Australian Government
Department of Health

Expanded ATAGI recommendations on winter COVID-19 booster doses for people at increased risk of severe COVID-19

The Australian Technical Advisory Group on Immunisation (ATAGI) have expanded their recommendations on the use of additional (booster) doses of COVID-19 vaccine.

info

Currency status
Current

Executive summary

The primary goal of the Australian COVID-19 vaccine program is to minimise the risk of severe disease, including hospitalisation and death, from COVID-19.

Currently, the COVID-19 vaccination program is targeted at preventing severe disease, by providing additional protection to those with risk factors for severe disease. On 25 March 2022, ATAGI recommended an additional winter booster dose (4th dose for most people) for the highest risk groups: people aged 65 years and above, residents of aged care or disability care facilities, people with severe immunocompromise and Aboriginal and Torres Strait Islander people aged 50 years or above.

In this updated advice, an additional winter booster is now also recommended for other people at increased risk, to be given 4 months after their first booster dose. This applies to people aged 16-64 who have:

- A medical condition that increases the risk of severe COVID-19 illness (see Table 1 for expanded groups).
- People with disability with significant or complex health needs or multiple comorbidities which increase risk of poor outcome from COVID-19.

Healthy people aged 16 to 64 years, who do not have a risk factor for severe COVID-19, are **not** recommended to receive an additional winter booster dose at this time, as their risk of severe illness after their first booster dose is likely to remain very low. This includes healthy people from occupational groups such as healthcare workers. Pregnant women who do not have an additional risk factor for severe disease (such as in Table 1) and who have received three doses of COVID-19 vaccine are also **not** currently recommended for a winter booster dose at this time.

As per previous advice, if an individual has had a recent confirmed SARS-CoV-2 infection, they should delay their winter booster dose until 3 months after their infection.

Comirnaty (Pfizer, from age 16 years) or Spikevax (Moderna, from age 18 years) are the preferred vaccines for a COVID-19 booster dose. Vaxzevria (AstraZeneca) can be used in people aged 18 or older when an mRNA vaccine is contraindicated, or where a person declines vaccination with an mRNA vaccine. Nuvaxovid (Novavax) can be used in people aged 18 or older if no other COVID-19 vaccine is considered suitable for that person.

ATAGI also encourages people to be vaccinated against Influenza. Influenza vaccine can be co-administered with the additional booster dose of COVID-19 vaccine. However, if a person is not yet eligible for their additional booster dose, influenza vaccine could be given ahead of the additional booster dose.

Background

ATAGI emphasises the importance of the first booster dose and notes that a substantial proportion of eligible people aged 16 years and older (approximately 30% as of 21 May 2022) have not yet received their first booster dose. These eligible people are strongly encouraged to receive their first booster dose promptly to maximise protection prior to winter against SARS-CoV-2 infection. It is important that all people are up-to-date with COVID-19 vaccination.

Since ATAGI's initial recommendations for an additional winter booster dose in selected populations (on 25 March), ATAGI has continued to review evidence on the need for additional doses in other population groups. While there is relatively preserved protection against severe disease after a primary COVID-19 vaccine course and a first booster dose, an additional booster dose (4^{th} dose for most people) provides a further increase in the level of protection against severe disease and death. This increased protection is of greatest benefit to people at high risk of severe disease.[1-3]

ATAGI now advises that additional population groups are recommended to receive a winter booster dose (see below).

Recommendations

The following groups are recommended to receive a winter booster dose of COVID-19 vaccine:

Groups recommended previously (advice from 25 March)

ATAGI recommends that people in these groups who have not yet received their winter booster should get one as soon as possible, factoring in timing of first booster and infection (if applicable).

- adults aged 65 years and older

- residents 16 years and older of aged care or disability care facilities
- people aged 16 years and older with severe immunocompromise as defined in the ATAGI statement on use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised
- Aboriginal and Torres Strait Islander adults aged 50 years and older.

Additional groups recommended (from 25 May 2022)

- People aged 16-64 years who have complex, chronic or severe conditions that are considered to increase their risk of severe illness from COVID-19 (Refer to Table 1).

Table 1: Additional groups recommended for a winter booster dose as of 25 May 2022

People in these groups are likely to have an ongoing increased risk of severe COVID-19 even after primary vaccination. These examples are not exhaustive and providers may include individuals with conditions similar to those listed below, based on clinical judgment

Category	**Examples**
Immunocompromising conditions	
Cancer	Non-haematological cancer including those diagnosed within the past 5 years or on chemotherapy, radiotherapy, immunotherapy or targeted anti-cancer therapy (active treatment or recently completed) or with advanced disease regardless of treatment. Survivors of childhood cancer.
Chronic inflammatory conditions requiring medical treatment with disease modifying anti-rheumatic drugs (DMARDs) or immune-suppressive or immunomodulatory therapies.	Systemic lupus erythematosus, rheumatoid arthritis, Crohn's disease, ulcerative colitis, and similar who are being treated.
Chronic lung disease	Chronic obstructive pulmonary disease, cystic fibrosis, interstitial lung disease and severe asthma (defined as requiring frequent hospital visits or the use of multiple medications).
Chronic liver disease	Cirrhosis, autoimmune hepatitis, non-alcoholic fatty liver disease, alcoholic liver disease.
Severe chronic kidney disease (stage 4 or 5)	
Chronic neurological disease	Stroke, neurodegenerative disease (e.g dementia, motor neurone disease, Parkinson's disease), myasthenia gravis, multiple sclerosis, cerebral palsy, myopathies, paralytic syndromes, epilepsy.
Diabetes mellitus requiring medication	

Category	Examples
Chronic cardiac disease	Ischaemic heart disease, valvular heart disease, congestive cardiac failure, cardiomyopathies, poorly controlled hypertension, pulmonary hypertension, complex congenital heart disease.
People with disability with significant or complex health needs or multiple comorbidities which increase risk of poor outcome from COVID-19	Particularly those with trisomy 21 (Down Syndrome) or complex multi-system disorders.
Severe obesity with BMI ≥ 40 kg/m^2	
Severe underweight with BMI < 16.5 kg/m^2	

Younger people (aged 16 to under 40 years) with conditions that increase their risk of severe COVID-19 may consider discussing the potential risks and benefits of a second booster dose with their treating doctor. There is a very rare risk of myocarditis and pericarditis after mRNA vaccines which is highest in this age group, particularly in males.[4] It is anticipated that this cohort may have an increased risk of myocarditis or pericarditis following the second booster, compared with other population groups (see ATAGI advice on Myocarditis and Pericarditis after mRNA COVID-19 vaccines).

The following groups are currently not yet recommended to receive an additional winter booster dose:

- healthy people aged 16 to 64 years of age who do not have any risk factors for severe COVID-19
- women who are pregnant without any other comorbidity that increases their risk of severe COVID-19
- people from occupational groups, such as healthcare workers, who do not have any other comorbidity that increases their risk of severe COVID-19.

Rationale

Anticipated benefits of 4th doses in adults with risk factors

Accumulating evidence suggests that the greatest benefit from a second booster dose of COVID-19 vaccine is in people at highest risk of severe disease outcomes. Studies from Israel show that the relative vaccine effectiveness in people aged ≥60 years of a second booster compared with a first booster dose given ≥4 months previously was 68% (95% CI, 59 to 74) against COVID-19–related hospitalisation and 74% (95% CI, 50 to 90) against COVID-19–related death.[3]

A second study in Israel in people aged ≥60 years reported that the incremental benefit from a fourth dose (second booster) against infection peaked at 3 weeks after vaccination, with a relative vaccine effectiveness of 64% (95% CI: 62.0%-65.9%) compared with after a third dose. The relative vaccine effectiveness against infection declined to 29.2% (95% CI: 17.7%-39.1%) by the end of the 10-week follow-up period. However, protection against severe COVID-19 was maintained at a high level (>73%) throughout the 9-week follow-up period.[2]

Evidence to define additional risk groups

Older age remains the strongest risk factor for severe outcomes from COVID-19, including death.[5,6] Compared with individuals aged 18-39 years, the risk of death was 6.1 times higher in people aged 65-74 years and 8.66 times in those aged ≥75 years in a study conducted prior to COVID-19 vaccine availability.[6] This relationship with age exists as a continuum, with a systematic review finding that case mortality increases by 7.4% per year of age.[7] This relationship persists even with high levels of primary vaccination in Australia, as indicated by the Australian population mortality rate during the Omicron wave, ranging from 0.2 per 100,000 in those aged 18-29 years compared to 388.8 in those aged ≥90 years.[8]

Studies conducted prior to vaccine availability found associations between numerous co-morbid medical conditions and severe COVID-19.[5,9] However, in general the increased risk of severe outcomes related to comorbidities has been less than that due to advancing age.[5,9] More recently, studies have reported on risk factors in individuals who have received 1 or 2 doses of a primary course of COVID-19 vaccination, noting this current ATAGI advice is for individuals who have received 3 doses of vaccine rather than 1 or 2 in many of the studies.[10,11] While the absolute risk (i.e., rate) of severe disease is lower in vaccinated than in unvaccinated individuals, studies investigating risk factors in the vaccinated population indicate a similar pattern of contribution to risk from increasing age, and to a smaller extent, from comorbidities. The number of comorbid conditions and risk factors also cumulatively increases an individual's risk of severe disease.[5,9,11,12]

A US study of risk factors in individuals after primary vaccination found immunosuppression, respiratory disease, chronic liver disease, chronic kidney disease, neurological disease, poorly controlled diabetes, and cardiac disease were all associated with increased adjusted odds ratios (aOR) for severe COVID-19 outcomes after primary vaccination, ranging from 1.44 to 1.91. This compared to age ≥65 years which showed an aOR of 3.22 compared to those aged 18-39 years.[11] This study did not evaluate risk based on degree of immunocompromise, and included cancer within the definition of immunocompromise.

A UK study found the incidence of COVID-19 mortality in individuals who had received 1 or 2 doses of vaccine was increased with various comorbid conditions including immunosuppression, HIV/AIDS, cirrhosis, neurological conditions, chronic kidney disease, blood cancer, epilepsy, chronic obstructive pulmonary disease, cardiovascular and peripheral vascular disease, and type 2 diabetes (aOR ≥1.2). The risk was particularly high in Trisomy 21 (Down syndrome) (12.7-fold increase), kidney transplantation (8.1-fold), and care home residency (4.1-fold). Significant underweight and obesity were both associated with an increased risk of COVID-19 mortality.[10]

Other studies have also identified a higher risk of breakthrough infection leading to hospitalisation among vaccinated people with immunocompromise or cancer.[13-16] A cohort study which included 45,253 vaccinated found a significantly increased risk for breakthrough infections in patients with cancer vs patients without cancer (HR, 1.24; 95% CI, 1.19-1.29), and a high risk of hospitalisation and mortality in those with breakthrough infection (31.6% and 3.9%, respectively).[16] A retrospective cohort study of 664,722 US vaccinated patients found that immunocompromised patients (including people with rheumatological conditions and cancer) had higher rates of breakthrough infection in the post-Delta period (8.6-15.7 per 1000 person-months) than non-immunocompromised patients (7.1 per 1000 person-months) and that rates of hospitalisation (20.7%) and severe outcomes (2.1%) were also higher than the non-immunocompromised population (14.8% and 0.7%) respectively.[15]

Rationale for not including other groups

While studies have shown that unvaccinated pregnant women are at higher risk of severe outcomes compared to non-pregnant women[17], these studies were from early in the pandemic. There is a relative lack of data on severe outcomes during the Omicron wave and in vaccinated or boosted individuals. In a small study which included 135 pregnant women (70 having received 2 doses and 13 with 3 or more

doses) infected with the Omicron variant, 0% of vaccinated versus 9.6% of unvaccinated women had moderate (lower respiratory tract involvement) or severe infection (reduced blood oxygen levels or lung infiltrates on imaging).[18] While there are no particular maternal or fetal safety concerns from use of COVID-19 vaccines in pregnant women, ATAGI considers that currently there is insufficient evidence of incremental benefit from second boosters to recommend routine administration of this dose at this point in time. ATAGI will continue to monitor emerging evidence in this population.

Additional boosters are not currently recommended for people aged 16-64 years who do not have any conditions associated with increased risk of severe COVID-19, nor for people based on occupation, e.g. healthcare workers. In particular, studies have shown that healthcare workers have a greater risk of acquiring SARS-CoV-2 infection in community settings than through exposure at work.[19,20] People in these groups without comorbidity have been demonstrated to retain good protection against severe illness from SARS-CoV-2 several months out from their first booster dose. Data from the United Kingdom shows vaccine effectiveness against hospitalisation specific to severe respiratory disease was still high at 76% at ≥105 days after first booster and 88% against COVID-19 related mortality at ≥10 weeks.[21]

As outlined in ATAGI's previous statement on recommendations on a winter booster dose of COVID-19 vaccine**,** an additional booster is likely to provide only modest and transient protection against infection with the Omicron variant and onward transmission. ATAGI recognises that in the context of very high rates of SARS-CoV-2 circulation, vaccination of additional groups at lower risk of severe disease may be warranted in the future, in order to prevent milder infection and reduce transmission in the short term. ATAGI will continue to monitor disease modelling and the epidemiology of SARS-CoV-2 and may recommend wider vaccination to combat rapid increases in disease transmission in the future if the need arises.

Safety considerations

Though data are limited, a fourth dose of mRNA COVID-19 vaccine has been demonstrated to be safe and well tolerated[22,23], with most adverse events being similar to previous doses and short-lived. Myocarditis and pericarditis are rare adverse events associated with mRNA COVID-19 vaccines which are known to occur more commonly among younger people aged 16-40 and among males. The incidence of myocarditis in males aged 16-29 years is approximately 1 person for every 30,000 given a first booster dose of the Pfizer COVID-19 vaccine.[4] Definitive myocarditis and pericarditis risks after second booster doses are not yet available. Data on the rate of myocarditis or pericarditis after a 4th dose are very limited; early data from Israel are imprecise due to low case numbers.[24]

More information

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