



UK National
Screening Committee



Screening Programmes

NHS Fetal Anomaly Screening Programme

Failsafe processes

Version: 1.1, October 2011

This publication was withdrawn July 2018

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 programmes 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>.

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 Fetal Anomaly Screening Programme

The main aim of the NHS screening programme for fetal anomaly ultrasound is to offer all pregnant women in England a minimum of 2 ultrasound scans. The first is an early scan, undertaken after 8 weeks gestation and used mainly for dating the pregnancy and confirming viability. The second ultrasound scan is offered between 18⁺⁰ to 20⁺⁶ weeks of pregnancy and screens for major structural anomalies.

The programme also ensures access to a uniform screening programme which conforms to an agreed level of quality for all pregnant women in England who undergo screening for Down's

syndrome. This is supported by information for women so that they are able to exercise informed choice.

More information on the NHS Fetal Anomaly Screening Programme can be found on their website at <http://fetalanomaly.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 on 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 pathways:

Fetal Anomaly Screening

http://eng.mapofmedicine.com/evidence/map/fetal_anomaly_screening1.html

Down's Syndrome Screening

http://eng.mapofmedicine.com/evidence/map/downs_syndrome_screening1.html

This publication was withdrawn July 2018

a. Down's Syndrome Screening

Failsafe Overview



Failsafe Descriptions

ID	Failsafe process	Opening the loop	Closing the loop	Ensuring the loop has been closed
1 & 2	Identification of eligible population & offer of Down's syndrome screening	<p>Identification of eligible population.</p> <p>All women offered/given written & verbal information about the dating scan & Down's syndrome screening test.</p> <p>All women offered first trimester 'combined' screening if CRL measures 45.0mm to 84.0mm.</p> <p>Second trimester screening to be offered where CRL is more than >84.0mm and HC is equal to or more than ≥101.0mm.</p>	<p>All eligible women in cohort offered screen</p> <p>Offer and maternal decision (accept or decline) about screening documented by health professional in woman's maternity record</p>	<p>Woman offered scans again by maternity health professional if no evidence of screening test documented in maternity record or upon enquiry.</p> <p>Local audit of offer, uptake & decision</p>
3 & 5	Screen those who accept the offer of dating & / or Down's syndrome screening	Health professional documents the woman's decision in her maternity record.	<p>Screeener checks pre-test information has been given & is understood then carries out screening test.</p> <p>The sonographer completes the scan procedure and documents the findings in the maternity record and hospital IT system.</p>	<p>Woman offered scan again if no documented evidence of screening test result</p> <p>All ID data and information is completed on the form and checked with the woman.</p> <p>Ensure blood is received in the</p>

This publication was withdrawn July 2018

			Ensure maternal blood sample taken for biochemical analysis if Down's syndrome screening is accepted.	laboratory
			Blood bottle & laboratory form labelled & completed correctly (+/- NT measurement) & sent to screening laboratory.	
4/6	Screening (dating scan) declined Follow up at delivery	Health professional explains the importance of fetal dating e.g. for Down's syndrome screening	Health professional documents the woman's decision in her maternity record.	NIPE offered within 72 hours of delivery.
7 & 10/13, 11/12, 14/15, 16/18/20	High risk result obtained	<p>Woman informed that she has a higher than expected chance of having a baby with Down's syndrome.</p> <p>A further scan with a specialist confirmatory test is offered.</p> <p>Woman offered/given pre-test information and procedure discussed. Consent obtained.</p>	<p>The findings are documented in the woman's maternity record & hospital IT system. Hard copy [thermal] and/or digital images are taken and put with the report.</p> <p>Data matched with records to ensure that it is the correct person and details.</p> <p>Health professional documents the woman's decision (accepted / declined) PND in her maternity record.</p> <p>If requested, diagnostic testing performed under ultrasound guidance (chorionic villus sampling [CVS] or amniocentesis depending on</p>	<p>Cytogenetic laboratory result (where performed) is recorded in the maternal notes.</p> <p>Positive result - woman chooses to either continue with (ensure paediatric referral is made & results of appointment are documented) or terminate her pregnancy. Histopathological examination offered post mortem.</p> <p>Ensure that specimen has been received in the laboratory.</p> <p>Re-offer if no documented evidence of test results in maternal notes.</p> <p>18⁺⁰ to 20⁺⁶ weeks</p>

This publication was withdrawn July 2018

			<p>gestational age). Sample of CVS tissue or amniotic fluid sent to cytogenetic laboratory in a labelled specimen bottle accompanied with a completed laboratory form.</p> <p>Anti-D immunoglobulin offered post procedure to all Rhesus-D negative women and decision and action documented in maternal record.</p> <p>If miscarriage occurs the correct procedures are undertaken and outcome recorded in maternal notes</p>	<p>fetal anomaly scan findings reported.</p> <p>NIPE offered within 72 hours of delivery.</p> <p>Local laboratory / hospital audit. DQASS data.</p> <p>Pregnancy outcome reported to obstetric/fetal medicine specialist and to local Congenital Anomaly Register (CAR) and NHS FASP.</p>
8/9	<p>Low risk result (screen negative)</p> <p>Follow up at delivery</p>	<p>Woman informed that she has a higher than expected chance of having a baby with Down's syndrome.</p>	<p>The findings are documented in the woman's maternity record & hospital IT system.</p>	<p>18⁺⁰ to 20⁺⁶ weeks fetal anomaly scan findings reported.</p> <p>NIPE offered within 72 hours of delivery.</p> <p>Local laboratory audit</p> <p>DQASS data</p>

This publication was withdrawn July 2018

b. Fetal Anomaly Screening

Failsafe Overview



Failsafe Descriptions

ID	Failsafe process	Opening the loop	Closing the loop	Ensuring the loop has been closed
2	Identification of eligible population and offer of screen	<p>Identification of eligible population.</p> <p>All women offered/given written and verbal information about the dating and fetal anomaly ultrasound scan.</p>	<p>All eligible women in cohort offered screen</p> <p>Offer and maternal decision about screening documented by health professional in woman's maternity record</p>	<p>Woman offered scans again by maternity health professional if no evidence of screening test documented in maternity record or upon enquiry.</p>
3	Screen those who accept the offer of dating & / or anomaly scan	<p>Health professional documents the woman's decision in her maternity record.</p>	<p>Screeners checks pre-test information has been given & is understood then carries out screening test</p>	<p>Woman offered scan again if no documented evidence of screening test result</p>
4/6	<p>Screening (dating scan) declined</p> <p>Follow up at delivery</p>	<p>Health professional explains the importance of fetal dating e.g. for Down's syndrome screening</p>	<p>Health professional documents the woman's decision in her maternity record.</p>	<p>NIPE offered within 72 hours of delivery.</p>
7	Fetal anomaly suspected (linked to 10)	<p>The woman is told of the scan finding(s).</p> <p>A second opinion may be sought (another sonographer or clinician).</p>	<p>The scan findings are documented in the woman's maternity record an hospital IT system. Hard copy [thermal] and/or digital images are taken and put with the report.</p> <p>Another sonographer or clinician re-scans the woman confirm or refute the original scan findings.</p>	<p>a-b. The sonographer/clinician's report is available in the woman's maternity record and backed up on the hospital IT system.</p>

This publication was withdrawn July 2018

8	Scan normal	Woman informed that no fetal anomalies found at the time of the dating scan.	The scan findings are documented in the woman's maternity record and hospital IT system. Hard copy [thermal] and/or digital images are taken of fetal measurements and put with report.	Health professional checks that record of consultation and scan report are in maternity record. 18+0 to 20+6 weeks fetal anomaly scan offered. NPE offered within 72 hours of delivery.
10	Refer to obstetrician	Woman is offered the opportunity to see either an obstetrician with ultrasound experience or fetal medicine specialist (unit within three working days)	The obstetrician or fetal medicine specialist confirms or refutes the scan findings.	Scan findings are documented and recorded in the woman's maternity record, hospital IT system and also sent to her obstetrician. Annual hospital Trust '10 conditions' audit (if confirmed) Notification of anomaly to local Congenital Anomaly Register - CAR where these exist (if confirmed)
11	Fetal screen results received and recorded	Screener enters individual screening test results into IT system or records manually	Report generated for inclusion in woman's hand held notes & findings discussed	Woman offered scan again if no documented evidence of screening test result
12	Screening declined	The sonographer acknowledges the	The sonographer documents the woman's decision in her maternity	Healthcare professional offers further appointment if

This publication was withdrawn July 2018

	woman's decision.	record.	no documented evidence of decline in hand held records at next antenatal appointment
			NIPE offered within 72 hours of delivery

13	Follow up at delivery	Newborn Physical and Infant Examination (NIPE) offered within 72 of delivery.	Findings documented in baby record and hospital IT system.	Findings which deviate from the norm are documented in the infant records and hospital IT system. Baby referred immediately to the local paediatric team. The hospital Trust undertakes the annual '10 conditions' audit. Notifying to the local Congenital Anomaly Register (CAR).
----	-----------------------	-------------------------------------------------------------------------------	------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

14	Fetal anomalies suspected	The woman is informed of the ultrasound finding(s). The woman is offered a second opinion by another sonographer or clinician. Her decision is documented in the maternity record.	Scan findings are documented by the sonographer in the woman's maternity record. Hard copy [thermal] and/or digital images are taken and put with the report. If woman agrees to a second opinion, another sonographer or clinician re-scans the woman and confirms or refutes the original scan findings. Second	a-b. The sonographer/ clinician's report is available in the woman's maternity record and backed up on the hospital IT system. Further appointment scheduled to see a fetal medicine specialist (unit).
----	---------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

This publication was withdrawn July 2018

			scan findings are documented by the health professional in the maternity record and hospital IT system. Hard copy [thermal] and/or digital images are taken and put with the report.	<p>Ultrasound report and images sent to fetal medicine specialist.</p> <p>Report from fetal medicine specialist detailing his/her conclusion of ultrasound scan.</p>
15	Scan normal	Woman informed that no abnormalities have been identified at the time of scan and that ultrasound cannot detect all problems.	Ultrasound findings documented in woman's maternity record and hospital IT system. Hard copy [thermal] and/or digital images of measurements are taken and put with the report.	<p>NIPE offered within 72 hours of delivery.</p> <p>Evidence of decision in maternity and infant record.</p> <p>If consent given for NIPE, evidence of examination report in infant record.</p>
16	Follow up at delivery	Woman offered NIPE within 72 hours of delivery. Information provided.	Offer and decision documented in maternity, infant record and hospital IT system.	If consent given for NIPE, evidence of examination report in infant record.
17	Refer to obstetrician	Woman is offered the opportunity to see either an obstetrician with ultrasound experience or fetal medicine specialist (unit) within three working days for further investigation. Maternal decision is documented in maternity record.	Scan findings are documented in the woman's maternity record and hospital IT system and a second copy is sent to the referring hospital Trust.	<p>The healthcare professional offers further appointment if no documented results in hand held records (or received by professional referring from Trust) at next antenatal appointment</p> <p>The hospital Trust undertakes the annual '10</p>

This publication was withdrawn July 2018

conditions audit
as required by
NHS FASP and
including
notifying to the
local Congenital
Anomaly
Register (CAR).

Woman offered
NIPE within 72
hours of
delivery.

This publication was withdrawn July 2018