

# How are vaccines shown to be safe?

## Vaccines are carefully tested

### How are vaccines tested?

**Safety research and testing is an essential part of developing vaccines.** Vaccine safety is first tested on animals. Then, if a vaccine is found to be safe in animal trials, it is evaluated in humans in three phases of clinical trials.

**Phase 1 trials:** The new vaccine is given to a small number (25–50) of healthy adults with the primary aim of assessing safety.

**Phase 2 trials:** If the new vaccine is found to be safe in Phase 1, it is then given to hundreds of people to determine: how effectively it stimulates immune responses; how much or how many doses need to be given in order to protect against the target disease; and whether there are any side effects.

**Phase 3 trials:** If the vaccine is found to be effective and safe, it is then given to many thousands of people to test whether it protects large populations from the target disease and check if there are any uncommon or serious side effects. Every vaccine given to Australian children must pass all of these phases before it is registered for use by the Therapeutic Goods Administration (TGA).



## Could there be side effects we don't know about yet?

Some side effects are so rare they can't be detected even after studying a vaccine in tens of thousands of people. Therefore, once vaccines are routinely used in communities, their safety continues to be monitored. Reports of possible side effects made by parents and health professionals are carefully reviewed. These reviews can signal the need for further investigation and studies. In addition, large populations of people who receive vaccines are often studied to identify whether there are any links between vaccination and rare or serious health conditions.

## What happens if a problem is suspected?

Any suspected problem with a vaccine signals the need for a thorough investigation by the TGA. These investigations involve other health authorities including immunisation program managers. Investigations usually involve more tests of vaccine quality and manufacturing processes and studies of vaccinated and unvaccinated people who have and who have not had reactions. If a suspected problem could be serious, authorities will consider a range of actions including suspending use of the vaccine during the investigation. This is what happened in 2010 when doctors and parents began reporting that some children were experiencing febrile seizures (fever fits) after receiving a particular brand of influenza vaccine. Febrile seizures are caused by a sudden increase in body temperature and are usually harmless.<sup>1</sup> Influenza vaccination for children was temporarily suspended until the matter could be investigated. The investigation found that children who received one brand of influenza vaccine – BioCSL Fluvax™ – experienced febrile seizures much more often than children who received the other brands. That vaccine is no longer registered for use in children less than five years of age but there are other seasonal influenza vaccines that children can have.

### About us

This fast fact sheet has been developed to help doctors and nurses to answer parents' questions about vaccinations by a group of researchers called the SARA H Collaboration. It was written by Nina Berry PhD and Julie Leask PhD from the University of Sydney, Margie Danchin PhD from the University of Melbourne, Tom Snelling PhD from the Telethon Kids Institute, and Kristine Macartney MD and Melina Georgousakis PhD from NCIRS. SARA H is funded by the Australian Government Department of Health.

### Further reading

[www.science.org.au/immunisation](http://www.science.org.au/immunisation)

[www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/safety-of-vaccines](http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/safety-of-vaccines)

### References

1. [www.rch.org.au/kidsinfo/fact\\_sheets/Febrile\\_Convulsions](http://www.rch.org.au/kidsinfo/fact_sheets/Febrile_Convulsions)