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July 2021

Changing the timing of the neonatal BCG immunisation programme to a 28-day immunisation programme

Dear Colleague,

This letter provides information on the forthcoming changes to the NHS neonatal Bacillus Calmette-Guérin (BCG) immunisation programme.

The BCG immunisation programme was introduced in the UK in 1953 and has undergone several changes in response to changing trends in tuberculosis (TB) epidemiology. The BCG vaccine is a live attenuated vaccine and is not given as part of the routine vaccination schedule but only when a child is at increased risk of coming into contact with TB. Eligible babies include all newborns whose parent/s or grandparent/s was born in a country where the annual incidence of TB is 40/100,000 or greater; and/or newborn babies living in areas of the UK where the annual incidence of TB is 40/100,000 or greater.

The BCG vaccine has been offered to babies that fall into one of the above categories soon after birth, often while the baby is still in hospital. The forthcoming evaluation of the addition of screening for Severe Combined Immunodeficiency (SCID) to the routine newborn screening test at five days of age makes it necessary to move the BCG vaccination to when a SCID screening outcome will be available, which will be by 28 days of age. This is to ensure that babies with SCID are not given the live attenuated BCG vaccine which is contraindicated in these babies.

The SCID screening evaluation is taking place in six areas across England and will cover about 60% of newborn babies (Manchester, Birmingham, Sheffield, Newcastle, London Great Ormond Street Hospital and London Southeast Thames). It is necessary to change the BCG programme nationally to ensure consistency and safety for all babies across the country and to guarantee data collection for the programme. This also provides an important opportunity to improve upon the existing BCG service.

The Joint Committee on Vaccination and Immunisation (JCVI) advised in the October 2018 meeting,¹ that the BCG vaccination is moved “from birth to after SCID screening results were available, as vaccination before testing would not be acceptable”. In February 2020², the JCVI noted that moving the timing of the BCG vaccination would not significantly impact on TB cases in England, and the benefits from SCID screening would outweigh any increase in TB disease.

This letter is aimed at health professionals who will be responsible for implementing the changes to the BCG schedule. We encourage you to share this guidance with all

¹ Minutes of the JCVI main committee meeting held on 03 October 2018:
<https://app.box.com/s/iddfb4ppwkmjtjusir2tc/file/349905639306>

² Minutes of the JCVI main committee meeting held on 04 and 05 February 2020:
<https://app.box.com/s/iddfb4ppwkmjtjusir2tc/file/636396626894>

those who will be involved in helping to deliver the national childhood immunisation schedule in your area.

Key points about the changes to the programme

- From 01 September 2021, eligible babies born on or after this date should be offered the BCG vaccine at 28 days or soon after.
- Providers are required to check the record for a negative SCID result, or confirmation that the child was not offered SCID screening, before administering the BCG vaccine. BCG immunisation appointment letters should include instructions for parents to bring the Red Book and the letter with the outcome of newborn bloodspot screening.
- Vaccination may be administered earlier than 28 days provided that a SCID result is available
- The vaccine will continue to be available to order through the [ImmForm website³](#). See Annex A for how to register for an ImmForm account.
- In the designated six areas SCID will form part of the routine newborn screening test at five days, with most results expected within 10-12 days. Those eligible babies that have participated in the SCID screening evaluation should have received their results of the screening test by 28 days when the BCG vaccine is scheduled.
- All live vaccines are contraindicated in babies with a SCID diagnosis. SCID screening status will need to be checked before the offer of the rotavirus vaccine (Rotarix) at the 8 week vaccination appointment. Further guidance for health professionals will be issued in a specific communication about the rotavirus programme.
- BCG vaccine contains a live attenuated strain of bacterium, derived from *Mycobacterium bovis*. BCG Vaccine AJV (AJ Vaccines) is the only licensed vaccine in the UK.
- The parents of any baby that has received a result suggesting SCID may be present will be contacted by a specialist immunology team and an appointment arranged within 24 working hours of this contact. This team will recommend further diagnostic tests to confirm whether the baby has a problem with their immune system or not. Following diagnostic tests and where these are negative, a letter confirming the outcome of the investigations will be issued to parents and copied to GP and Health Visitor. This letter also confirms that vaccinations can now be given as usual including BCG and rotavirus vaccine.
- There is no change to funding arrangements for the vaccine programme: the NHS neonatal BCG immunisation programme will continue to be funded through the CCG Maternity Tariff.

Additional information

³ ImmForm website: <https://portal.immform.phe.gov.uk/>

- All relevant immunisation information for parents and care givers, including the immunisations up to 13 months leaflet, will be updated and available on the [PHE Immunisation webpage](#)⁴ and available to order from the [Health Publications website](#).⁵
- Further detailed healthcare professional information and guidance, including training slides, will be available in the [Tuberculosis section of the PHE Immunisation webpage](#)⁶ from August 2021.
- The revised [Tuberculosis chapter of the Green Book](#)⁷ (Immunisation against infectious disease) will be published in August 2021.
- An updated [patient group direction \(PGD\) template](#)⁸ for the administration of BCG, will be available for NHS England and NHS Improvement areas to adopt and authorise for their commissioned services ahead of the change in delivery of the programme to those eligible babies.
- An updated schedule 2 document for the neonatal BCG immunisation programme including patient pathway.
- A summary of key issues relating to the changes in the schedule is set out in **Annex A**.
- Details of how the COVER programme (the routine quarterly and annual childhood vaccine coverage data collection) will be modified to capture data on uptake of the BCG programme are set out in **Annex B**.
- **Annex C** contains links to updated pathways for BCG vaccination data flows and patient care.

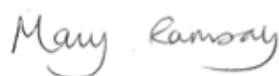
If you have any queries about the content of this letter please contact immunisation@phe.gov.uk

We would like to take this opportunity to thank all involved for their continuing hard work in delivering childhood immunisation programmes.

Yours faithfully



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⁴ PHE Immunisation website: <https://www.gov.uk/government/collections/immunisation>

⁵ Health Publications website: <https://www.healthpublications.gov.uk/Home.html>

⁶ Tuberculosis section of the PHE Immunisation webpage: <https://www.gov.uk/government/collections/immunisation#tuberculosis>

⁷ Tuberculosis chapter of the Green Book, chapter 32: <https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32>

⁸ BCG vaccine PGD template: <https://www.gov.uk/government/publications/bcg-patient-group-direction-pgd-template>

Annex A - summary of key issues relating to the changes in the BCG schedule

- This guidance is based on advice from the Joint Committee on Vaccination and Immunisation (JCVI)^{1,2}, the UK's independent advisory committee of immunisation experts. Full information will be available in the updated Tuberculosis chapter of the Green Book (Immunisation against infectious disease): [Tuberculosis: the green book, chapter 32 - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32)

Timing

- The BCG vaccine will continue to be offered to all eligible babies. Those born on or after 1 September 2021 will follow the new schedule. The vaccine should be given to eligible babies at 28 days or soon after. This may be at an earlier opportunity providing a SCID screening outcome result is available.

Vaccine supply

- The BCG vaccine will continue to be available to order through the [ImmForm website](#)³. Please ensure you have an ImmForm account to enable access. See the [ImmForm helpsheet](#)⁹ for information on registering for an ImmForm account.

Patient Group Directions

- An updated [PGD template](#)⁸ from Public Health England for the administration of the BCG will be available for NHS England and NHS Improvement areas to adopt and authorise for their commissioned services ahead of the requirement to administer BCG at 28 days.

Child Health Information Services (CHIS)

- NHS England and NHS Improvement has met with NHSX to coordinate the changes to data requirements to the CHIS system to support the new BCG pathway. Neonatal BCG eligibility data will be recorded on CHIS, which will provide a cohort denominator for the first time. BCG vaccinations given will also be recorded on CHIS as for other childhood vaccinations. This will support the collection of COVER data providing a more robust national data set and contribute to improvements in the programme overall.

⁹ ImmForm helpsheet: [How to register: ImmForm helpsheet - GOV.UK \(www.gov.uk\)](#)

SNOMED codes

- The recommended SNOMED codes for recording receipt of BCG in electronic patient records (CHIS/GP) are available at: <https://termbrowser.nhs.uk/>
- NHS England and NHS Improvement is responsible for the commissioning of CHIS and the NHS neonatal BCG immunisation programme. Parents and caregivers of eligible babies born on or after 1 September 2021 will be offered a vaccination appointment by a healthcare professional.
- Neonatal BCG providers will inform CHIS and the baby's GP following vaccination. General Practice must update their clinical records as appropriate. See **Annex C** for BCG vaccination data flows and patient care pathway information.

Funding and service arrangements

- NHS neonatal BCG immunisation programme is currently funded through the CCG Maternity Tariff. Funding arrangements will not change.
- A suite of updated neonatal BCG immunisation programme schedule 2/4/6 documents have been produced and have been used by regional commissioners when planning the revised service.

Information for parents, caregivers and health professionals

- The following immunisation leaflets for parents and caregivers have been revised to support the change to the programme. These are available to order from the [Health Publications website](#)⁵.

TB, BCG and your baby leaflet:

<https://www.gov.uk/government/publications/tb-bcg-and-your-baby-leaflet>

A guide to immunisation for babies during their first year of life:

<https://www.gov.uk/government/publications/a-guide-to-immunisations-for-babies-up-to-13-months-of-age>

- The BCG vaccine information for parents on the NHS website will be updated from August 2021: [BCG tuberculosis \(TB\) vaccine overview - NHS \(www.nhs.uk\)](#)
- Training slides detailing the schedule change will be available from August 2021 from the [Tuberculosis section of the PHE Immunisation webpage](#).

- A document entitled 'Changes to the NHS neonatal BCG vaccine schedule: Information for healthcare practitioners' which provides further information in relation to programme eligibility, scheduling and vaccine administration will be available from August 2021 from the [Tuberculosis section of the PHE Immunisation webpage](#).
- For advice on at risk groups, incomplete vaccination and those vaccinated abroad, please see the [Green Book](#) chapter and the Information for healthcare practitioners.

Annex B - COVER programme vaccine coverage data collection

The Coverage of Vaccine Evaluated Rapidly (COVER) programme is responsible for the data collection in England of Local Authority (LA) and GP level immunisation coverage data from Child Health Information Systems (CHISs) for children aged one, two and five years of age.

Collection of coverage of BCG vaccine evaluated at 12 months has been attempted at a national level, but the data on the eligible population (i.e. denominator) has been inadequate in the past. The information to enable this will be available going forward from 1 September 2021.

A new Information Standard for COVER will be submitted to the Data Standards Assurance Service (DSAS) for appraisal and then submitted to the Data Alliance Partnership Board (DAPB) for approval. There will be at least 6 months between the publication of a revised Information Standard and the first data submissions using the new standard.

In order to allow timely monitoring of BCG programme delivery, the new Information Standard will require BCG vaccine coverage to be evaluated in babies at 3 months of age in addition to the current evaluation at 12 months.

Specifications for the revised collection of vaccine coverage data through COVER will be available on the NHS Digital COVER Information Standard page:

<https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0089-cover-of-vaccination-evaluated-rapidly-cover>.

Annex C – BCG vaccination data flows and patient care pathways

Updated pathways for BCG vaccination data flows and patient care have been produced to support the change to the programme. These can be accessed from the Tuberculosis section of the PHE immunisation webpage:

<https://www.gov.uk/government/collections/immunisation#tuberculosis>