UK National Screening Committee

Screening Programmes

NHS Sickle Cell and Thalassaemia Screening Programme

Failsafe processes

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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 Sickle Cell and Thalassaemia Screening Programme

The NHS Sickle Cell and Thalassaemia Screening Programme was set up in England in 2001 following Government commitment in the NHS Plan (2000). It is the world's first linked antenatal and newborn screening programme.

The aims are to:

- Save lives through prompt identification of affected babies
- Offer informed choice to couples expecting a baby

- Support the development of a managed clinical care network such that people have fair access to quality services throughout England
- Raise public awareness of the disorders and challenge stigma

More information on the NHS Sickle Cell and Thalassaemia Screening Programme can be found on their website at http://sct.screening.nhs.uk/.

The Map of Medicine

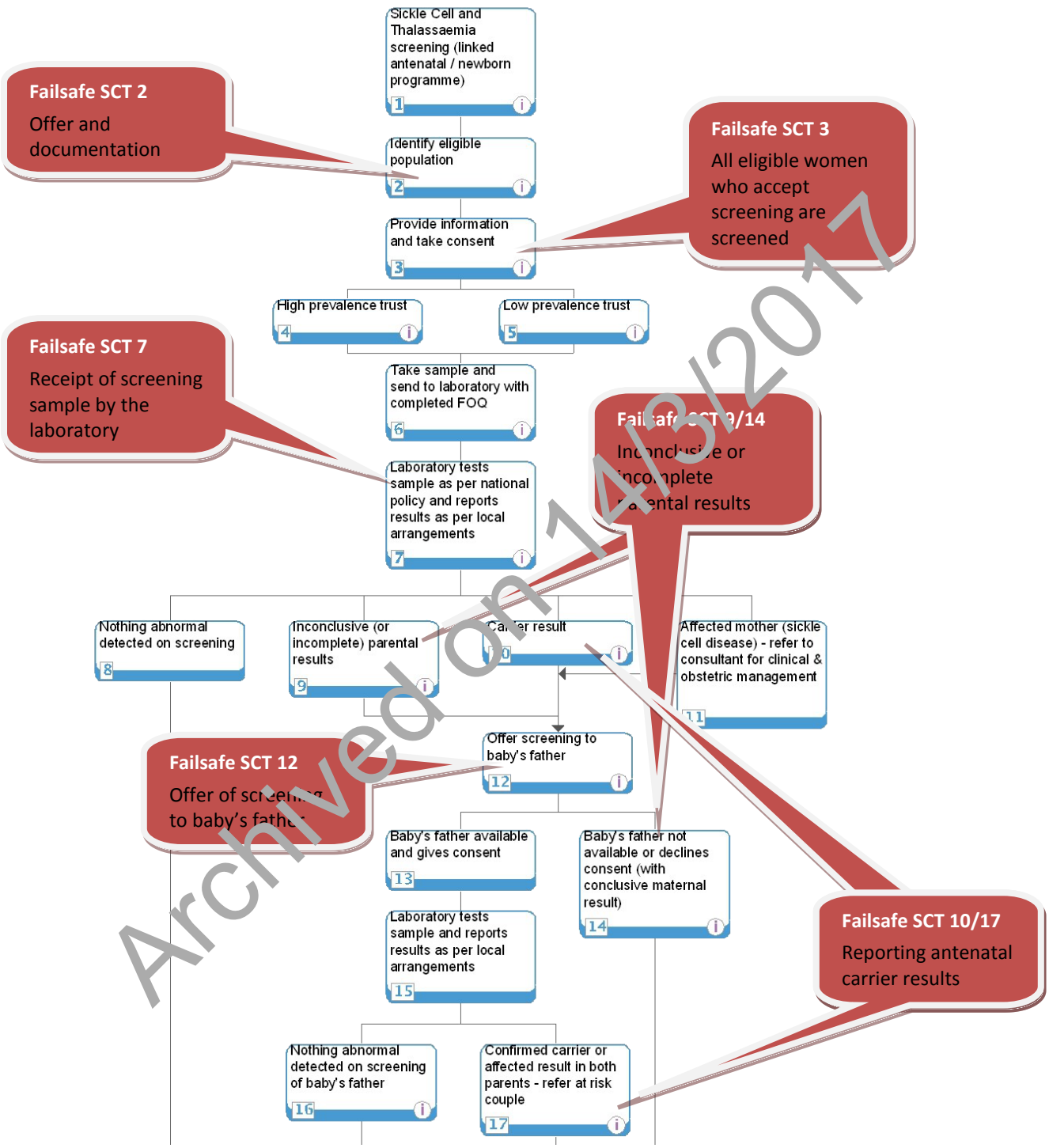
Map of Medicine is a visual representation of evidence-based, practice-informed care pathways for common and important conditions. Pathways are freely available for health professionals through NHS Evidence (http://www.mapofmedicine.com/england) and for the public on NHS Choices (http://healthguides.mapofmedicine.com/).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

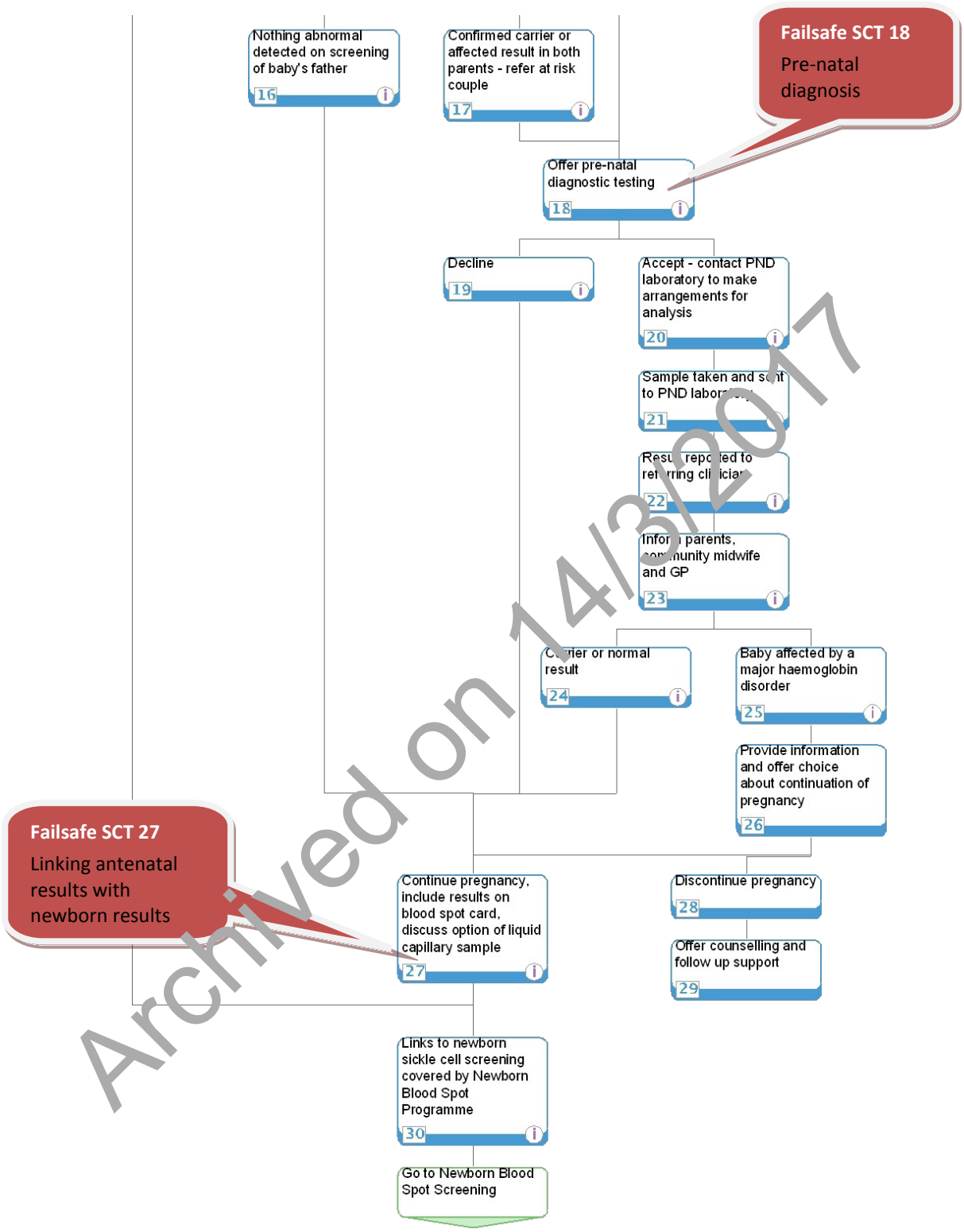
View the pathway:

Linked Sickle Cell and Thalassaemia Screening

http://eng.mapofmedicine.com/evidence/map/linked_sickle_cell_and_thalassaemia_screening1.html

Failsafe Overview





Failsafe Descriptions

Node(s)	Failsafe process	Opening the loop	Closing the loop	Ensuring the loop has been closed
2	Offer and documentation	Population identified: All pregnant women (including self-referrals) Information provided	Midwife or other healthcare professional takes informed consent and documents date of screening offer and whether screening was accepted or declined. Known carriers have review of couple carrier status and referred as appropriate.	Process should be in place to ensure regular checks that screening has been offered and documented. There should be systems in place to identify eligible population including movers-in and self-referrals and local policy for screening women in subsequent pregnancies. This failsafe corresponds to the denominator in KPI ST1, where all eligible women should be offered screening.
3	All eligible women who accept screening are screened	Informed consent taken and consent/decline recorded	FOQ completed, Blood samples taken and labelled as antenatal, and dispatched to antenatal laboratory together with completed FOQ.	Process in place to ensure: -blood samples are taken on all eligible women who accept screening -samples are recorded and received by laboratory; including regular checks to identify records with no screening outcome. In low prevalence trusts there should be local policy in place to ensure that the FOQ is completed on women whose samples are received without a completed FOQ, to avoid the risk of missing any affected pregnancies. In high prevalence trusts local policy should include systems to

				check that all women who want testing have been tested. This failsafe represents coverage and is measured by KPI ST1.
7	Receipt of screening sample by the laboratory	Blood samples clearly identifiable as antenatal taken and dispatched to the antenatal laboratory together with completed FOQ form (FOQ dispatched or transferred electronically)	Fit for purpose sample received by the laboratory together with a completed FOQ.	Process in place for regular, i.e. weekly checks of antenatal samples to cross reference with maternity information. If the sample is not fit for purpose or does not clearly indicate a request to screen, there should be a standard operating procedure in place detailing actions between the laboratory and the maternity services with named healthcare professionals responsible to ensure appropriate screens are undertaken. This can be measured by the denominator of KPI ST2.
9 / 14	Inconclusive or incomplete parental results	Laboratory receives and tests antenatal blood sample.	Prenatal diagnosis (PND) is offered to carrier woman if baby's father's results are not available or risk assessment of inconclusive results indicates potential at risk couple.	A local policy for inconclusive or incomplete parental results should be in place to perform a risk assessment and offer diagnostic testing, if required. Acceptance/ decline of PND should be recorded in notes. Offer of PND, and acceptance or decline should be documented in maternity notes, and used for review.
10 / 17	Reporting antenatal carrier results	Laboratory tests antenatal sample and reports results to lead professional responsible and/or requestor	Maternity unit or counsellor receives and documents carrier results and communicates to parents and	Local policy in place to check all carrier results have been documented in maternity notes, and the results communicated to parents and designated

		for dealing with carrier results	designated healthcare professional	healthcare professional and counselling offered about pregnancy options and future pregnancies. Local alert systems in place for ensuring carrier results are recorded on newborn bloodspot request card. There should be a check between laboratory and counsellor and regular local audit to ensure this failsafe is being met.
12	Offer of screening to baby's father	Antenatal laboratory reports mothers result as carrier, affected or inconclusive to requestor	Maternity units or other healthcare professional offer screening to the baby's father (before 11 weeks of pregnancy to identify 'at risk couples'). Informed consent taken, and consent/decline recorded	A local policy should be in place to ensure regular checks that screening has been offered to baby's father, if necessary and systems to ensure documentation of offer, uptake and decline of screening including incomplete parental results. This is a high risk area. Maternity units should document offer and acceptance or decline in maternity notes and keep a log of at risk couples and fathers tested.
18	Pre-natal diagnosis	At-risk couple identified (or inconclusive /incomplete parental results)	PND laboratory contacted to make arrangements for diagnostic test, sample taken, recorded in notes and healthcare professional and newborn laboratory informed of at-risk couple status.	Policy in place to record at-risk couples status, offer, acceptance/decline of PND, continuing high risk pregnancies in maternity notes, and robust communications with newborn laboratories by means of recording on blood spot cards and alert forms for ongoing pregnancies. Systems in place to document if women

				self-refer for PND. Offer of PND, and acceptance or decline should be documented in maternity notes, and used for review.
27	Linking antenatal results with newborn results (refer to newborn pathway node 2 'Check antenatal results and family history')	Maternity unit, counsellor or requestor receives screen positive antenatal results for women	Local policy for antenatal screening history (screening and diagnosis) to be reported to the newborn laboratory	A system must be in place to check the antenatal screening history of all affected babies. This failsafe should be audited by regular meetings to review a linked pathway as set out in the programme standards.