



Scottish Vaccine Update

Health Protection Scotland

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Special edition

Update on BCG vaccine supply

UNICEF have issued an update (available [here](#)) on the global BCG vaccine market noting that global supply is no longer constrained and is considered sufficient to meet country requirements.

Since 2015, stock of the only UK-licensed BCG vaccine has been interrupted. In response, Health Protection Scotland (HPS) issued advice (available [here](#)) on prioritisation of BCG vaccine stock for neonates and infants of recognized high-risk groups for tuberculosis (TB) or to tuberculin negative children under 6 years of age (groups A-C in Annex A). Ordering restrictions were introduced to manage this.

In 2016 Public Health England (PHE) on behalf of the UK secured an interim supply of BCG vaccine, from Intervax Ltd of Canada. Intervax BCG vaccine is a WHO prequalified vaccine and has been used extensively across the globe, but is unlicensed in the UK. PHE developed materials (Annex B) to support healthcare professionals delivering the BCG programme using Intervax BCG vaccine.

There is currently sufficient stock of Intervax BCG vaccine to extend the offer of vaccination to all eligible groups (Annex A).

Note – BCG vaccine availability will be monitored closely as future supply remains uncertain. We will continue to keep you up to date with the latest developments. Once a supply of UK-licensed BCG vaccine becomes available we will update NHS Scotland.

Ensuring all eligible groups can access BCG vaccine

NHS boards are asked to implement the following actions:

- to develop and implement plans that will enable all eligible groups to access BCG vaccine.
- in the first instance, ensure that the delivery of the neonatal programme is optimised to improve access for all eligible neonates, for example by immunising babies in maternity units prior to discharge. This may lead to an increase in wastage of doses in some areas.

- areas should then focus on offering BCG vaccine to children in the next highest priority group, C (previously unvaccinated children aged 1 to 5 years living in areas of the UK where the annual incidence of TB is 40/100,000 or greater; or with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater). This entails delivering a catch-up programme for eligible children who missed the vaccine during the period of constrained supply.
- please signpost any new providers using InterVax BCG vaccine for the first time to all the guidance and training resources [here](#).

Occupational Health

Use of BCG for occupational health purposes remains the lowest priority, however those at especially high risk of occupational exposure may require special consideration and should be assessed on an individual basis.

PHE are in the process of updating the InterVax BCG vaccine information and training materials so that they come in line with the advice contained in this special edition of Scottish Vaccine Update.

Annex A. Priority Groups for BCG Vaccine

Highest priority

- A. All infants (aged 0 to 12 months) with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater¹.
- B. All infants (aged 0 to 12 months) living in areas of the UK where the annual incidence of TB is 40/100,000 or greater².
- C. Previously unvaccinated children aged one to five years:
 - living in areas of the UK where the annual incidence of TB is 40/100,000 or greater; or
 - with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater. These children should be identified at suitable opportunities, and can normally be vaccinated without tuberculin testing.

1 For country information on prevalence see: www.who.int/tb/country/data/profiles/en/and www.gov.uk/government/publications/tuberculosis-tb-by-country-rates-per-100000-people.

2 Universal vaccination operates in areas of the country where the TB incidence is 40/100,000 or greater. This is applied for operational reasons since these geographical areas generally have a high concentration of families who come from regions of the world where the TB incidence is 40/100,000 or greater. The decision to introduce universal vaccination in an area is based on geography in order to target vaccination to children who may be at increased risk of TB in an effective way. It does not imply that living in areas that have an incidence of TB 40/100,000 or greater puts children at increased risk of TB infection. This is because most infections of children are likely to occur in household settings. Further, there has been little evidence of TB transmission in schools in the UK and little evidence of sustained transmission.

Moderate priority

- D. Previously unvaccinated, tuberculin-negative children aged from six to under 16 years of age with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater. These children should be identified at suitable opportunities, tuberculin tested and vaccinated if negative as per the Green Book section on tuberculin testing prior to BCG vaccination³.
- E. Previously unvaccinated tuberculin-negative individuals under 16 years of age who are contacts of cases of respiratory TB (following NICE recommended contact management advice)⁴.
- F. Previously unvaccinated, tuberculin-negative individuals under 16 years of age who were born in or who have lived for a prolonged period (at least three months) in a country with an annual TB incidence of 40/100,000 or greater.
- G. Previously unvaccinated, tuberculin-negative individuals under 16 years of age who are going to live or work with local people for more than three months in a country where the annual incidence of TB is 40/100,000 or greater.

Lowest priority

- H. Individuals at occupational risk.

Annex B.

Information materials for health professionals

- Healthcare professional factsheet and training slides available [here](#)
- Unlicensed BCG vaccine: advice for healthcare professionals available [here](#)
- InterVax EU Batch Release Certificate and Certificate of Analysis available [here](#)

Information materials for patients and parents

- Unlicensed BCG vaccine: guide for parents and carers available [here](#)
- Tuberculosis: the disease, its treatment and prevention available [here](#)
- TB, BCG and your baby leaflet available [here](#)

3 Green Book chapter on immunisation against TB: www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32.

4 NICE 2016. Tuberculosis NICE Guideline (NG33): www.nice.org.uk/guidance/ng33 and www.nice.org.uk/guidance/ng33/resources/tuberculosis-1837390683589.

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