about other potentially relevant variables were not provided by Public Health Ontario, 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,[44] contradicting at least one company, Pfizer, that in the Phase III trial asserted that immunity can be established after 7 days.[45] It follows that fully vaccinated individuals will be considered partially vaccinated up to 14 days after their shot, and individuals receiving their first dose will be categorized as unvaccinated up to 14 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.

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, when a cycle threshold (Ct) higher than 20 cycles is used to determine COVID-19 positivity, there is a very high likelihood of false positives, *i.e.,* that a person testing positive does not actually have an active and transmissible infection.[46] This limitation is now acknowledged by the Centers for Disease Control and Prevention (CDC).[47] For example, a Ct cut-off for positivity over 35 (Public Health Ontario officially uses a Ct of 35)[48] may result in up to a 85% false positive rate.[49] If these Ct levels are then used to describe “cases”, and asymptomatic low probability persons are most of tests conducted, it will inevitably generate inflated case numbers. 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.[46]

Given our current vaccine mandate climate, unlike their vaccinated counterparts, unvaccinated workers often have to undergo systematic asymptomatic testing.[50-53] This increase in sampling will invariably result in higher case counts in this population, based on the limitations of the PCR test, as well as the fact the data collection systems may not be able to eliminate multiple counts of the same infection.[54,55] It is also unclear whether there are differences in testing requirements between hospitalized individuals based on vaccination status. However, in this closely monitored population, any differences in policy based on vaccination status would likely impact outcomes, especially if there were financial incentives associated with testing or treating COVID-19 patients. Moreover, it is well established that SARS CoV-2 is transmitted more readily in communal living environments such as hospitals.[56] When interpreting the data, it is important to distinguish between individuals who were in the hospital for some non-COVID-19 related reason and test positive for SARS CoV-2 compared to those who are in the hospital due to a COVID-19 infection. As it is often unclear what Ct was used and whether there were differences in monitoring based on vaccination status thus Ontario COVID-19 data showing differences between the vaccinated and unvaccinated should be interpreted with great caution.

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, and ideally their use should be limited to hypothesis generation leading to confirmation in a well-conducted clinical trial.[57,58] Most importantly, their role in inferring causality is limited, and therefore care should be taken in using them to support major health policy decisions.

COVID-19 Risk Factors

There are some well-established factors that either increase risk of severe COVID-19 outcomes such as older age, obesity, diabetes co-morbidities,[43,59] or lower risk of severe disease such as naturally acquired prior immunity[60] and younger age.[61] As analyses are not always randomized and do not control for baseline factors, it is quite possible that differences in such factors in vaccinated and unvaccinated populations could be partially, or fully, driving the claimed effects. For instance, it is probable that those with naturally acquired immunity and those who have been ineligible for vaccination such as children under 12 years of age could be represented in higher proportions in the unvaccinated population, while the elderly and those at risk of severe disease would be more likely represented in the vaccinated group.

2) Concerns Regarding Effectiveness of Current Vaccination Policy

There have been three waves of COVID-19 cases from Nov 1, 2020 to January 4, 2022 after the initial wave in the spring of 2020 (Figure 1). The second and third waves peaked above 4,000 cases per day in Ontario each before receding 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, before dramatically shooting up to an unprecedented 18,000 cases per day by early January, more than 4-fold the size of prior peaks. As noted above, herd immunity should be achieved with a highly effective vaccine once some 50% of the population is immune. In this regard it should be noted that the third wave was receding before the 50% vaccination threshold was reached for the first shot in early May and that the shape of the decline of the curve did not change after this threshold was achieved. Such data suggest that natural immunity rather than vaccine-induced immunity was the driving factor in the decline of the third wave.

By early August 2021 at least 65% of the population had been fully vaccinated, and by mid-November 2021 the number was as high as 75% and slowly increasing over 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. High rates of full vaccination could explain the minimal rise in daily cases seen from August to September but the rise in cases could also 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.[50] It is notable that analyses justifying vaccine mandates conducted by the Ontario Science Table were conducted within this 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.

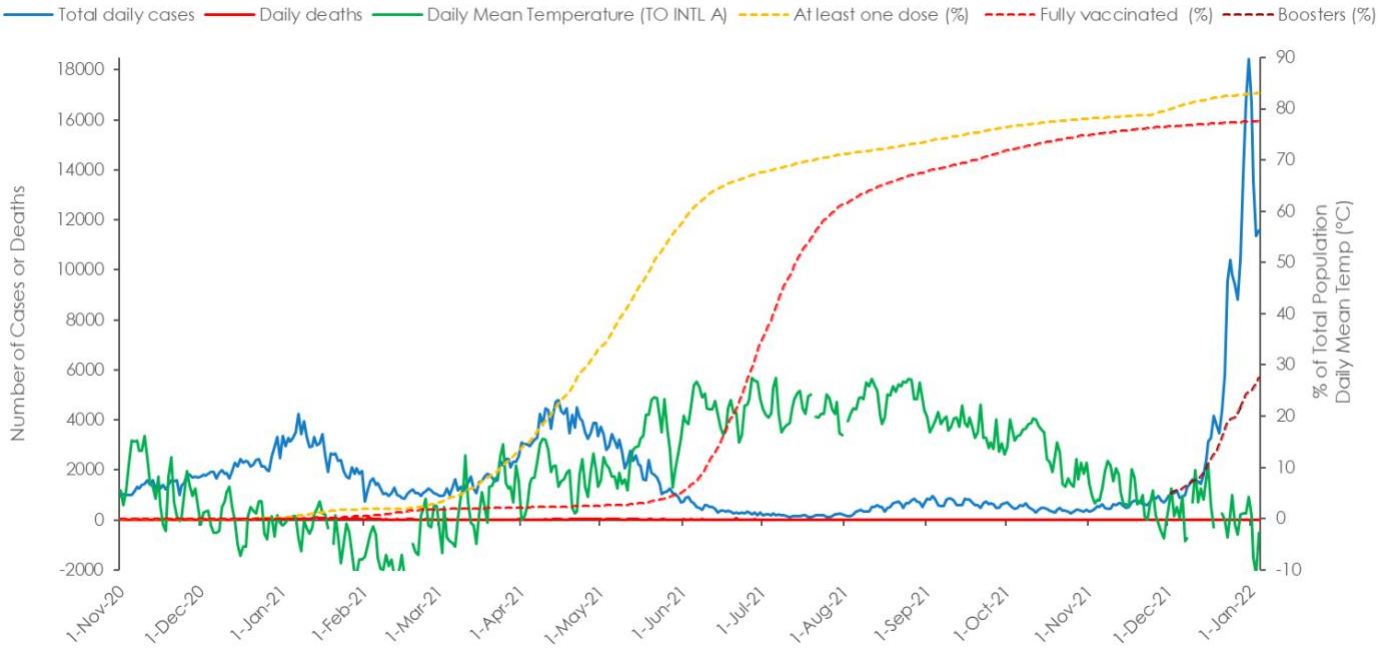

Figure 1: COVID-19 cases and deaths (data source: Public Health Ontario),[35] vaccination status in Ontario (data source: Government of Ontario, Ministry of Health, COVID-19 data catalog)[36] and mean temperature at Toronto International Airport (data source: Government of Canada, Historical Weather and Climate Data for the TORONTO INTL A, Ontario station)[37] 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 vaccine, the differences in case counts and rates were low and steady leading up to early October, at which point case counts in the two groups began to overlap and then by early December a surge in daily cases in the fully vaccinated typical of the infectious peaks of earlier waves was clearly apparent. By early January, 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 ineligible for vaccination.[64] As case counts were 6-fold higher in the fully vaccinated group compared to the unvaccinated group by mid to late December, the Ontario data does not provide compelling support for policy decisions recommending the vaccination of children younger than 11 years. At this time, the proportion of cases in the fully vaccinated had surpassed that of unvaccinated (7-day average: 87.89 per 100k 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.[62] It is apparent that the vaccine designed to combat the original Wuhan strain has become obsolete. Although increased infection rates in this group could be due to the vaccinated engaging in higher risk activities than the unvaccinated, it also possible that it shows vaccine enhanced disease, a concern raised in the Pfizer Safety Report.[63]

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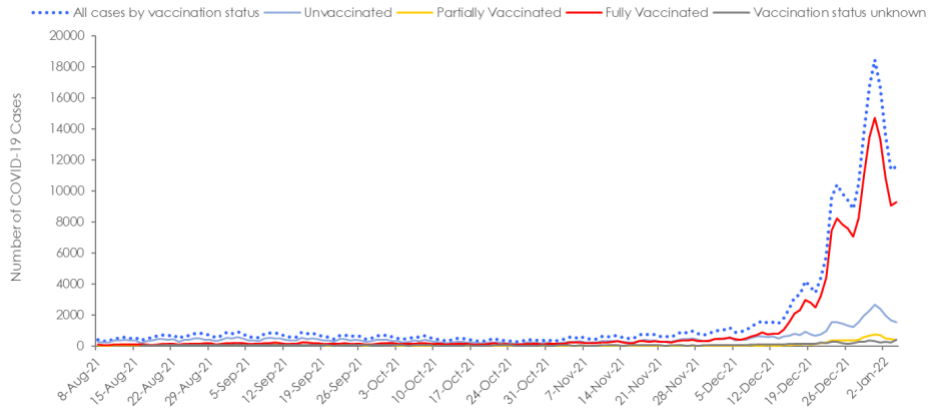

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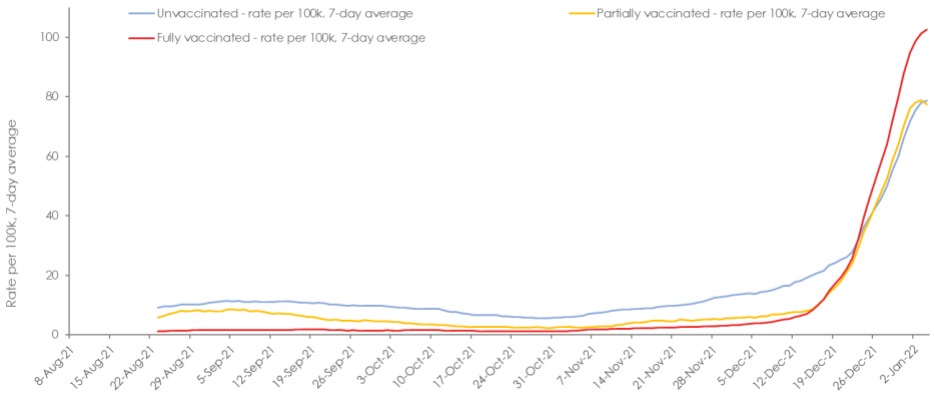

Figure 2: (A) Number of cases and (B) 7-day averaged case rates by vaccination status in Ontario from Aug 8, 2021 to Jan 4, 2022. Data source: Government of Ontario, Ministry of Health, COVID-19 data catalog.[36]

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 peaking at 148 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 and as of January 4, 2022, deaths for the fourth wave have not reached more than 13 deaths per day despite the dramatic surge in cases in December.

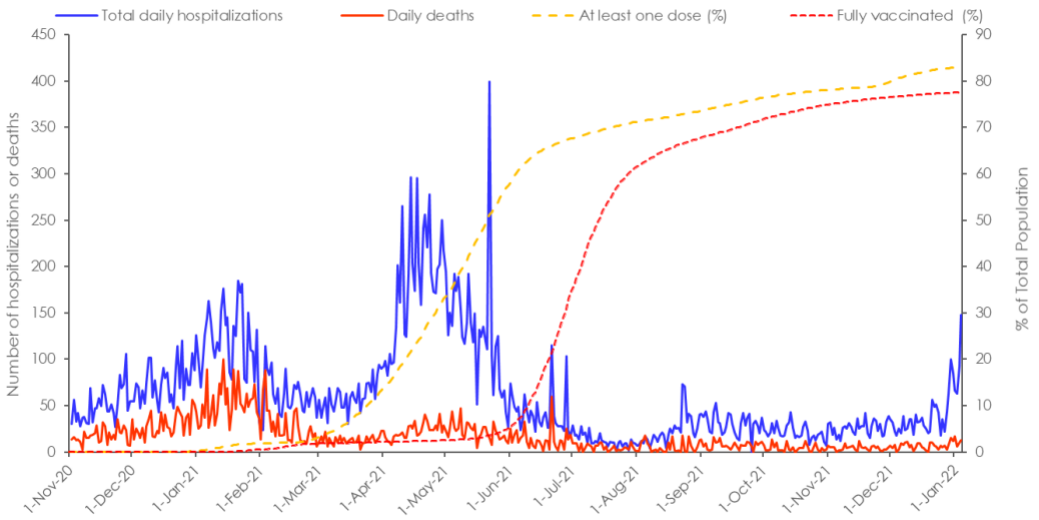

Figure 3: COVID-19 hospitalizations and deaths (data source: Public Health Ontario)[35] and vaccination status (data source: Government of Ontario, Ministry of Health, COVID-19 data catalog)[36] in Ontario from November 1, 2020 to January 4, 2022.

As mentioned, 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, serving to prevent more severe COVID-19 outcomes, including deaths. However, 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, meaning that they have a dysregulated immune system that makes it more difficult for them to develop sterilizing immunity and leaves them more susceptible to infection.[65] However, this 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.[66,67] 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.[68-72] This, coupled with the fact that many individuals within these facilities were at risk of severe disease,[68,69,71,73] that early treatment was

not provided to residents, and they experienced reduced rates of healthcare utilization when they needed the most,[74] and that 35% of residents had no hospitalization orders and 80% had do not resuscitate orders made outbreaks in these facilities more likely to be fatal.[66,67]

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 passed away, limiting the number of those vulnerable to infection. Many vulnerable residents died due COVID-19 infections, others died due to failure to thrive from being isolated for a full year, and another contingent may have died due to vaccine-related injury from being given vaccines that were not well studied in this group.[75] A CDC report on the VAERS system published in early 2021 reported that 69% of all reported vaccine-emergent deaths were in people living in long-term care facilities and occurred a median of 2 days after vaccination.[76] Although it is possible that the vaccines may have had some protective effect in high-risk populations**,** it is equally possible that failed health policy related to lockdowns and mass vaccination of elderly populations were also contributing factors.

Hospitalizations and ICU due to COVID-19 by Vaccination Status

Total in hospital and ICU due to COVID-19 by 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.[77] The number of people in ICU remained low and did not surpass more 200 beds during the time period studied, did not come close to approaching the ICU capacity for Ontario of 2,343 beds.[40] Although there were more unvaccinated compared to vaccinated people in the ICU throughout the initial time period

studied 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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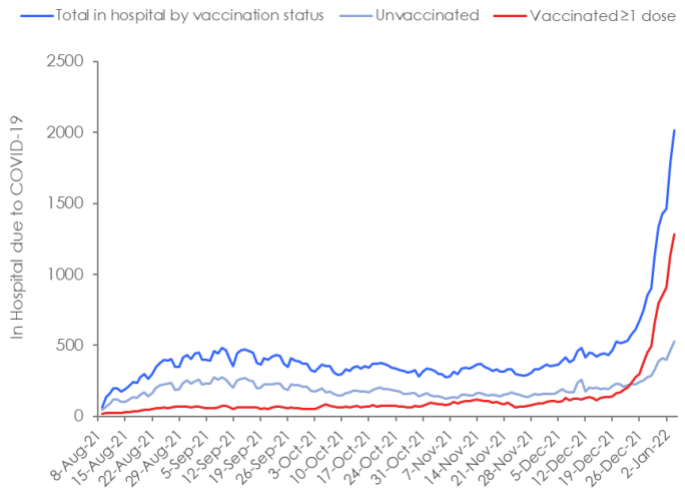

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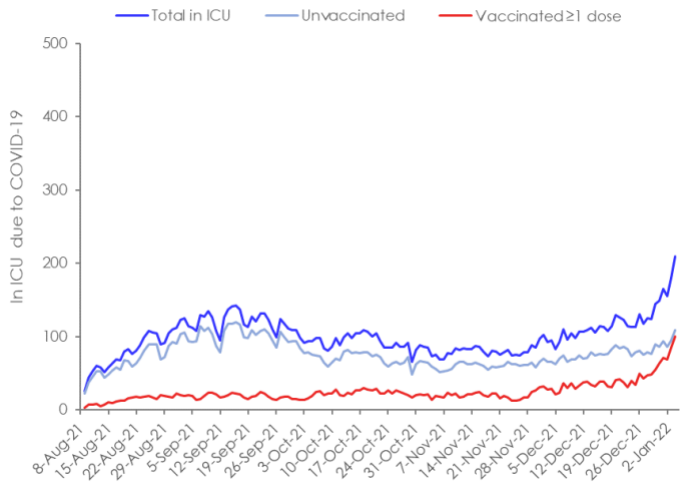

Figure 4: COVID-19 (A) Total hospitalized and (B) in ICU due to COVID-19 by vaccination status in Ontario from August 8, 2021 to Jan 4, 2022. Data source: Government of Ontario, Ministry of Health, COVID-19 data catalog[36]

Although it is possible that the vaccines were conferring protection from August through to the end of October, reducing the risk of severe disease and resulting in lower numbers of people in hospitalization or in ICU, 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 explanation could be that differences seen in early August to late October are 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. 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[41]. Although it is possible that the slight initial rise in people in hospital and ICU may reflect vaccine efficacy, the consistently low and comparable rates among the vaccinated and unvaccinated may more strongly reflect differences in monitoring and sampling more than differences in infectivity.

Another notable observation from this data is that despite surges in COVID-19 cases, total people in hospital and ICU remained low, suggesting that the new variant is either less virulent, that a clinically meaningful population level of immunity has now been achieved, or that there are fewer people at risk of severe disease either due to death or immunity. Regardless of the explanation, the findings to date call into question the need for further lockdowns and boosters.

3) Concerns Regarding the Safety of 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 among fully vaccinated adults.[45] The study also reported relative (74.6%) and absolute (0.5%) increases in severe adverse events, events that affect daily activity, require medical intervention or 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 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 (any 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.

Event	BNT162b2 (n)	Placebo (n)	Absolute Difference (p-value)[?]	Absolute Risk Change* (%)	Relative Risk Change* (%)
Cases 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 during placebo-controlled 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		

[¥] 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, ie. 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".[15] 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

Although there is a sophisticated system in place to monitor and track COVID-19 events, COVID-19 Ontario relies on a national passive surveillance system to capture 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.

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.[78] This suggests 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 which are not being factored into our policy decision-making.

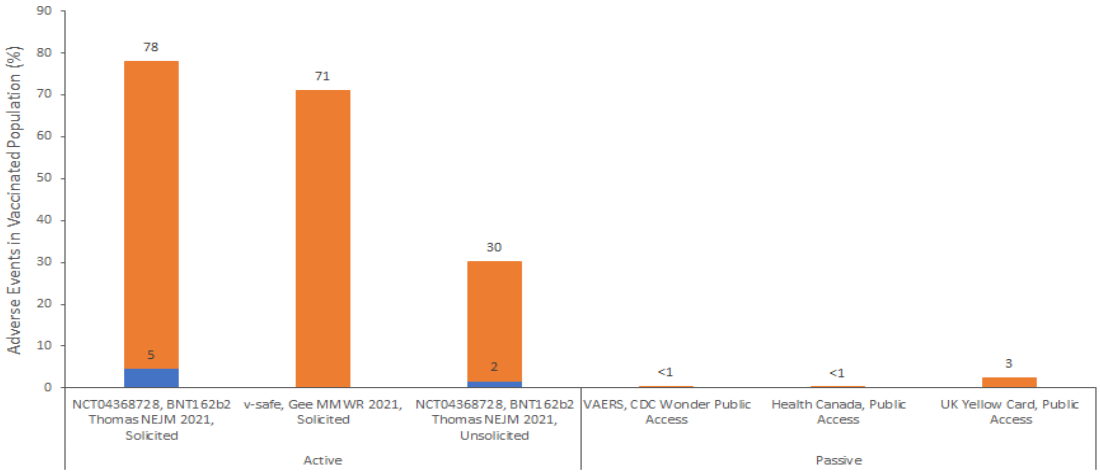

Figure 5: Rate of solicited and unsolicited adverse events in active surveillance studies of COVID-19 vaccines (NCT04368728 and v-safe) and proportion of adverse events following COVID-19 vaccination reported to passive surveillance systems (VAERS,[79] Health Canada[78] and UK Yellow Card[80]) relative to total vaccinated (≥1 dose) population.

Conclusion

Although health officials claim that the unvaccinated are driving infection rates and threatening to overload our ICU capacity, and that for this reason vaccine mandates are necessary to manage hospital capacity, a careful inspection of the actual data does not support those claims. First, we see that the type of analysis conducted to support these policies is based on low levels of evidence and on studies that are highly subject to bias. These studies show that although COVID-19 cases were higher among the unvaccinated from August through to mid-October, by early December it was clear that the majority of cases were among the vaccinated and that 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 rates. Finally, the policy did not adequately weigh the benefits of vaccination against the risks of vaccination which shows that the vaccines do more harm (ARI of 17.9% and 0.5%) than good (ARR of 3.7% and 0.1%).[45] In other areas of medicine we are optimizing care through scientific discourse and inquiry, reliance on the highest levels of evidence, personalized approaches to care, and informed consent.[81-83] Now that deaths and hospitalizations are largely uncoupled from case counts due to either high levels of immunity or the arrival of less virulent COVID-19 strains like Omicron, is it not time to end vaccine mandates and return to the established standards of care and excellence in medicine?

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