

# Influenza vaccines for Australians

This fact sheet provides information for immunisation providers on seasonal influenza vaccines that are available in Australia in 2020. It can be used in conjunction with the NCIRS fact sheet [Influenza vaccines – frequently asked questions](#) which provides responses to common questions about influenza viruses and seasonal influenza vaccines.

- Influenza remains a common cause of hospitalisation and death in Australia.
- Annual influenza vaccination is recommended for all people aged  $\geq 6$  months.
- Annual influenza vaccination is funded under the National Immunisation Program (NIP) for people aged  $\geq 6$  months who are at increased risk of severe influenza, including:
  - all Aboriginal and/or Torres Strait Islander people aged  $\geq 6$  months
  - all children aged 6 months to  $< 5$  years
  - all adults aged  $\geq 65$  years
  - people with specified medical conditions (refer to [Table 1](#))
  - pregnant women (during any stage of pregnancy).
- The strains used in seasonal influenza vaccines can change from year to year depending on which viruses are predicted to circulate in each upcoming season.
- For adults aged  $\geq 65$  years, the higher-immunogenicity adjuvanted quadrivalent influenza vaccine (aQIV; Fludax<sup>®</sup> Quad) is preferentially recommended over standard QIVs.
- Providers are reminded that influenza vaccinations given to people of all ages should be reported to the Australian Immunisation Register (AIR).
- Providers are also reminded to vaccinate pregnant women at any time of the year and any stage of pregnancy. Vaccination of pregnant women provides protection to mothers and their newborn infants.

**The Australian Technical Advisory Group on Immunisation (ATAGI) publishes annual [advice on the use of influenza vaccines in Australia](#).**

## The disease

Influenza or ‘the flu’ is an acute viral illness that mainly affects the respiratory system.

## Causative agent

Influenza is caused by influenza viruses which are classified as type A, B or C.<sup>1</sup> Only influenza A and B viruses are included in seasonal influenza vaccines as they cause the majority of disease in humans. Type A influenza viruses are further categorised into subtypes according to two kinds of proteins on their surface: haemagglutinin (H) and neuraminidase (N).<sup>1</sup> Type B influenza viruses are categorised into two lineages: Yamagata and Victoria. Both influenza A and B can be further broken down into different strains.

The genes for the H and N proteins on the virus surface mutate frequently, which results in constant change to influenza viruses. These minor changes to the H and N proteins of both

influenza A and B are referred to as 'antigenic drift' and result in new virus strains. Antibody cross-protection against drifted strains is likely to be reduced. If a major change happens in the H or N protein of influenza A, it is called 'antigenic shift'. Previous immunity is usually not adequate against disease from a 'shifted' strain. This creates the potential for a pandemic.

## Transmission

Influenza is spread easily, mainly through large particle droplets produced by sneezing and coughing.<sup>1,2</sup> Droplets containing the influenza virus also settle onto surfaces, and can then pass from hands to the nose, mouth or eyes. People with influenza can be infectious to others from 24 hours before symptoms start until 1 week after the start of symptoms. In previously healthy individuals, symptoms typically subside within 5–8 days.

People of all ages are susceptible to influenza. The percentage of people in the general community affected by flu each year is typically 5–10%, but may be up to 20% in some years. This percentage is higher for children, with 10–40% infected each year.<sup>1-3</sup> Influenza is more easily spread where large numbers of people gather together.<sup>1</sup> As such, infection rates may be 2–3 times higher in closed populations (e.g. childcare centres, aged care facilities, households).<sup>4,5</sup>

## Clinical features

Influenza symptoms usually have a sudden onset. The most common symptoms are:

- fever
- dry non-productive cough
- nasal congestion
- headache
- sore throat
- constitutional complaints such as myalgia, malaise and fatigue.

The elderly may present with atypical symptoms such as malaise and confusion, and more often develop respiratory complications.

Non-respiratory symptoms such as gastrointestinal complaints and calf muscle pain occur more frequently in children than in adults.<sup>1,3</sup>

Although most influenza infections are symptomatically worse and more severe than other viral upper respiratory tract infections, some may be mild.<sup>1-3</sup> Serious complications from influenza occur in a small proportion of people who are infected.<sup>1-3</sup> Complications include pneumonia, myocarditis and neurological complications, which can lead to hospitalisation and death. People at the highest risk of complications from influenza include those with pre-existing medical conditions. However, previously healthy people can also have severe complications.

## Diagnosis

Laboratory tests are required to confirm an influenza infection. The virus can be detected in a nose or throat swab by rapid antigen-based tests, viral culture or more commonly by molecular methods, such as polymerase chain reaction (PCR). Serological diagnosis can be established by measuring antibodies in acute and convalescent blood specimens.

## Treatment

Treatment of influenza, including bed rest, pain relief such as aspirin/paracetamol and fluid intake, generally aims to prevent or minimise symptoms.<sup>1-3</sup> Children and adolescents <16 years of age must not be given aspirin or aspirin-containing medications while sick with influenza because of

the increased risk of developing Reye syndrome, a condition that causes swelling in the liver and brain.

Antiviral medications such as oseltamivir or zanamivir, which require a prescription, can help reduce the severity and duration of symptoms of influenza. To be most effective, they need to be administered within 48 hours of symptom onset.<sup>1</sup>

## Prevention

Vaccination is the only way to specifically prevent influenza infection and its complications (refer to [Who should be vaccinated](#)).

Practising cough etiquette (such as covering the nose and mouth with a tissue when coughing or sneezing) and washing hands before eating can help reduce the likelihood of transmitting and contracting the influenza virus. Anyone who is unwell with influenza should stay home from work, school and social gatherings to prevent close contact with and transmission to other people.<sup>1-3,6</sup>

## Who should be vaccinated

Annual influenza vaccination is recommended for all people aged ≥6 months unless contraindicated (refer to [Contraindications](#)).

There are a number of groups who are at increased risk of influenza and its complications and so annual influenza vaccination is strongly recommended for these groups. For some of these groups, seasonal influenza vaccination is provided free of charge through the NIP on the basis of demonstrated cost-effectiveness as a public health intervention.<sup>7</sup> However, annual influenza vaccine should be actively promoted for all individuals at increased risk of severe complications from influenza, regardless of eligibility for a free vaccine.

Influenza vaccination is strongly recommended and funded on the NIP for the following groups:

- all Aboriginal and/or Torres Strait Islander people
- all children aged 6 months to <5 years
- all adults aged ≥65 years
- all people aged ≥6 months with medical conditions **listed in [Table 1](#)** which increase the risk of influenza complications
- pregnant women (during any stage of pregnancy).

Influenza vaccination is strongly recommended but not funded on the NIP for the following groups:

- people with certain medical conditions (in addition to those funded on the NIP):
  - Down syndrome
  - obesity (body mass index ≥30 kg/m<sup>2</sup>)
  - chronic liver disease
- residents and staff (including volunteers) of aged care and long-term residential care facilities
- homeless people
- carers and household contacts of those in high-risk groups
- commercial poultry or pork industry workers
- essential services providers
- travellers

Detailed information on influenza vaccine recommendations is provided in [The Australian Immunisation Handbook](#) (refer to [Additional resources for primary medical care/vaccination providers](#)).

**Table 1: Medical conditions that are associated with an increased risk of influenza complications and for which individuals are eligible for vaccination under the NIP\***

Category	Vaccination strongly recommended for (but not limited to) people with the following clinical conditions
Cardiac disease	Cyanotic congenital heart disease Congestive heart failure Coronary artery disease
Chronic respiratory conditions <sup>†</sup>	Severe asthma (for which frequent medical consultations or the use of multiple medications is required) Cystic fibrosis Bronchiectasis Suppurative lung disease Chronic obstructive pulmonary disease (COPD) Chronic emphysema
Chronic neurological conditions <sup>†</sup>	Hereditary and degenerative CNS diseases <sup>†</sup> (including multiple sclerosis) Seizure disorders Spinal cord injuries Neuromuscular disorders
Immunocompromising conditions <sup>‡</sup>	Immunocompromised due to disease or treatment (e.g. malignancy, transplantation and/or chronic steroid use) Asplenia or splenic dysfunction HIV infection
Diabetes and other metabolic disorders	Type 1 diabetes Type 2 diabetes Chronic metabolic disorders
Renal disease	Chronic renal failure
Haematological disorders	Haemoglobinopathies
Long-term aspirin therapy in children aged 6 months to 10 years	These children are at increased risk of Reye syndrome following influenza infection

\* Further details are provided in The Australian Immunisation Handbook (refer to [Additional resources for primary medical care/vaccination providers](#)).

† People who have any condition that compromises the management of respiratory secretions or is associated with an increased risk of aspiration should be vaccinated.

‡ People with certain immunocompromising conditions (i.e. haematopoietic stem cell transplant, solid organ transplant) receiving influenza vaccine for the first time post transplant are recommended to receive 2 vaccine doses at least 4 weeks apart (irrespective of age) and 1 dose annually thereafter.

## Contraindications

The only absolute contraindications to influenza vaccines are:

- anaphylaxis after a previous dose of any influenza vaccine
- anaphylaxis due to any vaccine component within influenza vaccine

Note: Egg allergy is not a contraindication to influenza vaccine. People with egg allergy, including anaphylaxis, can be safely vaccinated with a full dose of influenza vaccine.

## Vaccines

The 2020 southern hemisphere seasonal influenza vaccines contain:

- A (H1N1) – an A/Brisbane/02/2018 (H1N1)pdm09-like virus
- A (H3N2) – an A/South Australia/34/2019 2017 (H3N2)-like virus
- B (Yamagata lineage) – a B/Phuket/3073/2013-like virus
- B (Victoria lineage) – a B/Washington/02/2019-like virus

Vaccines are registered on the basis of evidence of their effectiveness and safety (refer to [Supplementary information](#)). Multiple registered influenza vaccine products are available each year. The age group(s) in which each vaccine can be used and their NIP availability vary. Refer to [Table 2](#) for the available seasonal influenza vaccines by brand and recommended age.

**Table 2: Seasonal influenza vaccines available for use in Australia in the 2020 influenza season, by brand and recommended age**

(from [ATAGI clinical advice on the administration of seasonal influenza vaccines in 2020](#) [Table 1])

Vaccine Registered age group	FluQuadri 0.50 mL (Sanofi)	Vaxigrip Tetra 0.50 mL (Sanofi)	Fluarix Tetra 0.50 mL (GSK)	Afluria Quad 0.50 mL (Seqirus)	Influvac Tetra 0.50 mL (Mylan)	Fluad Quad 0.50 mL (Seqirus)
6 to 35 months (<3 years)	✓	✓	✓*	x	x	x
≥3 to <5 years	✓	✓	✓*	x	✓	x
≥5 to <65 years	✓*	✓*	✓*	✓*	✓	x
≥65 years	✓	✓	✓	✓	✓	✓†

Ticks indicate age at which a vaccine is registered and available. Shaded boxes represent funding under the NIP.

\* Funding only for Aboriginal and Torres Strait Islander people, pregnant women and people who have certain medical conditions.

† Adjuvanted QIV preferred over standard QIVs.

More detailed information on seasonal influenza vaccines is provided in the *ATAGI advice for immunisation providers regarding the administration of seasonal influenza vaccines in 2020* (refer to [Additional resources for primary medical care/vaccination providers](#)).

## Dosage and administration

The preferred route of administration for influenza vaccines is by intramuscular injection; however, these may also be given by the subcutaneous route. The recommended number of vaccine doses varies by age and immune status of the vaccine recipient. Refer to [Table 3](#) for the recommended doses of seasonal influenza vaccine by age.

Although protection provided by influenza vaccine is generally expected to last for the whole season, optimal protection occurs within the first 3 to 4 months after vaccination.<sup>8,9</sup> While influenza continues to circulate, it is never too late to vaccinate.

All influenza vaccines available in Australia may be co-administered with any other vaccine (refer to [Supplementary information, Safety in infants and children](#)). Detailed information on the administration of influenza vaccines, including co-administration and vaccine interchangeability, is provided in [The Australian Immunisation Handbook](#) (refer to [Additional resources for primary medical care/vaccination providers](#)).

**Table 3: Recommended doses of influenza vaccine by age**

(from the current [Influenza disease chapter](#) of *The Australian Immunisation Handbook*)

Age	Dose	Number of doses needed in 1st year of influenza vaccination	Number of doses needed if person received 1 or more doses of influenza vaccine in a previous season
≥6 months to <9 years	0.5 mL	2 (given 4 weeks apart)	1
≥9 years	0.5 mL	1	1
People of any age who have recently had a haematopoietic stem cell transplant or solid organ transplant	0.5 mL	2 (given 4 weeks apart) in 1st year vaccinated after transplant	2 (given 4 weeks apart) in 1st year vaccinated after transplant then 1 annually

## Supplementary information

### Epidemiology

Influenza is a seasonal disease in temperate regions. Most cases in Australia occur during the winter months between June and September.<sup>10</sup> In the northern hemisphere, influenza usually occurs between December and April, whereas in the tropics, influenza can occur all year round.

Annual influenza epidemics are most often due to a single virus subtype or lineage. However, the circulating subtypes/lineages can vary year to year and different subtypes/lineages may appear sequentially or simultaneously in the same season.<sup>11</sup>

Influenza is an important cause of morbidity and mortality. The number of affected people varies considerably from year to year depending on the characteristics of the circulating virus strains and the level of immunity in the population. It has long been recognised that the impact of influenza is often substantially under-estimated.<sup>6,12</sup> Between 2006 and 2013 (excluding the 2009 pandemic year), an average of 100 deaths and approximately 5,100 hospitalisations due to influenza occurred annually in Australia.<sup>13</sup> In the 2017 influenza season, the highest levels of activity since the 2009 pandemic year were recorded. Around 1,100 deaths were reported nationally among notified cases of laboratory-confirmed influenza.<sup>14</sup> However, a mathematical modelling study estimated that influenza is likely to be associated with more than 3,000 deaths and 13,500 hospitalisations each year in Australia, just in people aged >50 years.<sup>15</sup>

There are a number of groups who are at a higher risk of influenza and its complications and who experience increased morbidity and mortality associated with influenza compared with the rest of the population. The highest rates of influenza notifications and hospitalisations are seen in the elderly and children <5 years of age.<sup>13</sup> Aboriginal and Torres Strait Islander people experience a greater disease burden from influenza than non-Indigenous Australians across all age groups.<sup>13,16</sup> In addition, people with certain underlying medical conditions such as chronic heart, lung and neuromuscular disease, among others, are also at increased risk of severe influenza complications compared with otherwise healthy individuals.<sup>17</sup> Pregnant women are more likely than other women to be hospitalised with influenza,<sup>18</sup> and infants born to mothers who contract influenza during pregnancy are at risk of preterm birth and low birth weight.<sup>19</sup>

## Vaccine effectiveness

The level of protection that influenza vaccine provides against influenza virus varies depending on several factors, including age, whether a person is immunocompromised, the level and severity of influenza activity and how good the match is between influenza strains in the vaccine and those circulating in the community.<sup>6</sup>

A systematic review estimated the overall efficacy of standard TIV against laboratory-confirmed influenza in healthy adults aged <65 years to be 59%, although efficacy varied by influenza season.<sup>20</sup> Similar levels of protection have been achieved in young children, with an estimated vaccine effectiveness of 65% against laboratory-confirmed influenza in those aged 6 to 59 months.<sup>21-23</sup>

Clinical trials of a QIV demonstrated equivalent antibody levels (an accepted surrogate for protection against influenza) to a standard TIV for the shared strains in adults and children aged >6 months and added protection against the additional B strain.<sup>24-27</sup>

The effectiveness of standard TIVs and QIVs is comparatively lower in older adults, especially in those aged ≥65 years.<sup>28,29</sup> In 2020 an adjuvanted QIV is available to possibly improve the protection provided by eliciting a greater antibody response.<sup>14</sup> Most evidence on the effectiveness of adjuvanted influenza vaccine compares adjuvanted TIV with standard dose TIV. There are no studies on the effectiveness of adjuvanted QIV, but a study comparing adjuvanted QIV with adjuvanted TIV showed that the adjuvanted QIV is not inferior in terms of generating immune responses against the shared strains and is superior for the B strain not included in the adjuvanted TIV.<sup>30</sup> In a large post-licensure study of community-dwelling adults aged ≥65 years, the adjuvanted TIV was estimated to be approximately 25% more effective against hospitalisation for influenza or pneumonia than the standard unadjuvanted TIV.<sup>31</sup>

## Vaccine safety

The common symptoms after influenza vaccination can mimic influenza infection, but are due to the vaccine's interaction with the immune system. The influenza vaccines currently registered in Australia do not contain live virus, so they cannot cause influenza.

Fever, headache, arthralgia and myalgia occur in <15% of those who receive influenza vaccine. Injection site reactions such as swelling, redness and pain are not uncommon. A higher rate of injection site reactions has been observed in clinical trials with adjuvanted TIVs registered for use in adults ≥65 years than that with standard TIVs.<sup>32</sup> More injection site reactions in the week after vaccination were seen among adjuvanted TIV recipients than in non-adjuvanted TIV recipients (around 35% versus 18%).<sup>32</sup> Less than 1% of local reactions following either adjuvanted TIV or standard TIV were severe.<sup>32</sup> A similar proportion of people vaccinated with Flud Quad (aQIV) experience injection site and systemic reactions as those vaccinated with Flud TIV.<sup>30</sup> These side effects may commence within a few hours of vaccination and can last for 1–2 days.<sup>6</sup>



Surveillance of influenza vaccine safety through active enhanced surveillance systems such as AusVaxSafety showed that in 2018 across all ages low rates of any adverse event (7.5%) and medical attendance (<0.7%) were reported after vaccination.<sup>33</sup> The fever rate in children aged <5 years after vaccination was <1.8%. In 2019, among adults aged ≥65 years receiving aTIV, the rate of any adverse event was 6.4% and the medical attendance rate was 0.2%.<sup>34</sup> In 2020, AusVaxSafety will conduct active surveillance in people of all ages and data will be made available on a weekly basis at [www.ausvaxsafety.org.au](http://www.ausvaxsafety.org.au).

More severe immediate adverse effects such as hives, angioedema or anaphylaxis are rare consequences of influenza vaccination.<sup>6,35,36</sup>

A small increased risk of Guillain-Barré syndrome (GBS) was associated historically with one influenza vaccine in the United States in 1976. But since then, close surveillance has shown that GBS has occurred at a very low rate of less than 1 in 1 million doses of influenza vaccine, if at all.<sup>37,38</sup>

## Safety in infants and children

Surveillance of influenza vaccine safety in young children through AusVaxSafety has shown that influenza vaccine is safe in children aged 6 months to <5 years, with low rates of fever (approximately 2%) and medical attendance (1%) reported after vaccination.<sup>33</sup>

In young children, febrile seizures can occur in susceptible children because of fever of any cause. They occur most often among children aged 12–23 months.<sup>39</sup> Febrile seizures related to influenza vaccination are uncommon: a large study of 69,391 children in the United States calculated a febrile seizure rate of 1.4 per 100,000 in vaccinated children aged 6–23 months.<sup>40</sup>

A slightly higher risk of fever and febrile seizures in children aged 6 months to <5 years (especially those aged 12–24 months) has been reported following the concurrent administration of inactivated TIV and the 13-valent pneumococcal conjugate vaccine.<sup>41</sup> This increased risk is small; furthermore, a second more recent study has not demonstrated the same association with febrile seizures and these two vaccines.<sup>42</sup> It is acceptable to administer these vaccines concurrently when both vaccines are indicated.<sup>43</sup>

## Safety in pregnant and lactating women

All influenza vaccines in Australia are inactivated vaccines, which can be safely given to pregnant women at any stage during pregnancy. The rate of adverse events after vaccination in pregnant women is no different from the rate in women who are not pregnant. In addition, studies of mother–baby pairs have shown that receiving the influenza vaccine while pregnant does not increase maternal or fetal complications during pregnancy.<sup>44</sup>

A number of high-quality studies have demonstrated that influenza vaccination during pregnancy provides protection not only to the mother but also to her newborn in the first few months of life when they are most vulnerable.<sup>45-49</sup> An extensive review showed that influenza vaccination during pregnancy is safe for both the mother and her infant,<sup>50</sup> and additionally provides protection against preterm birth and low birth weight.

Studies of influenza vaccine given to women who are breastfeeding are limited. However, the available evidence shows that vaccination with influenza vaccine in lactating mothers is safe and can provide protection to the infant.<sup>51</sup>

For further information, refer to the NCIRS fact sheet on [Vaccinations during pregnancy](#).



## Additional resources for primary medical care/vaccination providers

- [The Australian Immunisation Handbook](#)
- [Australian Government Department of Health immunisation website](#)
- [Australian Technical Advisory Group on Immunisation \(ATAGI\) advice for immunisation providers regarding the administration of seasonal influenza vaccines in 2020](#)

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