



COVID-19

Why CDC Measures Vaccine Effectiveness

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After the U.S. Food and Drug Administration (FDA) approves a vaccine or authorizes a vaccine for emergency use, experts continue to assess how well the vaccine is working in real-world conditions. These are known as vaccine effectiveness ("VE") studies. The goal is to understand how a vaccine protects people outside of strict clinical trial settings.

CDC and other partners assess how COVID-19 vaccines work in real-world conditions. Assessing how vaccines work in the real-world is important to:

- Learn if vaccines offer the same protection seen in clinical trials.
- Adjust vaccine recommendations, as needed.
- Learn why and how often breakthrough cases (people getting sick after vaccination) occur.
- Learn how vaccines protect against COVID-19 variants.
- Inform vaccine policy and vaccine distribution.
- Inform future development of vaccine technologies.

Clinical trial results show COVID-19 vaccines are effective.

Clinical trials provide data and information about how well a vaccine prevents a disease and about how safe it is. The Food and Drug Administration (FDA) evaluates these data, along with information from the manufacturer, to assess the safety and effectiveness of the vaccine. FDA then decides whether to approve a vaccine or authorize it for emergency use in the United States.

Based on evidence from clinical trials, all COVID-19 vaccines approved for use in the United States were effective at preventing laboratory-confirmed COVID-19 illness in people who received two doses and who had no evidence of being previously infected.

For more information on clinical trial data for each of the COVID-19 vaccines approved for use in the United States:

Pfizer-BioNTech	
Moderna	
J&J/Janssen	

More assessments take place after a vaccine is either approved or authorized for emergency use by FDA. The goal of these assessments is to understand more about the protection a vaccine provides under real-world conditions, outside of strict clinical trial settings.

Real-World COVID-19 Vaccine Effectiveness Can Differ

CDC and partners assess the effectiveness of COVID-19 vaccines approved or authorized for emergency use by FDA and recommended for public use in the United States.

CDC is assessing how well COVID-19 vaccines work in real-world conditions. Some real-world assessments observe both people who get vaccinated and those who don't to see how many people in each group become ill with COVID-19. Some assessments look at how COVID-19 vaccine effectiveness differs for people who are partially vaccinated compared to those who are fully vaccinated.

Many factors can affect how a vaccine works in real-world conditions. These factors include:

- Host factors such as people not included in clinical trials who may respond differently to the vaccine
- Virus factors such as variants
- Programmatic factors such as following dosing schedules or storing and handling vaccines properly

Understanding how COVID-19 vaccines work in real-world conditions will allow CDC, FDA, and other partners to ensure vaccines offer real-world protection against COVID-19.

Related Pages

- > COVID-19 Vaccine Effectiveness Research
- > Ensuring the Safety of COVID-19 Vaccines in the United States
- > Key Things to Know about COVID-19 Vaccines

More Information

Vaccine Effectiveness Presentation ☑ at the Oct. 22, 2020, FDA Vaccines and Related Biological Products Advisory Committee Meeting

FDA's Center for Biologics Evaluation and Research Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness [399 KB, 27 pages]
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Food and Drug Administration COVID-19 Vaccines
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Combat COVID: Information about Clinical Trials
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