Australian Immunisation Handbook

Responses to Public Consultation Submissions

Changes to the recommended use of BCG vaccine to prevent tuberculosis

Public consultation period: 6 October 2021 to 6 November 2021

Contents

1. Introduction

Public consultation for the revised BCG vaccine recommendations in the Australian Immunisation Handbook (the Handbook) was conducted over a four week period from 6 October 2021 to 6 November 2021, during which time the draft recommendations were available on the Citizen Space website. The Immunisation Branch invited a range of stakeholders, committees, working groups and interested people to provide submissions. A list of organisations formally invited to comment on the draft guidelines is provided in Appendix A.

This report outlines the public consultation comments received on the revised BCG vaccine recommendations. Eighteen submissions were received using the submission template provided on Citizen Space. Of these, ten were on behalf of an organisation or jurisdiction and eight were from individuals.

The Australian Technical Advisory Group on Immunisation (ATAGI) considered all responses from the public consultation in December 2021 and, where necessary, revised the recommendations in accordance with the submissions. Comments from the public consultation submissions and the ATAGI responses are summarised in the following section.

This report was submitted to the National Health and Medical Research Council (NHMRC) on 19 May 2022, reviewed at its meeting on 27 July 2022, and approved on 5 August 2022.

2. Summary of comments received through public consultation on updated tuberculosis vaccination recommendations for inclusion in the Handbook

No.	Organisation	Comment	Proposed Action	Rationale
1a	Individual	A potential benefit is more timely BCG [bacille Calmette–Guérin] vaccination for those patients >6 months where there is very low risk	**Reviewed. Change to made to recommendation.**	Comment noted with thanks. The wording of the benefits section of the public consultation document will be expanded to include improvement to timeliness of BCG vaccinations.
1b	Individual	An additional consideration would be the need for clear outline of individual risk assessment	**Reviewed. Change made to recommendation.**	Comment noted with thanks. The risk assessment for requiring BCG vaccine has been modified.
2a	Individual	No – I support removing pre-BCG Mantoux in low-risk cases	**Reviewed. No change in recommendation made.**	Comment noted with thanks.
2b	Individual	Page 9 – I strongly recommend amending the statement "Discuss this with state or territory tuberculosis services, or with a paediatric infectious diseases specialist." to add immunisation service and immunisation specialist	**Reviewed. Change made to recommendation.**	Comment noted with thanks. It is appropriate to expand the list of services to include BCG immunisation specialists such as a paediatric infectious diseases specialist or travel vaccine centres.
2c	Individual	With regards to this statement "travelling for more than 3 months" consider adding "cumulatively" to this time frame. A child travelling regularly in 4-week trips twice a year until the age of 5 times a year may still benefit from BCG.	**Reviewed. No change in recommendation made.**	Comment noted with thanks. As the 3 month period is arbitrary, we have decided to remove a precise estimate of length of travel, instead it should be considered for each individual as part of their overall risk assessment,

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				taking into account other factors.
3a	Individual	For the last 15 years, I've been doing very few TSTs [tuberculin skin tests] before giving BCG, including young children who've previously travelled to high-risk areas (unless there's a suggestion of exposure). I've yet to see an exaggerated local reaction.	**Reviewed. No change in recommendation made.**	Comment noted with thanks.
3b	Individual	I recommend BCG for all VFR [visiting friends and relatives] children <5 travelling to a high-incidence area for ANY length of time. The 3-month recommendation is arbitrary.	**Reviewed. Change made to recommendation**	Comment noted with thanks. The recommendation will be modified to remove the 3-month time travel requirement. Instead, the time period of travel will be noted as one of a few considerations for the risk assessment, which will inform whether a travelling child should receive BCG vaccine.
4	Individual	I think the new recommendations will improve the clinic flow of patients, especially in the under 5's, and limiting hospital visits in the COVID-19 era.	**Reviewed. No change in recommendation made.**	Comment noted with thanks.
5a	Travel Clinics Australia	"Ceasing TSTs in children of overseas-born parents will lead to an unacceptably high incidence of adverse events following immunisation (AEFI). This includes but is not limited to large and prolonged abscess formation, lymphadenopathy, TB [tuberculosis] infection, and associated pain and suffering for both parent and child. The high incidence of LTBI [latent tuberculosis infection] in overseas-born families results in the majority of reported active cases of TB occurring in this group. This has obvious	**Reviewed. No change in recommendation made.**	Comment noted with thanks. The new TST recommendation clearly indicates that the need for screening is based on individual risk assessment and takes into account such things as frequent travel to higher risk areas and contact

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		implications for their non-immune children <5 years of age. Many of these children will have spent time overseas in high-prevalence countries (eg India, China, Vietnam etc). (REF: 5% of Australians / 17% of overseas born Australians have LTBI. Justin Denholm, Ann-Marie Baker, Mark Timlin. Latent tuberculosis in the general practice context. Aust J Gen Pract. 2020 Mar;49(3):107-110. doi: 10.31128/AJGP-10-19-5139.) We propose children <5 years visiting countries of high prevalence for cumulative 3 months or more continue to be advised to have a TST prior to BCG vaccination." This proposal appears to be based on a single opinion piece article published 15 years ago, and which is oriented towards large public health facilities in a clear effort to reduce cost. There is clearly inadequate evidence overseas or in Australia to support this proposal. The Irish study from 15 years ago did not include the same high proportion of overseas-born parents from countries with high TB and LTBI endemicity as we have here in Australia. Prior to proceeding with this proposal, it is important to attempt to collect some Australian data with an appropriate scientific study. It is important to recognise the important and significant contribution of private medical facilities in providing BCG vaccinations, rather than only anecdotal clinical experience in hospital outpatient clinics.		with family members who may have TB.
5b	Travel Clinics Australia	The reasons given for ceasing TSTs (lack of training, workload, number of visits) are not valid reasons for ceasing the appropriate standard of medical care.	**Reviewed. No change in recommendation made.**	Comment noted with thanks. Some people targeted for tuberculosis vaccination

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		Training is widely available – for example, Travel Clinics Australia is just one of many organisations that have provided effective training in intradermal techniques to 100s of general practitioners and nursing staff throughout Australia over the last two decades. Workload is not onerous and routinely provided by trained staff at the clinics in private settings. Travellers are quite prepared and able to attend multiple clinic appointments, as they do for other travel vaccinations and especially if they are local.		(eg First Nations people in remote communities or people from refugee backgrounds) will not have access to private travel medicine clinics and require vaccination through the public system. In addition, the priority of the current recommendation changes is to improve timeliness of BCG vaccination in at-risk populations. Given the low incidence level of TB in Australia, TST screening is unlikely to change the outcome of whether an individual is recommended to have the BCG vaccine.
6	Department of Health [Victoria]	These recommended changes have the potential to improve service delivery within specialist BCG clinics in Victoria; wait times may be reduced if there is no need to undertake TST (eliminating the need for a follow-up appointment). We are supportive of these recommendations. Any opportunity to improve patient outcomes and improve advice to immunisation providers with a clear rationale, concise and consistent language, supported by examples, is welcomed.	**Reviewed. No change in recommendation made.**	Comment noted with thanks.
7	WA Department of Health, Office of the Chief Health Officer	No. The additional potential benefits and risks from the proposed changes have been adequately outlined.	**Reviewed. No change in recommendation made.**	Comment noted with thanks.

No.	Organisation	Comment	Proposed Action	Rationale
		WA Health is supportive of the proposed changes.		
8a	NSW Tuberculosis Program/Health Protection NSW	Potential benefits: • An increased number of at-risk children will be identified and offered BCG vaccination, leading to a reduction in the number and severity of cases of childhood TB in NSW [New South Wales]. • Provide impetus for the health system in NSW to resource the development and maintenance of a more active, risk-based approach to the provision of BCG vaccinations.	**Reviewed. No change in recommendation made.**	Comment noted with thanks. Implementation/resourcing matters will be managed by state and territory health departments.
8b	NSW Tuberculosis Program/Health Protection NSW	Potential risks: • The change to this version compared to the previous consultation draft for travel to >3 months (rather than a risk assessment) could mean young children (<2 years) travelling to high-risk settings, especially where they are staying in the community (eg family visits in Philippines, India, Papua New Guinea), are not recommended for BCG vaccination, even though this is potentially a higher risk than other categories where BCG is recommended. • Children at highest risk are not identified and not offered BCG vaccination, due to a lack of awareness/ lack of access to information about the benefits of BCG.	**Reviewed. Change made to recommendation**	Comment noted with thanks. The recommendation will be modified to remove the 3-month time travel requirement. Instead, time period of travel will be noted as one of a few considerations for the risk assessment, which will inform whether a travelling child should receive BCG vaccine.
8c	NSW Tuberculosis Program/Health Protection NSW	The volume of referrals/requests for BCG vaccination overwhelms existing resources. Unintended consequences: • Demand for BCG far exceeds supply, leading to (1) increased workload for TB services without benefit for the community; (2) frustrated/angry/litigious parents.	**Reviewed. Change made to recommendation**	Comment noted with thanks. Increased demand for BCG vaccination was added as a potential risk.

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8d	NSW Tuberculosis Program/Health Protection NSW	The proposed changes to the Handbook could make an additional 100,000 children eligible for BCG in NSW, plus another 25,000 per year (birth cohort with at least one overseas-born parent). NSW administers 1000–2000 BCG a year (in non-COVID and non-shortage years). As BCG is outside the National Immunisation Program, it is managed by a small number of accredited staff in NSW TB services. Lead-time to train a Registered Nurse to become an accredited, independent BCG vaccinator in NSW is 12–18 months (6 months for those with a pre-existing immunisation certificate) • With the current BCG accreditation process, it will take some time to expand capacity to manage the projected increase in BCG referrals. • Alternative processes to BCG accreditation should be explored and funded. • Potentially train nurses to administer BCG under medical supervision. Strategies to increase capacity to administer BCG are required, but will take time: • Engage with maternity services to risk assess families during antenatal visits and plan BCG at or soon after birth. • Engage with travel medicine services to provide BCG (as a travel vaccine). • Engage with general practice to establish BCG vaccination hubs in areas of high demand.	**Reviewed. No change in recommendation made.**	Comment noted with thanks. Implementation/resourcing matters will be managed by state and territory health departments.
8e	NSW Tuberculosis Program/Health Protection NSW	Whilst the removal of universal TST for children >6 months of age will potentially reduce healthcare visits, there is an increased focus on risk assessment, which will require	**Reviewed. No change in recommendation made.**	Comment noted with thanks. Each individual may be offered TST or BCG based on their individual risk. This is

No.	Organisation	Comment	Proposed Action	Rationale
		increased capacity to assess and determine whether BCG is indicated and whether a TST is required. Advice on risk matrix for each category of candidate for BCG: • Overseas traveller • Healthcare worker at risk of exposure to multidrug-resistant TB • Child born to parents born in high-TB-incidence countries – visiting relatives and friends, and risk of TB exposure in local community		indicated in the TB chapter of the Handbook and is the responsibility of the provider to determine. Decisions about resourcing clinics are managed by state and territory health departments.
8f	NSW Tuberculosis Program/Health Protection NSW	Some vaccinations are only indicated for at-risk populations in the National Immunisation Program. Could BCG be reconsidered in this context?	**Reviewed. No change in recommendation made.**	Comment noted with thanks. Population-specific/restricted vaccine funding on the National Immunisation Program requires an application to be made to the Pharmaceutical Benefits Advisory Committee (PBAC) by the vaccine sponsor and is outside the scope of this handbook update.

3. Appendix A – Public Consultation Distribution List

An email was sent on 6 October 2021 to the following organisations and committees to provide advice on the public consultation:

- Australian Health Protection Principal Committee
- Communicable Diseases Network Australia
- National Immunisation Committee
- ATAGI
- National Tuberculosis Advisory Committee
- Pharmaceutical Benefits Advisory Committee
- Advisory Committee on Vaccines
- General Practice Roundtable
- Royal Australasian College of Physicians
- Primary Health Networks
- Consumers Health Forum of Australia
- Australian Association of Practice Managers