UK National Screening Committee

NHS Screening Programmes

NHS Infectious Diseases in Pregnancy 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 Infectious Diseases in Pregnancy Screening Programme

The Infectious Diseases in Pregnancy Screening (IDPS) Programme is responsible for ensuring that women with hepatitis B, HIV, and syphilis are identified in pregnancy. All women are universally offered tests for these conditions early in pregnancy, and women with positive screen results are referred for assessment and management. This Programme is an essential component of strategies to prevent mother-to-child transmission of hepatitis B, HIV and syphilis, and well as safeguard the woman's own health.

The Programme also screens women for susceptibility to rubella infection to identify those whom postnatal MMR vaccination could protect future pregnancies.

It is a core service within the NHS in England and part of the family of Antenatal and Newborn Screening Programmes.

More information on the NHS Infectious Diseases in Pregnancy Screening Programme can be found on their website at http://infectiousdiseases.screening.nhs.uk/.

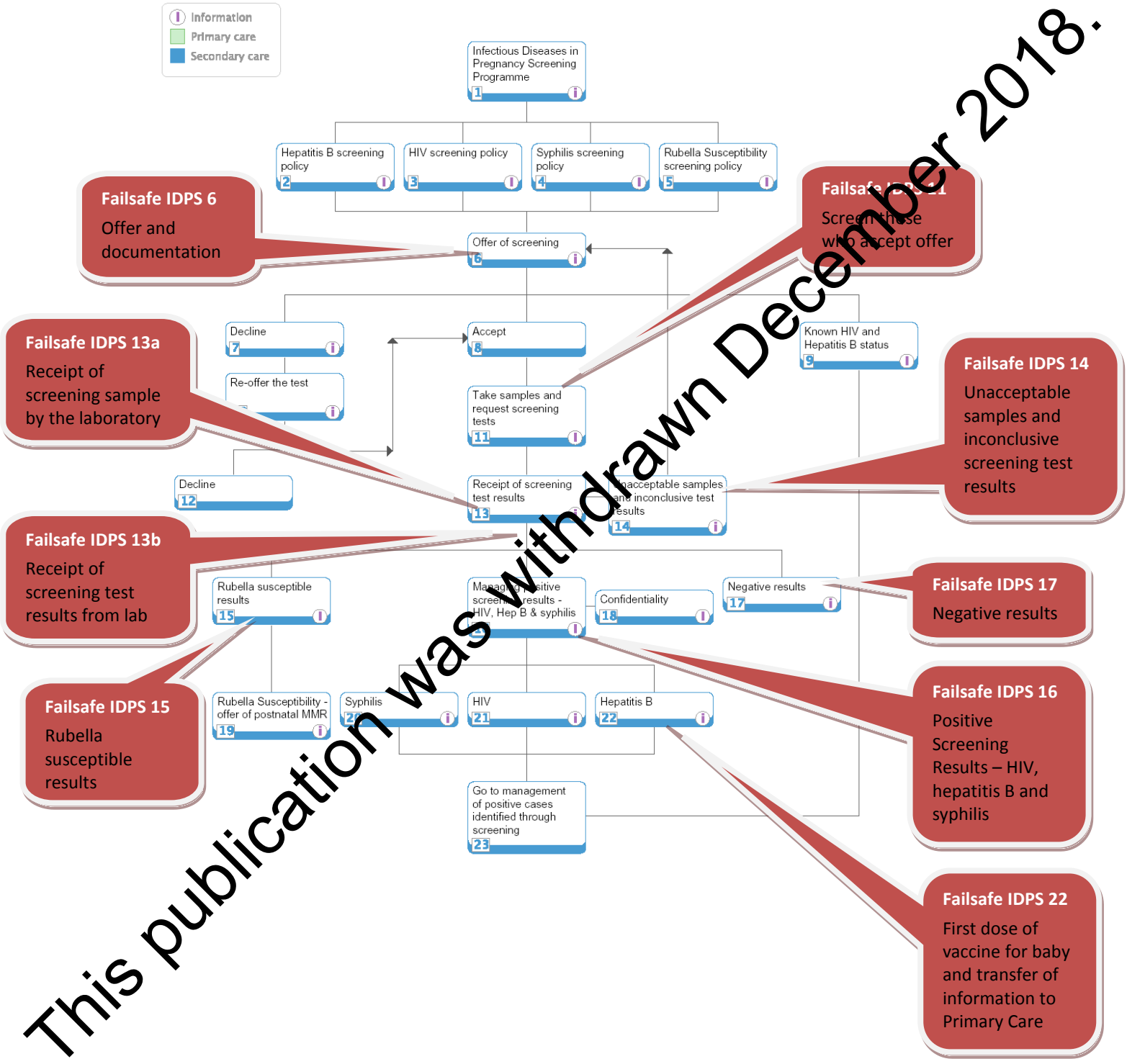
The Map of Medicine

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 IDPS pathway:

Infectious diseases in pregnancy screening – http://eng.mapofmedicine.com/evidence/map/infectious_diseases_in_pregnancy_screening1.html

Failsafe Overview



Failsafe Descriptions – Overview of Critical Points

Node(s)	Failsafe process	Opening the loop	Closing the loop	Ensuring the loop has been closed	Measure
6	Offer and documentation	The midwife should ensure informed choice for screening before a specimen is taken and tests requested.	Midwife requests screening tests, and documents date of screening offer, whether screening was accepted, declined for each infection or known to be HIV/hepatitis b positive. Screening is re-offered to all women who decline the initial offer, ideally by 28 weeks gestation.	Regular checks, by Healthcare practitioner at next contact with mother, to ensure documentation of initial offer, and re-offer if necessary.	Audit of notes
11	Screen those who accept the offer	A woman consents to be screened for all or some of the conditions	Blood samples taken, marked clearly as an antenatal sample, with date and time. Accurate and full completion of blood request form, including whether screening is accepted, declined or known to be HIV/hepatitis b positive. Then ensuring timely transfer to the lab, within one working day of the sample being taken.	Process in place to ensure blood samples are taken and recorded. Ensure safe and effective means of transferring/transporting samples, to be received by lab. Use of an IT system is preferable.	Audit
13a	Receipt of screening sample by the laboratory	Antenatal samples received at lab.	*Fit for purpose* sample received, with all mandatory fields on request form completed.	Process in place for regular, ie weekly, checks of antenatal samples to cross reference with maternity information. If the sample is not fit for purpose or does not clearly identify the requirements	Audit of lab records and review percentage not followed-up. IT alerts if possible.

				to screen, there should be a standard operating procedure in place detailing actions between the lab and the maternity services with named health care professions responsible to ensure appropriate screens are undertaken.	
13b	Receipt of screening test results from lab	Confirmed screening test results are received by maternity services.	Screening results received from lab within 10 working day and clearly specify whether the result is screen negative or screen positive, and documented	Process in place for the midwife to identify and follow-up results that have not been received within 10 working days, and specifically in preparation for the next routine antenatal visit. Two way cross-check process should be in place (both in maternity service and lab).	If the IT systems are not available to do this, you could use manual records/list between maternity and lab. KPI ID1 (for HIV) IT alerts if possible.
14	Unacceptable samples and inconclusive screening test results	Lab requests further samples.	Repeat specimens should be sent to the laboratory by the maternity unit, within 10 working days. For audit purposes lab records reasons for unacceptable sample.	Process in place to ensure the lab requests for repeat samples are identified and followed-up. Two way cross-check process should be in place (both in maternity service and lab).	Audit IT alerts if possible.
15	Rubella susceptible results	Susceptible to rubella infection results received by	At next antenatal visit, midwife to discuss postnatal MMR vaccination and obtain consent. The	Post natal MMR (1st dose) administered to woman who accepted the	Audit of notes

		maternity services.	offer, acceptance or decline should be reported, and arrangements made to ensure the vaccine is offered and administered before discharge from hospital.	offer prior to discharge from maternity services, and documentation made in hospital notes and discharge summary. Primary care informed i.e GP, of the need for 2nd dose.	
16	Positive Screening Results – HIV, hepatitis B and syphilis	Positive screening tests received by maternity services.	Woman should be contacted and informed of the result at a designated face-to-face appointment. Discuss the screening test result and make urgent arrangements for referral to specialist service and clinical assessment.	Clear documentation in maternity system of date of result receipt, date of referral and the date when the woman is seen by a relevant professional.	Audit
17	Negative results	Negative results received by maternity services.	Negative screening test results reported back to women before or at the next antenatal clinic, according to local protocol. All healthcare professionals should check all results, both positive and negative, are completed in handheld records at each contact.	Clear documentation on maternity system of date of result receipt for each condition tested.	Audit
22	First dose of vaccine for baby and transfer of information to Primary Care/Child Health Records	Hepatitis B positive woman identified through screening or known positive, offered vaccination for the baby.	First dose of vaccine (+/- HBIG) administered to neonate within the first 24 hours after birth. Communicate with Primary Care for completion of the vaccination schedule, including informing the relevant Child Health Records Department,	Audit to ensure the local HPA data matches the number of children requiring immunisation.	Audit of notes

	discussion with mother about the importance of completing the full schedule.