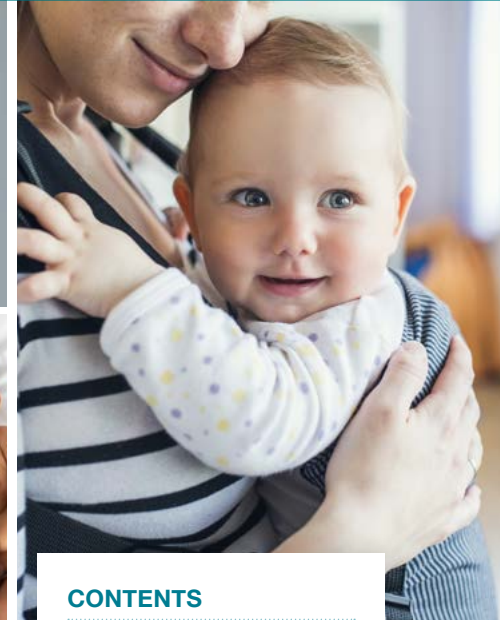




SCID and TB

a BCG Vaccine Update Special



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 per 100,000 or greater; and/or newborn babies living in areas of the UK where the annual incidence of TB is 40 per 100,000 or greater.

The BCG vaccine has been offered to babies that fall into one of the above categories soon after birth, often whilst the baby is still in hospital. The evaluation of the addition of screening for Severe Combined Immunodeficiency (SCID) to the routine newborn screening test at 5 days of age made it necessary to move the BCG vaccination to when a SCID screening outcome will be available, which may be available from around day 14 to 17 after birth. This is to ensure that babies with SCID are not given the live attenuated BCG vaccine which is contraindicated in these babies.

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The SCID screening evaluation is taking place in 6 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 meeting¹, that the BCG vaccination is moved 'from birth to after SCID screening outcome 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.

Main points about the changes to the programme

- from 1 September 2021, eligible babies born on or after this date should be offered the BCG vaccine by 28 days or soon after. It is possible to arrange BCG vaccination earlier than 28 days providing the appropriate SCID screen outcome is available
- providers are required to check the record for a negative SCID outcome, or confirmation that the child was not offered SCID screening, before administering the BCG vaccine. BCG immunisation appointment letters should include instructions for parents/guardians to bring the infant's Red Book and the letter with the outcome of newborn bloodspot screening
- vaccination may be administered earlier than 28 days provided that a SCID screen outcome is available
- the vaccine will continue to be available to order through the ImmForm website³
- in the designated 6 areas SCID will form part of the routine newborn screening test at 5 days, with most results expected within 10 to 12 days. Those eligible babies that have participated in the SCID screening evaluation should have received their outcome 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. See page 5 to 6 for details
- 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/guardians of any baby that has received an outcome suggesting SCID may be present will be contacted by a specialist immunology team and an appointment arranged within 1 working day 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/guardians 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

¹ Minutes of the JCVI main committee meeting held on 3 October 2018.

² Minutes of the JCVI main committee meeting held on 4 and 5 February 2020.

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

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

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 by 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 website³. Please ensure you have an ImmForm account to enable access. See the ImmForm helpsheet⁵ for information on registering for an ImmForm account.

BCG Vaccine AJV: patient group direction (PGD) template

An updated patient group direction (PGD) template⁴ for the administration of BCG, was made available for NHS England and NHSI areas to adopt and authorise for their commissioned services ahead of the change in delivery of the programme to those eligible babies.

Child Health Information Services (CHIS)

NHS England and NHSI 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.

SNOMED codes

The recommended SNOMED codes for recording receipt of BCG in electronic patient records (CHIS/GP) are available online at [weblink 1](#).

NHSE and NHSI are 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 page 5 for BCG vaccination data flows and patient care pathway information.

⁴ BCG vaccine PGD template: <https://www.gov.uk/government/publications/bcg-patient-group-direction-pgd-template>

⁵ ImmForm helpsheet: How to register: [ImmForm helpsheet](#)

Information for parents, caregivers and health professionals

Green Book on immunisation chapter 32 – Tuberculosis

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 is available in the updated Tuberculosis chapter of the Green Book (Immunisation against infectious disease): Tuberculosis: the green book, chapter 32 – GOV.UK ([weblink 2](#)).

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 website⁶.



TB, BCG and your baby leaflet

Paper copies of this leaflet are available to order for free or download in the following languages: [English](#), [Bengali](#), [Farsi](#), [Gujarati](#), [Hindi](#), [Nepali](#), [Panjabi](#), [Pashto](#), [Somali](#), [Tamil](#), [Ukrainian](#), and [Urdu](#).



TB, BCG and your baby quick links QR code poster

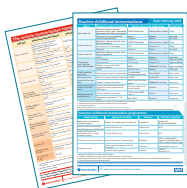
This poster contains QR codes to the English and translated versions of the TB, BCG and your baby leaflet is available to download ([weblink 3](#)).

A quick links poster with QR codes to the English and translated versions of the Pregnancy: how to help protect you and your baby leaflet is also available to download ([weblink 5](#)).



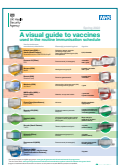
A guide to immunisation for babies up to 13 months of age

This information leaflet for parents about immunisations for babies up to 13 months has been updated. Copies are available to order ([weblink 4](#)).



Complete routine immunisation schedule and routine childhood immunisation schedule

The 2 schedules have been updated to include the recent changes including the BCG/SCID changes. Download them at [weblink 12](#) and [weblink 13](#).



A visual guide to vaccines

Download your copy today at [weblink 11](#).

⁶ <https://www.healthpublications.gov.uk/Home.html>

Training, advice and guidance

Training slide sets and guidance detailing the schedule change are available to download:

- introduction to TB ([weblink 14](#))
- administering BCG vaccination ([weblink 15](#))

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 is available at ([weblink 25](#)) SCID evaluation and change of timing of neonatal BCG.

For advice on at risk groups, incomplete vaccination ([weblink 6](#)) and those vaccinated abroad, please see the Green Book chapter 32 ([weblink 2](#)) and the Information for healthcare practitioners.

- BCG vaccine: information on the 28 day immunisation programme ([weblink 7](#))
- BCG vaccination and SCID screening: patient pathway ([weblink 8](#))
- BCG vaccination and SCID screening: data pathway ([weblink 9](#))

COVER programme vaccine coverage data collection

Cover of Vaccination 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, 2 and 5 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 (that is, 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.

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 BCG vaccination programme section of the UKHSA immunisation webpage at [weblink 10](#).

Key points about the impact of the SCID evaluation on rotavirus vaccination

This guidance applies to babies born on or after 1 September 2021, who will attend for their routine 8 week immunisation appointment from 27 October 2021.

Rotavirus (Rotarix®) vaccine is a live oral vaccine routinely given at 8 and 12 weeks of age as part of the infant immunisation schedule. All live vaccines, including Rotarix®, are contraindicated in babies who receive a SCID diagnosis.

In the areas participating in the SCID evaluation, SCID screening will form part of the routine newborn screening test at 5 days, with most results expected within 10 to 12 days. All babies should have a result available by 28 days, including those in non-screening areas where they will be assigned a 'SCID screening not offered' result.

Childhood Information Systems (CHISs) will receive SCID screening outcomes (as part of newborn blood spot results), and will inform practices when available and ahead of the 8 week immunisation appointment.

Practices should update their protocols to ensure that where SCID results (including SCID screening not offered) have been received by the practice, they are available in the patient record for the practice nurse at the 8 week immunisation appointment.

Parents and GP practices will receive a direct communication from the immunology team to alert them that a child has a suspected or confirmed SCID diagnosis and this will include information on which vaccines should not be given.

Immunisers should make reasonable efforts to ascertain the SCID screening outcome before administering rotavirus vaccine. This would involve checking for a record in the Red Book, the GP record, screening outcome information sent by CHIS, or with the parent or caregiver. In the absence of an abnormal SCID screening result, or if no result can be found, rotavirus vaccination can go ahead. UKHSA have developed an algorithm to assist immunisers with this check on the UKHSA rotavirus collection page ([weblink 16](#)). It is advised that practices include this algorithm in their local protocols.

In areas where SCID screening will not be offered routinely, immunisers need to be aware that there may be movers-in who have been tested and have a result available from another area.

It is important to use all opportunities to remind parents and caregivers to bring the Red Book and the letter with the outcome of newborn bloodspot screening when they are invited for their routine 8 week immunisation appointment. This could include an explicit mention in the invitation letter (CHIS or GP) and text message reminders.

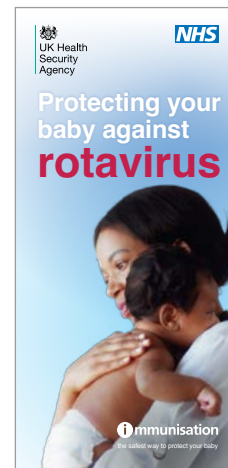
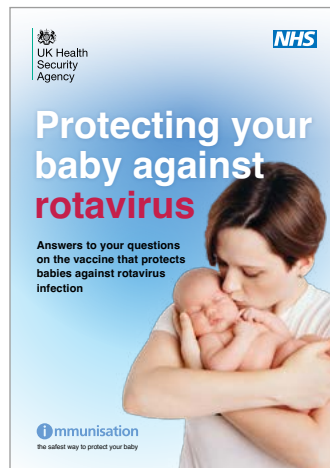
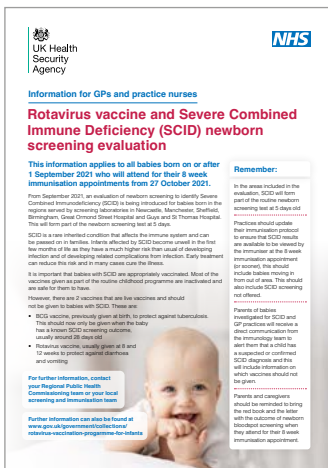
To ensure consistency and safety for all babies across the country, it is necessary for immunisation providers to adopt this guidance nationally, and regardless of whether the GP practice is located in an area participating in the SCID screening evaluation.

All relevant immunisation information for parents and caregivers will be updated and available on the UKHSA immunisation collection page ([weblink 17](#)) and available to order from the Health Publications website ([weblink 18](#)).

The Rotavirus vaccination programme training slideset is available to download.

- Rotavirus: the green book, chapter 27b ([weblink 19](#))
- Rotavirus vaccination programme: advice for health professionals ([weblink 20](#))

The current Patient Group Direction (PGD) ([weblink 21](#)) for the administration of Rotarix® already excludes those with a diagnosis of SCID.



An algorithm for the process of checking for SCID screening results at the routine 8 week appointment has been published ([weblink 22](#))

Guide to rotavirus for parents ([weblink 23](#))

Product code: 2021208R

Quick guide to rotavirus for parents ([weblink 24](#))

Product code: 2021209R.
Paper copies in English available to order

Weblinks

- Weblink 1 <https://www.snomed.org/>
- Weblink 2 <https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32>
- Weblink 3 <https://www.gov.uk/government/publications/tb-bcg-and-your-baby-leaflet>
- Weblink 4 <https://www.gov.uk/government/publications/a-guide-to-immunisations-for-babies-up-to-13-months-of-age>
- Weblink 5 <https://www.gov.uk/government/publications/pregnancy-how-to-help-protect-you-and-your-baby>
- Weblink 6 <https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status>
- Weblink 7 <https://www.gov.uk/government/publications/bcg-vaccine-information-on-the-28-day-immunisation-programme>
- Weblink 8 <https://www.gov.uk/government/publications/bcg-vaccination-and-scid-screening-patient-pathway>
- Weblink 9 <https://www.gov.uk/government/publications/bcg-vaccination-and-scid-screening-data-pathway>
- Weblink 10 <https://www.gov.uk/government/collections/bcg-vaccination-programme>
- Weblink 11 <https://www.gov.uk/government/publications/a-visual-guide-to-vaccines-poster>
- Weblink 12 <https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule>
- Weblink 13 <https://www.gov.uk/government/publications/routine-childhood-immunisation-schedule>
- Weblink 14 <https://khub.net/documents/135939561/536277049/UKHSA+Introduction+to+TB.pptx/da262aea-5c1f-0fae-b469-8656622e9258?t=1633442626694>

Weblinks

- Weblink 15 <https://khub.net/documents/135939561/536277049/UKHSA+Administering+BCG+Vaccination.pptx/8d9f0700-bb3e-2a20-73dd-4edaa3ec38a1?t=1633442625649>
- Weblink 16 <https://www.gov.uk/government/collections/rotavirus-vaccination-programme-for-infants>
- Weblink 17 <https://www.gov.uk/government/collections/immunisation>
- Weblink 18 <https://www.healthpublications.gov.uk/Home.html>
- Weblink 19 <https://www.gov.uk/government/publications/rotavirus-the-green-book-chapter-27b>
- Weblink 20 <https://www.gov.uk/government/publications/rotavirus-qas-for-healthcare-practitioners>
- Weblink 21 <https://www.gov.uk/government/publications/rotavirus-vaccine-rotarix-patient-group-direction-pgd-template>
- Weblink 22 <https://www.gov.uk/government/publications/rotavirus-vaccine-and-scid-newborn-screening-evaluation>
- Weblink 23 <https://www.gov.uk/government/publications/protecting-your-baby-against-rotavirus-leaflet>
- Weblink 24 <https://www.gov.uk/government/publications/protecting-your-baby-against-rotavirus-flyer>
- Weblink 25 <https://khub.net/documents/135939561/536277049/SCID+evaluation+and+Change+of+timing+of+neonatal+BCG.pptx/3831cf45-d4c2-c485-c10c-d2f25b46cabb?t=1633442625095>