National Immunisation Advisory Committee
An Coiste Comhairleach Náisiúnta um Imdhíonadh

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Appendix: Selective BCG Vaccination Programme — operational issues for NIAC consideration

Advice provided to the Minister for Health

Issued: 23 February 2026

About the National Immunisation Advisory Committee

The National Immunisation Advisory Committee (NIAC) is Ireland's National Immunisation Technical Advisory Group (NITAG). NIAC provides independent evidence-based recommendations and advice to the Minister for Health on immunisation and related health matters to inform health policy in Ireland.

First established in 1998, NIAC has been hosted by HIQA as a statutory function under Section 8(1)(g) of the Health Act 2007 (as amended) since 31 March 2025.

NIAC membership is voluntary, and includes nominees from the Royal College of Physicians in Ireland, its Faculties and Institutes, the Royal College of Surgeons in Ireland, the Irish College of General Practitioners, the Nursing and Midwifery Board of Ireland, the Infectious Diseases Society of Ireland, the Travel Medicine Society, the National Virus Reference Laboratory, the HSE's National Health Protection Office (NHPO) as well as members with expertise in gerontology and inclusion health, and lay members. Meetings are attended by representatives from the Department of Health and the Health Service Executive (HSE) including the HSE's National Immunisation Office (NIO). Representatives of the Health Products Regulatory Authority (HPRA) attend to provide regulatory advice in relation to vaccines. Representatives of the HSE's Health Protection Surveillance Centre (HPSC) attend to provide and support the interpretation of epidemiological data.

The NIAC Secretariat team, situated within the Health Technology Assessment (HTA) Directorate in HIQA, provides clinical, evidence synthesis, and administrative support to NIAC.

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Acronyms used in this appendix

ATAGI	Australian Technical Advisory Group on Immunisation
BCG	Bacillus Calmette-Guérin (vaccine)
HBC	high burden country
HIV	human immunodeficiency virus
HTA	health technology assessment
IGRA	interferon-gamma release assay
NIAC	National Immunisation Advisory Committee
NTBAC	National Tuberculosis Advisory Committee
MDR	multidrug-resistant
RR	rifampicin-resistant
SCID	severe combined immunodeficiency
TB	tuberculosis
TBI	tuberculosis infection
TST	tuberculosis skin test
WHO	World Health Organization

1. Introduction

Bacillus Calmette-Guérin (BCG) vaccine was in use in Ireland since the 1950s but became unavailable for procurement in 2015, so by default a "no BCG vaccine" policy has been in place in Ireland since that date. In 2015, the Health Information and Quality Authority (HIQA) published a health technology assessment (HTA) of a selective BCG vaccination programme. HIQA advised that, based on recent patterns of declining tuberculosis (TB) incidence, Ireland met the International Union Against Tuberculosis and Lung Disease criteria for stopping or changing the BCG vaccination policy. Based on cost-effectiveness analysis, HIQA estimated that selective vaccination was more effective and less costly than universal vaccination. HIQA noted that selective vaccination would protect children most at risk of TB while avoiding adverse effects of the vaccine in children that were least likely to benefit from vaccination. Given all these factors, HIQA advised that it was appropriate to change to a programme of selective vaccination.[(1)] In 2020, the National TB Advisory Committee (NTBAC) recommended that universal vaccination of all newborn infants be discontinued but that recommendations for the use of a selective or a no vaccination policy should be requested from the National Immunisation Advisory Committee (NIAC). In 2022, NIAC reviewed available evidence and issued recommendations for a selective BCG vaccination programme in children under five years of age at increased risk of exposure to TB.[(2)] NIAC recommended BCG vaccine for the following groups:

1. Neonates born to parents (or with other regular close contacts) with untreated sputum smear-positive pulmonary or laryngeal TB, once the neonate has completed chemoprophylaxis and is [*]Mantoux negative.
2. Neonates born in households with contacts from countries with a high TB, TB/HIV, or multidrug-resistant (MDR) TB burden.
3. All unvaccinated tuberculin skin test (TST) or interferon-gamma release assay (IGRA) negative children aged under five years born in a country with a high TB, TB/HIV, or MDR TB burden or living with a person who was born in a high burden country.

Paediatric TB notifications and the age specific incidence rate in 0 to 14-year-olds increased from 0.8 per 100,000 in 2023 to 1.3 per 100,000 in 2024 with an increase in cases seen in those aged less than one year of age (five cases in

[*] Mantoux is another name for tuberculin skin test (TST)

2024, compared with two and three cases in 2023 and 2022, respectively). The HSE is planning to implement a selective BCG vaccination programme for eligible groups with the first phase being for infants under 12 months of age in 2026. The HSE also plans to implement enhanced severe combined immunodeficiency (SCID) screening as part of the National Newborn Bloodspot Screening Programme in 2026. In this context, NIAC was asked to review two questions relating to the operationalisation of the 2022 NIAC recommendations. The first query related to whether high burden or high incidence should be used as an indicator of TB exposure risk. The second related to which populations require screening for TB infection (TBI) prior to BCG vaccination.

2. Methods

In response to queries received by NIAC from NTBAC, a focused review was conducted of World Health Organization (WHO) guidance and guidelines from high-income countries where a form of selective BCG vaccination is in place. Additional relevant literature was identified through forward and backward citation from these guidelines. A summary of the findings of this review and expert opinion from NTBAC were presented to NIAC in November 2025. The evidence reviewed and Committee considerations are outlined below.

3. Queries from the National TB Advisory Committee

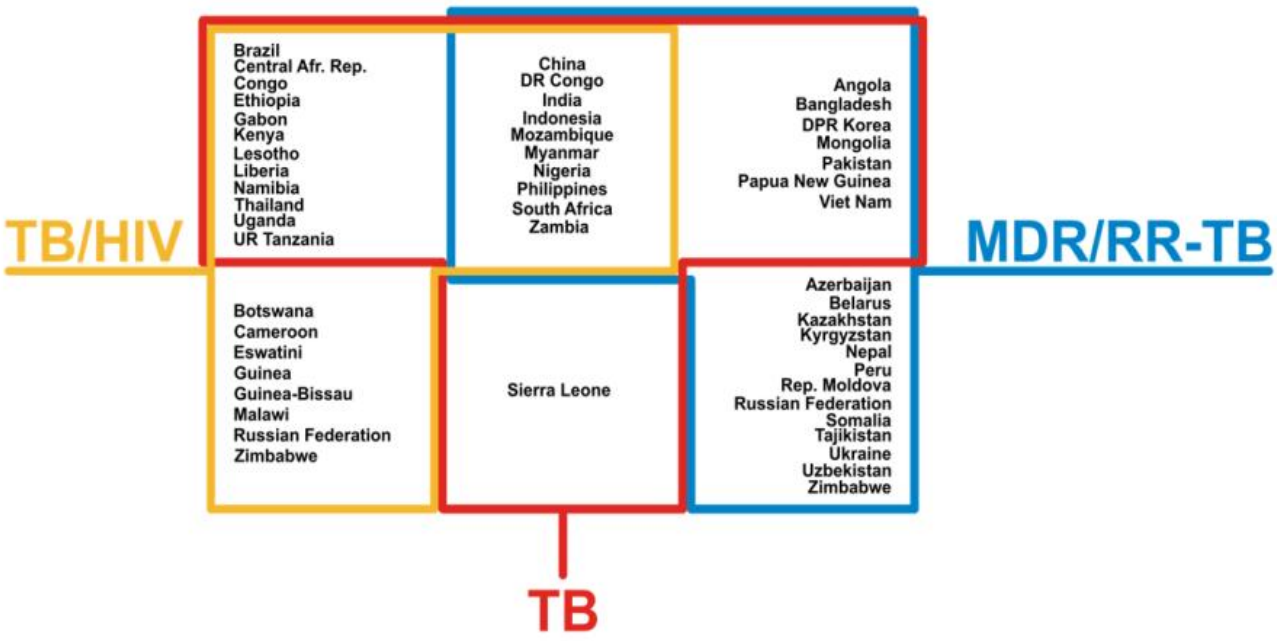
Question 1: Should countries with a high burden or high incidence of TB be used to identify populations at risk of exposure to TB?

TB Incidence and Burden

The WHO updates high-burden country (HBC) lists for TB, TB/HIV and MDR/rifampicin resistant (MDR/RR)-TB every five years. There are three lists, each containing 30 countries, with significant overlap between lists (Figure 1). These lists are determined using a 20+10 approach; each list includes the 20 countries with the highest TB burden plus 10 additional countries with the highest incidence who are not included in the top 20 high-burden countries globally.[3] Almost all countries included in high-burden lists have a TB incidence of 40 per 100,000 population per year or greater except for the Russian Federation and Belarus, which are included in the MDR/RR high-burden list, but whose overall reported incidence of TB in 2024 was 32 and 17 per 100,000 population, respectively.

Global lists of annual TB incidence per country are updated by WHO each year and are available via an online searchable tool.

Figure 1. The three global HBC lists for TB, TB/HIV and MDR/RR TB during the period 2021-2025 and their areas of overlap



Key: HIV – human immunodeficiency virus; MDR – multi-drug resistant; RR-TB – rifampicin-resistant tuberculosis; TB – tuberculosis.
Source: WHO.[3]

International Approach

The WHO uses incidence to determine recommendations for BCG vaccination, recommending a universal vaccination programme for newborns in countries or settings with a high incidence of TB (defined as incidence of greater than 40 per 100,000 population per year).[4] In the UK, high incidence (≥40 per 100,000) is used for risk identification for selective BCG vaccination. There is no selective BCG vaccination programme in Australia, but the Australian Technical Advisory Group for Immunisation (ATAGI) recommends BCG vaccination for children aged less than five years travelling to countries with high TB incidence (>40 per 100,000). Prior to updating recommendations in 2022, NIAC used the term "high endemicity" referring to countries with incidence rates of ≥40 per 100,000 to identify those at increased risk who were eligible for BCG vaccination.

Committee Considerations

NIAC considered that incidence constitutes a better approach to assessing risk, noting that the use of WHO high-burden lists would risk excluding infants whose families come from countries with small populations but high-incidence of TB where exposure risk could still be high. NIAC also noted that using incidence rather than burden as an indicator for exposure risk was in line with international approaches.

Question 2: Screening for Tuberculosis Infection Prior to BCG Vaccination

Background

In May 2022, adenosine deaminase deficiency SCID was added to the National Newborn Bloodspot Screening Programme. In January 2023, the Minister for Health approved the recommendation made by the National Screening Advisory Committee to implement T-cell receptor excision circles screening for SCID, which identifies a broader range of SCID subtypes. This enhanced SCID screening is planned to be implemented in 2026. The implementation of SCID screening in Ireland impacts the timing of BCG vaccination for infants born in Ireland as BCG is contraindicated in infants and children with SCID. In 2022, NIAC recommended BCG vaccination for:

1. Neonates born to parents (or with other regular close contacts) with untreated sputum smear-positive pulmonary or laryngeal TB, once the neonate has completed chemoprophylaxis and is Mantoux negative.
2. Neonates born in households with contacts from countries with a high TB, TB/HIV, or MDR TB burden.
3. All unvaccinated TST- or IGRA-negative children aged under five years born in a country with a high TB, TB/HIV, or MDR TB burden or living with a person who has been born in a high burden country.

The HSE Task and Finish Group, which is leading on implementing the selective BCG vaccine programme, has estimated that in order to allow sufficient time for the result of newborn SCID screening to be available to vaccinators, it is likely that many infants born in Ireland will be more than four weeks of age before BCG can be administered; that is, no longer a neonate. Thus, the question arose whether recommendation three above should be interpreted as a recommendation that all infants greater than four weeks of age who are eligible

for BCG vaccination require screening for TBI prior to vaccination. Screening for TBI can be performed using either a tuberculin skin test (TST) which requires two visits to a health care professional or a blood test called an interferon-gamma release assay (IGRA). Blood tests in infants in Ireland are not performed in primary care. Thus, screening for TBI in all BCG eligible infants born in Ireland would be challenging to operationalise and would present barriers to timely vaccination in the population where early vaccination would have the most benefit. In this context NIAC reviewed recommendations for TBI screening prior to BCG vaccination.

Benefits and Harms

Potential harms associated with BCG vaccination of infants and children with unrecognised TBI

An accelerated BCG reaction is early development of an induration or swelling (>0.5 cm in children or 1.0 cm in adults) at the injection site starting within 24-72 hours of vaccination. There is an association between accelerated BCG reaction and TBI. In a multivariate analysis among BCG naïve adult participants, latent TBI was the only factor associated with accelerated BCG reaction. Accelerated reaction was more common among those with a positive IGRA compared to those with a negative IGRA (OR 1.53 (95% CI: 1.04-2.24, p=0.03). Among those with an accelerated reaction, pain (64%), tenderness (74%) and swelling (100%) were more common than in those with a normal response. Regional lymphadenopathy was also more common, but occurred only in 4% of 755 vaccinees with an accelerated reaction.[5] Among young infants, the rate of accelerated reaction following BCG vaccine is not clearly defined in the available literature. In a small prospective study in the UK among infants who received BCG via the targeted programme, 21 out of 1,000 parents reported severe local deltoid reactions following vaccination.[6] Accelerated reactions may be more common in older infants. One study evaluating 532 infants in Taiwan reported skin reactions within one week in 80% of those aged five to eight months who received BCG vaccination; however, only four (0.7%) had ulcerative change.[7] In a meta-analysis of 14 studies (11 cross sectional and three case-control) in children, the sensitivity of accelerated BCG reactions for the diagnosis of active TB disease (confirmed or probable) ranged from 71-100%. This is higher than the TST sensitivity range (19-67%). Seven studies reported specificity. The combined specificity was 90% (95% CI: 85-94).[8]

International Recommendations

In the UK, there is a targeted BCG vaccination programme for at-risk infants. The Joint Committee on Vaccination and Immunisation recommends that a TST is necessary prior to BCG vaccination for: all individuals aged six years or over; infants and children under six years of age with a history of residence or prolonged stay (more than three months) in a country with an annual TB incidence of >40 per 100,000; those who have had close contact with a person with known TB; and those who have a family history of TB within the last five years.[9] In Australia, there is no infant programme, but BCG vaccination is recommended for infants and children travelling to countries with a high TB incidence. In this context, ATAGI recommends that the need for TST prior to BCG should be determined by an individual risk assessment that considers whether the person was born in a tuberculosis-endemic country (>40 cases per 100,000 population per year), has lived or travelled to a tuberculosis-endemic country or region (>40 cases per 100,000 population per year) or had exposure to a close contact with tuberculosis or who is under investigation for tuberculosis.[10] In Canada, where BCG is indicated, the National Advisory Committee on Immunisation recommends that all infants aged greater than six months of age should have a TST prior to BCG vaccination. For those infants less than two months of age, it is recommended to give BCG vaccine without prior TST because the risk of prior TB exposure is low and the sensitivity of the TST at detecting latent TBI is unknown. For those aged between two and six months, an individual risk/benefit assessment which considers the risk of prior TB exposure and potential loss to follow-up is recommended.[11]

Committee Considerations

NIAC emphasised that the benefits of BCG are greatest for the conditions that disproportionately affect young children, namely TB meningitis and miliary TB. Delays in administering BCG vaccine to screen for TBI may reduce the benefit of the intervention. Screening for TBI would lead to delays regardless of whether IGRA or TST are used. Administering a BCG vaccine to a child with TBI is not considered dangerous as accelerated BCG reactions are generally not protracted or severe. However, an accelerated reaction in infants is a sensitive test for the diagnosis of active TB disease. Committee members highlighted that it would be important in operationalising the BCG programme that there is awareness of the referral pathways in place for clinical assessment of infants with suspected TBI. NIAC discussed whether infants born in Ireland who are living in congregate

International Protection Accommodation Service settings should all be screened for TBI prior to BCG. It was considered that the benefit of timely vaccination in these infants at highest risk of exposure to TB would outweigh the potential risk of an accelerated BCG reaction. NIAC discussed whether an age cut-off should be used to determine automatic screening for TBI prior to BCG. Noting that there was not a strong evidence base for an age cut-off, the Committee considered there might be some benefit to aligning recommendations with the UK. NIAC agreed to recommend TBI screening with TST or IGRA prior to BCG for the following groups:

- All children and adults aged six years or older.
- Infants and children aged less than six years who were born in a country with an annual TB incidence of 40 per 100,000 or greater, or with a history of residence or prolonged stay (more than three months) in a country with an annual TB incidence of 40 per 100,000 or greater.
- Those born in Ireland or outside of Ireland who have had close contact with a person with known TB or who is under investigation for TB.

4. Acknowledgements

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5. References

1. Health Information and Quality Authority. HTA of BCG Vaccination Programme: 2015 [cited 2026 January]. Available from: https://www.hiqa.ie/reports-and-publications/health-technology-assessment/hta-bcg-vaccination-programme.
2. National Immunisation Advisory Committee. Selective Strategy for BCG Vaccination 2022 [cited 2026 Jan]. Available from: https://www.hiqa.ie/sites/default/files/NIAC/Recommendations_and_Advice/2022/20221010_NIAC_Recommendations_re._Selective_strategy_for_BCG.pdf.
3. World Health Organization. WHO global lists of high burden countries for tuberculosis (TB), TB/HIV and multidrug/rifampicin-resistant TB (MDR/RR-TB) 2021-2025: background document 2021 [cited 2026 January]. Available from: https://iris.who.int/handle/10665/341980.
4. World Health Organization. BCG Vaccines: WHO Position Paper-February 2018: 2018 [cited 2026 Jan]. Available from: https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/position-papers/bcg.
5. Villanueva P, Crawford NW, Croda MG, Croda J, Dalcolmo M, Jardim BA, et al. Accelerated Bacille Calmette-Guérin reactions: More than meets the eye. Heliyon. 2024;10(13):e32510.
6. Holliday T, Seddon J, Whittaker E. G157(P) Adverse events in infants following bcg vaccination: preliminary results. Archives of Disease in Childhood. 2019;104(Suppl 2):A64-A.
7. Huang CY, Chi H, Chang L, Chiu NC. Typical time courses and appearance of skin reactions at the site of Bacillus Calmette-Guérin vaccination for infants inoculated at 5-8 months of age. Vaccine. 2023;41(8):1529-35.
8. Villanueva P, Pittet LF, Nourse C, Curtis N. What is the significance of an accelerated BCG reaction in children? Arch Dis Child. 2022;107(5):507-12.
9. UK Health Security Agency. Tuberculosis, the greenbook chapter 32 [cited 2026 Jan]. Available from: https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32.
10. Australian Technical Advisory Group on Immunisation. Australian Immunisation Handbook: Tuberculosis [cited 2026 Jan]. Available from: https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/tuberculosis.

11. Public Health Agency of Canada. Bacille Calmette-Guérin (BCG) vaccine: Canadian Immunization Guide: [cited 2026 Jan]. Available from: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-2-bacille-calmette-guerin-vaccine.html.