

Influenza vaccines – Frequently Asked Questions

This fact sheet provides answers to common questions about influenza viruses and available vaccines, including the new influenza vaccine programs in 2023. More detailed information can be found in the NCIRS fact sheet Influenza vaccines for Australians.

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Questions about influenza virus and influenza vaccines

Q1. What's the difference between influenza and the common cold?

Influenza is a respiratory illness that occurs after an infection with influenza viruses. Influenza is often referred to as 'the flu'. Sometimes the term 'the flu' is used incorrectly to describe the common cold, other respiratory viruses or even gastrointestinal illnesses. This is because their symptoms can be similar to those caused by influenza. There are many different viruses and some bacteria that can cause these symptoms. The influenza vaccine will only protect you from the influenza virus. The following table compares symptoms from the common cold and influenza. Usually, influenza is more severe and lasts longer than a cold or other viral respiratory illness.

Cold	Symptom	Influenza
⊗	Fever	888
⊗	Headache	888
88	General aches and pains	888
88	Tired and weak	888
8	Extreme fatigue	888
888	Runny, stuffy nose	88
888	Sneezing	88
888	Sore throat	888
88	Chest discomfort, coughing	888

 $_{\Omega}$ = Rarely; $_{\Omega\Omega}$ = Sometimes; $_{\Omega\Omega\Omega}$ = Often

Table adapted from: Immunize Canada – Is it a cold or influenza? Available from: www.immunize.ca/sites/default/files/resources/176e.pdf (Accessed February 2023)

Q2. Is it worth getting the influenza vaccine? I'm a healthy person and have heard that influenza isn't serious.

Yes, it is important to get the influenza vaccine even if you are healthy. Most Australians who get influenza are quite sick for a few days with fever, aches and pains, and sore throat, and then recover without lasting effects (see Q1). However, influenza can cause serious illness in some people; this can lead to hospitalisation or even death.

It is not possible to predict who will be severely affected by influenza. Each year, previously healthy people are hospitalised and die from the virus. Although around 100 deaths and 5,100 hospitalisations due to influenza are reported each year,³ many cases don't get identified, so the true impact of influenza is much greater.

Apart from becoming ill, having influenza can be a big inconvenience. People can miss time from work or school because either they are too sick to attend or they have to take time off to care for a sick child. One study has shown that parents of children under 3 years of age missed an average of 3 days of work to stay home and care for their sick child.⁴ The estimated cost to the Australian healthcare system for GP visits and hospitalisations was \$115 million per year for each year between April 2000 and March 2006.⁵

In addition to protecting you from influenza, vaccination protects people around you. If you don't catch influenza, then you can't spread the infection. It is particularly important to protect vulnerable people who can't get the vaccine themselves or don't respond strongly to it, such as infants under 6 months of age and people who have low immunity.^{6,7}

The influenza vaccine is not completely protective, because the circulating influenza strain may change and people's individual response to the vaccine may differ. However, it is our best protection against infection and potentially serious complications, including death.

Given SARS-CoV-2 (the virus that causes COVID-19) continues to circulate, it is even more important to get an influenza vaccine to stay healthy, to protect others from getting influenza and to reduce the impact of influenza on our health systems.

Q3. Why do I need the influenza vaccine if there has not been any influenza in Australia?

Influenza is a highly contagious infection of the airways. It is often a mild disease, but it can cause serious illness in otherwise healthy people. It can affect people of all ages, and in some people it can cause hospitalisation and death.

Although during the COVID-19 pandemic there has been reduced circulation of influenza virus and lower levels of influenza vaccine coverage than in previous years, in 2022, with border protection measures easing and international travel resuming, Australia observed a resurgence of influenza, with the influenza season commencing earlier than in previous years. During 2023, influenza epidemiology may be atypical, particularly in the context of COVID-19.

Vaccination is a safe and effective way to protect yourself from serious disease caused by influenza. By getting vaccinated against influenza, you can also help protect other people, especially people who are too sick or too young to be vaccinated. The more people who are vaccinated in your community, the less likely the disease will spread.

Yearly influenza vaccination is recommended for people aged 6 months and older. Anyone who wants to protect themselves against influenza can talk to their immunisation provider about getting immunised (see Q7).

Q4. Why do healthy young children need an influenza vaccine?

Compared with older children and adults, infants and children under 5 years of age, including those without pre-existing medical conditions, are more likely to get severe influenza infection resulting in hospitalisation.^{3,8} In 2017, approximately 1 in 400 children were diagnosed with laboratory-confirmed influenza. Previously healthy children can become severely ill and suffer from influenza-associated complications such as pneumonia and encephalitis.⁹⁻¹¹

Q5. Why do children aged 6 months to <9 years who have never received influenza vaccine need 2 doses?

Children aged 6 months to <9 years receiving influenza vaccine for the first time need 2 doses, given at least 4 weeks apart to maximise the immune response to the vaccine strains.

Children who received one or more doses of influenza vaccine in a previous season only need one dose in the current and future seasons.

Q6. If my child is being vaccinated for the first time and requires two doses of the influenza vaccine, must the vaccine be the same brand?

Two different vaccine brands may be administered when two doses of vaccine are required, such as in children less than 9 years of age, provided the vaccine is licensed for the age group.

Q7. Which groups of people can get the influenza vaccine for free?

The influenza vaccine is funded by the government under the National Immunisation Program (NIP) for certain groups of people who are at the highest risk of severe influenza or are more likely to get complications from influenza than the general population. ¹² These groups include:

- children aged 6 months to under 5 years
- all Aboriginal and Torres Strait Islander people older than 6 months
- all adults aged 65 years and older
- pregnant women
- people with certain underlying medical conditions.

Since 2005, decisions on which vaccines are provided for free, and for whom, have been made following a process that involves the Pharmaceutical Benefits Advisory Committee.¹³ This ensures any government spending on a health intervention is cost-effective. This is important, since there is a limited amount of money that is available for health care in Australia and these funds need to be used for the greatest benefit for the whole population.

However, people who are not eligible for influenza vaccine on the NIP will still benefit from vaccination (see Q2). The <u>Australian Immunisation Handbook</u> – the national clinical guideline advising on the safest and most effective use of vaccines in Australia – recommends the influenza vaccine from 6 months of age. A range of providers (e.g. GPs, pharmacists) can administer private influenza vaccines. Influenza vaccines can be purchased for around \$20–\$30 each.

Q8. How do I protect myself from influenza if travelling to the northern hemisphere or returning to Australia?

Travellers may be exposed to the influenza virus at any time throughout the year, regardless of their destination. The influenza season in the southern hemisphere is mostly from May to September; in the northern hemisphere, it is from October to May. Influenza activity in the tropics has been reported throughout the year.

People travelling in large tourist groups or those travelling in confined spaces for days to weeks, such as on a cruise ship, are at particular risk of influenza. People can get infection either before departure or from travel to areas of the world where influenza may be circulating at that time.

Influenza vaccination is recommended if travelling, especially if it is known before travel that influenza is circulating in the destination region. Some brands of current southern hemisphere influenza vaccine are available from March through February the following year (when the vaccine expires). A northern hemisphere formulation of influenza vaccine may be preferred if travelling in the northern hemisphere during their influenza season, but this is generally unavailable in Australia (see Q10) The southern hemisphere formulation is considered an acceptable alternative; a second dose may be given late in the season even if the person has received this vaccine earlier in the same season (see Q9).

If you have returned to Australia from living or travelling overseas, consider getting vaccinated with the currently available local vaccine for optimal protection, if you have not had it before, regardless of the time of the year.

Q9. Is a second dose of influenza vaccine recommended before travel to the northern hemisphere?

Yes. Individuals who have received a current southern hemisphere influenza vaccine and are travelling to the northern hemisphere during their influenza season (usually October to May) may receive a second dose of influenza vaccine before travel (ideally, 2 weeks before departure). Further information about influenza vaccination and travellers is available in the Australian Immunisation Handbook.

Q10. Why are there different influenza vaccines in the northern hemisphere and the southern hemisphere?

The influenza vaccine is designed to protect against the four influenza viruses that are most likely to spread and cause illness among people during the upcoming influenza season.

Circulating strains of influenza virus vary each year in both the northern and southern hemispheres. Therefore, the influenza vaccine composition is reviewed each year based on which influenza viruses are making people sick, the extent to which those viruses are spreading and how well the previous season's vaccine protects against those viruses.

Annual influenza immunisation is hence strongly recommended to have the best possible protection against influenza disease and its complications.

Q11. How effective is the influenza vaccine in preventing influenza illness?

Extensive research has shown the influenza vaccine is effective. It takes 2 weeks to develop immunity after influenza vaccination.

How well the influenza vaccine works can vary among different people and in different years, as this depends on several factors, such as the age and health of the person receiving the vaccine and the match between the vaccine strains and those strains circulating in the community.

In young children and healthy adults under the age of 65 years who have received influenza vaccination, their likelihood of getting influenza will be reduced by around 50–60%, although this figure varies year by year.^{17,18}

People with an underlying medical condition, such as those with low immunity and elderly people, may not respond as well to the influenza vaccine as healthy adults, and so their level of protection from the vaccine may be less. However, among high-risk individuals, such as residents of aged care facilities, the vaccine prevents pneumonia and hospitalisation due to influenza. Because of the higher risk of severe influenza in elderly people, any protection provided by vaccination against influenza is worthwhile.

Because the vaccine is not 100% effective, a small proportion of people may catch the influenza virus after getting the vaccine. Influenza vaccine cannot give you influenza, because it does not contain a live virus. Sometimes people catch influenza before getting the influenza vaccine but their symptoms don't appear until shortly after being vaccinated. This may make them think the vaccine didn't work or even (mistakenly) that the vaccine made them sick.

Similarly, a person who is vaccinated against influenza may catch a different virus that is mistaken for influenza (see Q1). For instance, respiratory syncytial virus (RSV) and parainfluenza are viruses that cause symptoms similar to those of influenza, and which spread in the community at the same time as influenza and can cause severe illness and complications just like influenza.²⁰

Q12. The influenza vaccine is known to decrease in effectiveness after around three to four months. Does this mean I should get vaccinated a second time in the same year?

The influenza vaccine is made available ahead of each influenza season (the period of peak influenza circulation, which is typically May–September in most parts of Australia). While it is not possible to predict when the actual peak of influenza virus circulation will occur – and this may differ slightly every year – the vaccine should provide some protection against infection and severe illness. At present, a second vaccine is not recommended, except for some special population groups (see Q20), and this is not funded on the NIP.

Q13. What is an 'enhanced' influenza vaccine and how is it different from other influenza vaccines?

An enhanced influenza vaccine is one that is specifically designed to increase the response of the immune system to the vaccine. It can contain the standard amount of antigen but with an adjuvant (a compound that stimulates a higher immune response to a vaccine) or contain a higher amount of antigen but with no adjuvant.

In terms of serious complications and death rates, the highest disease burden from influenza occurs in elderly people.³ Elderly people do not respond as well to the influenza vaccine as younger adults do, because the immune system weakens with age. The level of protection they get from the influenza vaccine is usually less than that of a younger person. This underpins the need for 'enhanced' influenza vaccines for people 65 years of age and older to better protect them from influenza infection.

Two enhanced influenza vaccines are available for older people in 2023: Fluad Quad (adjuvanted) is available for people aged ≥65 years, and Fluzone High-Dose Quadrivalent is available for people aged ≥60 years.

Fluzone High-Dose Quadrivalent, an inactivated split-virus influenza vaccine, became available in Australia in 2022. It contains 240 micrograms of haemagglutinin (60 µg for each strain), four times the amount in standard-dose influenza vaccines. It has a similar safety and a superior effectiveness profile as the standard-dose influenza vaccines and a similar safety and effectiveness profile as the adjuvanted influenza vaccine. ²¹⁻²⁴ Both Fluzone High-Dose Quadrivalent and Fluad Quad are preferentially recommended over standard-dose influenza vaccine. There is no preference between Fluad Quad and Fluzone High-Dose Quadrivalent. Both vaccines are latex-free and safe in people with latex allergy.

While both enhanced vaccines are recommended in preference over standard-dose influenza vaccines for people aged ≥65 years, in 2023 only Fluad Quad is available free of charge via the NIP.

Q14. Are there any precautions associated with the Fluzone High-Dose Quadrivalent influenza vaccine?

Precautions to be taken when administering high-dose influenza vaccines are comparable to those for standard-dose and adjuvanted influenza vaccines. Fluzone High-Dose Quadrivalent is contraindicated in individuals with a history of severe allergic reaction after receiving any influenza vaccine and to any component of the vaccine. Although this is an egg-based vaccine, people with a history of anaphylaxis to egg can still receive it.

There are currently no specific data on the co-administration of Fluzone High-Dose Quadrivalent with other vaccines. However, people can receive it with other vaccines, including COVID-19 vaccines.

In addition, adverse events after vaccination with Fluzone High-Dose Quadrivalent are slightly more common than those with standard-dose influenza vaccines, but these are mostly mild and temporary. Adverse events following vaccination with high-dose influenza vaccines are similar to those following vaccination with adjuvanted influenza vaccines. Adverse events following vaccination with adjuvanted influenza vaccines.

Q15. When should I get the influenza vaccine and when is it too late in the season to get it?

It is recommended you get annual influenza vaccine before the influenza season starts. Immunisation providers should start giving vaccinations as soon as vaccine is available.

The peak of influenza activity in Australia can vary each year. Typically, it occurs between May and September, but infections can occur year-round. The timing of the influenza season may be different in 2023 as a result of measures to control the COVID-19 pandemic.

It is never too late in the year to get influenza vaccine. Vaccination should be available throughout the influenza season. (Note: most years, vaccine brands don't expire until the end of February the following year.) Evidence suggests optimal protection occurs in the 3–4 months following vaccination; vaccination before the expected winter peak is therefore advisable.^{29,30}

For pregnant women, influenza vaccine is recommended in every pregnancy and it is safe for the mother and the unborn baby to receive the vaccine at any stage of pregnancy. Women who are in their first trimester in the first quarter of the year may wish to wait until the current year's seasonal influenza vaccine becomes available rather than receive the previous year's influenza vaccine. Influenza vaccine can safely be given at the same time as pertussis vaccine.

Q16. Can I get an influenza vaccine at the same time as other vaccines, including childhood and COVID-19 vaccines?

Yes, you can receive influenza vaccine at any time before or after, or with, most other vaccines, including COVID-19 vaccines. Studies show that co-administration of COVID-19 and influenza vaccines is safe and produces a good immune response.

The COVID-19 vaccine does not protect against influenza, so you should still have your annual influenza vaccine.

For more information, refer to ATAGI clinical guidance for COVID-19 vaccine providers.

Q17. In adults over 65 years, can the influenza vaccine be given at the same time as the pneumococcal vaccine?

Yes, the influenza vaccine can be given simultaneously with, or at any time before or after, the pneumococcal vaccine.

Q18. I had influenza infection recently. Do I still need to get the influenza vaccine?

Yes, even if you have had influenza infection recently, you should get the influenza vaccine, as it can lower your risk of becoming ill from other strains of the influenza virus. Yearly influenza vaccination is recommended for people aged 6 months and older.

Q19. How long after COVID-19 infection can I have the influenza vaccine?

There is no set timeframe to wait between having a COVID-19 infection and having the influenza vaccine. Once you are feeling well and have no fever, you may receive an influenza vaccine.

Q20. Who needs to get more than one dose of influenza vaccine within a year?

People recommended to receive a second dose of influenza vaccine within a year include:

- children 9 years of age and younger receiving their influenza vaccine for the first time; 2 doses 4 weeks apart are required for an adequate immune response
- people who have had a haematopoietic stem cell transplant or solid organ transplant and are receiving influenza vaccine for the first time after the transplant
- pregnant women, who may be vaccinated with the next season's influenza vaccine if it becomes available in the latter part of their pregnancy, even if they were vaccinated with the previous season's vaccine prior to or earlier in pregnancy (see Q26)
- overseas travellers, who may benefit from a second dose of this season's influenza vaccine if going to the northern hemisphere winter and receiving the northern hemisphere formulation there is not feasible (see Q7, Q8 and Q9).

There is not enough evidence to routinely support a second dose in the general population at this time, even if the influenza vaccine was given early in the season. The few studies of antibody responses (an indirect measure of protection) following a second dose of influenza vaccine in the same season in adults have not shown consistent results. For example, in elderly people, two studies of a second vaccine dose at either 1 month or 3 months after the first dose did not show higher antibody levels, 31-33 while a third study suggested a better antibody response after a booster dose at 3 months in frail elderly patients. 34

Q21. Is the influenza vaccine available all year round?

The influenza vaccine is usually available from late March through February the following year (when the vaccine expires). This means there may be a gap of around 1–2 months where no influenza vaccine may be available.

Q22. What type of vaccine is the influenza vaccine?

All influenza vaccines available in Australia are either split virion (inactivated, 'split virus') or subunit vaccines (inactivated, fragments of the 'shell' of the virus). These vaccines do not contain live virus and cannot cause influenza illness.

The purified inactivated influenza virus used in vaccine preparation is cultivated in embryonated hens' eggs (standard influenza vaccines and adjuvanted influenza vaccine [with an additive to enhance immune response]) or propagated in mammalian cell lines (cell-based influenza vaccine). See Q24.

Q23. What are the ingredients of the influenza vaccine?

All influenza vaccines available in Australia are quadrivalent, meaning they contain 4 influenza virus strains – 2 influenza A subtypes and 2 influenza B lineages.

Standard (egg-based) influenza vaccines contain 15 μ g of haemagglutinin per strain per dose with no adjuvant. Similarly, the available cell-based influenza vaccine contains 15 μ g of haemagglutinin per strain per dose with no adjuvant.

The available adjuvanted influenza vaccine is egg-based and contains the standard 15 µg of haemagglutinin per strain per dose, with MF59 as the adjuvant. The adjuvanted influenza vaccine is formulated to induce a greater immune response than standard influenza vaccines.

High-dose (egg-based) influenza vaccines contain 60 μ g of haemagglutinin per strain per dose with no adjuvant. The high-dose influenza vaccine is also formulated to induce a greater immune response than standard influenza vaccines.

Although egg-based vaccines may contain traces of egg-derived protein (ovalbumin), they contain less than 1 µg of ovalbumin per dose.

Q24. What is a cell-based influenza vaccine?

Cell-based influenza vaccines are prepared in Madin-Darby canine kidney (MDCK) cells. This method is different from the traditional method of producing standard influenza vaccines, which involves hens' eggs. In recent years, there has been concern that the replication of influenza viruses in eggs during vaccine production results in antigenic changes that could make them less closely related to the circulating strains. This 'antigenic mismatch' has been a particular problem for influenza A/H3N2 subtypes and is thought to have contributed to lower influenza vaccine effectiveness in some years (particularly when A/H3N2 was the predominant strain).^{35,36}

Also, there is a logistical concern that supply of influenza vaccines could be compromised if there was a worldwide shortage of eggs or if rapid increases in vaccines were needed (e.g. in an influenza pandemic). Cell-based influenza vaccine production diversifies supply lines and theoretically mitigates the 'antigenic mismatch' issue of egg-based vaccine production.

Flucelvax Quad is currently the only cell-based inactivated influenza vaccine that has been registered for use in Australia. It is approved for use in people from 2 years of age. This vaccine is currently not funded under the NIP for any population groups.

Q25. Is the cell-based influenza vaccine preferred over standard (egg-based) influenza vaccines?

Although there are some theoretical advantages of cell-based influenza vaccines (see Q24), studies have shown that the cell-based influenza vaccine has a similar efficacy and safety profile to standard influenza vaccines.³⁷⁻⁴¹ There is no preferential recommendation for its use over the standard influenza vaccines.

Standard influenza vaccines are currently preferred for use in pregnancy, because a large body of evidence supports their safety in pregnant women. While the use of cell-based influenza vaccines in pregnancy has not been assessed, there are no theoretical concerns regarding their safety in pregnant women.

The remaining eligible population can receive either standard influenza vaccine or cell-based influenza vaccine.

Q26. Does taking paracetamol before getting the influenza vaccine reduce the effectiveness of vaccination?

Taking paracetamol prior to influenza vaccination is not routinely recommended. However, there are no known data that suggest the effectiveness of the influenza vaccine will be impacted if paracetamol is administered before influenza vaccination.

Q27. Does the influenza vaccine protect against bird flu?

The influenza vaccine protects against circulating influenza strains where human-to-human transmission is sustained. These circulating strains are influenza type A (H1N1 and H3N2) and influenza type B.

Avian (bird) flu viruses usually do not infect humans, although very rare cases have occurred. Two influenza A subtypes of avian flu (H7N9 and H5N1) have been responsible for causing human illness, but the risk to the general public is expected to be low.

Questions about the safety of influenza vaccines

Q28. Can the influenza vaccine cause influenza infection?

No. It is not possible for the influenza vaccine to give you influenza. This is because all influenza vaccines in use in Australia are 'inactivated' (i.e. the virus is killed) and the vaccine is either split into components or made up only of fragments of the outside 'shell' of the influenza virus; it is therefore not able to function like a whole live virus.⁴²

Sometimes the normal responses the body experiences after getting the vaccine (i.e. side effects) are similar to the early signs of influenza. This can make people think they have gotten influenza from the vaccine. For example, as well as swelling, redness and pain at the injection site, expected side effects of the vaccine are fever, tiredness and muscle aches, which also occur when you get influenza (see Q1, Q11). However, these side effects are a sign that the vaccine is triggering an immune response, which is what it is designed to do. The symptoms can start within a few hours of being vaccinated, last 1–2 days and are generally much milder than an actual influenza infection. They go away on their own once your body has successfully made an immune response to the vaccine, which will protect you from influenza virus.⁴³

Q29. How do we know that influenza vaccines are safe?

The safety of vaccines is reviewed and monitored at all stages of the vaccine development process – from initial lab-based research, to vaccine registration, to recommendations on the use of the vaccine to ongoing surveillance once the vaccine is being used in the population.

In Australia, the Therapeutic Goods Administration (TGA) is responsible for registering vaccines for use in the country. The TGA uses the latest research and testing kkinformation available to evaluate, and ensure the safety and efficacy of, vaccines. Independent medical and scientific advice on the safety, quality and efficacy of vaccines is provided by experts who make up the Advisory Committee on Vaccines (ACV).⁵⁴

Once vaccines are registered and in use, the TGA continues to monitor their safety and effectiveness through a national monitoring system. If the TGA receives information that there are safety concerns about a vaccine, the issue is investigated immediately.⁵⁵

Australia also conducts active safety monitoring of vaccines using a system called AusVaxSafety. AusVaxSafety collects adverse events data directly from patients via an SMS-based survey after vaccination at certain GPs and immunisation providers. Data are collected in near real-time and analysed for safety concerns. The latest safety data are available on the AusVaxSafety website.

Another important body is the Australian Technical Advisory Group on Immunisation (ATAGI).⁵⁶ This group advises the government on existing, new and emerging vaccines in relation to their effectiveness and use in Australian populations. ATAGI produces the <u>Australian Immunisation Handbook</u>, the national clinical guideline advising on the safest and most effective use of vaccines in Australia. ATAGI and the ACV work together with other bodies on the implementation of immunisation policies, procedures and vaccine safety.

Q30. Are there any side effects from influenza vaccines?

Common side effects

Approximately 10% of children who have an influenza vaccine experience swelling, redness or pain at the injection site. Between 1% and 10% of people who have an influenza vaccine experience a fever, headache, malaise (tiredness or lack of energy) or myalgia (muscle aches). These symptoms can last for 1–2 days. 43,57,58

Rare side effects

Approximately 1 in every 20,000 children who receive the influenza vaccine have a type of seizure known as a febrile convulsion.⁴⁹ This can happen when a baby's or child's temperature goes up suddenly (fever). Influenza infection itself can also cause fever and results in many more febrile seizures than vaccination.⁴⁷ In one study, 6% of children hospitalised with influenza suffered a febrile seizure.⁴⁸

In Australia in 2010, higher-than-expected numbers of fever and febrile seizures following influenza vaccination were detected in children under 5 years of age, particularly in children under 3 years of age. ⁵⁰ Upon investigation, the reports were linked to only one manufacturer's influenza vaccine and the issue was likely caused by the manufacturing process for that particular vaccine. ⁵¹⁻⁵³ This vaccine is no longer available in Australia.

Enhanced safety monitoring systems for influenza vaccines introduced in recent years, such as <u>AusVaxSafety</u> (see <u>Q29</u>), have confirmed that influenza vaccine is safe in children under 5 years, reporting low rates of fever and medical attendance after vaccination.⁴⁴

Very rare side effects

More serious side effects following influenza vaccination are very rare. Anaphylaxis occurs in approximately 1 per 1 million people who receive the influenza vaccine.⁵⁹ Guillain-Barré syndrome (GBS) has shown a very low rate of less than 1 in 1 million doses of influenza vaccine.⁶⁰ Studies have also shown that a person is more likely to get GBS from infection with the influenza virus than from the influenza vaccine.⁶¹ (see Q34).

Q31. I've been recommended to get the influenza vaccine when pregnant to protect myself and my baby. Is this safe?

Influenza vaccine is safe during pregnancy. The vaccine is recommended with every pregnancy and at any stage of pregnancy to protect both the mother and her unborn child against complications from influenza.

Influenza can cause severe disease in pregnant women and young babies. Getting sick with influenza while pregnant can lead to complications such as premature delivery and even perinatal death. For Young children, especially those younger than 6 months, are more likely to be hospitalised or die from influenza than older children.

During pregnancy, protective antibodies are transferred from the mother to the baby through the placenta. Babies born to women vaccinated against influenza while pregnant are less likely to be born prematurely or to have a low birth weight.^{63,64}

Maternal vaccination is estimated to reduce the risk of influenza in infants aged <6 months by 48%. 65-67 However, the protection wears off as babies reach 6 months of age, at which time they can start to receive the vaccine themselves. 68

Multiple safety studies have found no increase in foetal death, spontaneous abortion or congenital malformation after maternal influenza vaccination in pregnancy. The frequency of expected adverse events after vaccination, like injection site reactions, is the same in both pregnant and non-pregnant women. Influenza vaccine is also safe when given to mothers who are breastfeeding and can provide protection to the baby through antibodies that are transferred to the baby in breastmilk.

Pregnant women who received an influenza vaccine in 2022 should revaccinate if the 2023 influenza vaccine becomes available before the end of pregnancy. Women who received an influenza vaccine before becoming pregnant should revaccinate during pregnancy to protect the

unborn infant. Influenza vaccine can safely be given at the same time as pertussis and/or COVID-19 vaccine.

Q32. I'm a breastfeeding mother. Will influenza vaccine reduce my milk supply?

Influenza vaccine is safe for pregnant and breastfeeding women. Although there are little published data that specifically examine the impact of influenza vaccine on breastmilk production, influenza vaccines have been used in women who are breastfeeding for many years and decreased milk supply has not been identified as a <u>safety signal</u> (i.e. an adverse event that has been detected and is flagged for further monitoring) in any vaccine safety surveillance systems and is not listed as having an association with the influenza vaccine.

A review from the Netherlands on COVID-19 vaccines suggests that decreased milk supply after vaccination could be related to stress, which can happen as part of the body's immune response to vaccination, and it is theoretically possible that this could occur after other vaccines. Some people will feel unwell for a day or two after receiving the influenza vaccine. This is a sign that the vaccine has triggered an immune response. However, being infected with the influenza virus can make people sick for much longer and can reduce breastmilk supply in some women. The benefits of vaccination greatly outweigh any risks associated with vaccination.

If you have any concerns about receiving the influenza vaccine while you are pregnant or breastfeeding, you can speak to your regular healthcare professional or call <u>Tresilian</u>, the Australian Breastfeeding Association or <u>Karitane</u> for advice.

Q33. Can I get the influenza vaccine if I have an egg or a latex allergy?

Egg allergy

People with egg allergy can be safely vaccinated with any influenza vaccine (including egg-based vaccines, which usually contain less than 1 microgram of egg protein per dose, and the cell-based vaccine).

Reactions such as hives, angioedema (a skin reaction with swelling similar to hives) or anaphylaxis (severe allergic reaction) are rare side effects following influenza vaccination. They can occur as a result of an allergic response to something in the vaccine, such as egg protein.

Studies have shown that people with egg allergy, including egg-induced anaphylaxis, have safely received the influenza vaccine.^{70,71}

Australasian Society of Clinical Immunology and Allergy (ASCIA) guidelines should be referred to for additional information on influenza vaccination of individuals with an allergy to eggs, including risk, dosage and observation period.⁷²

Latex allergy

Influenza vaccines used in Australia are latex-free and safe for use by people with a latex allergy or sensitivity. Although the product information for Fluarix Tetra state that some presentations of the vaccine cannot be considered latex-free, these presentations are not supplied in Australia.

Q34. Can the influenza vaccine be given to someone who has had Guillain-Barré syndrome (GBS)?

People with a history of GBS whose first episode was not after vaccination have an extremely low risk of recurrence of GBS after vaccination.⁷³⁻⁷⁵ Vaccination is recommended for these people.

Vaccination is generally not recommended for people with a history of GBS whose first episode occurred within 6 weeks of influenza vaccination. There are limited data relating to people for whom the first episode occurred within 6 weeks of influenza vaccination (i.e. where the first

episode was possibly triggered by the vaccine). In these people, discuss the potential for GBS recurrence if vaccinated, the potential for exacerbation following influenza infection and other protective strategies (e.g. vaccination of household members). Vaccination can be considered in special circumstances.

GBS is a rare disorder in which the immune system damages nerve cells, causing muscle weakness and sometimes paralysis. The symptoms usually last for a few weeks, followed by a full or partial recovery. In very rare cases, people have died of GBS. The risk of the syndrome increases with age and is greatest for those aged 50 years or older. Diagnosis of GBS is complex and must be made by a doctor.

A small increased risk of GBS was found in people given a specific influenza vaccine in the United States in 1976.⁷⁶ Since then, close monitoring has shown that GBS has occurred at a very low rate of less than 1 in 1 million doses of influenza vaccine.⁶⁰ Studies suggest that a person is up to 15 times more likely to get GBS from infection with the influenza virus than from the influenza vaccine.⁶¹

Q35. Can the influenza vaccine be given to someone taking immune checkpoint inhibitors?

Immune checkpoint inhibitors are a class of monoclonal antibodies currently used in the treatment of a number of cancers, including metastatic melanoma, renal clear cell carcinoma, non-Hodgkin lymphoma, non-small cell lung cancer and other solid organ tumours.

Checkpoint inhibitors include:

- CTLA-4 inhibitors (such as ipilimumab)
- PD-1 and PD-L1 inhibitors (such as nivolumab and pembrolizumab).

People taking checkpoint inhibitors may have a higher risk of immune-related adverse events following immunisation with influenza vaccine.⁷⁷ Consult the person's treating oncologist about the risks and benefits of influenza vaccination in people taking treatments.

Additional resources for primary medical care/vaccination providers

- Influenza vaccines for Australians NCIRS fact sheet
- ATAGI advice on seasonal influenza vaccines in 2023
- Immunisation Australian Government Department of Health and Aged Care
- National Immunisation Program Schedule
- Sharing Knowledge About Immunisation (SKAI)

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