

March 15, 2022

Nirav D. Shah, JD, MD
Director
Maine Center for Disease Control and Prevention
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Dear Dr. Shah,

Over the past two years, I have closely followed the public reports related to the COVID-19 pandemic and our state's public health response to it. As a research scientist and a resident of Maine, I have been particularly interested in the data that the CDC releases weekly on breakthrough COVID-19 cases, associated hospitalizations, and deaths, in comparison to total COVID-19 cases, hospitalizations, and deaths.

It has come to my attention that Maine CDC's own data do not support the widely made claim that receipt of vaccination prevents hospitalization and death from COVID-19 infection. This led me to inquire further regarding the currently available data and the public health policies and communications from the Maine CDC and State of Maine, which I expect to be evidence-based.

I will specifically be addressing the breakthrough data that the Maine CDC publicly released between the time period of August 2021-December 2021. I'm using this date range for a few reasons. First, the Maine CDC began reporting on the total breakthrough cases in May of 2021, but without a comparative total case count.

When the data were updated on August 6, several additional categories appeared including breakthrough hospitalizations, deaths, as well as comparative totals for cases, hospitalizations and deaths "since Maine residents could first be fully vaccinated." (see Appendix A). This phrase refers to sometime in February 2021 when vaccines had just become widely available, but when population vaccination uptake was still low. By February 24, 2021 Maine had administered 328,357 doses of the COVID-19 vaccine with only 16.2% of residents having received their first dose and 8.2% of residents having received both doses (Sources: [ME CDC CV19 vaccine dashboard](#) and [Governor Mills Announcement](#)). In addition, the age based rollout did not occur until March 3, 2021 ([Governor Mills Announcement](#)). By comparison, on August 9, 80% of Maine adults had received at least one dose and 64% of the population aged 12 and older were "fully vaccinated" ([Governor Mills' statement](#), Source ME CDC CV19 vaccine dashboard August 9, 2021).

Secondly, I did not include January or February 2022 data due to the Maine CDC's backlog of positive test results. Therefore, data reported from August 6 to December 23, 2021 is the most reliable period for comparison.

For this time period we have the following data (see Appendix A and Appendix B):

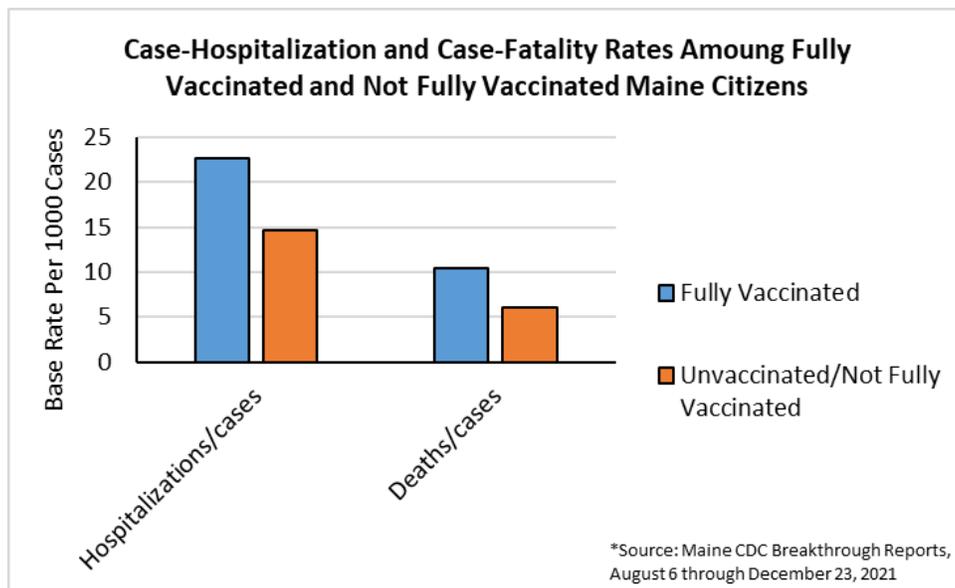
<i>Reported from Aug 6 - Dec 23, 2021</i>	Breakthrough / Fully Vaccinated	Unvaccinated / Not Fully Vaccinated	TOTALS
COVID-19 Cases	20197	48306	68503
COVID-19 Associated Hospitalizations	457	700	1157
COVID-19 Associated Deaths	211	316	527

*Note: individuals with unknown vaccination status may be included within the unvaccinated/not fully vaccinated cohort

Calculating the base rates per 1,000 cases for each group, breakthrough/fully vaccinated and the unvaccinated/not fully vaccinated, and comparing the rates of hospitalizations and deaths between the two cohorts provides the following results:

Case-hospitalization rates: there are 22.63 breakthrough hospitalizations per 1,000 breakthrough cases vs 14.49 unvaccinated/not fully vaccinated hospitalizations per 1,000 unvaccinated/not fully vaccinated cases. This indicates a 56% higher risk of hospitalizations for COVID-19 positive individuals who are fully vaccinated compared to COVID-19 positive individuals who are unvaccinated/not fully vaccinated.

Case-fatality rates: there are 10.45 fully vaccinated Mainers who died per 1,000 breakthrough cases vs 6.54 unvaccinated/not fully vaccinated people who died per 1,000 cases. This indicates a 60% higher risk of death for fully vaccinated COVID-19 positive individuals compared to unvaccinated/not fully vaccinated COVID-19 positive individuals.



Hospitalization-fatality rates: Data show no statistical difference in rates of death among fully vaccinated hospitalized patients compared to unvaccinated/not fully vaccinated patients.

This analysis recognizes the following limitations:

1. The total reported COVID-19 cases is likely undercounted: people with mild symptoms might not get tested and at-home tests are largely not reported.
2. The Maine CDC notes that reported breakthroughs are likely an undercount, indicating that vaccinated individuals may be less likely to get tested.
3. The Maine CDC does not provide any data regarding the percentage of breakthrough cases, hospitalizations or deaths that distinguishes between boosted and fully vaccinated. Base rates for Mainers with a booster are not available because those patients are included in the “Fully Vaccinated” cohort.
4. The public data is very sparse and does not include factors that may influence a person’s risk of hospitalization or death like age, comorbid conditions (diabetes, obesity, hypotension, hyperlipidemia etc), socioeconomic status, gender, race, ethnicity, course of treatment while in the hospital, accessibility to the COVID-19 vaccines, etc.
5. Comorbid or immunocompromised people could be more likely to be vaccinated, but people who are healthier overall may also be more likely to choose to be vaccinated.
6. The calculations assume that every death has a corresponding hospitalization.
7. Due to Maine CDC’s persistent positive case backlog, the months of January & February 2022 are excluded to avoid a skewed representation.

In the interest of full public transparency the Maine CDC and/or Maine DHHS must comment on the following questions:

1. How does Maine CDC classify patients with unknown vaccination status? Are they counted within the Unvaccinated/Not Fully Vaccinated cohort?
 - a. If not, how many COVID patients in hospitals have unknown vaccination status?
2. Does Maine DHHS keep the public up-to-date on any corrections to this data?
3. Does Maine DHHS ask for, track, or record whether a hospitalization is incidentally-related to COVID-19 (patient not admitted for COVID-19 but tested positive after admission), or whether COVID-19 is the primary reason for hospitalization?
4. Does Maine CDC or Maine DHHS collect other data that demonstrate vaccine efficacy relating specifically to Maine residents?
 - a. If additional information is not collected, how is Maine CDC and/or Maine DHHS determining vaccine efficacy?
5. What data are Maine CDC and Maine DHHS using to support their claim that receipt of vaccination prevents hospitalization and death from COVID-19 infection?

CDC recommendations have a significant impact and influence on state agencies, healthcare systems, school districts, colleges and private businesses. With this level of influence on the lives of Maine people, the CDC must also assume significant responsibility. It is critical for the public health community to fully inform citizens and politicians, most of whom have no expertise or background in infectious diseases or public health measures. The information given must be

March 15, 2022

honest, transparent, accurate, and devoid of bias. With this, the populace would have more trust in the CDC and DHHS, which in turn would hopefully lead to healthier outcomes for everyone. Moreover, a foundation of solid data is essential for lawmakers to ensure that public health policy and law making is evidence-based.

Thank you for your time, and I look forward to hearing your comments.

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Appendix A. ME CDC August 6, 2021 Data Release for COVID-19 Breakthrough Cases in Maine

[View Total Number of COVID-19 Vaccine Breakthrough Cases in Maine](#)

COVID-19 cases among individuals who have been fully vaccinated are classified as vaccine breakthrough cases. A person is considered fully vaccinated 14 days after receiving their final dose of the COVID-19 vaccine. Vaccine breakthrough cases are expected with any vaccine and the FDA-authorized COVID-19 vaccines are extremely safe and effective. Large-scale clinical studies found that COVID-19 vaccines prevented most people from getting COVID-19 illness, but like all vaccines, they are not 100% effective. Even though some vaccinated people may still get sick, data from these studies also showed that COVID-19 vaccines were very effective at preventing hospitalization and death from COVID-19. That means if you do not get sick after you're fully vaccinated, you still have a much lower chance of developing severe disease. More information about COVID-19 infections after vaccination can be found on the [federal CDC website](#).

Find information on where to get vaccinated in Maine [here](#).

These numbers likely reflect an undercount of the true number of breakthrough cases as not all cases are investigated to determine vaccine status and it takes time to validate vaccine status, delaying cases being included in the count.

- **Total Number of Validated Vaccine Breakthrough Cases: 712**
- Total COVID-19 cases since first date that Maine residents could be fully vaccinated: 36,785
- COVID-19 associated hospitalizations among breakthrough cases: 32
- COVID-19 associated hospitalizations since first date Maine residents could be fully vaccinated: 816
- COVID-19 associated deaths among breakthrough cases: 14
- COVID-19 associated deaths since first date that Maine residents could be fully vaccinated: 234

A COVID-19 associated hospitalization or death is defined as resulting from an illness that is clinically compatible with COVID-19 that is confirmed by an appropriate laboratory test. It is not necessary that COVID-19 be the primary cause of death or hospitalization.

Maine CDC updates these data weekly.
Updated August 6, 2021 at 10:11 AM.

<https://web.archive.org/web/20210812184913/https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/data.shtml>

Appendix B. ME CDC December 23, 2021 Data Release for COVID-19 Breakthrough Cases in Maine

– [View Total Number of COVID-19 Vaccine Breakthrough Cases in Maine](#)

COVID-19 cases among individuals who have been fully vaccinated are classified as vaccine breakthrough cases. A person is considered fully vaccinated 14 days after receiving their final dose of the COVID-19 vaccine. Vaccine breakthrough cases are expected with any vaccine and the FDA-authorized COVID-19 vaccines are extremely safe and effective. Large-scale clinical studies found that COVID-19 vaccines prevented most people from getting COVID-19 illness, but like all vaccines, they are not 100% effective. Even though some vaccinated people may still get sick, data from these studies also showed that COVID-19 vaccines were very effective at preventing hospitalization and death from COVID-19. That means if you do get sick after you're fully vaccinated, you still have a much lower chance of developing severe disease. Additional/booster doses of the COVID-19 vaccine, regardless of vaccine type, are not considered in the classification of a vaccinated individual as a breakthrough case. While information on additional/booster doses is being collected, the same approach is used to identify breakthrough cases. More information about COVID-19 infections after vaccination can be found on the [federal CDC website](#).

Find information on where to get vaccinated in Maine [here](#).

These numbers likely reflect an undercount of the true number of breakthrough cases.

- **Total Number of Reported Vaccine Breakthrough Cases: 20,909**
- Total COVID-19 cases since first date that Maine residents could be fully vaccinated: 105,288
- COVID-19 associated hospitalizations among breakthrough cases: 489
- COVID-19 associated hospitalizations since first date Maine residents could be fully vaccinated: 1,973
- COVID-19 associated deaths among breakthrough cases: 225
- COVID-19 associated deaths since first date that Maine residents could be fully vaccinated: 761

Data are through December 23, 2021.

A COVID-19 associated hospitalization or death is defined as resulting from an illness that is clinically compatible with COVID-19 that is confirmed by an appropriate laboratory test. It is not necessary that COVID-19 be the primary cause of death or hospitalization.

Maine CDC updates these data weekly.
Updated December 23, 2021 at 3:17 PM.

<https://web.archive.org/web/20211223201951/https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/data.shtml>