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Vaccine efficacy, effectiveness and protection

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This article is part of a series of explainers on vaccine development and distribution. Learn more about vaccines – from how they work and how they're made to ensuring safety and equitable access – in WHO's Vaccines Explained series.

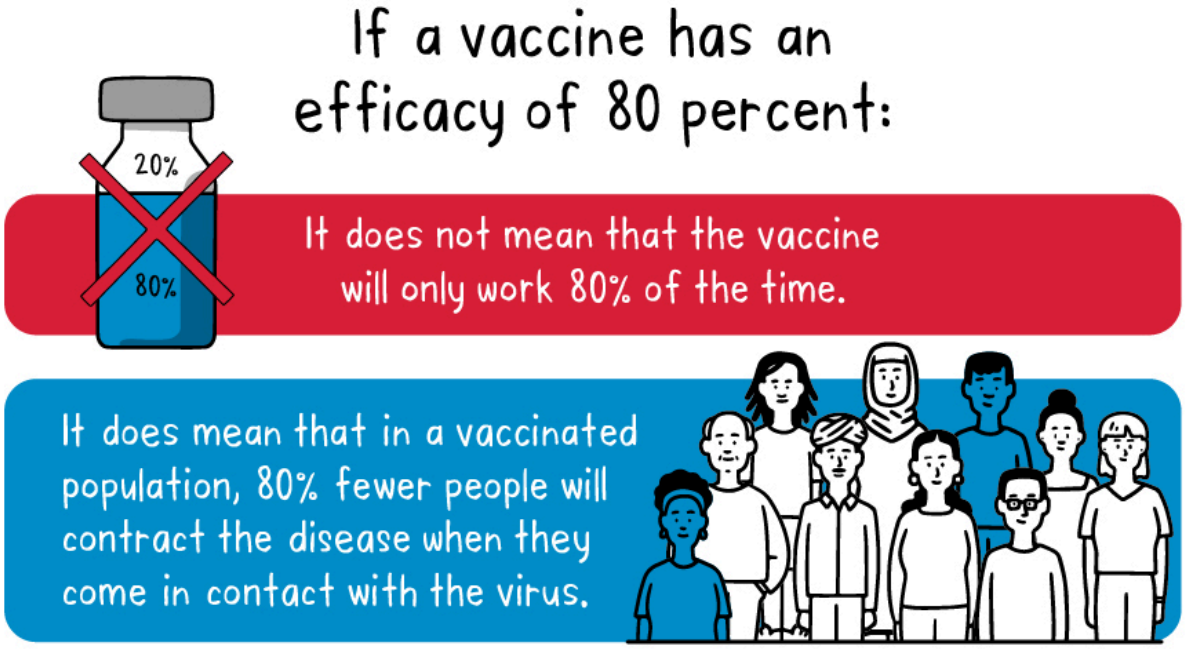
Vaccines are safe, effective and life-saving. Before approval by relevant regulatory agencies, vaccines undergo rigorous clinical trials to test their quality, safety and efficacy. After approval, they continue to be closely monitored for ongoing safety and effectiveness.

Vaccine efficacy and effectiveness

To understand how well vaccines work, it is important to distinguish vaccine efficacy and effectiveness

Vaccine efficacy is measured in controlled clinical trials. It is based on how many people who got vaccinated developed the 'outcome of interest' (usually disease) compared with how many people who got the placebo (dummy vaccine) developed the same outcome.

Vaccine efficacy tells us how much the vaccine lowers the risk of the outcome (e.g., getting sick) in a trial setting. For example, if a vaccine has an efficacy rate of 80%, it means that the vaccinated group had an 80% lower risk of developing disease than the unvaccinated group (those who received the placebo).



Vaccine effectiveness refers to how well vaccines work in the real world. Clinical trials include a wide range of people – a broad age range, both sexes, different ethnicities and those with known medical conditions – but they cannot be a perfect representation of the whole population.

Efficacy seen in clinical trials applies to specific outcomes in a study, whereas effectiveness measures how well the vaccines work in the real world. Effectiveness can differ from efficacy because we can't predict exactly how effective vaccination will be for a much bigger and more variable population getting vaccinated in actual conditions.

Vaccine protection and timing

Vaccines work by building strong protection against disease. Some vaccines require only one dose to build protection, while others need multiple doses spaced apart – called the primary series – to develop full protection.

For example, in a three-dose primary series, the first dose initiates some protection, and the second and third doses help reach maximum immunity and maintain the protection over time.

The optimal number of doses and schedule were determined in clinical trials and further assessed in effectiveness studies. Following the recommended vaccination schedule is essential effective and sustained protection.

Boosters

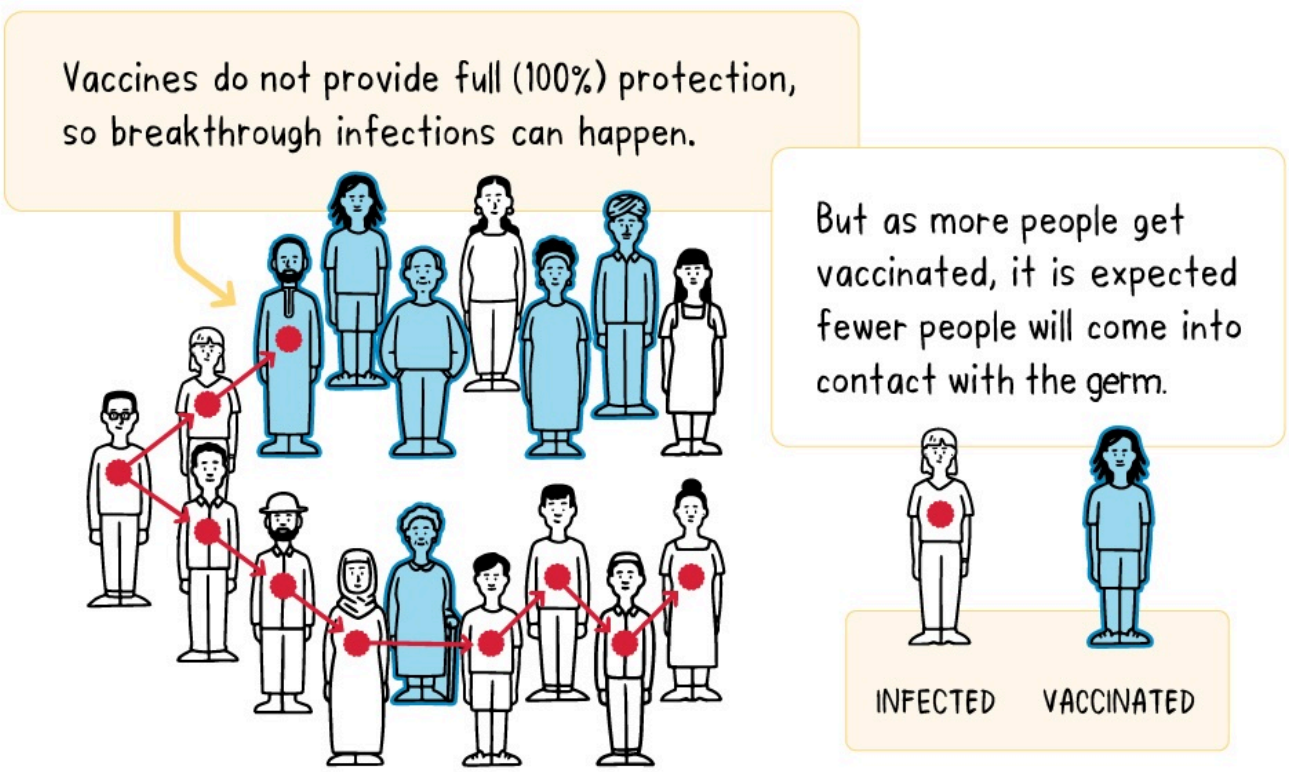
Protection from the initial dose or primary series may weaken over time. Booster doses help strengthen and extend the protection, keeping the immune system ready to fight off infections.

Health authorities recommend booster doses based on scientific evidence showing that additional doses can help enhance and extend protection. Sustained protection is needed, particularly for diseases with a higher risk of outbreaks.

Vaccine protection and infection

Vaccines can stop most people from getting sick, but not everyone. Even after someone receives all of the recommended doses and waits a few weeks for immunity to build up, there is still a chance that they can get infected. Vaccines do not provide full (100%) protection because of many factors, including our individual differences in immunity and response to infection.

Breakthrough infections' – where people get infected despite having been fully vaccinated – can occur.



If vaccinated people do get sick, they are likely to have milder symptoms, in general 'It is very rare for someone vaccinated to experience severe illness or die.

Vaccine protection and variants

Viruses and bacteria can change over time, sometimes leading to new variants that spread more easily or cause more severe disease. WHO continuously monitors these changes and updates guidance to ensure vaccines provide the best possible protection.