

Changes to the recommended use of BCG vaccines to prevent tuberculosis

Plain-language summary

Tuberculosis is an uncommon disease in Australia, but is much more common in some other countries. Tuberculosis most commonly involves the lungs, but can also cause disease in other parts of the body.

People with a higher risk of developing more severe types of tuberculosis include:

- young children
- older adults
- people with weakened immune systems

The risk of tuberculosis can be reduced using a vaccine known as bacille Calmette–Guérin, or BCG vaccine.

The tuberculin skin test (TST, also called a Mantoux test) is a way to identify people who have already been infected with tuberculosis. It is used to screen for infection in people who are thought to be at high risk for tuberculosis infection. People with a positive TST do not benefit from getting a BCG vaccine, and vaccination is not advised for people with a positive TST. This is because:

- the vaccine does not provide any additional protection against future tuberculosis disease in people who are already infected
- people with a positive TST may have excessive local reactions if they receive the vaccine

The current Australian Immunisation Handbook recommendation for TST screening is that all people over 6 months of age should have a TST before they receive a BCG vaccine. ATAGI wants to change this to only recommend TST in certain cases, based on an individual risk assessment. This is because:

- the potential side effects of giving BCG to a person with a positive TST are small
- not many clinics in Australia can do a TST, which can lead to delays in vaccination
- not many clinics in Australia provide BCG vaccination. This is because there are shortages of BCG vaccine, and the vaccine comes in multidose vials (so vaccine is wasted if there are not enough people to use the whole vial). The vaccine is also given intradermally (injected between the layers of the skin), and clinic staff need special training to do this. Doing TST as well increases clinic workload, and also means that parents and their children need an extra visit to a clinic
- BCG vaccination is most effective at preventing severe disease in children under 5 years of age. These children are highly unlikely to have had previous tuberculosis infection if they were born in Australia, unless they have other risk factors. This means the likelihood of a positive TST is also very low

Summary of revised recommendations

New recommendation

- A tuberculin skin test (TST; Mantoux) before BCG vaccination is only recommended in certain circumstances, based on a risk assessment

Recommendations with minor editorial changes to supporting information

- Aboriginal and Torres Strait Islander children aged <5 years in certain parts of Australia are recommended to receive BCG vaccine

Recommendations that have been reworded but not substantially changed

- Healthcare workers who are at high risk of exposure to drug-resistant tuberculosis may benefit from BCG vaccination
- Children aged <5 years born to parents from countries with high tuberculosis incidence may receive BCG vaccine, based on a risk assessment
- Children aged <5 years who are travelling for more than 3 months to settings with high tuberculosis incidence are recommended to receive BCG vaccine, based on a risk assessment
- Children aged <5 years who are born to parents with leprosy, have a family history of leprosy or have household contacts with leprosy are recommended to receive BCG vaccine, based on a risk assessment

Background

The Australian Technical Advisory Group on Immunisation (ATAGI) advises the Australian Government on clinical recommendations for vaccinations. ATAGI is proposing changes to the recommendations for the use of BCG vaccines to prevent tuberculosis.

The proposed changes reflect the current best clinical practice to prevent tuberculosis in the Australian context. The revised recommendations will be published online in the [Australian Immunisation Handbook](#).

About tuberculosis

Tuberculosis most commonly involves the lungs, but can also cause extrapulmonary disease (outside the lung). Almost all tuberculosis in Australia is caused by infection with the bacteria *Mycobacterium tuberculosis*.

Most people infected with *M. tuberculosis* never have any symptoms. Only people who have active pulmonary tuberculosis can spread the disease to other people.

Young children (especially those younger than 5 years of age), older adults and people who are immunocompromised have a higher risk of developing more severe types of disease. This includes disease that rapidly progresses or that spreads throughout the body and may also affect the brain (tuberculous meningitis).

Tuberculosis can be effectively treated with a combination of antibiotics, but in recent years, strains of *M. tuberculosis* that are drug resistant or multidrug resistant have emerged. Infections with drug-resistant organisms require prolonged treatment duration and management of significant side effects.

About the BCG vaccine

The risk of tuberculosis infection can be reduced using a vaccine known as bacille Calmette–Guérin, or BCG vaccine. In young children, vaccination provides more than 70% protection against severe types of disease.¹ In adults, vaccination may provide some protection against lung disease (studies range from showing no protection to 80% protection).¹

BCG vaccine is not part of the National Immunisation Program in Australia. It is only recommended for people at higher risk of *M. tuberculosis* infection and disease. The most common use of BCG vaccine in Australia is for children travelling to a high tuberculosis incidence country, or for Aboriginal or Torres Strait Islander children living in South Australia, Queensland or the Northern Territory.

There has been significant disruption to BCG vaccine supply in Australia and globally since 2012. The product that is registered in Australia (Sanofi BCG vaccine) has not been available since 2012. Multiple alternative BCG vaccines that are not registered in Australia have been used since 2012, through special prescribing arrangements.

Screening for tuberculosis

The tuberculin skin test (TST, also called a Mantoux test) is a way to identify people who have been infected with *M. tuberculosis* in the past. Identifying these people means that they will not be vaccinated, because the vaccine does not protect against disease in people who are already infected.

Tuberculosis in Australia

In Australia, tuberculosis is an uncommon disease. The annual notification rate has been stable since 1985, at approximately 5–6 cases per 100,000 population.² Most tuberculosis cases in Australia (more than 85%) occur in people who were born overseas, especially in:²

- India
- Vietnam
- the Philippines
- China
- Nepal

Notifications of tuberculosis are disproportionately higher in Aboriginal and Torres Strait Islander populations in some states and territories.² However, the national tuberculosis notification rate for Aboriginal and Torres Strait Islander people decreased by around 50% between 2010 and 2019 (data from the National Notifiable Diseases Surveillance System).

The rate of multidrug-resistant (MDR) tuberculosis in Australia has been low (less than 2% of notified cases), but the proportion of identified MDR tuberculosis cases has increased since 2006.³

Tuberculosis in other countries

The World Health Organization declared tuberculosis a global emergency in 1993, and recent reports have reaffirmed the threat to human health.⁴ In 2019, there were about 10 million new

cases of tuberculosis around the world. Most of these cases (87%) were from 30 high-burden countries.⁵

Rationale for updating recommendations

The current recommendation for TST screening is that all people over 6 months of age should have a TST before they receive a BCG vaccine. ATAGI proposes changing this to only recommend TST in certain circumstances, based on an individual risk assessment. This is because:

- BCG vaccination is most effective at preventing severe disease in children under 5 years of age, and is recommended for children travelling to countries with a high tuberculosis incidence. Australia has a low incidence of tuberculosis, and Australian-born children are unlikely to become infected in Australia without additional risk factors
- BCG vaccine disruptions have resulted in the use of multiple alternative BCG vaccines that are not registered in Australia. These vaccines have only been available in certain clinics. TST increases clinic workload and adds to the number of clinic visits required by parents and their children

ATAGI proposes the following changes to the use of BCG vaccines in Australia.

New recommendation

A tuberculin skin test (TST; Mantoux) before BCG vaccination is only recommended in certain circumstances, based on a risk assessment

The need for TST should be determined by an individual risk-based assessment that considers whether the person:

- was born in a tuberculosis-endemic country (>40 cases per 100,000 population per year)
- has travelled for a cumulative period of at least 3 months to a tuberculosis-endemic country or region (>40 cases per 100,000 population per year)
- has potential exposure to a close contact or family member with tuberculosis or who is under investigation for tuberculosis

If an immunocompetent person who was required to have a TST is confirmed to be negative (induration of <5 mm), they can receive BCG vaccine.

The TST uses tuberculin, a purified protein derivative. This causes a hypersensitivity reaction in people who have previously been infected with *Mycobacterium tuberculosis*. ‘False positive’ hypersensitivity reactions can also occur in:

- people who are infected with other (non-tuberculous) mycobacteria
- people who have previously received BCG vaccine

Health professionals must correctly administer and interpret the TST. Consult state or territory tuberculosis guidelines for advice.

Measles virus infection inhibits the response to tuberculin. TST-positive people may become TST-negative for 4–6 weeks after measles infection, and measles-containing vaccines have a similar effect.^{6,7} Because of this, the TST may be unreliable for at least 6 weeks in people who have recently received a measles-containing vaccine.

Interferon-gamma release assays (IGRAs) are a type of blood test that can detect *M. tuberculosis* infection (similar to the TST), but the TST is still the preferred method of screening for tuberculosis

infection. This is because of a lack of evidence supporting IGRA and uncertainty about whether hypersensitivity detected by TST is associated or not associated with an accelerated local reaction.⁸

Current recommendation

ATAGI currently recommends the following:

All people, except infants aged <6 months, are recommended to receive a tuberculin skin test (TST; Mantoux) before BCG vaccination

All people, except infants <6 months of age, should have a tuberculin skin test (TST; Mantoux) before BCG vaccination. Only immunocompetent people who have induration of <5 mm after a TST should receive BCG vaccine.

The TST uses a tuberculin purified protein derivative. This causes a hypersensitivity reaction in people who have a *Mycobacterium tuberculosis* infection. Hypersensitivity reactions can also occur in:

- people who are infected with other mycobacteria
- people who have previously received BCG vaccine

Health professionals must correctly administer and interpret the TST. Consult state or territory tuberculosis guidelines for advice.

The measles virus inhibits the response to tuberculin. Tuberculin-positive people may become tuberculin-negative for 4–6 weeks after measles infection, and measles-containing vaccines have a similar effect.^{6,7} Because of this, the TST may be unreliable for at least 4–6 weeks in people who have received a measles-containing vaccine.

Interferon-gamma release assays (IGRAs) are a type of blood test that can detect *M. tuberculosis* infection, but the TST is still the preferred method of screening for tuberculosis, unless the person has previously received BCG vaccine.⁸

Key differences

The previous recommendation was for all people aged 6 months and older to receive a TST before BCG vaccination.

The new recommendation is that TST should only be done in certain circumstances, and regardless of age. The supporting text lists the circumstances that should be considered as part of an individual risk assessment.

Evidence for the new recommendation

No randomised controlled trials have been conducted to compare the outcomes of BCG vaccination with and without prior TST. However, studies show that:

- rates of TST positivity in children and adults in low tuberculosis prevalence countries are low, which means the likelihood of providing BCG vaccine to someone who has latent tuberculosis infection or active tuberculosis (potentially leading to avoidable vaccine-associated adverse events) is low
- vaccine-associated adverse events in adults who are TST positive are generally localised and similar to the vaccine-associated adverse events experienced by people who are TST negative, although reactions occur more rapidly in people who are TST positive

Rate of TST positivity in children and adults in low tuberculosis prevalence countries

In Australia and similar countries with low tuberculosis prevalence, the risk of administering BCG vaccine to a person who has tuberculosis is very low. In Australia between 2003 and 2012, of children aged 0–14 years, only one Australian-born child was found to have active tuberculosis through onshore post-arrival screening. No tuberculosis cases in this cohort were identified through TST prior to BCG administration.⁹

In the Republic of Ireland (tuberculosis incidence of 10.4 cases per 100,000 population in 2003),¹⁰ a retrospective review of 1854 TSTs in children aged 3 months to 18 years between 2003 and 2006 showed that only 0.7% of children had a positive TST result (induration >5 mm).¹¹

In New York city, a study conducted between 1991 and 1998 examined the results of TST in new entrants aged 3–16 years. Despite the incidence rate of TB in the New York City population rising to 52 per 100,000 population in 1992, TST positivity (induration >10 mm) was:¹²

- 2.2% in all children in the study
- 0.5% in children who were locally born
- 1.0% in children who were born in countries with low tuberculosis incidence (<20 smear positive cases per 100,000)

In contrast, in a study in Sweden (6 cases per 100,000 population in 1991)¹³ of 2819 children aged 8 or 9 years without any known exposure to tuberculosis, 3.4% reacted with an induration of ≥ 6 mm. The reaction was thought to be due to non-tuberculosis mycobacteria exposure. None of the children who were TST positive were diagnosed with tuberculosis.¹⁴

Safety of BCG vaccine in adults with a positive TST result

A randomised controlled trial in South Africa compared the response to BCG vaccination in adults with latent tuberculosis infection before and after use of isoniazid. Among 72 adults aged 18–40 years:

- 35% reported injection site pain
- 68% reported erythema
- 86% reported induration
- 76% reported ulceration

Systemic reactions were uncommon, with headache most frequently reported. Transient axillary lymphadenopathy was noted in 10 participants.¹⁵ The reactogenicity in this study was comparable to that reported in a vaccination study among US adults who were TST negative.¹⁶

Recommendations with minor editorial changes to supporting information

Updated recommendation

Aboriginal and Torres Strait Islander children aged <5 years in certain parts of Australia are recommended to receive BCG vaccine

Aboriginal and Torres Strait Islander people in some states and territories have a significant burden of tuberculosis. BCG vaccine is recommended for young children living in these regions.¹⁷ Consult state and territory guidelines for more details on state and territory vaccination programs.

See also Vaccination for Aboriginal and Torres Strait Islander people.

Key differences

The recommendation for Aboriginal and Torres Strait Islander children in certain parts of Australia to receive BCG vaccine remains unchanged.

The supporting information for this recommendation has been reworded to indicate that Aboriginal and Torres Strait Islander populations in some states and territories have a higher burden of disease. These states and territories make decisions about whether to provide a BCG vaccination program for these populations.

Recommendations that have been reworded but not substantially changed

The wording of 4 recommendations has changed to help provide more clarity:

- 2 recommendations have been reworded to focus on who the vaccine would be given to, not who the vaccine would not be given to
- 2 recommendations have been reworded to provide greater clarity about the target age group of the recommendation

There are also minor editorial changes to the supporting text.

Updated recommendation

Healthcare workers who are at high risk of exposure to drug-resistant tuberculosis may benefit from BCG vaccination

Some occupational groups that are at high risk of exposure to drug-resistant tuberculosis may benefit from BCG vaccination because drug-resistant infections are difficult to treat. Examples include:

- healthcare workers at tuberculosis clinics or refugee health clinics
- people involved in autopsies
- embalmers
- laboratory workers who work with *Mycobacterium tuberculosis*

Other occupational groups that have an increased risk of tuberculosis are not routinely recommended to receive BCG vaccine because the evidence of benefit of BCG vaccination in adults is limited.

In the workplace, tuberculosis prevention and control should focus on:

- infection control measures
- employment-based screening

- therapy for latent tuberculosis infection

Current recommendation

Workers who may be exposed to tuberculosis in their jobs are not routinely recommended to receive BCG vaccine

Some occupational groups have an increased risk of tuberculosis, including:

- embalmers
- healthcare workers who are likely to encounter patients with tuberculosis — for example, staff at chest clinics, refugee health clinics
- people involved in autopsies

People in these occupations are not routinely recommended to receive BCG vaccine because:

- the evidence of benefit of BCG vaccination in adults is limited
- vaccination interferes with the interpretation of tuberculin skin test (TST) results

Consider BCG vaccination for TST-negative healthcare workers who are at high risk of exposure to drug-resistant tuberculosis. This is because drug-resistant infections are difficult to treat.

In the workplace, tuberculosis prevention and control should focus on:

- infection control measures
- employment-based TST screening
- therapy for latent tuberculosis infection

Updated recommendation

Children aged <5 years born to parents from countries with high tuberculosis incidence may receive BCG vaccine, based on a risk assessment

Tuberculosis is rare in children born in Australia. However, children born in Australia to parents from countries with a high tuberculosis incidence (>40 cases per 100,000 population per year) may have a higher risk of tuberculosis exposure in their early life.¹⁸ Children born outside of Australia may also be at high risk of disease. See Epidemiology.

BCG vaccination may be recommended in some cases, based on a risk assessment. Consult state or territory guidelines.

Current recommendation

Infants born in Australia to parents from countries with high tuberculosis incidence are not routinely recommended to receive BCG vaccine

Tuberculosis is rare in infants and young children born in Australia. However, infants born in Australia to parents from countries with a high tuberculosis incidence (>40 cases per 100,000 population per year) may have a higher risk of tuberculosis exposure in their early life.⁴ See Epidemiology.

These infants are not routinely vaccinated because of the uncertainty of the risks and benefits. However, BCG vaccination may be recommended in some cases, based on a risk assessment. Consult state or territory guidelines.

Updated recommendation

Children aged <5 years who are travelling for more than 3 months to settings with high tuberculosis incidence are recommended to receive BCG vaccine, based on a risk assessment

Children aged <5 years travelling to countries with a high tuberculosis incidence (>40 cases per 100,000 population per year) are at increased risk of acquiring tuberculosis and developing severe disease.² BCG vaccine is most effective at preventing severe tuberculosis (miliary tuberculosis and tuberculosis meningitis) in children. See Epidemiology and Vaccine information.

The risk depends on:

- the child's age — those aged <5 years are particularly at risk
- how long they are in the high-risk area
- the tuberculosis incidence at the destination

See the World Health Organization's country-specific incidence data.¹⁹

TST screening prior to vaccination is only required in some circumstances. Please refer to skin testing before vaccination for details.

Assess the need for BCG vaccination for young children who will be travelling to a country with high tuberculosis incidence for an extended period. Discuss this with state or territory tuberculosis services, or with a paediatric infectious diseases specialist.

Children should ideally receive the vaccine at least 3 months before departure. If relevant, consider future travel plans at birth.

BCG vaccine is not as effective in older children and adults. It is not routinely recommended for people in these age groups who are travelling to a country with high tuberculosis incidence.

Current recommendation

Children travelling to settings with high tuberculosis incidence are recommended to receive BCG vaccine, based on a risk assessment

Young children travelling to countries with a high tuberculosis incidence (>40 cases per 100,000 population per year) are at increased risk of acquiring tuberculosis and developing severe disease.² BCG vaccine is most effective at preventing severe tuberculosis (miliary tuberculosis and tuberculosis meningitis) in children. See Epidemiology and Vaccine information.

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Children should ideally receive the vaccine at least 3 months before departure. If relevant, consider future travel plans at birth.

BCG vaccine is not as effective in older children and adults. It is not routinely recommended for people in these age groups who are travelling to a country with high tuberculosis incidence.

Updated recommendation

Children aged <5 years who are born to parents with leprosy, have a family history of leprosy or have household contacts with leprosy are recommended to receive BCG vaccine, based on a risk assessment

BCG vaccine provides some protection against *Mycobacterium leprae*, the organism that causes leprosy.²⁰ Children aged <5 years with family or household contacts who have leprosy may be recommended to receive BCG vaccine, based on a risk assessment. Consult state or territory guidelines.

Current recommendation

Infants born in Australia to parents from countries with high tuberculosis incidence are not routinely recommended to receive BCG vaccine

BCG vaccine provides some protection against *Mycobacterium leprae*, the organism that causes leprosy.²⁰ Young children with family or household contacts who have leprosy may be recommended to receive BCG vaccine, based on a risk assessment. Consult state or territory guidelines.

Benefits

Barriers to BCG vaccination in Australia include:²¹

- lack of supply of a registered BCG vaccine
- intermittent supply issues over the past 10 years
- lack of awareness of the recommendations for BCG vaccination
- the recommendation to receive BCG vaccine at least 3 months before travel
- the need to attend a clinic for an initial visit for TST screening, with a follow-up visit 48 hours later to read the TST result and administer BCG vaccine

Benefits of removing the need for TST before BCG vaccination may:²²

- increase vaccination uptake
- reduce clinic visits
- reduce clinical staff workload

Potential risks

The potential risks that may arise from the new recommendations include the following:

- vaccine-associated adverse events in people who have undiagnosed tuberculosis infection, who would otherwise not have received BCG vaccine if they were identified as having tuberculosis infection by TST. However, because Australia is a low tuberculosis prevalence country, this risk is likely to be very small. Vaccine-associated adverse events in people who are TST positive occur more rapidly than in people who are TST negative

- increased use of BCG vaccines that are not registered in Australia. However, any unregistered BCG vaccines that are used in Australia through special prescribing arrangements have been assessed as safe by another country with similar regulatory standards to Australia

Preference and values

The proposed changes to the use of BCG vaccines are in line with best clinical advice. It is expected that the changes will reduce barriers to vaccination for people at risk of tuberculosis and reduce unnecessary workload for the clinics that provide these vaccinations. This is consistent with societal expectations of the best use of vaccines in Australia.

These recommendations are not funded under the NIP, but may be funded through state and territory programs. Immunisation providers are recommended to check the current funding status for each individual's situation.

Additional information to be included in the Australian Immunisation Handbook

The Handbook will also be updated to:

- remove the detail of the registered vaccine (Sanofi BCG vaccine), which is currently not available in Australia
- include more information about the vaccines that are not registered in Australia but are available through special prescribing arrangements

Glossary

A [glossary of technical terms](#) is available on the Australian Immunisation Handbook website.

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