Australian Government
Department of Health

Australian Technical Advisory Group on Immunisation (ATAGI) advice for immunisation providers regarding the administration of seasonal influenza vaccines in 2016

This document provides recommendations on the use, where not contraindicated, of seasonal influenza vaccines that are available in Australia in 2016. Additional advice on the use of influenza vaccines can be found in The Australian Immunisation Handbook 10th edition available on the Immunise Australia website.[a]

Key points:

- Annual vaccination is the most important measure to prevent influenza and its complications.
- Both quadrivalent influenza vaccine (QIV) and trivalent influenza vaccine (TIV) formulations are available in Australia in 2016. Age restrictions apply according to vaccine brand (refer to *Table 1*).
- ATAGI recommends the use of QIVs in preference to TIVs. However, TIVs are an acceptable alternative, particularly if QIVs are not available (refer to *Choosing between QIVs and TIVs*).
- Certain QIVs are funded on the National Immunisation Program (NIP) in 2016 for the following groups:
  - Aboriginal and/or Torres Strait Islander children aged 6 months to <5 years
  - Aboriginal and/or Torres Strait Islander persons aged ≥15 years
  - All adults aged ≥65 years
  - All persons aged ≥6 months who have a medical condition which increases the risk of influenza complications (refer to *Table 3*)
  - Pregnant women (during any stage of pregnancy).
- Influenza vaccination is also strongly recommended, but not funded, for other groups who are at increased risk of influenza and its complications (refer to *Other groups for whom influenza vaccination is strongly recommended*).

Seqirus (previously bioCSL*) Fluvax*® brand TIV is NOT recommended for use in children aged <9 years.

Introduction

Influenza is a respiratory illness caused by the influenza virus which affects people of all ages. Two types of influenza viruses, A and B, account for most human influenza disease. In the past few decades, two major subtypes of the type A influenza viruses have circulated seasonally among humans, A/H1N1 and A/H3N2. Currently circulating influenza B viruses belong to one of two lineages: Victoria or Yamagata. The predominant circulating strains of influenza viruses can vary each year.

Annual vaccination is the most important measure for the prevention of influenza and its complications. There are two types of inactivated influenza vaccines registered for use in Australia:

- **Trivalent influenza vaccine (TIV),** which contains **three** strains of influenza viruses (two A subtypes and one B lineage). TIVs have been in use in Australia for many years.
- **Quadrivalent influenza vaccine (QIV),** which contains **four** strains of influenza viruses (the same A subtypes and the B lineage in TIV, plus a second influenza B virus from the other B lineage). QIVs are made the same way as the TIVs and have been registered in Australia since 2014.

[a] www.immunise.health.gov.au

The strain composition of influenza vaccines for use in Australia is determined each year by the Australian Influenza Vaccine Committee based on information and recommendations from the World Health Organization. As the influenza strains included in seasonal influenza vaccines can change from year to year, and immunity to the vaccine wanes over time, influenza vaccination is required annually for continued protection against influenza.

The influenza virus strains included in the 2016 seasonal influenza vaccines are:

- A/California/7/2009 (H1N1)pdm09-like virus – *unchanged from 2015*
- A/Hong Kong/4801/2014 (H3N2)-like virus – *changed from 2015*
- B/Brisbane/60/2008-like virus, Victoria lineage – *changed from 2015 in TIV only (this strain was included in QIV formulations in 2015 and 2016)*
- **(QIV only)** B/Phuket/3073/2013-like virus, Yamagata lineage – *unchanged from 2015*

Vaccines available in 2016

Only certain QIVs are available for eligible groups on the NIP in 2016 (refer to *Eligibility for influenza vaccine on the NIP*, below). *FluQuadri® Junior* (Sanofi Pasteur) is funded for eligible children <3 years of age and *Fluarix® Tetra* (GSK) is funded for eligible children and adults aged ≥3 years. Both QIVs and TIVs will be available on the private market. It is important to note the age restrictions for the different influenza vaccine brands.

All seasonal influenza vaccines available for use in 2016 are summarised in *Table 1*.

Table 1 Seasonal influenza vaccines available and recommended for use in Australia in 2016, according to age and NIP eligibility

Vaccine / Age group	Quadrivalent influenza vaccine (QIV)			Trivalent influenza vaccine (TIV)		
	FluQuadri® Junior* (Sanofi Pasteur)	***FluQuadri®*†** (Sanofi Pasteur)	***Fluarix Tetra®*†** (GSK)	***Fluarix®*** (GSK)	***Influvac®*** (BGP Products)	***Fluvax®*‡** (Seqirus; previously bioCSL)
NIP funded (for eligible groups)						
<6 months	x	x	x	x	x	x
6–35 months (<3 years)	✓	*FluQuadri®* is not funded on the NIP in 2016	x†	TIVs are not funded on the NIP in 2016 (refer to rows below)		
≥3 years	x*		✓†			
Not NIP funded (available on the private market)						
<6 months	x	x	x	x	x	x
6–35 months (<3 years)	✓	x†	x†	✓	✓	x‡
3–8 years	x*	✓	x	✓	✓	x‡
≥9 years	x*	✓	x	✓	✓	✓

* The *FluQuadri® Junior* vaccine is 0.25 mL per dose and specifically registered for use in children aged 6 to 35 months only (refer to *Table 2 Number of doses and volume per dose for influenza vaccines, by age*).

† *FluQuadri®* and *Fluarix® Tetra* are 0.5 mL per dose and are registered for use in persons ≥3 years of age.

‡ Seqirus *Fluvax®* is registered for use in persons ≥5 years of age; ATAGI does not recommend the use of this vaccine in children aged <9 years (refer to *Use of Seqirus (previously bioCSL) Fluvax® in children*).

Dosage and administration

The preferred route of administration for all influenza vaccines in Table 1 is by intramuscular injection. The dose of vaccine to be administered varies by age and whether the person has been vaccinated against influenza in previous years, as outlined in *Table 2*.

Table 2 Number of doses and volume per dose for influenza vaccines, by age

Age	Dose	Number of doses required	
		In the first year of influenza vaccination	If previously received 1 or more doses of influenza vaccine
6 months to <3 years*	0.25 mL†	2	1
≥3 years to <9 years*	0.50 mL‡	2	1
≥9 years	0.50 mL‡	1§	1

* Children aged 6 months to <9 years receiving influenza vaccine for the first time require 2 doses, at least 4 weeks apart, to maximise the immune response to the vaccine strains. For children who have received 1 or more doses of trivalent or quadrivalent influenza vaccine in a previous year, only 1 dose of influenza vaccine is required in the current season and all seasons thereafter (irrespective of whether TIV or QIV is being used).

† If a child aged 6 months to <3 years inadvertently receives a 0.5 mL dose of influenza vaccine, no immediate action is necessary, and any additional dose(s) required that season or in future seasons should be given following standard recommendations. There is some evidence that a 0.5 mL dose of inactivated influenza vaccine is immunogenic and safe in children <3 years of age.[1,2] ***Note:*** *Fluarix® Tetra QIV brand is not registered for use in children aged <3 years and should not be administered to children in this age group* (refer to *Table 1*).

‡ If a child aged ≥3 years or an adult inadvertently receives a 0.25 mL dose of influenza vaccine, an age-appropriate dose (0.5 mL) should be repeated. Any additional dose(s) required that season or in future seasons should then be given following standard recommendations.

§ Two doses, at least 4 weeks apart, are recommended for persons with certain immunocompromising conditions (i.e. haematopoietic stem cell transplant or solid organ transplant) receiving influenza vaccine for the first time post transplant (irrespective of their age).

General recommendations for influenza vaccination

ATAGI recommends annual influenza vaccination for any person ≥6 months of age. However, there are a number of groups who are at increased risk of influenza and its complications for whom annual influenza vaccination is strongly recommended and should be actively promoted. For some of these groups seasonal influenza vaccination is funded under the NIP.

Eligibility for influenza vaccine on the NIP

Only certain QIV formulations (refer to *Table 1*) are available free under the NIP for the following individuals:

- Aboriginal and/or Torres Strait Islander children aged 6 months to <5 years
- Aboriginal and/or Torres Strait Islander persons aged ≥15 years
- All adults aged ≥65 years
- All persons aged ≥6 months with a medical condition (listed in *Table 3*) which increases the risk of influenza complications
- Pregnant women (during any stage of pregnancy).

Table 3 Medical conditions associated with an increased risk of influenza disease complications and for which individuals are eligible for vaccination under the NIP

Category	Vaccination strongly recommended for individuals with the following conditions
Cardiac disease	Cyanotic congenital heart disease Congestive heart failure Coronary artery disease
Chronic respiratory conditions*	Severe asthma (for which frequent hospitalisation is required) Cystic fibrosis Bronchiectasis Suppurative lung disease Chronic obstructive pulmonary disease (COPD) Chronic emphysema
Chronic neurological conditions*	Hereditary and degenerative CNS diseases* (including multiple sclerosis) Seizure disorders Spinal cord injuries Neuromuscular disorders
Immunocompromising conditions†	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

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

† Persons with certain immunocompromising conditions (i.e. haematopoietic stem cell transplant or 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 (refer to *Table 2*).

Other groups for whom influenza vaccination is strongly recommended

Annual influenza vaccination is also strongly recommended for persons in the following groups, although they are not eligible for NIP-funded influenza vaccines:

- Aboriginal and/or Torres Strait Islander children aged 5 years to < 15 years
- persons with Down syndrome
- persons with class III obesity (body mass index ≥40 kg/m2)
- persons with chronic liver disease
- children aged 6 months to <5 years
- residents of aged care facilities and long-term residential care facilities
- persons who may transmit influenza to children or adults at increased risk of influenza complications (e.g. healthcare workers)
- homeless people
- persons involved in the commercial poultry or pork industry, or in culling poultry or pigs during periods of confirmed avian or swine influenza activity
- persons providing essential services
- persons travelling during the influenza season, especially if it is known before travel that influenza is circulating in the destination region.

For more information refer to advice in *The Australian Immunisation Handbook* 10th edition.

Additional ATAGI advice on the use of influenza vaccines

Choosing between QIVs and TIVs

ATAGI recommends the use of QIV, in preference to TIV, for individuals for whom both formulations are available, due to the additional influenza B virus that it contains. The effectiveness of influenza vaccines, both QIVs and TIVs, depends on the age and immunocompetence of the recipient and the degree of similarity between the virus strains in the vaccine and those circulating in the community.

Clinical trials of QIVs suggest they are as safe and effective as TIVs.[2-5] Because QIVs contain an additional influenza B virus compared to TIVs, they have the potential to provide protection against a greater proportion of circulating influenza viruses in any season. There are many factors that impact the size of this potential additional benefit of QIVs over TIVs and so it cannot be predicted for any particular influenza season. These factors include:

- the proportion of all circulating influenza viruses attributable to the influenza B lineage that is not included in the TIV. This varies each year and has ranged from 0% (in 2000 and 2001) to 32% (in 2008).[6]
- the antigenic mismatch between the virus strains in the vaccine and those that are circulating
- the degree of cross-protection afforded by the virus strains in the vaccine to non-vaccine virus strains
- an individual's pre-existing immunity to the circulating strains of influenza.

For these reasons, TIVs are an acceptable alternative to QIVs and are expected to protect against the majority of circulating influenza viruses in most seasons. It is important that influenza vaccination is not delayed if an age-appropriate TIV is available and there are barriers to accessing QIV.

Interchangeability of QIVs and TIVs

Where 2 doses of influenza vaccine are indicated in a single season (refer to *Table 2 Number of doses and volume per dose for influenza vaccines, by age*), different brands of TIV or QIV are considered interchangeable (providing they are age-appropriate). Where possible, both doses should be administered using vaccines containing the same number of influenza strains (i.e. both with TIV or both with QIV) to ensure adequate priming of all influenza strains in the vaccine.

For individuals who only need 1 dose in 2016 and have already received a TIV this year, a further dose of QIV in 2016 is not recommended but is not contraindicated (refer to *Choosing between QIVs and TIVs*).

Co-administration of influenza vaccines with other vaccines

All inactivated influenza vaccines can be administered concurrently with any other vaccines. One study has demonstrated a slightly higher risk of fever and febrile convulsions in children aged 6 months to <5 years (especially those 12–24 months of age) with the concurrent administration of TIV and 13-valent pneumococcal conjugate vaccine (13vPCV), compared with giving these vaccines separately.[7] Given that the reported increase in risk was relatively small, and a more recent study[8] did not demonstrate the same association between febrile seizures and the concurrent administration of these two vaccines, administration of 13vPCV and inactivated trivalent influenza vaccine at the same visit is acceptable when both vaccines are indicated. However, immunisation service providers should advise parents of the possible risk and provide the option of administering these two vaccines on separate days (with an interval of not less than 3 days).

To date, there are no studies that assess the co-administration of QIVs with other vaccines. However, based on first principles and the similar manufacturing methods of both vaccine formulations, ATAGI's co-administration advice is applicable to both QIVs and TIVs.

Importance of influenza vaccination for pregnant women

Influenza vaccination is strongly recommended for pregnant women, and it is safe to administer influenza vaccine during any stage of pregnancy. Influenza vaccination will reduce the risk of complications from influenza in both the pregnant woman and the fetus during pregnancy, and also protects the infant against influenza in the first 6 months of life.[9-12]

Use of Seqirus (previously bioCSL) *Fluvax*® in children

Note: From October 2015, bioCSL influenza vaccines are marketed under the name Seqirus.

Seqirus *Fluvax*® is **not** registered for use in children aged <5 years due to high rates of fevers and febrile convulsions demonstrated in this age group in 2010. ATAGI does not recommend the use of this vaccine in children aged 5 to <9 years, unless an alternative vaccine is not available, as an increased risk of fever has also been demonstrated in this age group.

Reporting to the Australian Childhood Immunisation Register

From 1 January 2016, the Australian Childhood Immunisation Register (ACIR) began accepting vaccination information from all children, adolescents and young adults under the age of 20 years (expanded from under 7 years of age). Annual influenza vaccine doses administered to this age group should be reported to the ACIR, either electronically via Medicare Online or the ACIR secure Internet site, or by using a paper form (either an *Immunisation encounter form* or an *Immunisation history form*). Vaccination providers in Queensland and the Northern Territory who currently send data to the ACIR via their state/territory health department should continue to do so.

From September 2016, the ACIR will further expand to become the Australian Immunisation Register (AIR), capturing vaccinations given throughout a person's life at general practice and community clinics. More information can be found on the Department of Human Services (DHS) website.[b]

Reporting adverse events following immunisation

- Health professionals in Tasmania: report to TGA
- Health professionals in other jurisdictions: report to jurisdictional health departments
    - ACT (02) 6205 2300
    - NSW 1300 066 055
    - NT (08) 8922 8044
    - QLD (07) 3328 9888
    - SA 1300 232 272
    - VIC (03) 9345 4143 (SAEFVIC)
    - WA (08) 9321 1312
- Members of the public (e.g. parents and/or carers): report to their GP or usual vaccination provider, or they can report directly to the Adverse Medicines Events Line on 1300 134 237.
- Alternatively, anyone can report an adverse event directly to the TGA through the 'Report a problem' link on the TGA website.[c]

Further information

- *The Australian Immunisation Handbook*,[d] 10th edition[13]
- Immunise Australia website[e]
- Therapeutic Goods Administration (TGA) statement on 2016 influenza vaccines

[b] www.humanservices.gov.au
[c] www.tga.gov.au
[d] www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home
[e] www.immunise.health.gov.au

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