UK National Screening Committee

Screening Programmes

NHS Newborn Blood Spot Screening Programme

Failsafe processes

Version: 1.1, August 2011

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 Newborn Blood Spot Screening Programme

The UK Newborn Screening Programme Centre has responsibility for developing, implementing and maintaining a high quality, uniform screening programme for all newborn babies and their parents. The UK National Screening Committee recommend that all babies in the UK are offered screening for phenylketonuria (PKU), congenital hypothyroidism (CHT), sickle cell disorders (SCD), cystic fibrosis (CF) and medium-chain acyl-CoA dehydrogenase deficiency (MCADD).

More information on the NHS Newborn Blood Spot Screening Programme can be found on their website at http://newbornbloodspot.screening.nhs.uk/.

The Map of Medicine

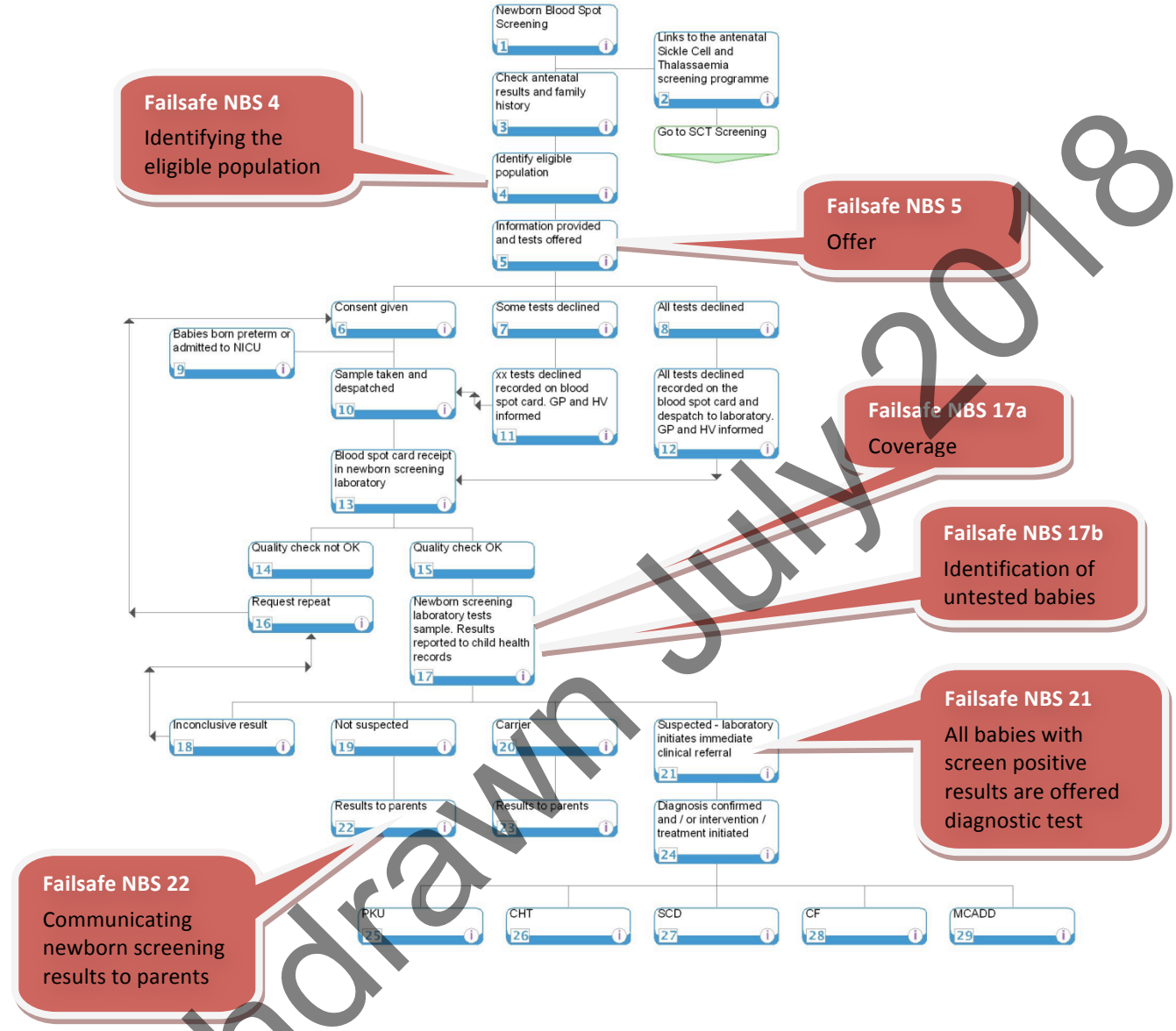
Map of Medicine is a visual representation of evidence-based, practice-informed care pathways for common and important conditions. Pathways are freely available for health professionals through NHS Evidence (http://www.mapofmedicine.com/england) and for the public on NHS Choices (http://healthguides.mapofmedicine.com/). 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 pathway:

Newborn blood spot screening

http://eng.mapofmedicine.com/evidence/map/newborn_blood_spot_screening1.html

Failsafe Overview



Failsafe Descriptions

Node(s)	Failsafe process	Opening the loop	Closing the loop	Ensuring the loop has been closed	Measure
4	Identifying the eligible population	New birth or baby one year of age or under moves into the PCT	Maternity unit/primary care send notification of birth/movement into the responsible PCT, to the child health records department	All babies accounted for on a child health information system	All eligible babies recorded on child health information system (See note 4)
5	Offer	Midwife takes sample according to consent/dissent of parent and records in maternity records and personal child health record. Blood spot card including declines sent to the laboratory for all new births	Status code 01 sample received in laboratory returned to maternity unit	Maternity units perform a daily search for untested babies to ensure all samples have been received and repeat sample requested in accordance with local pathway	Denominator = maternity units caseload/ number of babies eligible for blood spot screening Numerator = number of blood spot cards received in the laboratory (See note 5)
17a	Coverage	New birth or baby one year of age or under recorded on child health information system in the responsible PCT	Child health records department enter conclusive screening result for each condition onto the child health information system	Conclusive result recorded on the CHRD system for all 5 conditions by day 17. (A small percentage of samples cannot	Denominator = eligible babies recorded on a child health information system Numerator = conclusive screening result recorded on

				achieve the 17 days standard due to mutation analysis (CF, SCD) and repeat tests (preterm repeat and borderline TSH)	the child health information system, for each condition, by 17 days of age
17b	Identification of untested babies and those in whom screening is incomplete	New birth or baby one year of age or under recorded on child health information system in the responsible PCT	Child health records department enter screening status code, for each condition onto the child health information system	CHRDs perform regular checks (ideally daily, minimum weekly) to identify babies with null values or status codes 01 specimen received in laboratory or 03 repeat/further sample required, for any of the five conditions aged between 17 days and before their first birthday.	100% of CHRDs perform regular checks (ideally daily, minimum weekly) (See note 17b)
21	All babies with screen positive results are offered a diagnostic test	The newborn screening laboratory initiates clinical referral for screen positive	Baby attends for initial clinical assessment meeting timeliness standards for the relevant	Confirmation of attendance at first appointment with clinical team reported	Denominator = number of babies that screen positive for each condition

		babies	condition. Clinical teams should have in place mechanisms to follow-up any non-attendees' in a timely fashion	back to the referring laboratory on all babies with screen positive results (See note 21)	Numerator = number of babies with confirmation of attendance at first clinical appointment received in the laboratory
22	Communicating newborn screening results to parents	The PCT ensures that the child health records departments has a process for notifying screening results to parents	The child health records departments' records results on the child health information system and notifies results to health visitors for reporting to parents. Best practice is for the child health records department to inform parents of all 5 normal results by letter	The PCT ensures that parents have received results and they are recorded in the PCHR Responsibility for ensuring parents receive results lies with the health visitor	Not currently auditable (See note 22)

Notes:

4 Identifying the eligible population: new births are notified through birth notification processes. Older babies that move into a PCT are notified by a variety of routes. New family GP registration, child health and health visitor notification systems need to be in place to ensure 'moved in' babies are recorded in the child health information system in a timely way.

5 This 'failsafe' refers to the 'receipt of sample in laboratory failsafe' project that was supported for implementation by the UK NSC last year; however funding from DH is not yet confirmed.

17b Newborn screening programmes have coverage and early identification and referral for diagnosis as a key measurement of programme performance. E.g. for PKU dietary

treatment should start as early as possible (acceptable standard by 17 days of age and achievable standard by 14 days of age).

Regular checks to ensure early identification of babies with null or incomplete result, within an effective timeframe are an important failsafe. Failsafe reports are produced for follow-up, according to local protocols.

Those responsible for follow-up should ensure that the screening process is 'fast-tracked' and the sample taken within 48-72 hours of notification and despatched to the laboratory.

21 There is currently no failsafe mechanism for ensuring babies attend for initial clinical assessment. Responsibility for making the clinical referral according to local pathway lies with the referring laboratory. Responsibility for initial clinical assessment and follow up of babies that do not attend lies with the specialist centre/designated paediatrician. Laboratories hold the information on screen positive babies so it is logical that they provide the check that babies have entered into care. To achieve this, cooperation from the clinicians and funding from commissioners is required.

22 Receipt of results by parents is not currently auditable. KPI NBS 3 will measure the availability of 5 normal results on a child health information system at 6 weeks, which is a precursor to the child health records department to inform parents of all 5 normal results by letter.