A Deeper Dive into the Publicly Available Ontario Data

on COVID-19 Vaccination

A Report Prepared for

Member of Parliament,

by

Independent Researcher

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Introduction

As the SARS-CoV-2 virus moves into another phase with the Omicron variant, it is time to take stock of the current and available data on the various public health measures, such as lockdowns, masks, vaccines, mandates, passports, travel restrictions and other tools that have been utilized in the last two years. Today, we have more evidence than ever on all of these measures and their utility. Consequently, we have the ability to make informed decisions on how to move forward with a rational, data-driven strategy to deal with this phase of the pandemic.

As an independent researcher, it has been a long-standing interest to keep abreast of the existing and evolving pandemic related data. Public Health Ontario (PHO) and Public Health Agency of Canada (PHAC) have produced summarized data on COVID-19 vaccinations and this is now available to the public at large in reports and on their websites. It is therefore, an enormous opportunity to examine the current trends and patterns on vaccinations.

Purpose

I ne purpose is to conduct a deeper analytical dive into the graphs and charts of the publicity available data on vaccinations. It is hoped that this exploratory data analysis will highlight information to enable evidenced-based public health policy development for this stage of SARS-CoV-2.

The review and analysis have been conducted in collaboration with the following statistical/ analytical experts:

- a former Chief and a Chief currently in Statistics Canada
- three Senior Analysts currently in Statistics Canada
- a Professor in the Department of Mathematics and Statistics in a recognized Ontario post-secondary educational institution
- a Professor Emeritus and Distinguished Research Professor from the School of Mathematics and Statistics in a recognized Ontario post-secondary educational institution.

In addition, several editors have reviewed this report.

Caveat and Limitations

As the participating statistical experts did not have access to the raw data, the current exploratory analysis is solely based on the summarized data in the form of graphs and charts of the publicly available data from PHO and PHAC. As a result, the ability to conduct highly sophisticated analysis using rigorous statistical techniques is not possible. Therefore, the reporting is limited to key highlights for each figure.

Distribution

This report is prepared for the Liberal Party of Canada. However, it is available for distribution to as many levels of government wishing access to it. Currently, the contents herein have only been seen by the collaborators and those reviewing the document for accuracy or editing purposes. It has therefore, not been widely disseminated to other institutions, individuals or groups and is provided solely for public health policy development going forward in this phase of the pandemic.

Technical Notes, Definitions and Data Quality Issues

The technical notes and definitions used for the various figures in this report are not provided in this report. For further information on the technical notes shown in the screenshots of graphs and charts, see the following websites and reports:

- 1. publichealthontario.ca: a. ENHANCED EPIDEMIOLOGICAL SUMMARY Severe Outcomes among Confirmed Cases of COVID-19 Following Vaccination in Ontario: December 14, 2020 to May 23, 2022 b. SURVEILLANCE REPORT Severe Outcomes among Confirmed Cases of COVID-19 Following Vaccination in Ontario: December 14, 2020 to May 23, 2022
- 2. covid-19.ontario.ca
- 3. health-infobase.canada.ca.

Some of the data quality issues have been raised in regards to the data from PHO and PHAC and can be found in Appendix 1.

A Deeper Analytical Dive

This section presents the key highlights for various graphs and charts summarized in the Public Health Ontario (PHO) and Public Health Agency of Canada (PHAC) reports and websites. As such, screenshots of graphs and charts in this document have been taken directly from these sources.

The approach taken in this section is to pose various questions and then use available charts and graphs to answer them. The questions are as follows:

- 1. Do the COVID-19 vaccines prevent infection and hospitalization?
- 2. What are the trends in vaccinated and unvaccinated cases in the hospitals?
- 3. Are there more vaccinated or unvaccinated cases in the ICU and hospitals at present?
- 4. How does COVID-19 vaccination affect hospitalization rates for those 60 years and older?
- 5. How does COVID-19 vaccination affect death rates for those 60 years and older?
- 6. What is the impact of COVID-19 vaccination on hospitalization for various age groups?
- 7. What is the impact of COVID-19 vaccination on death for various age groups?
- 8. What are the most frequently reported adverse events associated with COVID-19 vaccines?
- 9. What age groups report having adverse events from the COVID-19 vaccines?
- 10. What gender reports having adverse events from the COVID-19 vaccines?

1. Do the COVID-19 vaccines prevent infection and hospitalization?

Figure 1. Hospitalized Confirmed Post-Vaccination Cases of COVID-19 By Number of Days From Dose Administration to Symptom Onset by Vaccination Status: Ontario, December 14, 2020 to May 22, 2022 (Source: <u>publichealthontario.ca</u>)



Figure 1 shows the cases who are vaccinated with at least one dose and are hospitalized over the period December 14, 2020 to May 22, 2022. According to the chart, we observe the following highlights:

- Overall, it is evident that the COVID-19 vaccines did not prevent infection or hospitalization since all of the cases (indicated by all colours on the chart) in the hospital are vaccinated. These cases represent "severe outcomes" as indicated by the title (in green).
- The highest number of cases are among those vaccinated but not yet protected (in grey).
- A rise in hospitalized cases occurs in the fully vaccinated (post-series completion in dark blue on the chart) within 5-6 months or by day 155 200.
- The fully vaccinated with a booster (post-booster dose in light blue) shows an increase in hospitalizations around the first 14 days. The higher frequency of hospitalization continues for about 2.5 months, after which there is even a larger number of cases in the hospital.

2. What are the trends in vaccinated and unvaccinated cases in the hospitals?

Figure 2. Hospitalized Confirmed Cases of COVID-19 by Symptom Onset Date: Ontario, December 14, 2020 to May 22, 2022 (Source: <u>publichealthontario.ca</u>)



Figure 2 shows the confirmed cases of COVID-19 in the hospital since the date of onset over the period, December 14, 2020 to May 22, 2022. According to the chart, we observe the following highlights:

- Hospitalizations peaked in mid-April 2021 and were largely among the unvaccinated (includes those with no vaccine or one dose less 14 days as shown in grey). At this time, less than 3% of the Ontario population was fully vaccinated (see Appendix 2, Chart 1) and therefore, most hospitalizations were among the unvaccinated.
- Around mid-January 2022, when approximately 77% of Ontarian were fully vaccinated (see Appendix 2 (Chart 2), about 2 times as many cases in the hospital were fully vaccinated/ boosted (post-series completion in dark blue and post-booster in light blue) as compared to the unvaccinated (in grey).
- Although there are more fully vaccinated/boosted cases in the hospital than the unvaccinated cases in January 2022, they represent less than their corresponding share of the Canadian population. On the other hand, the unvaccinated in the hospital are higher than their respective share of the population in January 2022.

• Around mid-April 2022, a large number of cases in hospital were among those with a booster (post-booster dose in light blue).

3. Are there more vaccinated or unvaccinated cases in the ICU and hospital at present?

Figure 3. Hospitalizations by vaccination status, Ontario, last updated June 3, 2022 (Source: <u>covid-19.ontario.ca</u>)

covid-19.ontario.ca 🔒							
Last updated: June 3, 2022 at 10:32 a.m. (EST)							
Hospitalizations by vaccination status							
Weekend and holiday reporting: Due to incomp data for hospital and ICU admissions is not upd	olete weekend and holiday reporting, vaccinatio ated on Sundays, Mondays and the day after ho	n status lidays.					
In ICU							
	Unvaccinated cases	10					
	Partially vaccinated cases	5					
	Fully vaccinated cases	61					
In hospital but not the ICU	1						
	Unvaccinated cases	81					
	Partially vaccinated cases	26					
	Fully vaccinated cases	414					

Figure 3 shows the hospitalizations by vaccination status. (Note: Definitions used in this chart are different from those for previous figures). According to the pie charts, the following key highlights are seen:

• Overall, there are 6 times more fully vaccinated cases (in light yellow) in the ICU than the unvaccinated cases (in dark brown) and 5 times more fully vaccinated cases (in light pink) in hospital than unvaccinated cases (in burnt red).

4. How does COVID-19 vaccination affect hospitalization rates for those 60 years and older?

Figure 4. Seven-Day Average Rate of COVID-19 Hospitalization per 100,000 Person Days Among Individuals 60 Years of Age and Older by Vaccination Status: Ontario, February 15 to May 22, 2022 (Source: <u>publichealthontario.ca</u>)



^{3.} Trends over time in hospitalizations should be interpreted with caution as hospitalization data may be incomplete or missing for case records where information was not gathered, reported to public health units or entered in CCM.

Figure 4 shows the seven-day average rate of COVID-19 hospitalizations per 100,000 person days by vaccination status for those 60 years or older, over the period February 15, 2021 to May 22, 2022. According to the graph, we observe the following highlights:

• In mid-January 2022, when over 92% of those 60 years and older were fully vaccinated (see Appendix 2, Chart 3), hospitalization rates are considerably higher among the unvaccinated (in black) as compared with the vaccinated (post-series completion in blue).

5. How does COVID-19 vaccination affect death rates for those 60 years and older?

Figure 5. Seven-Day Average Rate of COVID-19 Deaths per 100,000 Person Days Among Individuals 60 Years of Age and Older by Vaccination Status: Ontario, February 15 to May 22, 2022 (Source: <u>publichealthontario.ca</u>)



Figure 5 shows the seven-day average rate of COVID-19 deaths per 100,000 person days by vaccination status for those 60 years or more, over the February 15, 2021 to May 22, 2022 timeframe. According to the graph, we observe the following highlights:

 In mid-January 2022, when over 92% of those 60 years and older were fully vaccinated (see Appendix 2, Chart 3), death rates are considerably higher among the unvaccinated (in black) as compared with the vaccinated (post-series completion in blue).

6. What is the impact of COVID-19 vaccination on hospitalization for various age groups?

Figure 6. Rate of COVID-19 Hospitalizations per 100,000 Person Days by Vaccination Status and Age Group in the Previous 30 Days: Ontario (Source: <u>publichealthontario.ca</u>)



- Hospitalization data may be incomplete or missing for case records where information was not gathered, reported to public health units or er
 Rates for series completion and two booster doses are not shown due to instability arising from small counts.
- Post-one booster dose rates are not shown for children 5-11 years olds as this age group is not eligible for a booster dose.

Figure 6 shows rate of COVID-19 hospitalizations per 100,000 person days by vaccination status for those 60 years or more, over the last 30 days prior to May 22, 2022. According to the chart, we observe the following highlights:

- Vaccination made virtually no difference in the rate of hospitalization for all age groups except for those 60 years and older.
- An earlier PHO report shows a detailed breakdown illustrating the greatest benefit of vaccination was for individuals 70 years or more, while there is a smaller benefit to those 60 years and over (see Appendix 2, Chart 4).

7. What is the impact of COVID-19 vaccination on deaths for various age groups?

Figure 7. Rate of COVID-19 Deaths per 100,000 Person Days by Vaccination Status and Age Group in the Previous 60 Days: Ontario (Source: <u>publichealthontario.ca</u>)



Figure 7 shows the seven-day average rate of COVID-19 deaths per 100,000 person days by vaccination status for those 60 years or more, over the last 60 days prior to May 22, 2022. According to the chart, we observe the following highlights:

- Vaccination made virtually no difference for death rates in all age groups except those who were 60 years of age or greater.
- An earlier PHO report shows a detailed breakdown illustrating the greatest benefit of vaccination was for individuals 70 years or more, while there is a smaller benefit to those 60 years and over (see Appendix 2, Chart 5).

8. What are the most frequently reported adverse events associated with COVID-19 vaccines?

Figure 8. Number of the most frequently reported adverse events, up to and including May 13, 2022. (Source: <u>health-infobase.canada.ca</u>)



Figure 8 shows the most frequently reported Adverse Events Following Immunization (AEFI) up to and including May 13, 2022. According to this chart, the following highlights are observed:

- The top six most frequently reported adverse events include paraesthesia, vaccination site pain, headache, pruritus, dyspnoea and fatigue. These ranged from nearly 7000 events to about 4,600 out of a total of 116,988 reported events.
- Myocarditis and pericarditis are seen on the list at a frequency of about 1000 out of a total of 116,988 adverse events reported.
- Anaphylaxis, lip swelling, swollen tongue and dermatitis allergic are the least frequently reported adverse events, at somewhat less than 1000 out of a total of 116,988.

9. What age groups report having adverse events from the COVID-19 vaccines?



Figure 9. Number of adverse event reports by age group up to and including May 13, 2022 (n=46,146). (Source: <u>health-infobase.canada.ca</u>)

Figure 9 shows the age groups who report experiencing the most adverse events, up to and including May 13, 2022. According to the figure, we observe the following highlights:

- The age groups between 18 and 69 years of age have the most adverse event reports post-vaccination.
- The age group showing the highest number of reports of adverse events are those between 40 to 49 years, followed by those 50 to 59 years and then those 30 to 39 years of age.

10. What gender reports having adverse events from the COVID-19 vaccines?

Figure 10. Number of adverse event reports by age group and sex up to and including May 13, 2022 (n=46,149). (Source: <u>health-infobase.canada.ca</u>)



Figure 10 shows the number of adverse event reports by age and sex up to and including May 13, 2022. According to the figure, the following highlights are observed:

- The figure shows that females between age 18 to 80 years or older disproportionately report having adverse events as compared to their male counterparts.
- Females of childbearing ages between 18 to 59 years have the greatest combined number of adverse event reports.
- The age group of women with the most adverse event reports were those between 40 to 49 years.

Summary of Results

A deeper dive into the publicly available data on vaccination from Public Health Ontario (PHO) and Public Health Agency of Canada (PHAC) provide the following answers to the questions posed.

- 1. **Do the COVID-19 vaccines prevent infection and hospitalization?** Full vaccination does not prevent infection and hospitalization. Even full vaccination with a booster does not prevent infection or hospitalization.
- 2. What are the trends in vaccinated and unvaccinated cases in the hospitals? In-mid April 2021, when less than 3% of Canadians were fully vaccinated, most of the cases in hospital were unvaccinated. In mid-January 2022, when 77% of Canadians were fully vaccinated, there were more vaccinated cases in hospital than unvaccinated cases.
- 3. Are there more vaccinated or unvaccinated cases in the ICU and hospitals at present (June 3, 2022)? There are 6 times more cases that are vaccinated versus unvaccinated currently in ICU and 5 times more vaccinated cases that are in the hospital compared to unvaccinated cases.
- 4. How does COVID-19 vaccination affect hospitalization rates for those 60 years and older? Lower hospitalization rates are seen for those 60 years and older that are vaccinated compared to those that are unvaccinated.
- 5. How does COVID-19 vaccination affect death rates for those 60 years and older? Lower death rates are seen for those 60 years and older that are vaccinated compared to those that are unvaccinated.
- 6. What is the impact of COVID-19 vaccination on hospitalization for various age groups? Vaccination is showing virtually no benefit to hospitalization rates among all age groups except for those 60 years of age and older. Vaccination shows benefit especially to those 70 years or older.
- 7. What is the impact of COVID-19 vaccination on death for various age groups? Vaccination is showing virtually no benefit to death rates among all age groups except for those 60 years of age and older. Vaccination shows benefit especially to those 70 years and older.
- 8. What are the most frequently reported adverse events associated with COVID-19 vaccines? There are numerous reported risks associated with the COVID-19 vaccines. Among 50 listed, the most frequently reported include paraesthesia, vaccination site pain, headache, pruritus, dyspnoea, and fatigue; while less frequently reported events include myocarditis, pericarditis; the least frequently reported include anaphylaxis, lip swelling, swollen tongue and dermatitis allergic.
- 9. What age groups report having adverse events from the COVID-19 vaccines? Those individuals between 18 and 69 years of age report having adverse events.
- 10. What gender reports having adverse events from the COVID-19 vaccines? Females disproportionately report having adverse events to the vaccines.

Discussion

COVID-19 is the disease from a SARS-CoV-2 viral infection. This disease has been known to have an age gradient, meaning that the older one is, the greater the risk of severe outcomes. There is also a stratified risk based on how immunocompromised individuals are, meaning that the more immunocompromised, the greater the risk of serious outcomes. Among the authoritative sources, Statistics Canada reported early (November 2020) that "There is now clear evidence that people with pre-existing chronic conditions or compromised immune systems are at higher risk of dying of COVID-19, especially among those over the age of 80."¹ The Mayo Clinic also indicated that "People of any age can catch COVID-19. But it most commonly affects middle-aged and older adults....In the U.S., about 81% of deaths from the disease have been in people age 65 and older. Risks are even higher for older people when they have other health conditions." ²

The COVID-19 vaccines were an important tool utilized by governments around the world to combat SARS-CoV-2 infection and transmission. In an ideal world, vaccines for COVID-19 should be able to prevent infection, transmission and severe disease, while having minimal adverse reactions. If vaccines cannot prevent infection, they cannot prevent transmission or the spread of the virus. The publicly available Ontario data show that vaccination, in and of itself, does not guarantee the prevention of infection or hospitalization. A study of community transmission published in *Lancet Infectious Diseases* (December 2021) demonstrates that "fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts."³ This finding is confirmed in the latest Ontario data and further reinforces that vaccination is not preventing infection, hospitalization or transmission of the virus. Consequently, considerably more fully vaccinated cases are in the hospital and ICU than unvaccinated cases.

Breakthrough infections are not surprising as the Public Health Agency of Canada (PHAC) acknowledged in April 2021, that "even with high vaccine effectiveness, a percentage of people who are vaccinated against COVID-19 will still get sick and some may be hospitalized or die."⁴ It was also recognized by the U.S. Centre for Disease Control (CDC) as early as July 2021 when, following "large public events in a Barnstable County, Massachusetts, town, 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town during July 3–17; 346 [cases] (74%) occurred in fully vaccinated persons." This outbreak was due to Delta which was the predominant variant at that time. Seventy-nine percent of fully vaccinated individuals were symptomatic and four of the five in the hospital were fully vaccinated. ⁵ Therefore, it was clear that the vaccines which were developed on the basis of the spike protein on the original Wuhan strain of SARS-CoV-2, were losing effectiveness in preventing infection against Delta.

At this point in time, it is also well-established that vaccine efficacy wanes within 5-6 months. In fact, a systematic review by Daniel R. Feikin and colleagues in the *Lancet* provided "robust evidence of waning vaccine effectiveness over time." ⁶ By August 2021, the Director of the CDC, Rochelle Walensky, mentioned in her briefing that there was concerning evidence of waning vaccine effectiveness over time, and especially against the Delta variant. She was also concerned that protection against severe disease, hospitalization and death would decrease among those vaccinated early in the pandemic or those who were particularly at high risk. Hence, her recommendation was subsequent booster doses. ⁷

This complicated vaccination strategies because there was now a continuous need for people to get a booster every 5-6 months. Bloomberg News reported (January 2022) that "Repeat booster doses every four months could eventually weaken the immune response and tires out people, according to the <u>European Medicines Agency</u> (EMA)".⁸ If the immune system becomes weaker, it creates a susceptibility not only to COVID-19, but to all other circulating viruses. This is indeed why this regulatory agency did not endorse the booster-after-booster strategy. Even the CDC has been judicious in recommending boosters only for "certain" high-risk people.⁹

Boosters, while providing short-term protection, have disadvantages in the age of Omicron. For example, it was reported (early 2022) in *Cellular and Molecular Immunology* that there is immune escape with Omicron, meaning that this variant has the ability to escape vaccine-induced immunity as well as natural immunity. "The major reason that Omicron raises a great concern is its accumulated mutations, including more than 30 of those in the spike (S) protein." The significant number of mutations was responsible for reducing the effectiveness of the COVID-19 vaccines.¹⁰ Omicron is currently the most prevalent variant in Ontario and the data show that there are indeed more cases among the booster groups (see Appendix 2, Chart 6), potentially owing to immune escape with this variant or a weakened immune system or both. Another study on Pfizer boosters published in *Nature* "demonstrates significant waning of effectiveness of the third dose of the vaccine against infection within a few months after administration..."¹¹

The Ontario data on adverse events are available from The Canadian Adverse Event Following Immunization Surveillance System (CAEFISS). This is Canada's vaccine safety surveillance system which PHAC uses to track the Adverse Events Following Immunization (AEFI) reports from provincial/territorial health authorities. Based on the Ontario AEFI data, it is clear that there are at least 50 adverse events reported frequently. While all age groups reported adverse events, the age group most frequently reporting them are the 40 to 49 year olds; females report having adverse events more often than males. To obtain a more comprehensive picture for adverse events with the current COVID-19 vaccines, it may be worth examining the Canadian safety signals as well as those from the World Health Organization's VigiAccess, Europe's EudraVigilance, the U.S. CDC's Vaccine Adverse Events Reporting system, the U.K.'s Yellow Card Reporting Site and other surveillance systems not listed here.

While the vaccines do not prevent infection and hospitalization and indeed wane over time, it is nevertheless evident from the exploratory data analysis, that COVID-19 vaccination made some difference in outcomes for those 60 years and older. The Ontario data for this age group indicate that the rate of hospitalizations and deaths were lower among the vaccinated compared to their unvaccinated counterparts, with a greater difference seen among those at least 70 years of age. For all other age groups, differences in rates of hospitalization and death between the vaccinated and unvaccinated were negligible. Similar trends have been observed in Switzerland, U.S. and U.K. with the Swiss data being most comparable to the Ontario data due to the similarity of age categories. The difference between the vaccinated and unvaccinated deaths for all age groups in Switzerland were negligible, except for those 60 years of age and older.¹² This trend supports the notion that COVID-19 is a disease of the elderly and immunocompromised and that this demographic had the most to gain from vaccination despite the risk of potential adverse events.

Currently, there is a plethora of studies examining the potential benefit of vaccination for those with natural immunity. A nationwide Swedish study in *Lancet Infectious Diseases* (June 2022) concludes that "immunity acquired from a previous infection was associated with a low risk of SARS-CoV-2 reinfection and COVID-19 hospitalisation for up to 20 months. In head-to-head comparisons, immunity acquired from a previous infection plus either one or two doses of a COVID-19 vaccine was associated with a greater reduced risk of SARS-CoV-2 reinfection and COVID-19 hospitalisation for up to 9 months than previous infection only, although with small differences in absolute numbers during follow-up."¹³ Authors of another study in *Cureas* (October 2021) reported that "vaccination in the COVID-recovered may provide some incremental protective benefit, but the total size of this benefit is marginal". ¹⁴ They further concluded that "until further data is available, unvaccinated COVID-recovered individuals should be considered to have at least equal protection to their vaccinated COVID-naïve counterparts....National policy should reflect the need for clinical equipoise and restraint in vaccinating these individuals by mandate." ¹⁵

As more studies on the effectiveness and risks associated with the COVID-19 vaccines are published, monitoring the scientific literature is critical to the development of robust and relevant health policy recommendations. Nonetheless, it is evident that the Ontario data presented in this report support that COVID-19 vaccines can benefit those 60 years and older and especially, those at least 70 years of age. However, it is not so clear that they benefit those under 60 years of age. Consequently, one must question mass vaccination programs, mandates, passports and travel bans for all age groups, given the adverse events and the unknown long-term effects of the vaccines. While this report examines the Ontario data on vaccinations, it does not cover other domains such as the economic, social and psychological impacts of COVID-19 vaccine policies. From a public policy perspective, the potential public health benefits of vaccine policies must also be weighed against the risks in these other domains of public well-being. Indeed, there is a need to evaluate these domains empirically prior to setting or reinstating various vaccine measures as viable tools now and for future pandemics.

Conclusion

Although the scope of this report has been to examine the publicly available Ontario data, there are similar trends and patterns in other provinces as well as other countries. This has not been covered in this report due to time constraints and to ensure that the data analysis contained herein is as current, accurate and timely as possible. Nevertheless, due to the similarity of trends and patterns, numerous restrictions and bans have already been lifted internationally and provincially in the age of Omicron.

Given the statistical evidence provided in this report, the public health policy tools such as, mass vaccination campaigns, mandates, passports and travel restrictions need to be reevaluated for relevance in this phase of SARS-CoV-2. The abundance of evidence documented by Public Health Ontario (PHO), Public Health Agency of Canada (PHAC) and toptier scientific journals demonstrates that the vaccines do not prevent infection or hospitalization. The Ontario data show that vaccination currently makes little difference in terms of hospitalization and death rates for those below age 60. Additionally, since there are known risks of adverse events and unknown longterm effects, these must be considered in developing vaccine policies. The empirical evidence investigated in this report from PHO and PHAC does not support continuing mass vaccination programs, mandates, passports and travel bans for all age groups. Rather, it may be prudent to utilize a more targeted and cost-effective approach focused on vaccinating the high-risk group, while factoring in an individual's potential risk of vaccine-related adverse events.

Further Areas for Investigation

The following are some areas of on-going investigation for consideration. It is recommended that:

- 1. The exploratory data analysis conducted in this report be repeated every 3 months to monitor the evolving situation with regards to the COVID-19 vaccines.
- 2. The wealth of scientific literature be reviewed and monitored on an on-going basis to substantiate or challenge COVID-19 vaccination data findings.
- 3. The economic, social and psychological impacts of mass vaccination, vaccine mandates, passports and travel bans for the management of the pandemic be evaluated prior to setting or reinstating any vaccine policies.
- 4. The consequences of continuous boosters at regular intervals on the immune system be examined prior to adopting this strategy longterm.

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APPENDIX 1

Data Quality Issues

1. It is well established that COVID-19 data collected for all hospitals in Ontario made no distinction between those that were in the hospital *with* a positive PCR for SARS COV-2 and no symptoms versus those that were symptomatic in the hospital *from* Covid-19. Hence, data for hospitalizations and deaths for Covid-19 are likely over-estimated. As an example, the patient who is in the hospital with a broken leg but tested with a PCR positive was added to those that came to the hospitals with symptoms of Covid-19 in the counts for hospitalizations and deaths. An audit of the data collected from hospitals is needed to estimate the true counts of COVID-19-related hospitalizations and deaths.

2. Data for the "unvaccinated" includes those who have never been vaccinated as well as with those with one dose less 14 days and therefore, is not an accurate measure of the true vaccine naive population. The never-been-vaccinated population is likely to be considerably different in characteristics and behaviour than the vaccinated population and hence, the definition from a statistical perspective is not a meaningful way to report the data. A far superior way of reporting data and minimizing the confounding, would be to separate those that never received a vaccine and those with one-dose and are within 0 to 13 days. In fact, the one dose and two dose less 14 days are better combined together under a partially vaccinated category. This way, the analysis would be clear as to how completely unvaccinated people do relative to their partially vaccinated and fully vaccinated counterparts.

3. Another issue with the definitions of unvaccinated and vaccinated is that various reports use different definitions. These definitions need to be standardized to enable viewers of the graphs and charts to be consistent, especially when the lay public may not be looking closely at the definitions. For example, <u>publichealth.ontario.ca</u> use different definitions from those used in <u>covid-19.ontario.ca</u>. These are available in the PHO documents or on the websites provided earlier in this report.

4. Authors of the PHO reports admit that smaller counts in the unvaccinated (since only 8% of those 60 and older were technically "unvaccinated") do make the data unstable. Further research is warranted to examine this statistical issue of small counts and its contribution to data instability. A measure of instability would be helpful for readers to assess the validity of the data.

5. Authors of the PHO reports admit that data on trends over time in hospitalizations and deaths need to be interpreted with caution. This is because hospitalization and death data may be incomplete or missing for case records due to the fact that information was not gathered or reported to public health or even entered into the database from which the statistics were extracted. As such, it is not clear whether or not there are more incomplete/ missing cases for the vaccinated versus the unvaccinated population. If there is bias in any direction, then the analysis cannot stand, depending on the degree. Further investigation is needed to examine the bias in order to support the authors conclusions in regards to hospitalization and death rates.

6. It is worth mentioning that authors of the reports on adverse events following immunization (AEFI) acknowledge that the data only represent AEFIs reported to public health and those recorded in the database. As a result, all counts may be subject to reporting bias and underreporting. Better collection of safety surveillance data is needed to measure the true risks of adverse events, particularly if mandates are utilized as a health policy tool. Safety data is essential for providing informed consent where medical interventions are advocated.

APPENDIX 2

Additional Charts Used

Chart 1. The fully vaccinated in mid-April 2021 were less than 3% of the population.



Source: health-infobase.canada.ca



Chart 2. The fully vaccinated in mid-January 2022 were roughly 77% of the population.

Source: health-infobase.canada.ca

Chart 3. About 92% of the population of 60-69 years were fully vaccinated in Ontario by mid-January 2022.



Report week

Nat 2022

Starting April 24, 2022, vaccination coverage is reported every 2 weeks. This figure has been adjusted to reflect changes in reporting frequency, and numbers and percentages are displayed in the figure on a 2-week scale.

Source: health-infobase.canada.ca

0%

19 Der

2020

Chart 4. The greatest difference in hospitalization rates between the fully vaccinated and unvaccinated are in the 70+ age group.





Unvaccinated Post-series completion Post-one booster dose

Notes:

- 1. Includes intensive care unit (ICU) admissions.
- 2. Refer to the Technical Notes for a description of the methods used for rate calculations
- 3. High coverage, particularly in older age groups (e.g. 70+ year olds), and a small number of unvaccinated individuals has resulted in unstable rates in unvaccinated individuals over time.
- 4. Hospitalization data may be incomplete or missing for case records where information was not gathered, reported to public health units or entered in CCM.
- 5. Rates for series completion and two booster doses are not shown due to instability arising from small counts.

Source: <u>publichealth.ontario.ca</u>: ENHANCED EPIDEMIOLOGICAL SUMMARY, Confirmed Cases of COVID-19 Following Vaccination in Ontario: December 14, 2020 to March 27, 2022

Chart 5. The greatest difference in death rates between the fully vaccinated and unvaccinated are in the 70+ age group.



Figure 7. Rate of COVID-19 Deaths per 100,000 Person Days by Vaccination Status and Age Group in the Previous 60 Days: Ontario

Notes:

- 1. Refer to the Technical Notes for a description of the methods used for rate calculations.
- High coverage, particularly in older age groups (e.g. 70+ year olds), and a small number of unvaccinated individuals has resulted in unstable rates in unvaccinated individuals over time.
- 3. Death data may be incomplete or missing for case records where information was not gathered, reported to public health units or entered in CCM.
- 4. Rates for series completion and one booster dose and series completion and two booster doses are not shown due to instability arising from small counts.

Source: <u>publichealth.ontario.ca</u>: ENHANCED EPIDEMIOLOGICAL SUMMARY, Confirmed Cases of COVID-19 Following Vaccination in Ontario: December 14, 2020 to March 27, 2022

Chart 6. COVID-19 case rate per 100,000 (seven-day average) is highest among those vaccinated with a booster (green line) in the period between April 9, 2022 to May 8, 2022.

c	eee ovid-19.ontario.ca ≗			
COVID-19 ca	ises by vacci	nation sta	tus	
Graph Table Past	30 days 🔻			
All ages 0 to 4	5 to 11 12 to 17	18 to 39 40 to 59	60 plus	
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36	*			
90 30		~		
24 				
ate				
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See what we mean by:				
Not fully vaccinated cases Fully vaccinated cases Vaccinated-with booster do	se cases			
About this data				
For COVID-19 cases by vaccin vaccines.	nation status, vaccination	status is limited to H	lealth Canada appro	wed
Rate per 100,000 (7-day aver vaccination status for the pre by dividing the number of ca	age) is the average rate of evious 7 days as noted. Ra ses for a vaccination statu	f COVID-19 cases pe ite of COVID-19 case is, by the total numb	r 100,000 for each s per 100,000 is cale per of people with th	culated ne same
	101111100000			

Source: covid-19.ontario.ca