

# Massive study confirms safety profile of COVID-19 vaccines

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A study on 93 million individuals worldwide who received one of the major COVID-19 vaccines confirmed existing knowledge about the safety profile of these vaccines. Adverse events of special interest were rare and occurred at rates significantly lower than among individuals infected with SARS-CoV-2, the virus that causes COVID-19, as documented by prior studies.

For example, 36 million doses of the Moderna mRNA-1273 vaccine resulted in an approximate excess of 430 cases of myocarditis above the 105 expected (as derived from analysis of Figure 3 of the study). That is roughly 12 excess cases of myocarditis for every 1 million doses administered in a 42-day window post-vaccination.

By contrast, a prior study found an excess of 40 myocarditis cases per million SARS-CoV-2 infections in a 28-day window after a positive test, a rate 3.3 times higher—in a shorter window—than what the study observed for the Moderna mRNA-1273 vaccine.

Notably, myocarditis with two doses of the Moderna mRNA-1273 vaccine was the second highest effect size overall—and the highest that could be reported with confidence—found by the study. All other adverse events of special interest occurred at far lower rates.

The researchers studied data from the Global COVID Vaccine Safety Project, an effort overseen by the multinational Global Vaccine Data Network. The data were from 10 sites in eight countries in Europe, South America, Oceania and North America.

The study looked at the three most commonly administered vaccines: Pfizer/BioNTech BNT162b2, Moderna mRNA-1273 and Oxford/Astra Zeneca/Serum Institute of India ChAdOx1. The latter vaccine was withdrawn from multiple national vaccination programs in 2021 in response to an increased occurrence of cerebral venous sinus thrombosis, a finding confirmed by this study.

There were 99 million individuals who received over

242 million vaccine doses included in the analysis. The researchers used a 42-day window after vaccination to look for adverse events of special interest, resulting in over 23 million person years of follow-up in total. These extraordinary numbers lent an unprecedented power to detect rare events and provided narrow confidence intervals for all but the rarest events.

Due to its size, the study had the power to uncover previously undetected adverse events of special interest. The only potential such event was acute disseminated encephalomyelitis due to the Moderna mRNA-1273 vaccine, but the excess number of cases was a minuscule five. The resulting confidence interval was therefore wide, and thus the results must be interpreted with caution. The researchers plan to analyze this event further in the Global COVID Vaccine Safety Data Project.

The study primarily reported its results as observed to expected event ratios, or OE ratios. It estimated expected event numbers using pre-COVID data from 2015 to 2019, with the exception of Denmark, for which the study used data from 2019-2020. It compared these expected event numbers with the numbers observed in the Global COVID Vaccine Safety Project, computing 95 percent confidence intervals on each OE ratio.

The fact that the results are reported as OE ratios can sometimes be misleading. The fact that two doses of the Moderna mRNA-1273 vaccine had an OE ratio of 6.1 for myocarditis might lead one to overestimate their personal risk. Although a risk of myocarditis six times higher than baseline sounds high, the extremely low expected rate of myocarditis multiplied by six is still extremely low. For the over 12 million people who received exactly two doses, there were merely approximately 266 excess cases, or an incidence rate of 0.000022.

Besides myocarditis, the statistically significant “safety signal” adverse events varied by vaccine. For the Pfizer/BioNTech BNT162b2 vaccine, the only safety

signal was myocarditis.

For the Moderna mRNA-1273 vaccine, the safety signals were myocarditis, pericarditis, and the acute disseminated encephalomyelitis mentioned previously (with just five excess events). The OE ratios for these events varied by number of doses given.

For the Oxford/Astra Zeneca/Serum Institute of India ChAdOx1 vaccine, the safety signals were Guillain-Barre syndrome, cerebral venous sinus thrombosis, and pericarditis. The latter, as with acute disseminated encephalomyelitis with the Moderna mRNA-1273 vaccine, occurred only with three doses and was too rare to give confidence in the results.

As the researchers note, their results are consistent with prior studies. All COVID-19 vaccines have undergone a high level of scrutiny, which has shown repeatedly that the vaccines are safe.

This study once again refutes anti-vaccination disinformation, most often but not entirely promulgated by the far-right. One study on vaccine misinformation on social media found that the most common theme was safety concerns.

Given the strength of the study and the fact that it cuts to the core of anti-vaccination messaging, the only responses possible were either ignoring the study or grossly misrepresenting it. Most of the notorious anti-vaccination personalities largely ignored it.

The top six of the “Disinformation Dozen” ignored the study. A 2021 report by the Center for Countering Digital Hate found that this group of 12 personalities was responsible for approximately 65 percent of online vaccine disinformation.

Robert F. Kennedy Jr., number two of the “Disinformation Dozen,” made no reference to the study on X/Twitter. However, at least one member of the “Disinformation Dozen,” Erin Elizabeth, took the other tack and misrepresented the findings entirely, saying the findings affirmed “safety concerns” promulgated by anti-vaccine disinformation campaigns, when they clearly do nothing of the sort.

Additionally, a piece in the Daily Mirror—Sri Lanka misrepresented the study’s findings, claiming falsely that it validated skeptics’ vaccine safety concerns. The piece also quotes Dr. Vinya Ariyaratne, the immediate past president of the Sri Lanka Medical Association (SLMA), as saying scientific principles were “abandoned” during the pandemic in relationship to the vaccines. This is another lie commonly peddled by the anti-vaccine movement.

The working class must base its program on scientific evidence, which makes abundantly clear that the COVID-19 vaccines are safe and effective at reducing one’s risk of severe disease, hospitalization and death, and appear to reduce one’s risk of developing Long COVID. They must be freely available to the entire global population to provide this protection, and not distributed based on the private profit interests of the pharmaceutical monopolies.

However, while the vaccines still provide a certain level of protection, the complete abandonment of all public health measures by every capitalist government has enabled SARS-CoV-2 to undergo rapid viral evolution, rendering existing vaccines increasingly ineffective at preventing infection. As a result, the danger looms over society that a far more deadly and immune-evasive variant could evolve, rendering existing vaccines worthless.

It is critical that massive resources be invested in next-generation nasal, mucosal and pan-coronavirus vaccines, which could potentially provide sterilizing immunity against all future variants as well as other types of coronaviruses that threaten to spill over into human society.

The capitalist response to the pandemic has laid bare that a society controlled by a tiny layer of financial oligarchs, whose bought-and-paid-for politicians subordinate public health to private profit along nationalist lines, is wholly incapable of advancing such scientific endeavors or public health more broadly.

Only a socialist public health program aimed at eliminating COVID-19 and other pathogens globally through the use of masks, mass testing, indoor air purification, vaccines, the proper application of social distancing measures, and other public health measures, can put an end to the ongoing needless suffering and death of the global population.

The international working class, armed with a socialist program and in alliance with the most advanced scientists, is the only social force capable of carrying out the necessary reorganization of the global economy to both stop the COVID-19 pandemic and protect humanity from future pandemics.



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