



BCG vaccine supply and ordering

Update on BCG vaccine supply

UNICEF have issued an update (see [web link 1](#)) 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, PHE issued advice (see [web link 2](#)) 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 on ImmForm to manage this.

In 2016 PHE 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.

PHE has concluded that 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 PHE will write to commissioners and providers.

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Ensuring all eligible groups can access BCG vaccine

NHS England commissioners and Screening and Immunisation Teams (SITs) are asked to implement the following actions:

- work with partners from the local health economy 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. Commissioners are asked to contact the vaccine supply team – vaccinesupply@phe.gov.uk – to discuss options if they anticipate large volumes of vaccine wastage due to changes in service delivery.
- 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.
- provide the vaccine supply team – vaccinesupply@phe.gov.uk with details of any additional providers that need to be given access to ordering via ImmForm.
- please signpost any new providers using InterVax BCG vaccine for the first time to all the guidance and training resources at [web link 3](#).

Occupational Health

Occupational health providers are now able to order InterVax BCG vaccine through ImmForm. There is currently a restriction of 2 packs per fortnight for these accounts and this restriction will remain under review.

We 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 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.

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.

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.

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

Annex B.

Information materials for health professionals

Healthcare professional factsheet and training slides:
www.gov.uk/government/publications/intervax-bcg-vaccine-training-slideset-for-healthcare-professionals

Unlicensed BCG vaccine: advice for healthcare professionals:
www.gov.uk/government/publications/unlicensed-bcg-vaccine-advice-for-healthcare-professionals

Special edition of Vaccine Update which includes priority groups for InterVax BCG:
www.gov.uk/government/publications/vaccine-update-issue-247-june-2016-special-edition

InterVax EU Batch Release Certificate and Certificate of Analysis:
www.gov.uk/government/publications/intervax-bcg-vaccine-certificates

Information materials for patients and parents

Unlicensed BCG vaccine: guide for parents and carers:
www.gov.uk/government/publications/unlicensed-bcg-vaccine-guide-for-parents-and-carers

Tuberculosis: the disease, its treatment and prevention:
www.gov.uk/government/publications/tuberculosis-the-disease-its-treatment-and-prevention--2

TB, BCG and your baby leaflet:
www.gov.uk/government/publications/tb-bcg-and-your-baby-leaflet

Web links

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| web link 1 | https://www.unicef.org/supply/index_70361.html |
| web link 2 | https://www.gov.uk/government/publications/vaccine-update-issue-244-april-2016-bcg-supply-special-edition |
| web link 3 | https://www.gov.uk/government/collections/immunisation#tuberculosis |