For Information: Paediatricians, Neonatologists and Heads of Midwifery

13 February 2017

Dear colleague,

Re: BCG vaccine shortage

There has been a global shortage of BCG vaccine. In addition, the PHE contracted supplier of the only UK licensed BCG vaccine, Statens Serum Institut (SSI) in Denmark, has experienced manufacturing issues that have severely affected vaccine availability for the national immunisation programme. This vaccine is currently unavailable and future supplies are not currently guaranteed.

Use of unlicensed BCG vaccine

To enable the neonatal BCG immunisation programme to continue, PHE has successfully secured an interim supply of BCG vaccine, from InterVax Ltd of Canada (manufactured in Bulgaria). This vaccine has been a WHO prequalified vaccine for 25 years and has been used extensively across the globe. The vaccine is, however, not licensed in the UK and is presented in multi-dose glass ampoules rather than vials.

Who should receive BCG vaccine?

During this period of constrained vaccine supply, PHE has issued advice on the prioritisation and use of BCG vaccination in the UK (Annex A). The most effective use of BCG vaccine is to give it as soon as possible after birth to prevent at-risk infants from developing severe disease, such as miliary tuberculosis (TB) and TB meningitis. The risk of serious TB decreases with age and BCG vaccination offers less protection in older children and adolescents. Therefore, routinely vaccinating older children is not recommended by the World Health Organization.

What about children who have missed BCG vaccine?

Local NHS England teams are putting plans in place to maximise the use of available vaccine and, where possible, catch up children who are still likely to benefit from vaccination. For more information on local programme delivery and catch-up plans, please contact your NHS England Screening and Immunisation Team. Parents should be reassured that the overall risk of TB in unvaccinated children in the UK is very low, and that the main way to stop TB from spreading is to make sure that people with active TB are diagnosed early and treated correctly.
Information materials

PHE has developed a suite of materials (Annex B) to support healthcare professionals delivering the BCG programme. Given the diversity of BCG vaccine provision across both acute and community settings, we are aware that the routine national communication channels may not reach all providers. PHE works closely with NHS England Screening and Immunisation Teams (SITs) to ensure local providers of BCG immunisation services are kept up-to-date with developments.

Yours sincerely,

[Signature]

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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 greater\(^1\).
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 greater\(^2\).
C. Previously unvaccinated children aged one to five years 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 vaccination\(^3\).
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, available at web link 5).
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.

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\(^1\) For country information on prevalence see: [http://www.who.int/tb/country/data/profiles/en/](http://www.who.int/tb/country/data/profiles/en/)
\(^2\) 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.
Annex B.

**Information materials for health professionals:**

Healthcare professional factsheet and training slides:

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

Special edition of Vaccine Update which includes priority groups for InterVax BCG

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

Template letter to communicate with parents whose babies missed BCG immunisation

**Information materials for patients and parents**

Unlicensed BCG vaccine: guide for parents and carers:

Tuberculosis: the disease, its treatment and prevention