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The 23 authors of an Aug. 8 study of adolescents in Brazil and Scotland found Pfizer's COVID-19 vaccine efficacy waned "from 27 days after the second dose." The researchers recommended more research be done on the need for booster doses.

# By Suzanne Burdick, Ph.D.





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The effectiveness of Pfizer's-BioNTech COVID-19 vaccine against symptomatic COVID-19 infection among adolescents "rapidly declined over time," waning from just 27 days after the second dose, according to

Pfizer Vaccine Efficacy in Teens Wanes 27 Days After Dose 2, Study Shows • Children's Health Defense

the 23 authors of a new study that analyzed data from more than 600,000 teens in Brazil and Scotland.

The study, published Aug. 8 in The Lancet Infectious Diseases, analyzed nationwide data from 503,776 COVID-19 tests of 2,948,538 adolescents — ages 12-17 — in Brazil from Sept. 2, 2021, to April 19, 2022, and 127,168 tests of 404,673 adolescents in Scotland from Aug. 6, 2021, to April 19, 2022.

The Omicron variant was surging in both countries during the time period of the study.

COVID-19 vaccine rollout for adolescents began in August 2021 in Scotland and September 2021 in Brazil, said the University of Minnesota's Center for Infectious Disease Research and Policy.

The study showed vaccine efficacy began to decline 27 days after the second dose for both countries, plummeting to 5.9% (95% CI 2.2–9.4) in Brazil and dropping to 50.6% (95% CI 42.7–57.4) in Scotland at 98 days after adolescents received the second dose.

While protection against symptomatic COVID-19 dropped dramatically in both countries less than one month after the second dose, protection against severe illness — defined as hospitalization or death within 28 days — remained above 80% in Brazil from 28 days to 98 days and beyond.

The authors sought to assess protection against severe illness in Scotland but were unable to do so because so few cases of severe COVID-19 in adolescents in Scotland were reported during the time of the study.

The authors concluded that "two doses are insufficient to sustain protection against symptomatic disease" in adolescents and recommended more research be done on the need for booster doses.

They did not mention any risk factors for multiple doses of the vaccine for this age group, including increased risk, especially for boys, of myocarditis/pericarditis.

The researchers said they undertook the study because "no data so far" had reported protection over time against severe outcomes in adolescents during the Omicron era.

"To our knowledge," they reported, "this is the first nationwide study to evaluate vaccine effectiveness over time against severe COVID-19 among adolescents during the Omicron-dominant period."

## How the researchers conducted the study

The 23 researchers — 12 from the UK, 10 from Brazil and one from New Zealand — used what is called a "test-negative case-control" study design that compares data from two groups: a "case" group of individuals who tested positive for a particular illness — in this case, COVID-19 — and a "control" group of individuals who tested negative for the illness.

When compared to other research designs, this design has the advantage of producing "similar participation rates, information quality and completeness," according to a November 2020 report published in Epidemiology, and "will in some circumstances lead to less bias."

After designing the study, the researchers completed their analyses in a few steps.

First, the team, including first author Pilar T V Florentino, Ph.D., who works with the Oswaldo Cruz Foundation's Center of Data and Knowledge Integration for Health in Brazil, gathered nationwide health data, including COVID-19 test results in both countries for adolescents ages 12-17 who had shown "symptoms indicative of COVID-19" during the study time period.

In Brazil, researchers assessed these data using the national online COVID-19 case reporting system (e-SUS Notifica) used by healthcare providers. In Scotland, researchers accessed the data via a standard patient form that was filled in by the patient and healthcare provider during the visit.

The researchers noted, "We excluded [COVID-19] tests from individuals who did not have symptoms, were vaccinated before the start of the national vaccination program, received vaccines other than [Pfizer's-BioNTech] BNT162b2 or a SARS-CoV-2 booster dose of any kind, or had an interval between their first and second dose of fewer than 21 days."

The study authors also excluded:

- Negative COVID-19 tests that were recorded within 14 days of a previous negative test.
- Negative tests recorded within 7 days after a positive test.
- Any test done within 90 days after a positive test.
- Tests with missing sex and location information.

The team analyzed 503,776 Brazilian COVID-19 tests and 127,168 Scottish COVID-19 tests.

Next, they measured how much time elapsed since the first or second Pfizer-BioNTech vaccine dose in adolescents who tested positive for COVID-19 (the "case" group) — by using polymerase chain reaction (PCR) tests in Scotland, or by PCR or antigen tests in Brazil — and then compared those numbers to the length of time since the first or second Pfizer-BioNTech vaccine dose in adolescents who tested negative (the "control" group).

Finally, the researchers used statistical analyses to generate a vaccine effectiveness score, expressed as a percentage, which allowed them to make statements about how effective the vaccine was at various time points after COVID-19 vaccination during the Omicron wave versus the Delta wave.

"Vaccine effectiveness," they said, "peaked at 14–27 days after the second dose in both countries during both waves, and was significantly lower against symptomatic infection during the Omicron-dominant period in Brazil (64.7% [95% CI 63.0–66.3]) and in Scotland (82.6% [80.6–84.5]), than it was in the delta-dominant period (80.7% [95% CI 77.8–83.3] in Brazil and 92.8% [85.7–96.4] in Scotland)."

### They added:

"In summary, our findings indicate that protection against symptomatic infection with the Omicron variant rapidly decreases over time after two doses [of the Pfizer-BioNTech vaccine]."

The study was funded by several groups including the UK Research and Innovation (Medical Research Council), the Scottish Government, Health Data Research UK BREATHE Hub, Oswaldo Cruz Foundation (Fiocruz), Fazer o Bem Faz Bem program, Brazilian National Research Council and Wellcome Trust.

However, these groups "had no role in [the] study design, data collection, data analysis, data interpretation, or writing of the report," according to the researchers.

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# Earlier study of Pfizer-BioNTech vaccine in U.S. teens also showed 'reduced effectiveness' again Omicron

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The research team said their study is the first nationwide evaluation of the effectiveness of Pfizer-BioNTech's vaccine over time against severe COVID-19 in adolescents.

But a prior study done in the U.S. reported similar findings, as previously reported by The Defender.

The earlier U.S. study, published March 30 in The New England Journal of Medicine, showed "reduced effectiveness" of Pfizer's vaccine against the Omicron variant among children 12 and older.

The study, funded by the U.S. Centers for Disease Control and Prevention (CDC), involved 1,185 patients, 88% of whom were unvaccinated.

During the "Delta-predominant period" in the U.S. (July 1 to Dec. 18, 2021), the researchers reported vaccine effectiveness against hospitalization for COVID-19 among adolescents 12-18 was 93% 2-22 weeks after vaccination.

During the "Omicron-predominant period" in the U.S. (Dec. 19, 2021, to Feb. 17, 2022), among adolescents in the same age group, vaccine effectiveness fell to 40% against hospitalization for COVID-19, 79% against critical COVID-19 and 20% against noncritical cases of the virus.

This group's median interval since vaccination was 162 days.

The study looked at the Omicron variant, not the more contagious Omicron subvariant, BA.2, which is now dominant in the U.S., according to the CDC.

The authors emphasized their finding that vaccination protected against critical illness from COVID-19.

They wrote:

"Although two doses [of the Pfizer-BioNTech vaccine] provided lower protection against Omicronassociated hospitalization than against delta-associated hospitalization among adolescents 12 to 18 years of age, vaccination prevented critical illness caused by either variant."

Last month, the U.S. Food and Drug Administration (FDA) granted full approval of Pfizer's Comirnaty COVID-19 vaccine for adolescents ages 12-15.

In a July 8 press release, the FDA said the approval followed a "rigorous analysis and evaluation of the safety and effectiveness data," and the Pfizer-BioNTech vaccine "has been, and will continue to be authorized for emergency use in this age group since May 2021."

Mary Holland, Children's Health Defense president and general counsel, called the approval "headspinning."

Holland said:

"The FDA failed to convene an expert committee and failed to appropriately weigh the risk-benefit profile of this vaccine for this age group. Even Vaccine cheerleader Dr. Paul Offit acknowledged FDA decisions are being made based on political pressure, not science when, in commenting on the agency's vote last week to allow reformulated booster shots, he said it felt like 'the fix was in.""

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### Suzanne Burdick, Ph.D.

Suzanne Burdick, Ph.D., is an independent journalist and researcher based in Fairfield, lowa.

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#### Ektor57 • 13 days ago

There is less than 1% efficacy at the start. You get no protection from anything. What remains is that your body is attacked by gene altering mRNA spike proteins.

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Ricky Ricardo A Ektor57 • 12 days ago

... and yet this idiotic 'debate' continues. They are not vaccines and they are **not** protecting anyone from

anything I have would have believed that this society