Failsafe in the NHS Newborn Hearing Screening Programme

**Introduction**

The UK National Screening Committee (UK NSC) is developing Quality Assurance (QA) processes across all the national non-cancer screening programmes in the English NHS.

The aim of QA is to provide information to the public and professionals about the quality of screening programmes. Quality assurance and performance management are an integral part of all national screening programmes to ensure that all programme achieve the highest possible standards. Part of this work involves the development of failsafe processes and Map of Medicine care pathways.

Further details of cross programme QA, including the work on failsafe, can be found at [http://www.screening.nhs.uk/quality-assurance](http://www.screening.nhs.uk/quality-assurance).

**What is Failsafe?**

Screening should be offered to the eligible population in a timely manner; and those who are screened should receive their results (whether positive or negative) with sufficient information to understand them, and have them acted on appropriately. The value of a screening programme will be diminished if appropriate action is not always taken to ensure that the right people are invited to be screened, or if the right action is not taken to follow up those with abnormal test results.

Failsafe is a back-up mechanism, in addition to usual care, which ensures if something goes wrong in the screening pathway, processes are in place to (i) identify what is going wrong and (ii) what action follows to ensure a safe outcome.

Most risks and errors in a screening pathway can be predicted. They often arise from systems failure occurring along the screening pathway, as opposed to individual error. A failsafe is a mechanism to “design out” or reduce these risks. It is a back-up mechanism, in addition to usual care, which ensures if something goes wrong in the screening pathway, processes are in place to identify the error and correct it before any harm occurs.

**The Failsafe Process**

Failsafe should be a ‘closed loop’ process. The effective monitoring of failsafe requires the point at which a required activity is commenced and the point at which it is concluded to be noted (usually through a systematic process and/or an IT system), and a system to ensure that all opened loops have been closed within an appropriate timescale.

**Opening the loop** – a trigger which indicates that a process requiring a failsafe control for an individual has started; for example a pregnancy reported either by self referral or through primary care triggers the offer of an antenatal screening test.

**Closing the loop** – an event or a stage of the screening pathway which denotes the conclusion of a process requiring failsafe control for an individual; for example, the dispatch of a letter to inform parents that the results of newborn blood spot screening are normal. There may be a number of events that can result in a particular loop being closed; for example, a loop which is opened by a ‘condition suspected’ antenatal screening result might be closed by diagnostic testing confirming that the pregnancy is not affected, by parental choice to continue an affected pregnancy, or by termination of an affected pregnancy.
Ensuring the loop has been closed – an additional check, usually on a group of individuals, to identify any individual for whom a failsafe loop has been opened but not closed within a defined timescale; for example a systematic check that a sample card has been received at the screening laboratory for all babies born 17 or more days previously.

Most screening pathways will involve multiple failsafe loops at different levels of detail. Loops can exist within other loops; for example, a failsafe loop to ensure that every screen positive woman is offered diagnostic testing can exist within a broader loop ensuring that every woman who is screened is notified of the screening result.

Implementation of Failsafe

For this failsafe strategy to be implemented requires action at national, regional and local level. The main roles and responsibilities are outlined below.

National: Screening programmes have assessed the screening pathway and identified areas of high risk that require failsafe measures. Assessments have considered the probability of an error occurring and the severity of the consequence, with this drawing on the learning from serious incidents. Each programme has developed a diagram superimposed on their Map of Medicine pathway(s) showing the key risks along the screening pathway.

Regional: The regional team will provide expert advice on reducing risks in local programmes to providers, commissioners and SHAs. They will assess the robustness of local arrangements through audit, as part of peer review and in the investigation of incidents. They will act as a conduit for information and dialogue between national, regional and local level.

Commissioners: Commissioners are expected to incorporate the national guidance to reduce risk within service specifications and to oversee their implementation and functioning. The PCT, via its screening lead, is responsible for ensuring that the whole pathway is commissioned and that the elements communicate properly to make all failsafes work. Working with providers, they should ensure that safeguards are in place throughout the screening pathway and for high risk groups. This will require clarity about roles and responsibilities of different providers, particularly at the interfaces.

Providers: All providers are expected to review and risk assess local pathways in the light of the national guidance and work with Commissioners to develop, implement and maintain appropriate risk reduction measures. This should involve mechanisms to audit implementation and report incidents. Effective implementation requires routine staff training and development and may need changes to local roles and responsibilities. Provider organisations are also expected to ensure that appropriate links are made with internal governance arrangements, such as risk registers.

The NHS Newborn Hearing Screening Programme

The NHS Newborn Hearing Screening Programme (NHSP) offers all new parents the opportunity to have their baby’s hearing screened within the first few weeks of life. It is a core service within the NHS in England and part of the family of Antenatal & Newborn Screening Programmes.

More information on the NHS Newborn Hearing Screening Programme can be found on their website at [http://hearing.screening.nhs.uk/](http://hearing.screening.nhs.uk/).
The Map of Medicine

Map of Medicine is a visual representation of evidence-based, practice-informed care pathways for common and important conditions. Pathways are freely available for health professionals through NHS Evidence (http://www.mapofmedicine.com/england) and for the public via NHS Choices (http://healthguides.mapofmedicine.com). They are also signposted from each screening programme’s website and from the UK Screening Portal (http://www.screening.nhs.uk/mapofmedicine). They have been developed to provide accurate information on screening for health professionals and to promote safe, high quality screening services throughout the NHS.

View the NHSP-related pathways:

Newborn hearing screening –
http://healthguides.mapofmedicine.com/choices/map/newborn_hearing_screening1.html

Early audiological assessment (including permanent childhood hearing impairment management pathway) –

NOTE : this pathway is currently (November 2010) undergoing major revision along with NHSP guidelines

This publication was withdrawn July 2018
Failsafe Overview

A. Main screening pathway

Failsafe NHSP main 2
Identification of eligible population and offer of screen

Failsafe NHSP main 9/10
Screen those who accept the offer

Newborn hearing screening

Check eligibility

Eligible for screening

Consider risk factors for hearing loss

Provide information and take consent

Not eligible for screening

Consider referral for early audiological assessment

Screen those who accept the offer

Neonatal intensive care unit (NICU) or special care baby unit (SCBU) screening protocol

Go to NICU/SCBU protocol

Well baby screening protocol

Hospital based screening service

Go to well baby protocol

Community based screening service
B. Well baby pathway

Failsafe NHSP well baby 3/9
Follow up of those who move out of pathway i.e. who do not complete the pathway

Failsafe NHSP well baby 18
All babies with positive screen results are offered diagnostic test

Failsafe NHSP well baby 2/7
All screen results received and recorded

Newborn hearing screening well baby protocol

Automated oto-acoustic emission (AOAE) screening test

AOAE no clear response in one or both ears

Automated auditory brainstem response (AABR) screening test

AABR no clear response in one or both ears

Missed or incomplete AABR

Offer appointment to complete screen or consider referral, as appropriate

Missed or incomplete AOAE screening test

Offer appointment to complete screen or consider referral, as appropriate

Refer for audiological assessment at appropriate age

AOAE of clear response in one or both ears

Other risks requiring surveillance?

If risks are present, consider referral for audiological assessment

If risks are absent, discharge (with ongoing vigilance)

Refer for audiological assessment at appropriate age

Refer for early audiological assessment

Consider referral for early audiological assessment
C. NICU/SCBU baby pathway

**Failsafe NHSP NICU 4**
Follow up of those who move out of pathway i.e. who do not complete the pathway.

- **Missed or incomplete AAOAE or AABR screening test**
  - Offer appointment to complete screen or consider referral, as appropriate

- **AAABR clear response in both ears and AOAEE no clear response in both ears**
  - Consider referral for audiological assessment

- **AAABR clear response in both ears and AOAEE clear response in both ears**
  - Refer for audiological assessment at appropriate age

- **AAABR clear response in both ears and AOAEE no clear response in one ear**
  - If risks are present, consider referral for audiological assessment

- **AAABR no clear response in one or both ears**
  - Refer for early audiological assessment

- **Other risks requiring surveillance**
  - If absent, discharge (with ongoing vigilance)

**Failsafe NHSP NICU 2/3**
All screen results received and recorded.

**Failsafe NHSP NICU 13**
All babies with positive screen results are offered diagnostic test.

This publication was withdrawn July 2018.
D. Audiological assessment pathway

Failsafe NHSP assessment 1
All who accept diagnostic test get it
E. Permanent childhood hearing impairment management pathway

- Management of permanent childhood hearing impairment
- Share information with families
- Agree next steps and formulate plan
- Consider urgent referral to cochlear implant team
- Refer urgently to cochlear implant team

Failsafe NHSP PCHI
All with condition enter next stage of pathway
### Failsafe Descriptions

<table>
<thead>
<tr>
<th>Node(s)</th>
<th>Failsafe process</th>
<th>Opening the loop</th>
<th>Closing the loop</th>
<th>Ensuring the loop has been closed</th>
<th>NHSP Local Programme Management Task</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main 2</strong></td>
<td>Identification of eligible population and offer of screen</td>
<td>Population identified, eligibility established</td>
<td>All eligible babies offered screen</td>
<td>eSP is populated with birth notifications direct from NN4B. If there are processes in place locally in the event of NN4B is not available, a local process to identify new registrations &lt;3m corrected age. Request pending with C4H (Connecting for Health) to supply these direct as for birth notifications.</td>
<td>- Patient Journey (Daily)</td>
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<td>Screeners check eligibility before screening offered</td>
<td>Programme Centre monitors use of inappropriate screening outcomes via eSP</td>
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<td></td>
<td>Well baby 2 / 7</td>
<td>NICU 2 / 3</td>
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<tr>
<td>Screen results</td>
<td>All screen results received and recorded</td>
<td>All screen results received and recorded</td>
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<td></td>
<td>Screener uploads individual screening test results electronically into eSP. Any manual entries recorded on a log and checked by local manager (hospital programmes).</td>
<td>Screener sets screening outcomes in eSP (hospital programmes).</td>
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<tr>
<td></td>
<td>Local Manager/admin clerk enter results into eSP from paper record sent in by screener (Community programmes).</td>
<td>Local Manager/admin clerk sets screening outcomes in eSP (community programmes).</td>
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<tr>
<td></td>
<td>Note: eSP suggests correct screening outcome based on test results profile</td>
<td>Note: eSP suggests correct screening outcome based on test results profile</td>
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<tr>
<td></td>
<td>Local screening manager audits accuracy of screening outcomes as per national guidance</td>
<td>Local Managers audit manually entered results using monthly audit report supplied by PC (hospital programmes).</td>
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<td></td>
<td>PC supplies programmes with monthly audit reports showing records with “clear response” screening outcomes without supporting test results</td>
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<tr>
<td></td>
<td>Patient Journey (Daily)</td>
<td>Data Management - discrepant data/manual entries (Monthly)</td>
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<tr>
<td></td>
<td>Screen outcome differs from eSP suggested outcome (Weekly)</td>
<td>Data Quality Checks - Exports (Monthly)</td>
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<tr>
<td></td>
<td>Incomplete outcomes (Monthly)</td>
<td>QS Headline Reports (Quaterly)</td>
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<td></td>
<td>NHSP Trends - ongoing review of programme performance</td>
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</tbody>
</table>
Failsafe in the NHS Newborn Hearing Screening Programme

<table>
<thead>
<tr>
<th>Well baby</th>
<th>All babies with positive screen results are offered diagnostic test</th>
<th>Screen outcomes are given to parents verbally and in writing by the screener at the time of test. Screener makes a referral for a diagnostic audiological assessment for screen positives.</th>
<th>Screen outcomes differ from eSP suggested outcome (Weekly)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NICU 13</td>
<td></td>
<td>Audiology appointment date and attendance recorded in eSP</td>
<td>Patient Journey (Daily)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Screening Manager checks screen positives appointed in audiology as per national guidance</td>
<td>Transfers and Shares (Daily)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For screen positives time from screen completion to first offered diagnostic test is published to site in PC report, to QA team and via</td>
<td>Screen outcome differs from eSP suggested outcome (Weekly)</td>
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<td></td>
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<td>Audiological assessments - check</td>
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</table>

PC supplies Local managers with monthly audit report listing all test results electronically uploaded where the result has been changed from No Clear Response to Clear Response.

Local Managers use Community data checker software to check results in eSP agree with results recorded on screening equipment (Community Programmes).

PC publishes regular (quarterly/monthly) reports showing % screen complete by age 4wks, 5 wks and 3 months and % screening outcomes set by 3m.

This publication was withdrawn July 2018
## NHSP Trends

- **all screen referrals have appointments** (Weekly)
- **Data Quality Checks** - Exports (Monthly)
- **Screen Referral and Yield Report** - review audiology data quality (Monthly)
- **NHSP Trends** - ongoing review of programme performance

### Assessment 1

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Action</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>All who accept diagnostic test get it</td>
<td>Appointment for audiological assessment received by parents</td>
<td>Diagnostic assessment completed and results entered in eSP</td>
</tr>
<tr>
<td></td>
<td>Screening Manager checks screen positives attended audiological assessment as per national guidance</td>
<td>Screening Manager audits time from screen completion to first attended assessment</td>
</tr>
<tr>
<td></td>
<td>For screen positives time from screen completion to attendance at assessment will be published in the next release of NHSP Trends</td>
<td></td>
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</tbody>
</table>
## PCHI 1

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
<th>Pathway Stage</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>All with identified condition</td>
<td>Audiology refer all with identified condition to Early Intervention Service</td>
<td>Next stage of pathway</td>
<td>Early Intervention service contacts the family</td>
</tr>
<tr>
<td>Time from confirmation of Permanent Childhood Hearing Impairment (PCHI) to referral to early intervention audited locally</td>
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</tbody>
</table>

## Well baby 3 / 9 NICU 4

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
<th>Pathway Stage</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow up of those who move out of pathway i.e. who do not complete the pathway</td>
<td>GP and HV notified if screen not completed</td>
<td>Next stage of pathway</td>
<td>Audiology offer targeted follow up at 8m to those who did not complete the screen</td>
</tr>
<tr>
<td>Screening manager audits offer and attendance at targeted follow up</td>
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</table>

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