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1. Home (https://www.gov.uk/)
2. NHS newborn blood spot (NBS) screening programme (https://www.gov.uk/topic/population-screening-programmes/newborn-blood-spot)
3. Newborn blood spot screening: failsafe solution user guide (https://www.gov.uk/government/publications/newborn-blood-spot-screening-failsafe-solution-user-guide)

- Public Health England (https://www.gov.uk/government/organisations/public-health-england)

Guidance

NBSFS operational level agreements for laboratory users

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OGL

The use of the national Newborn Blood Spot Failsafe Solution (NBSFS) is mandated in service specification No. 19, NHS Newborn Blood Spot Screening 2018/19 (https://www.england.nhs.uk/publication/public-health-national-service-specifications) in sections 2.2, 2.3, 3.6, 3.25, 4.2 and 5.6.

The regular and correct use of NBSFS promotes the achievements of the nationally agreed standards for Newborn Blood Spot Screening (https://www.gov.uk/government/collections/nhs-population-screening-programme-standards#newborn-blood-spot-(nbs)), in particular:

- standard 1a: coverage (CCG responsibility at birth)
- standard 2: timely identification of babies with a null or incomplete result recorded on the child health information system
- standard 4: timely sample collection
- standard 5: timely receipt of a sample into the newborn screening laboratory
- standard 6: quality of the blood spot sample
- standard 7a: timely taking of a second blood spot sample for CF screening
- standard 7b: timely taking of a second blood spot sample following a borderline CHT screening
- standard 7c: timely taking of a second blood spot sample for CHT screening for preterm infant
- standard 9: timely processing of CHT and IMD (excluding HCU) screen positive samples
- standard 11: timely entry into clinical care

The NBSFS operational level agreements (OLAs) outline standards for good practice for all users of the NBSFS and are designed to promote the achievement of these objectives.

The NBSFS OLAs are published in separate documents for different groups of user:

- part A: maternity users
- part B: child health record department users
- part C: newborn blood spot (NBS) screening laboratory users

0.1 Terminology

'Daily' denotes Monday to Friday, excluding bank holidays.

'Maternity user' applies to all users who access the maternity NBSFS including those working in maternity hospitals, community midwifery units, neonatal units and special care baby units.

'Child Health Record Department (CHRD) user' applies to all users who access the CHRD NBSFS.

'Laboratory user' applies to all users who access the laboratory NBSFS, including clinical scientists and administrators.

1. Laboratory users

1.1 OLA C1: timely upload of data onto NBSFS system

Statement: NBS screening data must be uploaded at least daily onto the NBSFS system to ensure that babies who may have missed screening can be followed up with minimal delay.

Responsibility of users: Screening data must be uploaded to NBSFS as soon as feasible so as to mitigate the effect of records going in to an amber status (12 days of age or older) and initiating checking processes by the maternity units.

Receipt and screening outcome updates need to be uploaded into NBSFS within 24 hours of its availability within the Laboratory Information Management Systems (LIMs).

1.2 OLA C2: NBSFS card file upload reporting of issues to system provider

Statement: Where NBS cards cannot be uploaded into the NBSFS the issue must be reported to system provider Northgate Public Services as soon as practicable and on the day the issue is encountered.

Responsibility of users: where a significant error is encountered in uploading NBS cards into the NBSFS, the laboratory must ensure the system provider technical team is notified of the issue as soon as practicable. This must take place on the day the issue is encountered and be done via the NBSFS helpdesk.

Newborn blood spot failsafe solution helpdesk

Email NBSFS.helpdesk@nhs.net

Phone 0845 070 2778

'Significant error' relates to a failure in uploading the file into the NBSFS, or where a large proportion of the records in the file are reported with errors. The term 'errors' does not include records reported that require:

- manual matching
- manual validation
- duplicate records

Notification to the system provider of a failure to upload (irrespective of reason) will allow for appropriate information to be provided to maternity units, advising them of:

- the possibility of a delay in matching sample cards with babies records
- that there may be an increase in babies records going to an amber status

1.3 OLA C3: Checking the uploaded data on the NBSFS system

Statement: The NBS screening data upload must be checked daily to ensure that the upload has been completed successfully and any errors must be corrected.

Responsibility of users: the NBSFS provides feedback when an upload of screening data is undertaken. Currently, there are 2 routes to uploaded screening data into the NBSFS:

- manual upload
- automated upload

1.4 Manual upload

The user uploading the screening data is responsible for:

- reviewing the confirmation information provided by the NBSFS on completion of the upload
- ensuring action is undertaken relating to any errors reported as part of the upload

1.5 Automated upload

The user receiving the electronic confirmation message (usually via email) provided by the NBSFS on completion of the upload is responsible for ensuring action is undertaken relating to any errors reported as part of the upload.

1.6 Periods of absence

Where there is a nominated laboratory user who receives the NBSFS upload confirmation message (screen or email) the laboratory must ensure adequate coverage of the notification message during periods of absence.

This may mean:

- setting up a 'forwarding rule' within their email system
- ensuring the notification email is directed to another user
- ensuring the notification email is always directed to more than one recipient

1.7 OLA C4: Processing only NBS cards which are identified with the baby's NHS number

Statement: Only NBS cards which include the baby's NHS number should be accepted and processed to maximise the accuracy of the screening test.

Responsibility of users: process (for reporting or NBSFS purposes) only NBS cards which include the baby's NHS number.

Reject specimen (for reporting or NBSFS purposes) and request a repeat sample when the NBS card has been submitted without the NHS number included.

1.8 OLA C5: processing NBS cards according to nationally agreed quality standards (laboratory users)

Statement: NBS cards must be processed according to the nationally agreed quality standards to maximise the accuracy of the screening test. A good quality blood spot card:

- has been taken at the right time
- contains enough blood to perform all the tests
- has not been contaminated
- has data fields correctly completed
- has not expired

- has not been in transit for more than 14 days

Responsibility of users: Process (for reporting or NBSFS purposes) NBS cards according to nationally agreed quality standards.

Reject (for reporting or NBSFS purposes) specimen and request a repeat sample when the NBS card has been submitted which does not meet the required standard.

1.9 OLA C6: NBSFS manual validation of sample cards

Statement: NBS cards uploaded to NBSFS which go into the laboratory sites manual validation queue must be processed within 48 hours. Cards that go into the NBSFS manual validation queue will not be matched with a baby's record until its validity has been assessed and confirmed by a laboratory technician.

Responsibility of users: Process NBS cards in the NBSFS manual validation queue within 48 hours.

1.10 OLA C7: NBSFS checking the 'screening incomplete' list

Statement: The 'screening incomplete' list must be checked regularly, preferably daily and at the very least, weekly. Any incomplete records accounted for and followed up as appropriate.

All records must have a completed outcome against all tests (usually 9 tests) as soon as possible. Note that only '03' or 'not received' records flag up on the maternity or CH tracking page and only laboratory users will be aware of other records with incomplete outcomes.

Responsibility of users: check the 'screening incomplete' list regularly (preferably daily but at least weekly) and resolve any outstanding results as soon as possible. Respond to emails about the 'screening incomplete' list from the system provider within 48 hours.

1.11 OLA C8: maintaining continuity of service (regular user away)

Statement: When the regular user is away, on planned or unplanned leave, a substitute is appointed to take on NBSFS responsibilities.

Responsibility of users: So that the NBSFS is checked daily, there must be cover when the regular user is away, by another authorised and competent NBSFS user. Ideally, cover should be planned and handover given, but the user's manager should be aware of the user's NBSFS responsibilities and have arrangements in place for a substitute if leave is unplanned.

1.12 OLA C9: Maintaining continuity of service, new users

Statement: When the regular user leaves or changes role, a successor is appointed to take on NBSFS responsibilities.

Responsibility of users: The NBSFS laboratory site lead should contact the NBSFS helpdesk to terminate the access for the current user and arrange access for the new user. If the user leaving is the NBSFS laboratory site lead, the current site lead should, where possible, contact the NBSFS helpdesk with details of the new site lead, prior to their departure.

1.13 OLA C10: Reporting problems relating to the NBSFS system

Statement: All problems with the NBSFS must be reported promptly to identify and resolve problems with the NBSFS as quickly as possible. Examples of system problems include delays in uploading data for reasons including:

- system failures
- resourcing issues
- postal problems
- demographic download failures
- automatic upload errors
- unexplained errors in data upload
- unexplained error messages

Responsibility of users: Report record problems as soon as they are identified using the record query form (RQF) where appropriate to the NBSFS helpdesk email.

For urgent problems, and technical issues, call the NBSFS helpdesk.

It is important to report problems, even if local solutions can be arranged, to ensure that all problems are recorded and monitored.

Confidential information must not be given over non secure emails. Only nhs.net can be used to send confidential and patient identifiable information such as name and NHS number.

If the problem is not rectified appropriately, escalate the matter using the escalation process OLA C11.

Screening incidents and serious incidents related to NBSFS should also be reported using the existing incident procedures and the Screening Quality Assurance Service (SQAS) (regions) advised.

1.14 OLA C11: Reporting other problems relating to NBSFS, and escalation process

Statement: Problems related to the NBSFS must be followed up promptly to identify and resolve them as quickly as possible. For NBSFS system problems see OLA C10.

Examples of other problems include:

- maternity users not transferring or accepting transfers promptly
- labs not uploading results in a timely way
- CHRDs not communicating effectively
- unsatisfactory response to helpdesk enquiries

Responsibility of users: Please note that:

- midwife administrators should first contact their NBS screening coordinator for advice
- laboratory administrators should first contact their laboratory director for advice
- minor problems and isolated events should be raised directly with the individuals concerned

Serious, persistent or unresolved problems should be managed using the escalation processes as described below.

1.15 Process for midwifery users

1. Contact screening coordinator of relevant maternity unit.
2. Escalate to midwife clinical manager (for example, matron or head of midwifery).
3. Escalate to, SQAS (regions).
4. Escalate to, NHS Newborn Blood Spot Screening Programme Team via PHE.screeninghelpdesk.nhs.net.

1.16 Process for CHRD users

1. Contact CHRD manager in the relevant CHRD.
2. Escalate to, SQAS (regions).
3. Escalate to, NHS Newborn Blood Spot Screening Programme Team via PHE.screeninghelpdesk.nhs.net.

1.17 Process for laboratory users

1. Contact director of newborn screening in the relevant NBS lab.
2. Escalate to, SQAS (regions).
3. Escalate to, NHS Newborn Blood Spot Screening Programme Team via PHE.screeninghelpdesk.nhs.net.

1.18 Problems for system provider Northgate Public Services

1. Contact NBSFS helpdesk.
2. Escalate to, NHS Newborn Blood Spot Screening Programme Team via PHE.screeninghelpdesk.nhs.net.

1.19 Changes to laboratory information management system (LIMS)

Before any significant change to their LIMS, laboratories should contact Northgate Public Service (NPS) to arrange a discussion about the implications for the NBSFS. This should be done via the NBSFS helpdesk (https://www.gov.uk/government/publications/newborn-blood-spot-screening-failsafe-solution-user-guide/nbsfs-operational-level-agreements-for-laboratory-users#nbsfs-helpdesk). This discussion will help to identify:

- the extent of testing needed before uploading results from the new or updated LIMS
- if any assistance is needed from the LIMS provider and NPS

Typically this discussion will involve informing NPS of any changes to Comma Separated Values (CSV) files. You should tell them which fields have been extracted, or any changes you have made to the number of files expected per day (for example, separate or combined files for '01', and results message).

Laboratories must ensure they carry out appropriate testing of receipt and reporting of results, partial results ('n' conditions) if applicable, and re-reporting. The testing strategy should ensure all available Newborn Blood Spot status codes and sub-codes are tested and verified.

NPS will support each laboratory's own testing activity by making available a test system in to which laboratories can either manually upload test files into the failsafe or can utilise the test version of the automated upload process.

2. Responsibility of NBSFS system provider NPS

Statement: a detailed description of the NPS responsibilities is defined in the NBSFS contract, schedule 4, service level agreement (SLA). Contact the newborn blood spot programme team for details..

Responsibility of system provider (NPS): inform users in a timely way if there are system availability or performance problems which may affect users in line with the agreed NPS and the programme's SLA response and fix times. For example, a delay in the day's upload of data, or a significant problem which may lead to large numbers of screened infants appearing on the tracking page.

NPS will advise users of the issue by placing advisory information on the NBSFS login page if the following 2 things happen:

- laboratories have not uploaded data or have experienced a large number of errors in the upload
- the laboratory has notified NPS of the issue

They will also:

- process unmatched sample cards and match to appropriate birth records in a timely manner
- provide users with information about when the daily laboratory upload in their area takes place so that users can select optimal time for using system
- provide data which may be accessed by SQAS and programme team for the purposes of monitoring quality
- ensure training materials are available and up to date
- generate and terminate user accounts in a timely way
- cascade information about significant system problems affecting users, as agreed with the programme team
- respond to enquiries/problems/serious incidents as agreed in the SLA
- respond to complaints as specified in the SLA

3. Responsibility of the NHS Newborn Blood Spot Screening Programme

Statement: The NBSFS is delivered from the NHS Newborn Blood Spot Screening Programme. (https://www.gov.uk/guidance/newborn-blood-spot-screening-programme-overview)

Responsibility of NHS Newborn Blood Spot Screening Programme: It is the responsibility of the programme to:

- report to the newborn screening programmes IT Software Delivery Board (or equivalent)
- work with system provider Northgate Public Services to provide a high quality NBSFS service
- monitor the quality of the service provided by the system provider
- monitor the support provided by the system provider, including the service desk
- hold the system provider to account in line with contractual agreements

- maintain a risk register
- appoint a clinical safety officer to oversee clinical safety
- develop the service in conjunction with the NBSFS user group
- respond to escalated issues
- escalate issues to the relevant antenatal and newborn national screening programmes lead
- ensure training and information resources are available for users of the system
- provide information and updates to users and other stakeholders
- monitor the use of the system and produce reports according to agreed criteria
- make available reports for quality assurance personnel and other stakeholders

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- maintain a risk register
- appoint a clinical safety officer to oversee clinical safety