

Bivalent Booster Bomb: Latest mRNA Vax Only

30% Effective—More Doses Equals Greater Risk

for COVID-19

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Staff at TrialSite | Quality Journalism

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A group of prominent Cleveland Clinic physicians and biomedical researchers have led a few major, real-world data-driven studies, the results of which have fundamentally challenged the official COVID-19 vaccine narrative. Infectious disease doctor [Nabin Shrestha](#), MD along with infection control practitioner [Patrick Buke](#), MPH CIC and biomedical researcher [Amy Nowacki](#), PhD and colleagues first demonstrated in early summer 2021 in a study of 52,238 health care employees at the prestigious Cleveland integrated health system the power of [natural immunity](#). [TrialSite was the first media](#) to showcase the findings and no other major media or trade press such as STAT bothered to cover such results at the time. Why? The data went counter to politics given under the national public health emergency the executive branch was driving a specific agenda. Then by late 2022 in a [bombshell of a study](#) the trio and their colleagues were at it again. This time conducting a large retrospective study of 51,977 subjects, including 10,804 healthcare employees receiving the bivalent mRNA booster dose, Cleveland Clinic investigators' data revealed that the greater the number of mRNA doses, the more the incidence of SARS-CoV-2, in what TrialSite declared was not a good look for the mRNA COVID-19 vaccines. TrialSite authored [multiple reports](#) on this troubling unfolding set of data that was picked up on by some conservative media by this point. The major media and trade press remained generally silent on the matter. Last month the Cleveland Clinic team uploaded to the preprint server more troubling COVID-19 vaccine data. Finding that among 51,011 Cleveland Clinic employees, the bivalent COVID-19 vaccine

booster was 30% in preventing infection during the time when the virus strains predominant in circulation in the Cleveland area was also factored into the vaccine.

True, all of the aforementioned research remained in preprint form, meaning for whatever reason these large, well-designed observational studies were not peer reviewed. But many times, neither were many study/press releases industry released during the pandemic, which the *New York Times* and trade news like *STAT* pounced on. What's going on? Is Cleveland Clinic's large data set not worthy of mention?

Cleveland Clinic

The Latest Bombshell Data

Tracking 51,011 employees of the integrated health system, the trio of study authors and their colleagues sought to understand the level of protection the bivalent mRNA vaccine produced by Pfizer-BioNTech or Moderna would afford the 51,011 study subjects.

Examining the cumulative incidence of COVID-19 over the weeks after administration of the bivalent BA.4/BA.5 vaccine—the only version of the COVID-19 mRNA vaccines now available in the United States—the study authors ran Cox proportional hazard regressions against vaccine protection time-dependent covariants of the data. Adjusting for the pandemic phase as well as the number of vaccines doses received Shrestha et al breakdown the findings:

Category	#	%
Previous documented episode of COVID—19	20,689	41%
Received at least two doses of COVID-19 vaccine	42,064	83%
COVID-19 infection during the study	2,452	5%

Shrestha and colleagues do note an overall vaccine effectiveness of 30% (95% CI, 20-39%). These are not very good results, and most certainly were not touted by the Centers for Disease Control and Prevention (CDC), Food and Drug

Administration (FDA) or the National Institutes of Health (NIH) or for that matter, not surprisingly, the White House press office.

They finalize that for the retrospective study subjects last exposure 6-9 months previously associates with twice the risk of COVID-19. Moreover, those subjects that were last exposed 9-12 months previously faced a 3.5 times higher risk when comparing both to the last exposure to COVID-19 within 90 days of the study.

But the bombshell, the elephant in the room cannot be ignored by the major media and trade press anymore. The authors reiterate their findings which first surfaced in 2022:

“Risk of COVID-19 increased with time since the most recent prior COVID-19 episode and with the number of vaccine doses previously received.”

Limitations

Like all studies this latest Cleveland Clinic observational investigation brought with it limitations. In the preprint manuscript the study authors explain the limitations followed by possible mitigating factors. TrialSite reminds that the scientific community is not supposed to take study findings that haven't been peer-reviewed and claim as evidence. Although this practice occurred all the time during the pandemic. The CDC would often provide limited data for example, not peer reviewed and the White House would embrace and use in their COVID-19 press conferences justifying the mass vaccination program.

Importantly the real-world investigators acknowledge that more systematic study of persons that have received multiple doses of COVID-19 vaccine must be further studied.

Cleveland Clinic

The major integrated health systems shares on its website that its one of the top global healthcare systems: among the largest and highest quality. With 77,000 caregivers, 22 hospitals and 275 outpatient facilities in locations around the world, [Cleveland Clinic](#) is a preeminent research institution, with many trial sites

across a wide range of therapeutic focus area. The integrated health care system conducts over [200 clinical trials](#) at any one time.

Nabin K. Shrestha, MD

Lead Research/Investigator

- [Nabin K. Shrestha](#), MD, Cleveland Clinic, Department of Infectious Diseases
- [Patrick C. Burke](#), MHP, CIC, Cleveland Clinic, Infection Prevention
- [Amy S. Nowacki](#), PhD, Cleveland Clinic, Quantitative Health Sciences
- [James F. Simon](#), MD, MBA, Enterprise Business Intelligence
- [Amanda Hagen](#), MD Cleveland Clinic, Occupational Health
- [Steven M. Gordon](#), MD Cleveland Clinic, Department of Infectious Diseases