

## Influenza

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### INFLUENZA VACCINES FOR AUSTRALIANS: INFORMATION FOR IMMUNISATION PROVIDERS

#### Disease and epidemiology

- Influenza viruses are orthomyxoviruses.
- Influenza types A and B are clinically important.
- Influenza is an acute viral illness that mainly affects the respiratory system.
- People at most risk of complications from influenza include those with pre-existing medical conditions, such as chronic lung and heart disease, the elderly and pregnant women. However, even healthy people can get severe influenza.
- In Australia, there are, on average, 85 deaths and over 4,000 hospitalisations recorded as being due to influenza illness each year.

#### Who should be vaccinated

- Annual influenza vaccination is recommended for any person  $\geq 6$  months of age who wants to protect themselves from influenza, unless there is a contraindication.
- Children aged 6 months to  $< 5$  years should not receive the 2011 Fluvax<sup>®</sup> vaccine. Other vaccine brands can be used in this age group.
- People with risk factors for severe influenza, including those aged 6 months to  $\leq 9$  years, should be vaccinated using an age-appropriate 2011 seasonal influenza vaccine.
- Children aged  $\geq 6$  months can receive influenza vaccination annually.

#### Vaccines

- Influenza vaccines in Australia are either split virion or subunit vaccines prepared from purified inactivated influenza virus.
- Influenza vaccines normally contain three recommended strains of virus – two current influenza A subtypes and influenza B.
- The vaccines may contain traces of egg-derived proteins.
- When there is a good match between the influenza strains in the vaccine and those causing current disease, the vaccine can prevent illness in about 70–90% of healthy children and adults.

## The disease

Influenza, or ‘the flu’ as it is often called, is an acute viral illness that mainly affects the respiratory system. Flu symptoms usually start with a sudden onset of chills, shakes, headache, muscle aches, fever and dry cough. The respiratory symptoms then become more prominent. Sometimes abdominal complaints (such as pain and diarrhoea) and involvement of other body systems occurs. Older people who have caught the flu may not have a fever. The flu is often ‘self-limiting’ (i.e. it resolves

spontaneously) but it can cause severe illness and life threatening complications.<sup>1-3</sup>

Influenza is more than a bad cold. Many people confuse influenza with illnesses caused by other respiratory viruses (such as the common cold virus, rhinoviruses, respiratory syncytial virus [RSV], and adenoviruses). The table below compares the symptoms of influenza with those of a cold.<sup>3,4</sup>

SYMPTOMS	DISEASE	
	Influenza	Cold
Time sick	At least a week	1 to 2 days
High fever	Common	Rare, usually only mild fever if any
Muscular pains	Common	Rare
Shivering	Common	Rare
Runny nose	Rare, usually dry sensation initially	Common

However, sometimes illness caused by other respiratory viruses can’t be easily distinguished from influenza.

When the diagnosis of influenza isn’t certain (and hasn’t been confirmed by a laboratory test), the illness is often called ‘influenza-like illness’.

The influenza viruses are orthomyxoviruses that are classified antigenically as types A, B or C.<sup>3</sup> Influenza type A is the most common and is usually associated with the most serious forms of disease and large epidemics. Influenza type B is generally associated with smaller outbreaks. As influenza viruses circulate around the world, the virus strains are continually changing.

Influenza viruses are sub-classified by the two types of proteins on their surface, known as the haemagglutinin (H) and neuraminidase (N) antigens.<sup>3</sup> The process by which these proteins change to produce new strains of the virus is called ‘antigenic drift’. A major change in the virus structure is known as ‘antigenic shift’. This leads to a completely new H or N type becoming established in the human population. The two subtypes of influenza A currently circulating in the population are known as A(H1N1) and A(H3N2).<sup>3</sup> In 2009 a new ‘shifted’ H1N1 strain emerged causing a global influenza pandemic and

becoming the predominant circulating strain during 2010 (see [Epidemiology](#)).

Serious complications from the flu occur in a small number of people.<sup>1-4</sup> People at most risk of complications from influenza include those with pre-existing medical conditions such as chronic lung and heart disease. However, previously healthy people can also have severe complications. Pneumonia, myocarditis (inflammation of the heart muscle) and neurologic complications can all arise directly from the virus. Secondary bacterial infections, such as pneumonia, can also cause severe complications and death.<sup>4</sup>

### Transmission

Influenza is spread easily, mainly through people sneezing and coughing.<sup>2,3</sup> Droplets containing the influenza virus also settle onto surfaces, such as telephones, door knobs, etc., and can then pass from hands to the nose, mouth or eyes. People with influenza infection can be infectious to others for the 24 hours before symptoms start, and can continue to be infectious for about a week or more once the symptoms have appeared; their level of infectiousness usually diminishes

over time. Influenza is more easily spread where crowds of people gather.<sup>3</sup>

People of all ages get the flu. In the general community, the percentage of people affected by flu is typically 5–10%, but may be up to 20% in some years. In households and ‘closed’ populations, such as nursing homes, attack rates may be 2–3 times higher.<sup>4</sup> The flu is actually very common in healthy children, with 10–40% infected each year and approximately 1% of these infections resulting in hospitalisations.<sup>2,3</sup>

### Diagnosis

The only way to be certain that someone has influenza is to collect either a nose or throat swab, to detect the influenza virus, or to collect blood samples (during their illness and about 2 weeks after their illness), to check for an antibody (serologic) response to the virus. For the nose/throat test to be the most reliable, testing needs to be performed within 2–3 days of symptoms commencing. These tests are not used very often in the community, but are more commonly done in hospitalised patients who are suspected of having the flu.

When there is a lot of influenza activity in the community, and the symptoms described above are present, there is a high probability that an illness is due to influenza. Some GP practices and emergency departments may use ‘point-of-care’ rapid antigen testing for influenza (on nose/throat specimens) which can give a result right away.<sup>3</sup> These tests may be useful for early diagnosis of influenza, particularly for patients in whom treatment with antiviral drugs is considered.

### Treatment

Treatment of influenza generally aims to prevent or minimise symptoms. Treatment includes bed rest until the fever subsides, pain relief such as aspirin or paracetamol, and high fluid intake.<sup>1-3</sup> Children <16 years of age must not be given aspirin or aspirin-containing medications while sick with influenza. This is due to the increased risk of children developing Reye syndrome, a form of encephalitis and liver degeneration.

Antiviral medication can help reduce the severity and duration of symptoms of influenza. This medication requires a prescription and, to be effective, needs to be administered within 48 hours of symptoms first occurring.<sup>3</sup>

### Prevention

There are two major ways of preventing influenza: preventing contact with the virus and vaccination to provide immunity to it.

Precautions against contact include cough etiquette, like covering the nose and mouth with a tissue when coughing or sneezing. Washing hands before eating or drinking can also help to further reduce exposure to influenza. Avoid close contact with people who are sick. If unwell with influenza, stay home from work, school and social gatherings.<sup>1-5</sup>

The administration of influenza vaccine to individuals at risk of complications is the most important measure in preventing or attenuating influenza infection and preventing mortality.

### Epidemiology

Influenza is a seasonal disease with most cases in Australia occurring during the winter months between June and September.<sup>6</sup> In the northern hemisphere, influenza usually occurs between December and April, whereas in the tropics, flu can occur all year round. In Australia, there are, on average, 85 deaths and over 4,000 hospitalisations recorded as being due to influenza illness each year. However, these figures are certainly an underestimate.<sup>5,6</sup> Occasionally there have been worldwide outbreaks of influenza, known as ‘influenza pandemics’, which have occurred with the global spread of a new influenza A virus strain (or subtype). The influenza pandemic of 1918 (‘Spanish flu’) was estimated to have killed 10–40 million people. The 1957 ‘Asian flu’ and the 1968–69 ‘Hong Kong flu’ pandemics were not as dramatic as the 1918 pandemic. For example, although the Hong Kong flu was reported to have infected many people, the mortality rate was lower than that seen during the 1918 pandemic.<sup>5</sup>

### Currently circulating influenza strains

In June 2009, the World Health Organization declared a pandemic of a novel subtype A H1N1 influenza virus which originated in swine; the pandemic started in Mexico and the USA. Concerns were raised by health officials because a number of severe cases occurred in otherwise healthy young adults. Influenza normally affects the very young and the very old, but these age groups were not heavily affected during this pandemic.

By December 2009, more than 208 countries and overseas territories or communities reported laboratory-confirmed cases of pandemic H1N1 influenza, including at least 9,596 deaths. Evidence from multiple outbreak sites demonstrated that the pandemic H1N1 virus rapidly established itself and was the dominant influenza strain in most parts of the world. The clinical picture of pandemic H1N1 influenza appeared to be largely consistent across all countries with the majority of patients experiencing

mild illness. Risk factors for severe disease included obesity, pregnancy, diabetes mellitus and, in Australia, being of Aboriginal or Torres Strait Islander descent. Although the virus can cause very severe and fatal illness, including in young and previously healthy people, the number of such cases remains small. The Global Influenza Surveillance Network (GISN) continues to monitor the global circulation of influenza viruses, including pandemic, seasonal and other influenza viruses infecting, or with the potential to infect, humans.

In Australia during the 2010 influenza season, reported influenza activity was mild, likely due to population immunity and vaccination.

## Who should be vaccinated

The 9th edition of *The Australian Immunisation Handbook* (2008) states that, unless there is a medical condition or a contraindication that precludes a person from receiving influenza vaccine, annual influenza vaccination is recommended for any person  $\geq 6$  months of age who wishes to reduce the likelihood of becoming ill with influenza.<sup>6</sup>

Most importantly, there are certain people who should definitely be vaccinated each year. This includes the following groups:

- a. all people aged  $\geq 65$  years\*
- b. all Aboriginal and Torres Strait Islander people aged  $\geq 15$  years\*
- c. those who have a medical condition or 'risk factor' which puts them at higher risk of severe influenza\* (this includes chronic lung disease, including severe asthma; heart disease; chronic neurologic conditions that may cause breathing difficulties; other chronic illnesses, such as diabetes; and pregnancy)<sup>7</sup>
- d. people who frequently come into contact with at-risk persons (including contacts in occupational or residential settings, such as health professionals).

\* indicates that the influenza vaccine is funded via the National Immunisation Program (NIP)<sup>8</sup>

For further information regarding who should receive influenza vaccination, please refer to the 9th edition of *The Australian Immunisation Handbook*<sup>6</sup> available at <http://immunise.health.gov.au>

### Babies and children

Children aged  $\geq 6$  months can receive influenza vaccination annually (unless they have a medical contraindication to vaccination).<sup>9</sup> Children aged  $\leq 9$  years

who are receiving influenza vaccine for the first time need to be given two doses of influenza vaccine.<sup>6</sup> These doses are administered at least 4 weeks apart. If a child  $\leq 9$  years of age being vaccinated *for the first time* did not receive the second dose (within the same year), then he/she should have two doses administered the following year.

Children aged  $\geq 6$  months to  $< 3$  years receive a smaller dose of influenza vaccine than older children and adults. Children aged  $< 6$  months must not be vaccinated with the currently available influenza vaccines.<sup>6</sup>

The pandemic H1N1 influenza A strain, which was in the 2010 southern hemisphere trivalent seasonal influenza vaccines, is again incorporated in the 2011 seasonal vaccine. In Australia and New Zealand during 2010, an increase in the incidence of high fevers and febrile convulsions occurred in children aged  $< 5$  years who received one brand of the 2010 seasonal influenza vaccine, Fluvax<sup>®</sup> or Fluvax<sup>®</sup> Junior (CSL). Children aged 6 months to  $< 5$  years should not receive the 2011 Fluvax<sup>®</sup> vaccine. Fluvax<sup>®</sup> is not registered for use in this age group in 2011. Immunisation with another registered, age-appropriate 2011 seasonal influenza vaccine is strongly recommended for any child, including those aged 6 months to  $\leq 9$  years, with a medical condition placing them at increased risk of complications from influenza (see advice from the Therapeutic Goods Administration at <http://www.tga.gov.au/safety/alerts-medicine-seasonal-flu-110310.htm>).

### Pregnant women

It is recommended that influenza vaccine be offered in advance to women planning a pregnancy, and to pregnant women who will be in the second or third trimester during the influenza season, including those in the first trimester at the time of vaccination. Influenza vaccination is estimated to prevent 1–2 hospitalisations per 1,000 women vaccinated during the second or third trimester.<sup>5-7</sup>

The rate of side-effects from vaccinating pregnant or breastfeeding women is no different to the rate in other individuals.

### Who shouldn't be vaccinated

The following people should not be vaccinated with influenza vaccine (i.e. the vaccine is contraindicated):

- anyone who has experienced anaphylaxis (a severe form of a generalised allergic reaction) following a previous dose of any influenza vaccine
- anyone who has experienced anaphylaxis following any vaccine component
- children  $< 6$  months of age

- anyone with anaphylactic sensitivity to eggs. However, new evidence endorsed by The Australasian Society of Clinical Immunology and Allergy (ASCIA) indicates that certain people with severe egg allergy may still be able to receive influenza vaccines but this must be undertaken in consultation with a medical specialist.<sup>10</sup>
- children aged 6 months to <5 years should not receive the 2011 Fluvax<sup>®</sup> vaccine. Fluvax<sup>®</sup> is not registered for use in this age group in 2011. Two other vaccine brands are approved and registered for use in this age group (see advice from the Therapeutic Goods Administration at <http://www.tga.gov.au/safety/alerts-medicine-seasonal-flu-110310.htm>).

### Precautions

During 2011, Fluvax<sup>®</sup> may still be used in children aged 5 years to ≤9 years when no timely alternative vaccine is available. If Fluvax<sup>®</sup> is administered, parents should be informed of the potential increased risk of fever but that febrile convulsions are rare in this age group.

Patients with a history of Guillain-Barré Syndrome (GBS) have an increased likelihood of developing the syndrome again and the chance of them coincidentally developing the syndrome following influenza vaccination may be higher than in individuals with no history of GBS. Therefore, the risk from influenza vaccination should be weighed against the benefits to the individual patient of influenza prevention.<sup>5,6</sup>

Influenza vaccination should be delayed when a person has a high fever or other moderately severe illness, but can generally be given once the illness is resolved.

### Vaccines

All the influenza vaccines currently available in Australia are either split virion or subunit vaccines prepared from purified inactivated influenza virus which have been cultivated in embryonated hens' eggs.<sup>6</sup> The vaccines may contain traces of egg-derived proteins. Most influenza vaccines also contain a trace amount of antibiotic(s) but the specific antibiotic type varies from manufacturer to manufacturer. The product information sheet of each vaccine brand lists all the ingredients included in that vaccine formulation. More general information on vaccine ingredients can be found in the NCIRS fact sheet [Vaccine components](#).

Influenza vaccines normally contain the three recommended strains of virus – two current influenza A subtypes and influenza B, representing circulating viruses.<sup>5,6</sup> The composition of the vaccines for use in Australia is determined by the Australian Influenza Vaccine committee. Other forms of influenza vaccine,

such as live attenuated intranasal vaccine, have not yet been licensed in Australia.<sup>11</sup>

### Current influenza vaccines

Details of the currently registered influenza vaccines and recommended ages for their respective use can be found on the Immunise Australia website (ATAGI vaccine advice) at

<http://www.health.gov.au/internet/immunise/Publishing.nsf/content/immunise-atagi-vaccine-advice>

### Administration

Most influenza vaccines registered in Australia are administered by either intramuscular or subcutaneous injection. The intramuscular route causes fewer local reactions and is preferred.<sup>6</sup> In 2010, Intanza<sup>®</sup>, an intradermally administered influenza vaccine for use in persons aged 18–59 years, became available. This vaccine is presented in a specifically designed syringe (Micro-Injection System) that will deliver 0.1 mL of vaccine intradermally. Intradermally administered influenza vaccine is considered to be of equivalent efficacy to intramuscularly administered influenza vaccines.

People should receive their annual influenza vaccination before the start of the influenza season. Generally, influenza vaccines are available in Australia from the beginning of March of each year. This ensures people are protected during Australia's peak influenza season which is generally between June and September. Generally it takes between 7 and 14 days for an immune response to the vaccine to develop and for a person to be protected from influenza. Getting the influenza vaccine will not stop you from getting influenza if you are already infected at, or shortly after, the time of vaccination.<sup>5,6,11</sup>

For further information about influenza vaccines, please refer to Chapter 3.9 *Influenza* of the 9th edition of *The Australian Immunisation Handbook* (2008)<sup>6</sup> and vaccine advice from the Australian Technical Advisory Group on Immunisation at <http://www.health.gov.au/internet/immunise/Publishing.nsf/content/immunise-atagi-vaccine-advice>.

## Recommended doses of influenza vaccine

Age	Dose	Number of doses (first vaccination)	Number of doses* (subsequent years)
6 months–<3 years	0.25 mL	2†	1
3–9 years	0.5 mL	2†	1
>9 years	0.5 mL	1	1

\* If a child 6 months to ≤9 years of age receiving influenza vaccine for the first time inadvertently does not receive the second dose within the same year, he/she should have two doses administered the following year.<sup>6</sup>

† Two doses at least 1 month apart are recommended for children aged ≤9 years who are receiving influenza vaccine for the first time. The same vial should not be re-used for the two doses.

### Vaccine effectiveness

Influenza vaccine provides varying levels of protection against influenza.<sup>5,7</sup> This can vary depending on the age of the person being vaccinated and the degree to which the vaccine ‘matches’ with circulating strains. For example, in older people, influenza vaccine is about 30–40% effective in preventing symptoms of the flu, 50–60% effective against hospitalisation due to influenza, and 70–80% effective against death from complications of influenza.<sup>5,6,11</sup> Influenza vaccination also appears to reduce the risk of heart attacks and strokes.<sup>5</sup> When there is a good match between the influenza strains in the vaccine and those causing current disease, the vaccine can prevent illness in about 70–90% of healthy children and adults. The vaccine is less effective in those with an impaired immune system.<sup>5-7,11</sup>

### Vaccine safety

Local side-effects, such as swelling, redness and pain at the injection site, are common after receiving flu vaccine and occur in more than 10% of people who receive the vaccine. Fever, tiredness and myalgia (muscle aches) also occur commonly (1–10%).

These side-effects may commence within a few hours of vaccination and can last for 1–2 days.<sup>5,6</sup> In children <5 years of age, these adverse events may be more pronounced. Post-vaccination symptoms may mimic influenza infection, but none of the currently licensed influenza vaccines contain live virus, so they cannot ‘cause’ influenza.

Immediate more severe adverse effects, such as hives, angioedema or anaphylaxis, are very rare consequences of influenza vaccination. They probably represent an allergic response to a residual component of the manufacturing

process, most likely egg protein.<sup>5,6</sup> People with a history of anaphylaxis after eating eggs, or a history of a severe allergic reaction following exposure to egg protein, should consult with an allergy specialist to determine their suitability for the influenza vaccine (see ‘[Who shouldn’t be vaccinated](#)’ above).

### Children aged ≥6 months to <5 years

The expected rate of febrile convulsions following administration of seasonal trivalent influenza vaccines is usually less than 1 per 1,000 doses in this age group.

An extensive Australian investigation during the 2010 influenza season found that the rate of febrile convulsions was up to 1 per 100 (1%) in children aged <5 years vaccinated with the 2010 seasonal influenza vaccine Fluvax<sup>®</sup> or Fluvax<sup>®</sup> Junior.<sup>12-14</sup>

Analysis of reports to the Therapeutic Goods Administration (TGA) indicated that there was no increase in risk of fever or febrile convulsions following administration of either Vaxigrip<sup>®</sup> or Influvac<sup>®</sup> vaccines.<sup>12</sup> This was supported, for Influvac<sup>®</sup>, by data from parental reports in two Australian studies which found a low incidence of fever, especially high fever, in children, and, for Vaxigrip<sup>®</sup>, by data from Medsafe, the New Zealand regulator, and a New Zealand parental report study.<sup>12-15</sup>

### Contraindications/precautions

See ‘[Who shouldn’t be vaccinated](#)’ above.

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### Useful websites (accessed May 2011)

Australian Technical Advisory Group on Immunisation (ATAGI) statement: Clinical advice for immunisation providers regarding the administration of 2011 trivalent seasonal influenza vaccines. March 2011.

[http://immunise.health.gov.au/internet/immunise/Publishing.nsf/content/A1ECFAA9C9857C11CA25776D000471C2/\\$File/ATAGI-advice-march2011.pdf](http://immunise.health.gov.au/internet/immunise/Publishing.nsf/content/A1ECFAA9C9857C11CA25776D000471C2/$File/ATAGI-advice-march2011.pdf)

Therapeutic Goods Administration (TGA). Seasonal influenza vaccines. March 2011.

<http://www.tga.gov.au/safety/alerts-medicine-seasonal-flu-110310.htm>

Health Insite

<http://www.healthinsite.gov.au/topics/InfluenzaVaccine>

The Australian WHO Collaborating Centre for Reference and Research on Influenza

<http://www.influenzacentre.org/>

Better Health Victoria

[http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Flu\\_influenza?OpenDocument](http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Flu_influenza?OpenDocument)