

Scottish Vaccine Update

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Pertussis vaccination now recommended for pregnant women from 16 weeks gestation

The Scottish Government has recently advised, in CMO(2016)08 letter, available [here](#), that vaccination of pregnant women against pertussis can now take place from week 16 of pregnancy onwards. The Green Book chapter on pertussis has been updated (available [here](#)).

This is a result of advice from the Joint Committee on Vaccination and Immunisation (JCVI), in February 2016, that maternal pertussis vaccination can take place from week 16 of pregnancy. The JCVI minutes are available [here](#). It follows the publication of a study (available [here](#)) which shows vaccination earlier in pregnancy would be likely to improve neonatal antibody levels and would increase opportunities during pregnancy for vaccination. The change in advice also provides additional benefit where delivery may be premature.

Vaccination should be offered from gestational week 16 to maximise the likelihood that the baby will be protected from birth. Women may still be immunised after week 32 of pregnancy but this may not offer as high a level of passive protection to the baby. Vaccination late in pregnancy may, however, directly protect the mother against disease and thereby just reduce the risk of exposure to her infant.

For women who have not received the vaccine in pregnancy, pertussis-containing vaccine can be offered in the two months following birth i.e. up until their child receives their first dose of pertussis-containing vaccine.

Training resources for registered health practitioners produced by NES will be updated and will be available [here](#)

Information for the public, including leaflets and posters are also being updated and will be available [here](#) on the Immunisation Scotland website.

Reassuring parents on administering multiple vaccines to infants in one session

Some parents have expressed concerns about the number of injections administered in one session, particularly at 12 months of age when four injections are given in one visit. Studies have demonstrated that there are no harmful effects from administering multiple vaccines in one session. Parents can also be reassured that offering multiple vaccines in this way is a routine occurrence around the world with no harmful effects being identified. Equally, there is no evidence to support arguments of “overloading” the immune system.

From the moment a child is born, they are exposed to a huge number of bacteria and viruses on a daily basis which the immune system is able to cope with and, as a result, become stronger. Immunisation helps to improve our protection against harmful diseases at the very earliest opportunity.

Parents should not be encouraged to have these vaccines separately because delaying immunisation inevitably delays protection. The immunisation schedule has been designed to

ensure optimal protection against diseases that are most common in the very young such as whooping cough, pneumococcal, Hib and meningococcal disease.

These diseases can be life-threatening and it is important for children to receive protection at the earliest possible opportunity. It is important to make parents aware that a delay in protection caused by separate immunisations could increase the risk of disease.

BCG vaccine availability

Due to on-going manufacturing delays at the Statens Serum Institut (SSI) in Denmark, ordering for BCG vaccine is temporarily suspended across the UK. A small stockpile has been retained for distribution across the UK for use in urgent circumstances.

Where stocks are available locally, please see below for advice on prioritisation for using this stock and information on the expiry date of the most recently supplied batch.

Work continues to secure a suitable replacement BCG vaccine as soon as possible; however it is unlikely that any alternative will be available until later in 2016. Updates will be published through Scottish Vaccine Update.

BCG prioritisation

During this period of constrained BCG vaccine supply, Health Protection Scotland (HPS) endorses the World Health Organisation's statement ([here](#)) and the updated guidance below provides advice on prioritisation of remaining BCG vaccine to neonates and infants of recognised high-risk groups for tuberculosis (TB) or to tuberculin-negative children under 6 years of age (groups A-C below). Immunisers are therefore asked to be responsible in utilising remaining stocks for these groups first. Older children (aged 6 to under 16 years of age) who are eligible for the vaccine (groups D-G below), are a lower priority.

BCG vaccination for occupational health reasons (group H below) remains lowest priority during this period of constrained BCG vaccine supply. However, those at especially high risk of occupational exposure may require special consideration. Occupational health departments and infection control teams are advised to reinforce their local TB infection control precautions to all staff. Where a health care worker or student is found to be tuberculin negative and is eligible for BCG, vaccination is not required before that individual is cleared to work. Vaccination can then be undertaken when further stock becomes available, expected later this year.

Groups eligible for vaccination

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 1 to 5 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 (please see Green Book section on tuberculin testing prior to BCG vaccination, available [here](#))

- E. Previously unvaccinated tuberculin-negative individuals under 16 years of age who are contacts of cases of respiratory TB (following recommended contact management advice, available [here](#)).
- 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.

In addition HPS recommends a case by case opportunistic approach for infants that were eligible but missed vaccination previously.

1. For country information on TB see <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.

BCG vaccine availability and use of batch 114022A beyond expiry (29/02/2016)

The BCG vaccine manufactured by the SSI that was recently distributed (batch 114022A) has an expiry of 29 February 2016. As further BCG vaccine supply from SSI is delayed the MHRA has agreed that it is acceptable to use batch 114022A for up to six months past its current expiry date, based on the known stability of the SSI BCG vaccine and on review of additional information provided by the manufacturer.

SSI BCG vaccine from batch 114022A should therefore be retained and can be used past the labelled expiry date, outside of the marketing authorisation, until 31 August 2016. Batch 114022A of SSI BCG vaccine will not be re-labelled and a joint Scottish Government and HPS letter explaining the extension is being sent out with deliveries and should be kept with the BCG vaccine. The letter is available [here](#).

The administration of SSI BCG vaccine batch 114022A between 29 February 2016 and 31 August 2016 will be outside of the marketing authorisation (off-label) but there is no licensed alternative in the UK. MHRA have advised that a medicine which is for use outside its licensed indications can be included in a PGD. This use should be formally noted by the organisation but there is no requirement to amend existing PGDs for administration of the product.

As there is a global shortage of BCG, this batch may represent the only suitable UK supply for some months, and therefore BCG vaccine from Batch 114022A must not be discarded.

BCG administration and reducing wastage

Immunisers are encouraged to organise the administration of BCG vaccinations in ways that optimise the use of the current multi-dose vials, for example by scheduling patients requiring BCG into the same clinic.

The number of doses extracted from a reconstituted vial in practice varies, depending on the specific type of syringe and needle used, as well as on the surplus of vaccine removed during vaccination. Adherence to guidelines on the administration of BCG vaccine, including syringe and needle type, can maximise the number of doses obtained from each vial. Guidance on administration of the BCG vaccine can be found [here](#) and [here](#).

Green Book Updates

The Green Book is available [here](#).

Chapter 24 pertussis updated to recommend that immunisation of pregnant women can now take place from week 16 of pregnancy onwards. The updated chapter is available [here](#).

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Scottish Vaccine Update information on vaccine supplies is based upon information obtained from Public Health England Vaccine Update issue 242 and 244