

Influenza vaccine efficacy, effectiveness and impact explained



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There are three general terms that are used to describe how well a vaccine works in any given influenza season: vaccine efficacy, vaccine effectiveness and vaccine impact.

Vaccine efficacy

Refers to the reduction in disease, due to vaccination, as shown in research studies carried out under controlled conditions e.g. randomised clinical trials. While this type of study is considered the gold standard to confirm the protective effects of vaccination, there are important limitations. Clinical trials are often performed in healthy populations, and usually exclude people with medical conditions and pregnant women. For vaccines that need multiple doses, people are more likely to follow the vaccine schedule if they are enrolled in a trial than they would in “real life”. Clinical trials usually enrol too few people to see changes in rare but important outcomes, such as hospital admission or death.

Vaccine effectiveness

Refers to the reduction in clinical outcomes due to vaccination in the “real world” after a program has been implemented. These outcomes may include disease incidence, or other measures such as general practice attendance with disease, or hospital admission with disease. Vaccine effectiveness is often lower than vaccine efficacy, because it includes people in whom the immune responses to vaccines may not be as strong as healthy people in clinical trials, and because adherence to vaccine schedules may not be as good as in clinical trials. Vaccine effectiveness is usually estimated from observational studies.

Vaccine impact

Refers to the reduction in disease incidence in the population attributed to the vaccine. This includes factors such as vaccine coverage and effectiveness, as well as potential indirect protection due to a reduction in disease spread (“herd protection”). The degree of indirect protection depends on how contagious the disease is, how different populations come into contact with each other, how many people get vaccinated, and the degree to which vaccination reduces disease spread. The effect of vaccination on disease spread in the population may be different to the protection against the disease in individuals.

Influenza vaccines

There are two main types of influenza that cause disease in humans: A and B. Within influenza type A, two subtypes are common: A/H1N1pdm09 and A/H3N2. Within influenza type B, there are two lineages: Victoria and Yamagata. Influenza vaccines can be trivalent influenza vaccines (TIV), which contain representative viruses for both influenza A subtypes and one influenza B lineage; or they can be quadrivalent vaccines (QIV), which contain representative viruses for both influenza A subtypes and both influenza B lineages. The composition of influenza vaccines for the Southern Hemisphere is reviewed in September each year by the World Health Organization, and then subsequently by the Australian Influenza Vaccine Committee.

Influenza vaccines have a long history of use. Their efficacy and ability to provoke an immune response have been demonstrated in clinical trials, and their effectiveness is monitored routinely in

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adults and children. The effectiveness of the influenza vaccine is likely to vary from season to season because the vaccine viruses may not completely match the circulating influenza viruses that are infecting people. While epidemiological evidence of effectiveness usually requires the gathering of data at the end of season, surveillance of circulating viruses during the season can provide an earlier assessment of vaccine match.

In Australia, several different surveillance systems monitor influenza vaccine effectiveness each season. The outcomes measured in Australia are traditionally presentations to general practice with confirmed influenza, and admissions to hospital with confirmed influenza. How certain we are that the estimate reflects the true vaccine effectiveness depends largely on the number of people captured by surveillance; therefore, the estimates are generally less precise earlier in the season, and in seasons with fewer cases of influenza.

Generally, interim vaccine effectiveness estimates in Australia are generated in September, in preparation for the WHO Consultation and Information Meeting on the Composition of Influenza Virus Vaccines for Use in the Southern Hemisphere Influenza Season. Final vaccine effectiveness estimates in Australia are generated in January, after the conclusion of the season and checks for data quality and integrity. Interim vaccine effectiveness estimates are usually quite similar to final estimates, but can be less precise because there is less data available in September.

In general, influenza vaccine effectiveness has been found to vary between 30-60%. This implies that, on average, a vaccinated person is 30-60% less likely to experience the outcome being measured (e.g. influenza leading to attendance at a general practice or hospitalisation) than an unvaccinated person. The estimated effectiveness of the vaccine may depend on a number of factors – the outcome being measured, the age group predominantly affected (vaccine effectiveness is generally lower in older people than in younger adults and children), and the match between vaccine and circulating influenza strains (generally protection against infection with A/H1N1pdm09 is greater than against A/H3N2).