

Clinical Standards ~ *October 2005*

Pregnancy and Newborn Screening

© NHS Quality Improvement Scotland 2005

ISBN 1-903961-53-X

First published October 2005

You can copy or reproduce the information in this document for use within NHSScotland and for educational purposes. You must not make a profit using information in this document.

Commercial organisations must get our written permission before reproducing this document.

www.nhshealthquality.org

Contents

1	Background on NHS Quality Improvement Scotland	2
2	Development of Clinical Standards	3
3	An Introduction to Pregnancy and Newborn Screening	5
4	Development of the Clinical Standards for Pregnancy and Newborn Screening	11
5	Clinical Standards for Pregnancy and Newborn Screening	15
	Standard 1 – Service Provision and Monitoring	16
	Standard 2 – Pregnancy Screening: Down’s Syndrome and Neural Tube Defects	24
	Standard 3 – Pregnancy Screening: Communicable Diseases	31
	Standard 4 – Newborn: Bloodspot Screening	37
	Standard 5 – Newborn: Hearing Screening	45
6	Appendices	53
	Appendix 1 Pregnancy Screening Protocol Summary	54
	Appendix 2 Membership of the Pregnancy and Newborn Screening Standards Project Group	56
	Appendix 3 Evidence Base	57
	Appendix 4 Glossary of Terms	61

1 Background on NHS Quality Improvement Scotland

NHS Quality Improvement Scotland (NHS QIS) was set up by the Scottish Parliament in 2003 to take the lead in improving the quality of care and treatment delivered by NHSScotland.

We achieve our objectives through four key functions that link together:

- setting standards
- reviewing and monitoring performance
- providing advice and guidance on effective practice
- supporting staff to improve services.

We deliver our commitments to the public and to NHSScotland by following an approach that is:

- **independent** - we reach our own conclusions and report on what we find
- **open and transparent** - we explain what we do, how and why we do it, and what we find, using language and formats that are easy to understand and to access
- **sensitive and professional** - we recognise needs, beliefs and opinions and respect and encourage diversity.

Our work is:

- **partnership-focused** - we work with patients and the public, NHSScotland and many organisations to improve the quality of care and avoid duplication
- **evidence-based** - we base our conclusions and recommendations on the best evidence available
- **quality-driven** - we make sure our own work is monitored and evaluated, internally and externally.

2 Development of Clinical Standards

Basic principles

A major part of the remit of NHS Quality Improvement Scotland (NHS QIS) is to develop and run a national system of quality assurance of clinical services. Working in partnership with healthcare professionals and members of the public, NHS QIS sets standards for clinical services, assesses performance throughout NHSScotland against these standards, and publishes the findings. The standards are based on the patient's journey as he or she moves through different parts of the health service. A wide range of diseases and services have already been addressed including diabetes, maternity services and anaesthesia.

The standards set by NHS QIS are clear and measurable, based on appropriate evidence, and written to take into account other recognised standards and clinical guidelines. The standards are:

- written in simple language and available in a variety of formats
- focused on clinical issues and include non-clinical factors that impact on the quality of care
- developed by healthcare professionals and members of the public, and consulted on widely
- regularly reviewed and revised to make sure they remain relevant and up to date
- achievable but stretching.

Clinical governance and risk management standards

Every patient using healthcare services should expect these to be safe and effective. The NHS QIS *Standards for Clinical Governance & Risk Management* will ensure NHS Boards can provide assurance that clinical governance and risk management arrangements are in place, and are supporting the delivery of safe, effective, patient-focused care and services.

The clinical governance and risk management standards underpin all care and services delivered by NHSScotland and provide the context within which NHS QIS service and condition-specific standards apply. They should be read in conjunction with all our standards.

The clinical governance and risk management standards are effective from November 2005 and are available on request from NHS QIS or can be downloaded from the website (www.nhshealthquality.org).

Process

For each project in the work programme, NHS QIS appoints a group comprising appropriate healthcare professionals and members of the public to:

- oversee the development of, and consultation on, the standards and self-assessment framework
- recommend an external peer review process.

The way in which standards are developed is a key element of the quality assurance process. Project groups working on behalf of NHS QIS are expected to:

- adopt an open and inclusive process involving members of the public, voluntary organisations and healthcare professionals
- work within NHS QIS policies and procedures
- test the measurability of draft standards by undertaking pilot reviews.

Assessment of performance against the standards

The framework for the NHS QIS review process is as follows.

- Once the standards have been finalised, each relevant NHS Board is asked to undertake a self-assessment of its service against the standards.
- A review team visits the NHS Board on behalf of NHS QIS to follow up this self-assessment exercise with an external peer review of performance in relation to the standards.
- NHS QIS reports the findings for the NHS Board, based on the self-assessment exercise and on the external peer review.

All the processes being developed by NHS QIS are subject to review and evaluation, to help improve the quality assurance system.

3 An Introduction to Pregnancy and Newborn Screening

Screening is a public health service offered to groups of the population to identify risk of a particular condition. Screening tests are not compulsory but are offered to help individuals make informed choices about their health and the health of their child. There is an ethical obligation on agencies to ensure that the timely provision of services meets the needs identified through the screening process.

Prior to accepting or declining the offer of a screening test, it is important that individuals receive information about the screening in which they are about to participate. While some screening tests have the potential to save lives, or improve quality of life by making possible the early diagnosis of a serious condition, they are not both 100% sensitive and 100% specific.

Pregnancy and newborn screening are considered to be important components of good healthcare that should both underpin and inform child and family health and wellbeing and the provision and design of maternity care and child health services.

Screening is a two-stage process. Usually, the first-line test indicates only a risk or probability that a particular condition is present. A second, diagnostic test is required for confirmation. For example, in some cases, the first test provides information on possible infection in the mother herself and infection would be confirmed by further tests before action is taken.

Pregnancy screening

In Scotland all pregnant women are eligible for screening. Information on pregnancy screening is provided to women at an early stage in their pregnancy (ideally before the initial booking visit). A woman's decision to accept or decline the screening tests is recorded in her maternity record, but irrespective of her decision she will continue to receive the full range of normal pregnancy care.

Down's syndrome is a congenital condition, which is associated with moderate to severe learning disability and a spectrum of other health problems. Down's syndrome can vary in degree of severity, and many people with this condition are able to lead fulfilling lives. In the absence of screening and pre-natal diagnosis the current birth incidence in Scotland would be around 1 in 600 babies. Older mothers are more likely to conceive a child with Down's syndrome than younger mothers. However, the majority of Down's syndrome babies are born to younger women as this is when most women have babies. The screening tests which may detect this condition are a blood test carried out at 15-20 weeks of pregnancy or a combined blood test and ultrasound screening test at 11-14 weeks of pregnancy. The ultrasound scan measures the thickness of the fluid-filled area at the back of the fetal neck (called 'nuchal translucency' or NT). The bigger the measurement, the higher the risk of Down's syndrome being present. Women should be aware that these tests may detect abnormalities other than Down's syndrome. About 1 in 20 women will have a screening result that indicates a higher chance of an affected pregnancy. Diagnostic testing, including, chorionic villus sampling (CVS) or amniocentesis, is then offered to provide a definitive

diagnosis. There is a small risk of miscarriage with these invasive tests. The 15–20 week blood test can identify 6 out of 10 pregnancies with Down's syndrome and the combined test 8 out of 10 affected pregnancies.

Neural tube defects, such as spina bifida and anencephaly, affect approximately 1 in every 500–1,000 pregnancies in Scotland. Babies with spina bifida have an opening in the bones of the spine, and the nerves to the lower part of the body are damaged. This can result in difficulties with walking and bowel and bladder control. Sometimes there is also a learning disability due to hydrocephalus (an accumulation of fluid in the brain) which often accompanies spina bifida. There is a wide variation in the level of disability caused by this condition and many people with spina bifida are able to lead fulfilling lives. In babies with anencephaly, the skull and brain are not properly formed. These babies generally die before or very soon after they are born.

The screening test involves taking a small blood sample from the woman at approximately 15–16 weeks of pregnancy (usually the same sample that is used for the Down's syndrome test described previously) and the concentration of a substance called alphafetoprotein (AFP) is measured. If the AFP result is normal, there is only a small chance that the baby will have a neural tube defect and no further testing is required. An elevated result, which would be expected in around 1 in 25 women, indicates that there is an increased risk of the baby being born with a neural tube defect and an ultrasound scan will be arranged to show whether or not an abnormality is present. The blood test can detect around 8 out of 10 pregnancies affected with a neural tube defect.

Communicable diseases

A Health Department Letter (HDL 52) issued in June 2002 recommended that human immunodeficiency virus (HIV) testing should be offered routinely to all pregnant women as part of their antenatal care. This test was introduced in Scotland throughout 2002 and forms part of the integrated programme of antenatal screening to limit risk for a number of communicable diseases (hepatitis B, syphilis and rubella as well as HIV). The primary aim of screening women for these conditions is to ensure a plan for treatment and management for affected individuals and their babies.

Tests for infection with HIV, hepatitis B and syphilis, and immunity to rubella are carried out on serum obtained from a single blood sample taken at the first antenatal visit. Occasionally a second blood sample may be required for technical reasons to confirm a test result. Tests for HIV, syphilis and rubella are based on the detection of a specific antibody to each. The test for hepatitis B virus detects viral antigen in the same sample.

HIV can be transmitted from a mother to her baby. The risk of HIV transmission from a mother to her baby can be up to 25% when no treatment is given. Detecting the HIV antibody in the mother's blood at any stage of pregnancy, but preferably early on, can help to bring transmission to under 2% through antiviral treatment and appropriate delivery. Screening for HIV involves taking a blood sample which is tested for antibodies to HIV. All positive test results indicating a possibility of HIV are confirmed by retesting, using a

different test method. The combination of two tests produces high accuracy with minimal risk of false results. HIV antibody tests exceed the performance of most other infectious disease tests in both sensitivity and specificity.

Although these tests are very sensitive, there is an interval known as a 'window period'. This is the period between the onset of infection with HIV and the appearance of detectable antibodies to the virus. This period is usually less than a month, however, it may be longer for some individuals. It is important that women are aware that despite being given a negative test result, it could be that antibodies are not yet present and therefore the result given could be false. If a woman feels she has been/continues to be at risk of exposure to the virus, further 3-monthly testing should be offered throughout pregnancy.

Hepatitis B infection can be transmitted from mother to infant, leading to generally asymptomatic infection but lifelong carriage of the virus and greater risk of cirrhosis of the liver and of hepatocellular carcinoma later in life. Perinatal transmission of the hepatitis B virus occurs if the mother has an acute infection in pregnancy or if she is a chronic carrier of hepatitis B. This can be prevented by identifying a baby at risk before birth and offering immunisation starting in the first 2 days of life.

Syphilis infection can have consequences for both mother and infant, but detection of infection early in pregnancy allows appropriate antibiotic treatment to prevent transmission. About 50% of infected mothers will be asymptomatic and the causal agent, *treponema pallidum* can cross the placenta at any stage of pregnancy. However, maternal antibiotic therapy can prevent nearly all congenital syphilis.

Rubella infection used to be a common mild infection of childhood, and is characterised by a short period of illness and a rash. If rubella is contracted during the first trimester of pregnancy it can lead to severe abnormalities in the baby, including deafness and eye and heart disease. The incidence has been largely reduced by immunisation of children and young women before conception, but there is a continuing need to look for evidence of immunity in pregnant women to ensure congenital rubella syndrome is very unlikely in Scotland.

Newborn screening

A Health Department Letter (HDL 34) issued in April 2001 outlined the National Screening Committee's recommendation for the introduction of a standardised, quality assured, co-ordinated programme for newborn screening services for phenylketonuria (PKU) and congenital hypothyroidism (CHT). A subsequent Health Department Letter (HDL 51), issued in June 2001, outlined the National Screening Committee's recommendation for the introduction of a phased neonatal hearing screening programme. A further Health Department Letter (HDL 73), issued in September 2001, endorsed proposals for the introduction of a standardised neonatal cystic fibrosis (CF) screening programme.

Although most babies are perfectly healthy when born, a small number have abnormalities of body chemistry (metabolism) which can lead to problems with growth and development. Some of these problems can be detected through a blood test. This involves taking a small

amount of blood from a baby's heel which is transferred to a special card to produce a blood spot. Midwives usually take blood samples from babies within the first week of life. This sample is used to test for three main conditions:

- phenylketonuria
- congenital hypothyroidism
- cystic fibrosis.

Hearing impairment also affects a small number of newborn babies each year and hearing tests have been developed which can help identify affected infants at an early stage.

NHS Boards are responsible for ensuring that screening of all babies is offered and all results are reported to the NHS Board for input onto the department of community child health records system. In addition positive results are reported to the consultant paediatrician/audiologist, GP, and the NHS Board who will initiate treatment and/or further testing.

Phenylketonuria affects around 1 in every 8,000 babies born in Scotland. It is a condition that is inherited when both parents are asymptomatic carriers of one active and one inactive copy of the gene. Inheriting two inactive copies of the gene causes deficiency of a liver enzyme known as phenylalanine hydroxylase which, in turn produces high levels of phenylalanine in all body fluids. Babies with PKU cannot metabolise phenylalanine, which is a component of all natural protein in every day foods, eg milk, fish, eggs and cheese. If phenylalanine levels remain high this results in severe damage to the baby's brain. Babies diagnosed with this condition must be seen by a paediatrician as soon as possible and started on a special diet. Therapy for PKU relies on the partial elimination of phenylalanine from the diet. Since phenylalanine is present in all proteins this requires the use of chemically defined protein substitutes with a limited amount of natural protein. The effectiveness of therapy is monitored by regular blood samples which accurately measure the phenylalanine level. With prompt treatment the baby is very likely to develop normally. The treatment is life-long and effective management requires a multidisciplinary team comprising doctors, dieticians, clinical biochemists, psychologists and pharmacists.

Congenital hypothyroidism affects approximately 1 in every 3,500 babies born in Scotland. Babies affected by this condition are unable to produce enough of the hormone thyroxine either because their thyroid gland is missing or it is not working effectively. This condition is corrected by giving thyroxine by mouth, which will help the baby to grow normally. However, if left untreated it will result in slower than normal growth and severe learning difficulties.

Cystic fibrosis is an inherited condition and affects 1 in every 2,500 babies born in Scotland. The organs most likely to be affected are the pancreas and the lungs, causing poor digestion and chest infections. Screening for CF involves the bloodspot specimen being tested in two stages. The first stage tests for a substance called immuno reactive trypsinogen (IRT), which is usually present in increased amounts in the blood of babies with CF during

their first few weeks of life. When the IRT is high, deoxyribonucleic acid (DNA) analysis is performed on the same bloodspot sample, to look for the commonest genetic mutations associated with CF in the Scottish population. Early treatment may help affected children to maintain good nutrition and minimise chest infections, leading to improved quality of life.

Newborn hearing screening

The prevalence of permanent congenital hearing impairment (PCHI) is approximately 1-2 per 1,000 babies born in the UK. This means that approximately 60-65 babies born in Scotland each year are affected. The new Universal Newborn Hearing Screening (UNHS) Programme is more effective in detecting hearing impairment than the current distraction test, which is carried out when the infant is 7-8 months old. The sensitivity of the health visitor distraction test is very low and hearing difficulties are often not detected until children are at least 18 months old, and sometimes not until they are 3½ years old. UNHS is offered shortly after birth, thus reducing the age at which deafness is confirmed and therefore improving the wellbeing of the child in terms of education and social needs. Positive results are reported to the audiologist and appropriate diagnostic assessments arranged.

There are two types of screening tests. The Otoacoustic Emissions (OAE) test involves transmitting sounds to the inner part of a baby's ear, known as the cochlea, through an ear piece placed in the baby's ear. A healthy cochlea will produce a faint echo. The response to the sound in each ear is recorded. The Automated Auditory Brainstem Response (AABR) test involves three sensors being placed on a baby's head. Earphones, which transmit clicking sounds, are placed over a baby's ears. The baby's brain activity in response to the sound is recorded. Both screening tests are performed while the baby is settled. Screening tests do not cause any pain or discomfort to the baby.

Screening programmes

Antenatal screening for neural tube defects began in Scotland in 1975 and screening for Down's syndrome in 1987. Newborn screening was introduced for PKU in 1965, for CHT in 1979 and for CF in 2003. Although initially there was inequality in the provision of these services and variation in the type and quality of services provided, screening in pregnancy and in the neonatal period has been steadily developed and is now offered to all women and babies in Scotland. Throughout this period however, there has been no provision of standards or performance targets relating to the overall programme or to specific screening tests.

In February 2001, the Scottish Executive Health Department published *A Framework for Maternity Services in Scotland*. The Framework presents a template for best practice in maternity care in Scotland. One of the principles within the Framework states that: 'A comprehensive antenatal diagnostic and screening service should be available and offered to women in order to detect, where possible, any maternal problems or fetal abnormalities at an early stage.'

Health Department Letters (HDLs) also issued in 2001, recommended that standardised, quality assured and co-ordinated pregnancy and newborn screening programmes should be established with arrangements in place from April 2002. The newborn screening programme was also to be modernised and developed to deliver a more standardised quality assured programme. The subsequent HDL(2001)51 recommended the introduction of a universal newborn hearing screening programme to detect hearing impairment in babies. Lothian and Tayside NHS Boards were identified as pathfinder sites for newborn hearing screening in preparation for the national roll-out of the programme across Scotland.

4 Development of the Clinical Standards for Pregnancy and Newborn Screening

The pregnancy and newborn screening standards apply to specific elements of the service.

As a first step in addressing the standards for pregnancy and newborn screening, NHS Quality Improvement Scotland (NHS QIS), appointed a project group, chaired by Canon Bob Fyffe, Minister, Perth. The Pregnancy and Newborn Screening Standards Project Group is multidisciplinary and includes healthcare professionals and members of the public. The Group first met in August 2002, and its membership can be found in Appendix 2.

The standards produced by the Group have been split into five broad areas.

Standard 1 - Service Provision and Monitoring

Standard 2 - Pregnancy Screening: Down's Syndrome and Neural Tube Defects

Standard 3 - Pregnancy Screening: Communicable Diseases

Standard 4 - Newborn: Bloodspot Screening

Standard 5 - Newborn: Hearing Screening

The standards will be used by NHS QIS to assess performance in these areas in NHS Boards throughout Scotland where pregnancy and newborn screening services are provided.

The following key points underpin the *Clinical Standards for Pregnancy and Newborn Screening*.

Overarching principles – pregnancy screening

- The aim of screening services in pregnancy is to enable women and their partners to make an informed choice about continuing the pregnancy, or to accept treatment at an early stage when it is likely to be more effective. The emphasis should be on identifying unborn babies at high risk as early as possible to ensure that the woman and her partner have adequate time and opportunity for discussion with healthcare professionals, who can support them through difficult decisions.
- Relevant information, which outlines the benefits and risks of screening, should be provided in a user-friendly manner so that women and their partners can make an informed choice. Information should be available at appropriate stages in pregnancy.
- The pregnancy screening programme must reach all eligible women irrespective of their status, race or any special needs requirements.
- With regard to confidentiality in pregnancy, the woman is the only individual who has legal rights to consent to the screening test and receive the results.
- Healthcare professionals and support staff at all stages and levels in the screening programme should be appropriately trained.
- A woman's satisfaction with the screening process is enhanced if multidisciplinary team working across all the components of the programme is co-ordinated and monitored by the NHS Boards.

Overarching principles – newborn screening

- Newborn screening involves bloodspot and hearing tests offered to all apparently healthy-term infants, or pre-term infants, with the possibility of detecting a serious disease before any symptoms are evident.
- The aim is to offer treatment at an early stage when it is likely to be more effective. The emphasis should be on performing high quality bloodspot and hearing tests, with rapid reporting, as key components of the programme so that repeat tests are minimised and parents have confidence in the value of the process.
- Relevant information, which outlines the benefits and risks of screening, should be provided in a user-friendly manner so that women and their partners can make an informed choice. This information should be made available in advance of the date when the screening test is scheduled.
- The offer of newborn screening tests must reach all eligible infants irrespective of parental status, race or any special needs requirements.
- With regard to confidentiality in newborn screening, the woman has legal rights to consent to the screening tests and receive the results. The biological father has legal rights to consent to the screening test and receive the results only if he is married to the mother or has sought legal parental responsibility.
- Staff at all stages and levels in the screening programme should be appropriately trained.
- Parental satisfaction is enhanced when there is multidisciplinary team working across all the components of the programme, co-ordinated and monitored by the NHS Boards.

Clinical Standards for Pregnancy and Newborn Screening

The *Clinical Standards for Pregnancy and Newborn Screening* seek to establish quality assurance throughout all aspects of the pregnancy and newborn screening process for mothers and babies resident in an NHS Board area. Whilst it is acknowledged that a range of other conditions may be screened for in some NHS Board areas, these standards only cover those included in the recognised national screening programmes, as designated by the Scottish Executive Health Department. These standards represent the key elements of care for the screening process up to the point of diagnosis.

NHS QIS has developed a review process to assess the pregnancy and newborn screening programmes against the finalised screening standards. In addition to the role of national co-ordination of the programmes, the National Services Division, NHS National Services Scotland, was actively involved in work relating to the development of these standards and the review process, by providing information on both service developments and national policy on a Scottish and UK basis. As the pregnancy and newborn screening programmes evolve, the standards will be reviewed and updated.



Format of standards and definition of terminology

All standards set by NHS QIS follow the same format.

- Each standard has a **title**, which summarises the area on which that standard focuses.
- The title is followed by the **standard statement**, which explains the level of performance to be achieved.
- The **rationale** section provides the reasons why the standard is considered to be important.
- The standard statement is expanded in the section headed **criteria**, which states exactly what must be achieved for the standard to be reached. Most criteria are **essential**, in that it is expected that they will be met wherever a service is provided. Other criteria are **desirable**, in that they are being met in some parts of the service and demonstrate levels of quality which other providers of a similar service should strive to achieve. Each project group is responsible for determining which criteria are essential and which are desirable. The criteria are numbered for the sole reason of making the document easier to work with, particularly for the assessment process. The numbering of the criteria is not a reflection of priority. The distinction between 'essential' and 'desirable' is the only way in which criteria have been prioritised.

Evidence base

Sources of information consulted or referred to during the development of these standards can be found in Appendix 3.

5 Clinical Standards for Pregnancy and Newborn Screening

Standard 1 – Service Provision and Monitoring

Standard 2 – Pregnancy Screening: Down’s Syndrome and Neural Tube Defects

Standard 3 – Pregnancy Screening: Communicable Diseases

Standard 4 – Newborn: Bloodspot Screening

Standard 5 – Newborn: Hearing Screening

Standard 1 ~ Service Provision and Monitoring

Standard Statement 1a:

Standardised national programmes for pregnancy and newborn screening are available and offered in all NHS Board areas.

Rationale

There is evidence that optimised pregnancy screening programmes can identify a high proportion of pregnancies affected by the conditions screened for, which facilitates early detection and allows informed choice regarding management.

References: 1, 5, 8, 28, 29, 30, 31, 32, 33, 34

There is evidence that optimised newborn screening programmes can identify risks of specific conditions, which promotes early detection and treatment management.

References: 10, 23, 24, 25, 26

Essential Criteria

- 1a.1 There is an accredited consultant in public health medicine or accredited specialist in public health at NHS Board level responsible for overseeing and monitoring the provision of pregnancy and newborn screening in their area. (Specific responsibility may be delegated to key staff as appropriate.)
- 1a.2 There is a named healthcare professional(s) at an operational level co-ordinating the provision of pregnancy and newborn screening.
- 1a.3 Every NHS Board has a named multidisciplinary screening co-ordinating group(s) with lay involvement that meets at least annually, and reports annually to the NHS Board, either directly or via an appropriate subcommittee.
- 1a.4 This group is responsible for ensuring that pregnancy and newborn screening is developed in accordance with current national guidance.



Standard Statement 1b:

All NHS Boards have written protocols available for pregnancy and newborn screening which take account of the national specifications and local circumstances.

Rationale

All women and babies should be offered the same standard of screening regardless of where they live.

References: 2, 3, 6, 7, 8, 10, 14, 15

Essential Criteria

1b.1 Written protocols, which take account of national screening specifications and local circumstances, are in place for:

- pregnancy screening
 - Down's syndrome and neural tube defects
 - HIV; rubella; syphilis and hepatitis B
- newborn screening
 - phenylketonuria (PKU); congenital hypothyroidism (CHT) and cystic fibrosis (CF)
 - hearing.

1b.2 NHS Boards have arrangements in place to ensure that the screening protocols can be met and monitored at least annually.

Standard 1 ~ Service Provision and Monitoring (continued)

Standard Statement 1c:

All NHS Boards ensure that the pregnancy and newborn screening programmes are informed by audit including evaluation and implementation of change (where necessary).

Rationale

Audit is essential to ensure standardised and quality assured pregnancy and newborn screening programmes and to establish the sensitivity and specificity of screening. It also helps to identify variations in practice, encourages examination of the reasons for these and helps to identify the changes that are required to effect improvements.

References: 3, 6, 8, 10, 14, 15

Essential Criteria

- 1c.1 The full audit cycle (collection, evaluation of data and implementation of change) of the pregnancy and newborn screening programmes is overseen by the multidisciplinary screening co-ordinating group.
- 1c.2 Each discipline involved in providing the pregnancy and newborn screening programmes contributes to and participates in the full audit cycle.
- 1c.3 Women's, parents' and carers' experience of the screening process is included as part of the audit cycle(s).

Desirable Criterion

- 1c.4 Information technology arrangements are in place to support the audit cycle(s).


Standard Statement 1d:

Laboratories providing pregnancy and newborn screening services meet recognised professional standards and the screening tests undertaken are subjected to rigorous internal quality control and external quality assessment.

Rationale

There is evidence that laboratories accredited and working to agreed standards achieve a high level of reporting accuracy. Quality assurance is essential to provide an independent assessment of the performance of laboratory screening tests.

Reference: 4

Essential Criterion

1d.1 All screening laboratories are accredited by an appropriate body, eg Clinical Pathology Accreditation (UK) Ltd.

Standard 1 ~ Service Provision and Monitoring (continued)

Standard Statement 1e:

There are clear links between each NHS Board, the local clinical service and the screening laboratories.

Rationale

Explicit communication channels are essential as pregnancy and newborn screening programmes are multiprofessional and are provided on a regional or national level.

References: 2, 3, 6

Essential Criterion

1e.1 There are clearly defined processes for ensuring information flow between the local clinical service for each NHS Board and the screening laboratory.



Standard Statement 1f:

There is a senior member of the laboratory staff at consultant level responsible for each element of the pregnancy and newborn screening service.

Rationale

The responsibilities and accountabilities associated with testing and reporting and for the management and development of the laboratory service are consistent with the duties of a consultant grade.

Reference: 4

Essential Criterion

1f.1 There is a designated senior member of the laboratory staff responsible for each element of the pregnancy and newborn screening service.

Standard 1 ~ Service Provision and Monitoring (continued)

Standard Statement 1g:

There is a system in place to enable all newborn babies to be registered within the NHS Board and to ensure registration on the Community Health Index (CHI).

Rationale

Registration is necessary to identify babies resident in the NHS Board area to enable the screening process to take place.

Essential Criteria

- 1g.1 There is a mechanism in place to ensure all newborn babies are notified to the local child health department.
- 1g.2 There is a weekly check to ensure that all babies notified to the local child health department have been recorded on the CHI.

Desirable Criterion

- 1g.3 There is a twice-weekly check to ensure that all babies notified to the local child health department have been recorded on the CHI.



Standard Statement 1h:

There is training and ongoing education for healthcare professionals involved in pregnancy and newborn screening.

Rationale

Minimum standards can be reproduced more consistently through the use of standardised training. Staff with good communication skills who are sensitive to the needs of women/parents/carers achieve increased satisfaction with the screening process.

Reference: 35

Essential Criteria

- 1h.1 Relevant education and training on newborn hearing screening is available for all new healthcare professionals during induction.
- 1h.2 Existing staff who provide the screening service should be able to demonstrate evidence of continuing professional development relevant to screening.
- 1h.3 A record of all training/education sessions is maintained by a named person.
- 1h.4 Local training and education is monitored and reviewed by a named person(s).
- 1h.5 Healthcare professionals contribute to the screening service only after successful completion of training.

Standard 2 ~ Pregnancy Screening: Down's Syndrome and Neural Tube Defects

Standard Statement 2a:

Pregnancy screening for Down's syndrome and neural tube defects, conforming to national guidelines, is offered to all women.

Rationale

Optimised screening programmes can identify a high proportion of pregnancies affected by Down's syndrome and neural tube defects.

National guidelines for pregnancy screening promote equity of provision and care.

Essential Criterion

2a.1 There is a protocol in place to offer all women screening tests for the following conditions at the most appropriate stage in their pregnancy:

- Down's syndrome
- neural tube defects.

The protocol also includes procedures for follow-up diagnostic testing.



Standard Statement 2b:

All women receive clear information (written or in other formats) to help them to make an informed choice about pregnancy screening for Down's syndrome and neural tube defects.

Rationale

Good communication and provision of information during pregnancy reduces anxieties and concerns about a baby's health and wellbeing.

References: 3, 7, 8

Good communication before screening reduces unnecessary delays, anxieties and concerns.

Reference: 13

Essential Criteria

- 2b.1 All women are informed about the screening process taking into account their physical, cultural, ethical, educational and mental health needs.
- 2b.2 Information provided to women before and during appropriate antenatal visits conforms to national guidelines and includes:
- information about the screening test and the test method
 - an explanation that the tests are optional
 - an explanation of the limitations of screening tests
 - the meaning and potential consequences of screening results
 - the options available following results
 - information regarding other conditions which the screening process may detect
 - how further information and support can be obtained.
- 2b.3 Information is provided to all women at least 48 hours in advance of the screening tests, unless precluded by late presentation.
- 2b.4 An opportunity to discuss this information is provided.
- 2b.5 The decision to accept or decline testing is recorded.
- 2b.6 A protocol is in place to allow women who have opted out of screening to be screened or referred for an appropriate assessment at a later date, if wished.

Standard 2 ~ Pregnancy Screening: Down's Syndrome and Neural Tube Defects (continued)

Standard Statement 2c:

There is a clearly defined regional or local protocol for informing women of the results of screening tests, which addresses the most appropriate methods of communication for the local population.

Rationale

Women have a right to know how and when they will receive the results of the screening tests.

Reference: 2

There is evidence that delayed reporting increases anxiety. To further reduce anxiety it is important that women receive information regarding their result in a format that they can easily understand.

Reference: 13

It is essential that the woman and involved professionals are informed about the outcome of the screen as soon as possible in order to put in place any supports that may be required. There is evidence that delays in follow-up testing can increase anxiety. It is important that women receive information regarding follow-up testing.

Essential Criteria

- 2c.1 All women are informed of the timescale within which the results will be made available, the format in which they will be communicated, and by whom.
- 2c.2 All results are communicated to the woman.
- 2c.3 All higher chance screening results are communicated to the woman as soon as possible after the screen and no later than 10 days after the laboratory report is issued.

Desirable Criterion

- 2c.4 All results are communicated in writing to the woman within 15 days of the blood sample being drawn.



Standard Statement 2d:

Support is available for all women who have received a higher chance screening result.

Rationale

The opportunity to discuss concerns with healthcare professionals can support women through a difficult decision-making process. Higher chance screening results generate anxiety which can be reduced by appropriate counselling and support.

References: 2, 3, 6, 8

Essential Criteria

- 2d.1 All women have access to appropriately trained healthcare professionals, to discuss results, treatment options and/or further tests, within 5 days of receiving the results.
- 2d.2 Information is provided to women on support groups for the conditions being screened.

Standard 2 ~ Pregnancy Screening: Down's Syndrome and Neural Tube Defects (continued)

Standard Statement 2e:

Laboratory reports are issued for all screened pregnancies with minimum delay and the content conforms to the nationally agreed minimum data set.

Rationale

Rapid reporting minimises anxiety and allows follow-up testing (where indicated) to be carried out as early as possible in pregnancy.

Reference: 2

Interpretation of screening results must take into consideration a number of maternal and pregnancy variables.

References: 1, 5, 8

The minimum data set ensures that the report is accurate and easily interpreted.

Essential Criteria

2e.1 95% of pregnancy screening reports are issued from the laboratory to an appropriate healthcare professional within 3 working days of receipt of the specimen at the laboratory.

2e.2 Interpretation of results takes account of:

- maternal variables including date of birth, maternal weight and maternal smoking status
- pregnancy variables including gestational age previous affected pregnancies and information, if offered by the mother, regarding the use of donor eggs or assisted conception.

Standard Statement 2f:

Screening laboratories combine appropriate markers with other identifiable risk factors to derive a risk of Down's syndrome and neural tube defects.

A risk threshold or agreed cut-off point is used as the criterion for offering follow-up diagnostic testing.

Rationale

Sensitivity and specificity of screening is influenced by the choice of markers. Choice of threshold risk determines the number of women who will be offered follow-up testing and the proportion of Down's syndrome and neural tube defect pregnancies detected.

References: 1, 5, 8

Essential Criterion

2f.1 The markers used in the laboratory conform to those in Appendix 1.

Desirable Criteria

- 2f.2 The follow-up rate for Down's syndrome screening is 5-7% in a typical screened population using a threshold risk of 1 in 250 at term.
- 2f.3 The detection rate is at least 85% of Down's syndrome cases by first trimester (11-14 weeks) combined ultrasound and biochemical (CUB) screening using a threshold risk of 1 in 250 at term.
- 2f.4 The detection rate is at least 60% of Down's syndrome cases by second trimester (15-20 weeks) screening using a cut-off risk of 1 in 250 at term.
- 2f.5 The follow-up rate for neural tube defects screening is 2-4% in a typical screened population using a cut-off maternal serum alphafetoprotein (MsAFP) level of 2.0 MoM at 15-20 weeks.
- 2f.6 The detection rate is 80-90% of pregnancies with open neural tube defects using a cut-off MsAFP level of 2.0 MoM at 15-20 weeks.

Standard 2 ~ Pregnancy Screening: Down's Syndrome and Neural Tube Defects (continued)

Standard Statement 2g:

The laboratory workload for the pregnancy screening programmes is adequate to generate stable median and screen positive rates on a monthly basis and large enough to contain sufficient Down's syndrome and neural tube defect pregnancies to allow meaningful annual audit of detection rates.

Rationale

Small sample numbers affect the calculation of median and false positive results and limit the experience of the laboratory in dealing with affected pregnancies and complications. Reference: 9

Essential Criteria

- 2g.1 The laboratory processes a minimum of 1,000 pregnancy screening samples annually.
- 2g.2 Laboratories processing between 1,000 and 5,000 serum screening specimens annually are part of a network of laboratories measuring the same screening markers and using common analytical methods and risk calculation software, so that the combined workload exceeds 5,000 specimens annually.
- 2g.3 Laboratories processing more than 5,000 serum screening specimens annually may function independently and participate in multidisciplinary audit at local and Scottish level.

Standard 3 ~ Pregnancy Screening: Communicable Diseases

Standard Statement 3a:

Pregnancy screening for communicable diseases, conforming to national guidelines, is offered to all women.

Rationale

National guidelines for pregnancy screening promote equity of provision and care. Conditions screened for are those where testing at an appropriate stage maximises the chance of detection and allows treatment which can improve the long-term outcome and development of affected children.

References: 23, 24, 25, 26, 27

Essential Criteria

3a.1 There is a protocol in place to offer all women the following screening tests at the most appropriate stage in their pregnancy:

- HIV
- rubella
- syphilis
- hepatitis B.

The protocol also includes procedures for follow-up diagnostic testing.

Standard 3 ~ Pregnancy Screening: Communicable Diseases (continued)

Standard Statement 3b:

All women receive clear information (written or in other formats) to help them to make an informed choice about pregnancy screening.

Rationale

Good communication and provision of information during pregnancy reduces anxieties and concerns about the mother and baby's health and wellbeing.

References: 3, 7, 8

There is evidence that providing information about tests and investigations reduces anxiety and encourages participation.

References: 19, 20, 21

Good communication before and after screening reduces unnecessary delays, anxieties and concerns.

Reference: 13

Essential Criteria

- 3b.1 All women are informed about the screening process taking into account their physical, cultural, ethical, educational and mental health needs.
- 3b.2 Information provided to women during appropriate antenatal visits conforms to national guidelines and includes:
- information about the screening test and the test method
 - an explanation that the tests are optional, though strongly recommended
 - an explanation of the limitations of screening tests
 - the meaning of screening results
 - the options available and potential consequences of testing and not testing
 - how further information and support can be obtained.
- 3b.3 Information is provided to all women at least 48 hours in advance of the screening tests, unless precluded by late presentation.
- 3b.4 An opportunity to discuss this information is provided.
- 3b.5 The decision to accept or decline screening is recorded.
- 3b.6 A protocol is in place to allow women who have opted out of screening to be screened or referred for an appropriate assessment at a later date, if wished.



Standard Statement 3c:

There is a clearly defined regional or local protocol for informing women of the results of screening tests, which addresses the most appropriate methods of communication for the local population.

Rationale

Women have a right to know how and when they will receive the results of the screening tests.

Reference: 2

There is evidence that delayed reporting increases anxiety. To further reduce anxiety it is important that women receive information regarding their result in a format that they can easily understand.

Reference: 13

It is essential that the woman and involved professionals are informed about the outcome of the screen as soon as possible in order to put in place any supports that may be required. There is evidence that delays in follow-up testing can increase anxiety. It is important that women receive information regarding follow-up testing.

Essential Criteria

- 3c.1 All women are informed of the timescale within which the results will be made available, the format in which they will be communicated, and by whom.
- 3c.2 All results are confirmed to the requesting clinician in writing within 21 days of the screen being performed.
- 3c.3 All non-positive results are communicated to the woman by 20 weeks of pregnancy unless precluded by late presentation.
- 3c.4 All positive results are communicated to the woman within 21 days of the screen test.

Desirable Criterion

- 3c.5 All results are communicated in writing to the woman within 21 days of the screen test.

Standard 3 ~ Pregnancy Screening: Communicable Diseases (continued)

Standard Statement 3d:

Support is available for all women who have received a clinically significant screening result.

Rationale

The opportunity to discuss concerns with healthcare professionals can support women through a difficult decision-making process. Clinically significant screening results generate anxiety among carers which can be reduced by appropriate counselling and support.

References: 2, 3, 6, 8

Essential Criteria

- 3d.1 All women have access to appropriately trained healthcare professionals, to discuss result(s), treatment options and/or further tests within 5 days of receiving the result(s).
- 3d.2 Information is provided to women on support groups for the conditions being screened.



Standard Statement 3e:

Laboratory reports are issued for all screened pregnancies with minimum delay and the content conforms to the nationally agreed minimum data set.

Rationale

Rapid reporting minimises anxiety and allows follow-up testing (where indicated) to be carried out as early as possible in pregnancy.

Reference: 2

The minimum data set ensures that the report is accurate and easily interpreted.

Essential Criteria – HIV, HBV and syphilis

- 3e.1 95% of the expected results (ie negative for these infections) are issued from the laboratory to the named clinician within 5 working days.
- 3e.2 All screen positive samples undergo confirmatory tests and results are issued to the named clinician within 15 days.

Essential Criteria – rubella

- 3e.3 95% of the expected results (>10 international units of rubella IgG antibody present) are issued to the obstetric team within 10 working days.
- 3e.4 All rubella antibody negative samples undergo a second test on the original sample and results are issued to the obstetric team within 15 days.

Standard 3 ~ Pregnancy Screening: Communicable Diseases (continued)

Standard Statement 3f:

The laboratory workload for the pregnancy screening programmes is adequate to generate stable median and screen positive rates on a monthly basis and large enough to allow meaningful interpretation of detection rates.

Rationale

Small sample numbers affect the calculation of median and false positive results and limit the experience of the laboratory in dealing with affected pregnancies and complications.
Reference: 9

Essential Criterion

- 3f.1 Laboratories processing screening samples for HIV and communicable diseases are part of a network with an established protocol for prompt referral of reactive samples to a specialist laboratory for HIV, hepatitis B or syphilis.

Standard 4 ~ Newborn: Bloodspot Screening

Standard Statement 4a:

Newborn bloodspot screening, conforming to national guidelines, is offered to all women/parents/carers for their babies.

Rationale

National guidelines for newborn bloodspot screening promote equity of provision and care. Conditions screened for are those where testing at an appropriate stage maximises the chance of detection and allows treatment which can improve the long-term outcome and development of affected children.

References: 23, 24, 25, 26, 27

Essential Criteria

4a.1 There is a protocol in place to offer all women/parents/carers the following bloodspot screening tests for their baby in the newborn period:

- phenylketonuria (PKU)
- congenital hypothyroidism (CHT)
- cystic fibrosis (CF).

The protocol also includes procedures for follow-up diagnostic testing.

4a.2 PKU, CHT and CF screening tests are offered for all babies between 96 and 168 hours of life (4-7 completed days).

4a.3 A protocol is in place for screening babies who are ill, transfused or born prematurely.

Standard 4 ~ Newborn: Bloodspot Screening (continued)

Standard Statement 4b:

All women/parents/carers receive clear information (written or in other formats) to help them to make an informed choice about newborn bloodspot screening.

Rationale

Good communication and provision of information during pregnancy and after birth reduces anxieties and concerns about a baby's health and wellbeing.

References: 3, 7, 8

Good communication before and after screening reduces unnecessary delays, anxieties and concerns.

Reference: 13

Women/parents/carers should be given written information antenatally about all newborn screening tests to allow time to reflect on this before making a decision.

References: 15, 16

Essential Criteria

- 4b.1 All women/parents/carers are informed about the screening process taking into account their physical, cultural, ethical, educational and mental health needs.
- 4b.2 Information is provided to all woman/parents/carers at least 48 hours in advance of their baby's screening tests, unless precluded by late presentation.
- 4b.3 An opportunity to discuss this information is provided.
- 4b.4 The decision to accept or decline testing is recorded.
- 4b.5 In all cases where bloodspot testing has been declined, a card containing the baby's details is marked 'declined' and sent to the laboratory.
- 4b.6 A protocol is in place to allow women/parents/carers who have opted out of screening to have their baby screened or referred for appropriate assessment at a later date, if wished.


Standard Statement 4c:

There is a clearly defined regional or local protocol for informing women/parents/carers of the results of screening tests, which addresses the most appropriate methods of communication for the local population.

Rationale

Delayed reporting increases anxiety. To reduce anxiety it is important that women/parents/carers receive information regarding their result in a format that they can easily understand.

Reference: 13

It is essential that the woman/parents/carers and involved professionals are informed about the outcome of the screen as soon as possible in order to put in place any supports that may be required.

Essential Criteria

- 4c.1 All women/parents/carers are informed of the timescale within which the results will be made available, and the format in which they will be communicated, and by whom.
- 4c.2 Following the screen, all results are communicated to the woman/parent/carer within 8 weeks, precluding premature or sick babies.
- 4c.3 All positive results are communicated to women/parents/carers as soon as possible after the screen and no later than 14 days from specimen collection for PKU and CHT, and 27 days from specimen collection for CF.

Desirable Criterion

- 4c.4 All results are communicated in writing to women/parents/carers.

Standard 4 ~ Newborn: Bloodspot Screening (continued)

Standard Statement 4d:

Support is available for all women/parents/carers who have received a positive screening result which requires further action.

Rationale

The opportunity to discuss concerns with healthcare professionals can support women/parents/carers through a difficult decision-making process. Positive screening results generate anxiety among carers which can be reduced by appropriate counselling and support.

References: 2, 3, 6, 8

Essential Criteria

- 4d.1 All women/parents/carers have access to appropriately trained healthcare professionals, to discuss results, treatment options and/or further tests within 3 days of receiving the results.
- 4d.2 Information is provided to women/parents/carers on support groups for the conditions being screened.



Standard Statement 4e:

The quality of the newborn bloodspot screening service is continually assessed and monitored.

Rationale

Regular review of the laboratory screening service is essential to assess the effectiveness of screening and compliance with the standards.

Essential Criteria

- 4e.1 There is a failsafe protocol for action on positive cases.
- 4e.2 95% of positive CHT and PKU cases have started treatment by 14 days of age, unless deliberately delayed for further testing.
- 4e.3 95% of positive cases of CF have started treatment within 35 days of age, unless deliberately delayed for further testing, assessment and/or treatment.
- 4e.4 100% of positive cases of CF have started treatment within 42 days of age, unless deliberately delayed for further testing, assessment and/or treatment.
- 4e.5 100% of positive cases have started treatment for CHT and PKU within 21 days of age, unless deliberately delayed for further testing.

Desirable Criteria

- 4e.6 100% of positive CHT and PKU cases have started treatment by 14 days of age, unless deliberately delayed for further testing.
- 4e.7 100% of positive cases of CF have started treatment within 35 days of age, unless deliberately delayed for further testing, assessment and/or treatment.

Standard 4 ~ Newborn: Bloodspot Screening (continued)

Standard Statement 4f:

Laboratory reports are issued for all screened pregnancies and newborn babies with minimum delay and the content conforms to the nationally agreed minimum data set.

Rationale

Rapid reporting minimises anxiety and allows follow-up testing (where indicated) to be carried out as early as possible.

Reference: 2

The minimum data set ensures that the report is accurate and easily interpreted.

Essential Criteria

4f.1 95% of results are issued from the laboratory to an appropriate healthcare professional within 2 working days of receipt of specimen by laboratory.

4f.2 Interpretation of results takes account of:

- age at specimen collection
- health indicators on card
- feeding status.



Standard Statement 4g:

The laboratory workload for the newborn bloodspot screening programme conforms with national recommendations.

Rationale

Small sample numbers affect the calculation of median and false positive results and limit the experience of the laboratory in dealing with abnormalities.

Reference: 9

Essential Criterion

4g.1 The laboratory processes a minimum of 25,000 screening samples annually.

Standard 4 ~ Newborn: Bloodspot Screening (continued)

Standard Statement 4h:

The NHS Board has a failsafe mechanism in place to ensure a screening result is recorded for all babies registered on the CHI.

Rationale

The local registration system ensures that appropriate screening tests are offered to all babies.

Essential Criteria

- 4h.1 There is a local failsafe protocol for all babies registered on the CHI to ensure that a bloodspot screening result has been recorded by 20 days of age.
- 4h.2 99.5% of infants who have undergone screening tests for CHT, PKU and CF either have a screening result available or are recalled for repeat testing by 20 days of age.
- 4h.3 99.5% of eligible infants are offered bloodspot testing/retesting within 1 week of identification.

Standard 5 ~ Newborn: Hearing Screening

Standard Statement 5a:

Newborn hearing screening, conforming to national guidelines, is offered to all women/parents/carers for their babies.

Rationale

There is evidence that early identification of hearing loss and appropriate intervention by 26 weeks of age is the most effective strategy for the maximisation of development of language in deaf and hard of hearing infants and toddlers.

References: 10, 11, 12

National guidelines for newborn hearing screening promote equity of provision and care.

Essential Criteria

- 5a.1 There is a protocol in place to offer hearing screening for all babies under the age of 26 weeks resident in the NHS Board area which includes procedures for diagnostic testing.
- 5a.2 Newborn hearing screening is offered for all babies born within the NHS Board area within the first 4 weeks of life, unless born prematurely or ill.
- 5a.3 A protocol is in place for screening babies who are born prematurely or ill.

Standard 5 ~ Newborn: Hearing Screening (continued)

Standard Statement 5b:

Newborn hearing screen-rescreen arrangements are in place in all NHS Boards.

Rationale

Effective newborn hearing screen-rescreen arrangements, which allow tracking of babies within an NHS Board area and beyond, improve uptake, coverage and clinical outcomes. Reference: 35

Essential Criteria

- 5b.1 95% of all infants complete the hearing screening process by 10 weeks of age.
- 5b.2 A local protocol is in place for the management of non-attenders and babies born outside the NHS Board area.
- 5b.3 A follow-up protocol is in place, appropriate to the outcome of the screen and any risk factors the baby may have for acquired and progressive hearing loss.

Desirable Criterion

- 5b.4 98% of infants complete the hearing screening process by 10 weeks of age.



Standard Statement 5c:

All women/parents/carers receive clear information (written or in other formats) to help them to make an informed choice about newborn hearing screening.

Rationale

Good communication and provision of information throughout pregnancy and after birth reduces anxieties and concerns about a baby's health and wellbeing.

References: 3, 7, 8

Providing information about hearing screening reduces anxiety and encourages participation.

References: 19, 20, 21

Good communication before and after screening reduces unnecessary delays, anxieties and concerns.

Reference: 13

Women/parents/carers should be given information about all newborn hearing screening antenatally and given time to reflect on this before making a decision.

References: 15, 16

Essential Criteria

- 5c.1 All women/parents/carers are informed about the screening process taking into account their physical, cultural, ethical, educational and mental health needs.
- 5c.2 Information is provided to all women/parents/carers at least 48 hours in advance of their baby's screening tests unless precluded by late presentation.
- 5c.3 An opportunity to discuss this information is provided.
- 5c.4 The decision to accept or decline screening is recorded.
- 5c.5 A protocol is in place to allow women/parents/carers who opted out of screening to have their baby screened or referred for an appropriate assessment date, if wished.

Standard 5 ~ Newborn: Hearing Screening (continued)

Standard Statement 5d:

There is a clearly defined regional or local protocol for informing women/parents/carers of the results of screening tests, which addresses the most appropriate methods of communication for the local population.

Rationale

Women/parents/carers have a right to know how and when they will receive the results of the screen.

Delayed reporting increases anxiety. To further reduce anxiety it is important that women/parents/carers receive information regarding their result in a format that they can easily understand.

Reference: 13

It is essential that women/parents/carers and involved professionals are informed about the outcome of the screen as soon as possible in order to put in place any supports that may be required.

Delays in follow-up testing can increase anxiety. It is important that women/parents/carers receive information regarding follow-up assessments.

Essential Criteria

- 5d.1 All women/parents/carers are informed of the timescale within which the results will be made available, and the format in which they will be communicated, and by whom.
- 5d.2 Women/parents/carers are informed of the outcome of the screen immediately after the screening episode is completed (or in special circumstances, as soon as possible thereafter). For those requiring follow up, appropriate written and verbal information is provided.
- 5d.3 A 'refer' hearing screen result is forwarded to the primary care team within 5 days of the screen being performed.
- 5d.4 A bilateral pass result is forwarded to the relevant child health surveillance system within 3 days and is forwarded on from there to the primary care team within a further 10 days.



Standard Statement 5e:

The number of babies required to attend clinics for repeat screening and diagnostic assessments is kept to a minimum.

Rationale

Recall, for whatever reason, is associated with an increased level of anxiety. Non-attendance rates rise each time a repeat attendance is required.

Essential Criteria

- 5e.1 Less than 8% of 'well babies' completing an initial screening episode (which may comprise 2 OAEs and an AABR) will be recalled for repeat screening.
- 5e.2 Less than 3% of the 'well baby' population screened will be referred for diagnostic assessment.
- 5e.3 All babies screened who do not demonstrate a satisfactory response on screening are referred for a full audiological assessment.
- 5e.4 95% of babies referred for a full audiological assessment complete this by 26 weeks of age.

Desirable Criteria

- 5e.5 Less than 5% of 'well babies' completing an initial screening episode will be recalled for repeat screening.
- 5e.6 98% of babies referred for full audiological assessment complete this by 26 weeks of age.

Standard 5 ~ Newborn: Hearing Screening (continued)

Standard Statement 5f:

Support is available for all women/parents/carers whose babies do not have a clear response bilaterally on the newborn hearing screen.

Rationale

The opportunity to discuss concerns with healthcare professionals can support women/parents/carers through the assessment and diagnostic process. A 'refer' result may generate anxiety among women/parents/carers which can be reduced by appropriate counselling and support.

References: 2, 3, 6, 8, 15

Essential Criteria

- 5f.1 All women/parents/carers have access to appropriately trained healthcare professionals, to discuss results, management options and/or further assessments.
- 5f.2 Information is provided to women/parents/carers about support groups.



Standard Statement 5g:

There is training and ongoing education for healthcare professionals involved in newborn hearing screening.

Rationale

A healthcare organisation requires staff to be qualified and trained to an appropriate standard to meet the needs of the population it serves. Review of individual competencies and continuing professional development (CPD) are essential.

Minimum standards can be reproduced more consistently through the use of a standardised training tool. There is evidence that staff with good communication skills who are sensitive to the needs of the women/parents/carers and have good baby handling skills achieve better screening results.

Reference: 35

Essential Criteria

- 5g.1 Relevant education and training on newborn hearing screening is available for all new healthcare professionals during induction of new staff or existing staff when the service is implemented locally.
- 5g.2 Newborn hearing screeners complete the nationally agreed training package, or equivalent, before commencing screening unsupervised.
- 5g.3 Existing staff who provide the screening service should be able to demonstrate evidence of continuing professional development relevant to screening.
- 5g.4 A record of all training/education sessions is maintained by a named person.
- 5g.5 Local training and education is monitored and reviewed by a named person(s).
- 5g.6 Healthcare professionals contribute to the screening service only after successful completion of training.

Standard 5 ~ Newborn: Hearing Screening (continued)

Standard Statement 5h:

The NHS Board has a failsafe mechanism in place to ensure screening is offered and a result is recorded for all babies registered on the CHI.

Rationale

The local registration system enables the newborn hearing screening service manager to ensure that hearing screening is offered for all babies.

Essential Criteria

- 5h.1 There is a local failsafe protocol to ensure that all babies registered on the CHI have been offered hearing screening by 4 weeks of age.
- 5h.2 Follow-up action is taken where screening has been accepted but no results have been recorded.
- 5h.3 99.5% of all infants with no recorded results are offered hearing screening testing/retesting within 4 weeks of identification.

6 Appendices

Appendix 1	Pregnancy Screening Protocol Summary
Appendix 2	Membership of the Pregnancy and Newborn Screening Standards Project Group
Appendix 3	Evidence Base
Appendix 4	Glossary of Terms

Appendix 1: Pregnancy Screening Protocol Summary

The following screening tests are offered to all women at the most appropriate stage in their pregnancy depending on local provision, gestation at presentation, and in some cases, maternal choice:

Screening for:	Gestation	Screening test
Down's syndrome	11-14 weeks Or	Combined nuchal translucency (NT) scan and biochemical screening (MsFbhCG, PAPP-A and maternal age)
	15-20 weeks	Biochemical screening (MsAFP, MshCG and maternal age)
Neural tube defects	10-14 weeks	1st antenatal visit ultrasound scan
	15-20 weeks Or	Biochemical screening by MsAFP
	18-20 weeks	Routine anomaly scan
HIV	10-14 weeks/1 st antenatal appointment (still worthwhile up to the point of delivery)	<ul style="list-style-type: none"> • Confirmation of positive result is obtained by further antibody testing on primary sample. • Confirmation of a screen positive result occurs in the laboratory, using at least two assays based on different components, before any release to the obstetric team. • Confirmation of identity is obtained from repeat sample. Management of woman is transferred to an obstetrician according to local guidelines.

Rubella	10-14 weeks/1 st antenatal appointment	<p>If screen shows lack of immunity advise antenatal care team to ensure:</p> <ul style="list-style-type: none"> • serological test for infection (IgM) is repeated on contact with or development of a rash at any stage throughout pregnancy • lack of immunity is confirmed by a second assay on the primary sample.
Syphilis	10-14 weeks/1 st antenatal appointment	Confirm with a range of tests to establish infectivity. Advise on maternal treatment.
Hepatitis B	10-14 weeks/1 st antenatal appointment	<ul style="list-style-type: none"> • Confirmation of a screen positive result is carried out using a hepatitis B surface antigen neutralisation test on the primary sample. • Establish the acute or chronic nature of infection by testing for additional serological markers of hepatitis B infection.

Diagnostic follow-up

Down's syndrome	11-14 weeks	Chorionic villus sampling (CVS)
	Or	
	15 weeks +	Amniocentesis
Neural tube defects	18-20 weeks	Detailed ultrasound anomaly scanning

Appendix 2: Membership of the Pregnancy and Newborn Screening Standards Project Group

Name	Title	NHS Board Area/Organisation
Canon Bob Fyffe (Chair)	Minister	Tayside
Dr David Aitken	Consultant Clinical Scientist, Director of Pregnancy and Newborn Screening Laboratories	Greater Glasgow
Ms Sally Amor	Specialist in Public Health	Pregnancy & Newborn Screening Co-ordinators Group
Dr Ian Auchterlonie	Consultant Paediatrician	Grampian
Dr Richard Brooker	Consultant Paediatrician	Grampian
Dr Alan Cameron	Obstetrician	Greater Glasgow
Dr Jim Chalmers	Consultant in Public Health Medicine	Information Services, NHS National Services Scotland
Dr Heather Cubie	Consultant Clinical Scientist (Virology)	Lothian
Dr Malcolm Donaldson	Consultant Paediatrician, Endocrinologist	Greater Glasgow
Ms Lyn Hutchison	Project Manager	National Services Division, NHS National Services Scotland
Mrs Anyta Lodge	Lay Representative	Tayside
Dr Sheena MacDonald	General Practitioner	Royal College of General Practitioners
Mrs Joan Mackenzie	Laboratory Newborn Screening Co-ordinator	Greater Glasgow
Dr Ann MacKinnon	Associate Specialist (Paediatric Audiology)	Tayside
Mr Alan MacQueen	Family Officer	National Deaf Children's Society
Mrs Mary Nesbitt	Senior Chief Audiologist (Head of Paediatric Audiology)	Lothian
Dr Andrew Powls	Neonatologist	Greater Glasgow
Mrs Audrey Robertson	Co-ordinator of Newborn Hearing Screening	Lothian
Mrs Lucy Robertson	Midwife Sister	Lanarkshire
Mrs Margaret Rule	Lay Representative	Borders

Support from NHS Quality Improvement Scotland was provided by the Standards Development Team, led by Ms Hilary Davison, Standards Development Team Manager.

Appendix 3: Evidence Base

Down's syndrome and neural tube defects

- 1 Wald N, Kennard A, Hackshaw A, et al. 1998. Antenatal Screening for Down's Syndrome. *Health Technology Assessment*, 2(1): 1-112.
- 2 Drife J and Donnai D, eds. 1991. *Antenatal Diagnosis of Fetal Abnormalities (Proceedings of RCOG 23rd Study Group, London, 1990)*. London: Springer Verlag.
- 3 Working Party of the Royal College of Gynaecologists (RCOG). 1993. *Report of RCOG Working Party on Biochemical Markers and the Detection of Down's Syndrome*. London: Royal College of Gynaecologists.
- 4 Burnett D, Blair C, Haeney M, et al. 2002. Clinical Pathology Accreditation: Standards for the Medical Laboratory. *Journal of Clinical Pathology*, 55(10): 729-733.
- 5 Aitken D, Crossley J and Spencer K. 2002. Prenatal Screening for Neural Tube Defects and Aneuploidy. in Rimoin D, Connor J, Pyeritz R and Korf B, eds. *Emery and Rimoin's Principles and Practice of Medical Genetics*. 4th ed. London: Churchill Livingstone: 763-801.
- 6 Balmer S, Bowens A, Bruce E, et al. 2000. *Quality Management for Screening: Report to the National Screening Committee*. Leeds: Nuffield Institute for Health. www.nuffield.leeds.ac.uk/downloads/screening.pdf [full document] URL accessed 28/06/04.
- 7 Blackwell Scientific [publisher]. 2001. Special Issue: Informed Choice in Screening. *Health Expectations*, 4(2).
- 8 Ritchie K, Boynton J, Bradbury I, et al. 2004. *Routine Ultrasound Scanning before 24 Weeks of Pregnancy: Health Technology Assessment Report 5*. Glasgow: NHS Quality Improvement Scotland.
- 9 National Down's Syndrome Screening Programme for England. 2004. *Antenatal Screening - Working Standards*. Northants: National Down's Syndrome Screening Programme for England. www.nelh.nhs.uk/screening/dssp/working_standards.pdf [full document] URL accessed 28/06/04.

Universal newborn hearing screening

- 10 Davis A, Bamford J, Wilson I, et al. 1997. A Critical Review of the Role of Neonatal Hearing Screening in the Detection of Congenital Hearing Impairment. *Health Technology Assessment*, 1(10): i-iv, 1-176.
- 11 Yoshinaga-Itano C, Sedey A, Coutter D, et al. 1998. Language of Early and Later Deafened Children with Hearing Loss. *Paediatrics*, 102: 1161-1171.
- 12 Stokes J. 1999. Learning to Listen. in Stokes J, ed. *Hearing Impaired Infants: Support in the First 18 Months*. London: Whurr Publishers. p197-230.
- 13 Clinical Standards Board for Scotland. 2002. *Clinical Standards: Generic*. Edinburgh: Clinical Standards Board for Scotland.
www.clinicalstandards.org/pdf/finalstand/generic.pdf [access to full document]
URL accessed 28/06/04.
- 14 Scottish Executive. 2001. *Neonatal Hearing Screening Report*. Edinburgh: Scottish Executive. www.show.scot.nhs.uk/sehd/publications/neonatal/neonatal.htm [access to full document] URL accessed 28/06/04.
- 15 National Deaf Children's Society. 2000. *Guidelines for the Early Identification and Audiological Management of Children with Hearing Loss*. Quality Standards in Paediatric Audiology, Vol. IV. London: NDCS.
www.ndcs.org.uk/information/ndcs_publications/early_ident.html [access to full document] URL accessed 28/06/04.
- 16 Tyler S and Evans M. 2002. *Quality Assurance Review of the Information Materials Developed for the NHS Newborn Hearing Screening Programme*. Report to the Child Subgroup of the National Screening Committee. www.nhsp.info/prots.shtml [access to full document] URL accessed 28/06/04.
- 17 Fortnum H, Summerfield A, Marshal D, et al. 2001. Prevalence of Permanent Childhood Hearing Impairment in the United Kingdom and Implications for Universal Neonatal Screening: Questionnaire Based Ascertainment Study. *British Medical Journal*, 323: 536-539.
- 18 NHS Newborn Hearing Screening Programme. *NHSP Quality Assurance and Management - National Standards: Checklist for Review of Local Performance against National Standards*. www.nhsp.info/documents/qamanagement.shtml [electronic source]
URL accessed 28/06/04.
- 19 Watkin P, Baldwin M, Dixon R, et al. 1998. Maternal Anxiety and Attitudes to Universal Neonatal Hearing Screening. *British Journal of Audiology*, 32(1): 27-37.

-
- 20 Weichbold V, Welzl-Mueller K and Mussbacher E. 2001. The Impact of Information on Maternal Attitudes Towards Universal Neonatal Hearing Screening. *British Journal of Audiology*, 35(1): 59-66.
- 21 Hergilis L and Hergilis A. 2000. Universal Neonatal Hearing Screening - Parental Attitudes and Concerns. *British Journal of Audiology*, 34(6): 321-327.
- 22 Cunningham M and Cox E. 2003. Hearing Assessment in Infants and Children: Recommendations Beyond Neonatal Screening. *Paediatrics*, 111(2): 436-440.

Cystic fibrosis

- 23 Farrell P, Kosorok M, Rock M, et al. 2001. Early Diagnosis of Cystic Fibrosis through Neonatal Screening Prevents Severe Malnutrition and Improves Long-Term Growth. *Paediatrics*, 107(1): 1-13.
- 24 Wang S, O'Leary L, FitzSimmons S, et al. 2002. The Impact of Early Cystic Fibrosis Diagnosis on Pulmonary Function in Children. *Journal of Pediatrics*, 141(6): 804-810.

Phenylketonuria

- 25 Beasley M, Costello P and Smith I. 1994. Outcome of Treatment in Young Adults with Phenylketonuria Detected by Routine Neonatal Screening between 1964 and 1971. *Quarterly Journal of Medicine*, 87(3): 155-160.
- 26 Smith I, Beasley M and Ades A. 1990. Intelligence and Quality of Dietary Treatment in Phenylketonuria. *Archives of Disease and Childhood*, 65(5): 472-478.
- 27 Ades A, Walker J, Jones R, et al. 2001. Coverage of Neonatal Screening: Failure of Coverage or Failure of Information Systems. *Archives of Disease in Childhood*, 84(6): 476-479.

Communicable diseases

- 28 Scottish Executive Health Department (SEHD). *Offering HIV Testing to Women Receiving Antenatal Care. NHS HDL(2002)52*. Edinburgh: Scottish Executive. www.show.scot.nhs.uk/sehd/mels/HDL2002_52.pdf [full document] URL accessed 28/06/04.
- 29 Cradock-Watson J. 1991. Laboratory Diagnosis of Rubella: Past, Present and Future. *Epidemiology and Infection*, 107(1): 1-15.
- 30 Salisbury D and Begg N, eds. 1996. *Immunisation against Infectious Disease*. London: Department of Health; HMSO.

- 31 Morgan-Capner P and Crowcroft N on behalf of the PHCS Joint Working Party of the Advisory Committees of Virology and Vaccines and Immunisation. 2000. Guidance on the Management of, and Exposure to, Rash Illness in Pregnancy (Including Consideration of Relevant Antibody Screening Programmes in Pregnancy). *Communicable Disease and Public Health*, 5(1): 59-71.
- 32 Public Health Laboratory Service and Communicable Disease Surveillance Centre with the PHLS Working Group. 1998. *Antenatal Syphilis Screening in the UK: A Systematic Review and National Options Appraisal with Recommendations (Report to the National Screening Committee)*. London: Public Health Laboratory Service.
- 33 Connor N, Roberts J and Nicholl A. 2000. Strategic Options for Antenatal Screening for Syphilis in the United Kingdom: A Cost Effective Analysis. *Journal of Medical Screening* 7(1): 7-13.
- 34 Scottish Office Department of Health. 1998. *Screening of Pregnant Women for Hepatitis B, and Immunisation of Babies at Risk. HSC 1998/127*. Edinburgh: Scottish Office Department of Health.

Other references

- 35 Hall D and Elliman D. 2003. *Health for All Children*. 4th ed. Joint Working Party on Child Health Surveillance. Oxford: Oxford University Press.

Appendix 4: Glossary of Terms

abnormality	A finding requiring further investigation/treatment.
accreditation	A process, based on a system of external peer review using written standards, designed to assess the quality of an activity, service or organisation.
affected pregnancy	A pregnancy where the baby has a particular condition, such as Down's syndrome or neural tube defects.
alphafetoprotein (AFP)	A hormone that occurs naturally during pregnancy. The level of AFP can be detected by a maternal blood test, and can aid in assessing the risk of Down's syndrome or neural tube defects.
amniocentesis	A test carried out during or after 15 weeks of pregnancy for fetal abnormality. The test involves the removal of a small amount of fluid from the amniotic sac using a needle through the abdominal wall, for diagnostic purposes.
anencephaly	One of the two main types of condition which together are known as neural tube defects. The other condition is spina bifida. In babies with anencephaly, the skull and the brain are not properly formed.
antenatal	Relating to the period between conception and birth.
antibody	A protein produced in the blood, in response to the presence of harmful substances (called antigens) which it then destroys.
antigen	A substance that the body identifies as 'foreign', eg bacteria, cancer cells, transplanted tissue cells and pollen. The body generates antibodies to destroy antigens.
antigen neutralisation test	A test using a substance which is capable, under appropriate conditions, of inducing a specific immune response and of reacting with the products of that response.
assay	A laboratory test.
assisted conception	Medical help to conceive a baby, eg in vitro fertilisation.
asymptomatic infection	An infection without obvious signs or symptoms.
audiologist	A healthcare professional specialising in the measurement of hearing and the management of hearing impairments or hearing loss.
audiology	The science dealing with hearing impairments, their detection and management.
audit	The measuring and evaluation of care against agreed standards with a view to improving practice and care delivery.
Automated Auditory Brainstem Response (AABR) test	A hearing assessment carried out on newborn babies, which records brain activity in response to sounds.
biochemical	Relating to the chemical processes and substances occurring in living things.

biochemical screening	Screening tests to assess for disorders of the body's chemistry, such as phenylketonuria (PKU) and congenital hypothyroidism (CHT).
child health surveillance system	A system used by NHS Boards to monitor certain aspects of child health and development.
chorionic villus sampling (CVS)	A test carried out usually up to 14 weeks of pregnancy. The test involves the removal of a small amount of tissue from the placenta.
chronic	Describes a disease or infection lasting a long time.
cirrhosis	Liver disease which is marked by the degeneration of cells and thickening of the tissue, as scar tissue replaces healthy cells.
Clinical Pathology Accreditation (CPA) UK	An accreditation process which requires laboratories to meet pre-determined standards. Website: www.cpa-uk.co.uk
clinical scientist	A specialist who manages and develops methods of analysis and interpretation of patient samples, to assist with the investigation, diagnosis and treatment of diseases.
communicable disease	Any disease that is transmissible either directly or indirectly.
Community Health Index (CHI)	A unique patient identifier that is allocated to every patient registered with a GP in Scotland. It is entered onto a database that underpins a wide range of patient care processes in Scotland. There are strict controls on access to patient identifiable details.
conception	The beginning of a pregnancy marked by the fertilisation of an egg by a sperm cell.
congenital	A disease or abnormality which is present at birth.
congenital hypothyroidism (CHT)	A rare condition in which a baby is born with a defect of the thyroid gland. This results in an underproduction of thyroxine.
congenital rubella syndrome	Fetal infection with the rubella virus during the first trimester of pregnancy, resulting in a series of congenital abnormalities including heart disease, deafness and blindness.
continuing professional development (CPD)	A formal process of ongoing commitment to learning for healthcare professionals overseen and monitored by the Royal Colleges or other professional bodies. Participation in CPD maintains and enhances professional standards of work and develops the ability to recognise good practice.
CUB screening	A combined ultrasound and biochemical test to determine the risk of a fetus having a condition such as Down's syndrome.
cystic fibrosis (CF)	An inherited disorder, characterised principally by chronic lung disease, a deficiency of pancreatic enzymes needed for digestion, and high levels of electrolytes (eg sodium, potassium and chloride) in sweat.

data set	A list of required and specific information relating to a specific disease.
diagnosis	Identification of an illness or health problem by means of its signs and symptoms. This involves ruling out other illnesses and causal factors for the symptoms.
diagnostic test	A test to confirm the presence of a condition.
dietician	An expert in nutrition who helps people with special health needs plan the kinds and amount of foods to eat.
DNA	Deoxyribonucleic acid. Material in the nucleus (of the cell) that codes what that cell will become structurally and functionally.
Down's syndrome	A medical condition that is present from birth. It causes learning difficulties and can be associated with other health problems such as heart defects.
enzyme	A protein that acts as a catalyst for biochemical reactions in the body, to speed up a biochemical reaction in the cell.
evaluation	The study of the performance of a service (or element of treatment and care) with the aim of identifying successful and problem areas of activity.
evidence-based	Evidence-based clinical practice is an approach to decision making in which the clinician uses the best evidence available, in consultation with the patient, to decide upon the option which suits that patient best.
external quality assessment	A service where participating clinical laboratories are sent samples on a regular basis. They test these samples as if they had come from patients. The results are returned to centres which provide a report that compares the participant's performance with that of all laboratories and/or groups of laboratories using the same test method(s).
failsafe	Reliable back-up.
false positive	A test result which indicates an abnormality when one does not exist.
fetus	Clinical term for an unborn child, more than 8 weeks after conception.
gene	A distinct sequence of DNA forming part of a chromosome, which provides the genetic blueprint for all offspring.
genetic mutation	A change in the DNA of a cell, or the change this causes in a characteristic of the individual.
gestational age	The number of weeks which have passed in pregnancy since conception.

GP	General Practitioner. Also known as a family doctor.
guidelines	Systematically developed statements which help in deciding how to treat particular conditions.
Health Department Letter (HDL)	Formal communications from the Scottish Executive Health Department to NHSScotland (formerly known as Management Executive Letter - MEL).
health visitor	A public health nurse who has undertaken extra training in child development and health promotion, and who works in the community, either with a GP practice or according to a specific area.
healthcare professional	A person qualified in a health discipline.
hepatitis B	A virus commonly spread through contact with infected blood products (through transfusion) or blood contaminated needles. It may also be spread sexually or from mother to baby during pregnancy. It is a virus which infects the liver. It can be carried in the blood for many years before causing any signs of illness.
hepatocellular carcinoma	A cancer arising from the major cell of the liver (hepatocytes). Infection with hepatitis B or C increases the risk of developing the cancer. Also known as primary liver cancer.
higher chance	A screening test result which indicates an increased chance of abnormality.
HIV	Human immunodeficiency virus is the virus that causes AIDS (acquired immunodeficiency syndrome). Women can pass HIV to their babies during pregnancy, childbirth, and also through breastfeeding.
human chorionic gonadotrophin (hCG)	A hormone that occurs naturally during pregnancy, which is present in the blood and urine.
hydrocephalus	An accumulation of fluid in the brain. Hydrocephalus often accompanies spina bifida.
hypothyroidism	An underactive thyroid, which produces an insufficient amount of thyroid hormones.
IgM	One of the five main types of antibodies: IgA, IgD, IgE, IgG and IgM. These antibodies work by recognising and binding to infecting organisms, 'marking' them for destruction by other cells in the immune system.
immunisation	An artificial way of creating protection against certain infections, by using relatively harmless antigens that come from, or are similar to the micro-organisms that cause the diseases.

immuno reactive trypsinogen (IRT)	A protein of pancreatic origin found in the bloodstream which is used to measure the risk of cystic fibrosis in a newborn baby.
Management Executive Letter (MEL)	Formal communications from the Scottish Executive Health Department to NHSScotland, now known as Health Department Letters (HDLs).
marker	A sign or substance which is used to determine the risk of having a particular medical condition.
median	The middle observation of a series arranged in ascending order. This can also be stated as: the number in the middle of a set of increasing numbers (eg the median of the following numbers is 5: 1,2,5,8,9).
metabolism	All chemical reactions that occur in the body using absorbed nutrients to provide energy and make new or replacement body substances.
MoM	Multiple of the median. A measurement used to record the results of some antenatal screening tests.
monitoring	The systematic process of collecting information on the performance of clinical or non-clinical activities, actions or systems. Monitoring may be intermittent or continuous. It may also be undertaken in relation to specific incidents of concern or to check key performance areas. Monitoring is used to appraise strengths, weaknesses, opportunities and threats.
MsAFP	Maternal serum alphafetoprotein.
MsFβhCG	Maternal serum free beta-human chorionic gonadotrophin.
MshCG	Maternal serum human chorionic gonadotrophin.
multidisciplinary	An approach combining the knowledge, skills and expertise of a range of organisations and professionals.
National Deaf Children's Society (NDCS)	A UK charity which is solely dedicated to the support of all deaf children, young deaf people, carers, families and professionals working on their behalf. Website: www.ndcs.org.uk
National Services Division (NSD)	The division of NHS National Services Scotland with responsibility for ensuring the provision of national screening programmes and specialist services on behalf of NHSScotland. Website: www.show.scot.nhs.uk/nsd/
neonatal	A term used to describe the first 28 days of a baby's life.
neural tube defect	Birth defects that involve the incomplete development of the brain or spinal cord and/or protective coverings for these organs. The two main types of neural tube defects are anencephaly and spina bifida.

NHS	National Health Service
NHS Board	There are 23 NHS Boards of two types: 15 territorial boards responsible for healthcare in their areas and eight special health boards which offer supporting services nationally. See NHS Board (territorial) and Special Health Board.
NHS Board (territorial)	There are 15 territorial boards, the mainland being covered by 12 and the island groups (Orkney, Shetland and the Western Isles) by three. They are responsible and accountable for strategic planning, service delivery, performance management and governance within their local areas. Each NHS Board uses the organisational building blocks of NHS direct care, such as community health partnerships or operating divisions, in a way which suits its geography and population. NHS Boards work together in regional planning arrangements for those services which require that wider perspective. See Community Health Partnership, NHS operating division, and single-system working. Website: www.show.scot.nhs.uk/organisations/orgindex.htm
NHS operating division	NHS operating divisions are committees of an NHS Board, with schemes of delegated authority setting out their operational responsibility for the delivery of health services. NHS operating divisions came into being after the abolition of NHS Trusts. See NHS Board.
NHS Quality Improvement Scotland (NHS QIS)	NHS QIS has been established (January 2003) to lead in improving the quality of care and treatment delivered by NHSScotland. To do this it sets standards and monitors performance, and provides NHSScotland with advice, guidance and support on effective clinical practice and service improvements. Website: www.nhshealthquality.org
NHS Trust	NHS Trusts were dissolved on 31 March 2004, as part of the move to single-system working. NHS Trusts were organisations responsible for providing a group of healthcare services for the local population. An Acute Trust provided hospital services. A Primary Care Trust provided primary care/community health services. See NHS Board.
NHSScotland	The National Health Service in Scotland
nuchal	Relating to the region of the back or nape of the neck.
nuchal translucency (NT)	How the collection of fluid at the back of a fetus' neck appears on an ultrasound scan.
obstetric(s)	The branch of medicine and surgery that deals with pregnancy and childbirth.
obstetrician	A doctor specialising in pregnancy and childbirth.

Otoacoustic Emissions (OAE) test	A neonatal screening test to detect risk of hearing impairment in babies.
paediatrician	A specialist doctor who treats children and infants.
PAPP-A	Pregnancy-associated plasma protein-A
patient	A person who is receiving care or medical treatment. A person who is registered with a doctor, dentist, or other healthcare professional, and is treated by him/her when necessary. Sometimes referred to as a user.
peer review	Review of a service by those with expertise and experience in that service, either as a provider, user or carer, but who are not involved in its provision in the area under review. In the NHS Quality Improvement Scotland approach, all members of a review team are equal.
permanent congenital hearing impairment (PCHI)	Hearing loss which is present at birth.
perinatal	Relating to the period starting a few weeks before birth, including the birth, and a few weeks after the birth.
pharmacist	A qualified professional who understands the nature and effect of medicines and how they are produced and used to prevent and treat illness, relieve symptoms or assist in the diagnosis of disease. Pharmacists use their expertise for the wellbeing and safety of users and the public.
phenylalanine hydroxylase	An enzyme which processes phenylalanine, an amino acid. Phenylalanine is necessary for growth in infants.
phenylketonuria (PKU)	A rare inherited metabolic disorder which prevents the normal use of protein. A substance called phenylalanine builds up in abnormally high amounts in the body. Very high amounts can damage the brain. The condition can be successfully treated if diagnosed shortly after birth.
placenta	An organ within the uterus joining mother and offspring, and which sustains the pregnancy.
premature	Born before 37 weeks of gestation.
pre-natal	The period between conception and birth.
pre-term	Born before the expected date of delivery.

primary care	The conventional first point of contact between a patient and the NHS. This is the component of care delivered to patients outside hospitals and is typically, though by no means exclusively, delivered through general practices. Primary care services are the most frequently used of all services provided by the NHS. Primary care encompasses a range of family health services provided by family doctors, dentists, pharmacists, optometrists and ophthalmic medical practitioners.
process	A series of actions or steps taken in order to achieve a particular end.
protein	Proteins are a string of linked amino acids whose order is specified by a gene. They are the primary component of cells, essential for growth and repair, build up most of the structures in cells and play a crucial role in virtually all biological processes in the body. All enzymes are proteins and are vital for the body's metabolism.
protocol	A strategy which defines appropriate action in specific circumstances. Protocols may be national, or agreed locally to take into account local requirements.
psychologist	A specialist in the scientific study of the mind and trained in assessing emotional and behavioural problems.
quality assurance (QA)	Improving performance and preventing problems through planned and systematic activities including documentation, training and review.
quality control	Steps that are taken to ensure a service is of sufficiently high quality.
reactive	A positive result.
referral	The process whereby a patient is transferred from one professional to another, usually for specialist advice and/or treatment.
rubella	A highly contagious virus also known as German measles.
Scottish Executive	The devolved government for Scotland.
Scottish Executive Health Department (SEHD)	The Scottish Executive Health Department is responsible for health policy and the administration of NHSScotland. Website: www.show.scot.nhs.uk/sehd
screening	A public health service offered to groups of the population to identify risk of a particular condition or disease. This therefore involves examination of people with no symptoms, to detect unsuspected disease and conditions.
screening programme	The systematic and co-ordinated screening process.

self-assessment	Assessment of performance against standards by individual/clinical team/NHS operating division/NHS Board providing the service to which the standards are related.
sensitivity	The probability that when a person has a condition it will be picked up by the test.
serological test	A test performed on serum to determine if specific disease and antibodies are present.
serum	The clear fluid portion of blood that is left when the blood clots.
Special Health Board	The name given to Health Boards with a national remit. These boards are focused on specific areas, for example NHS Education for Scotland, or NHS Quality Improvement Scotland. Special Health Boards match regional NHS Boards in terms of administrative grading. Website: www.show.scot.nhs.uk/organisations/specialhbs.htm
specificity	The probability that when a person does not have a condition the test will be negative.
specimen	A biological sample.
spina bifida	A neural tube defect which affects the spinal cord.
syphilis	A sexually transmitted disease caused by bacteria. Syphilis may also be passed on from mother to baby during pregnancy.
threshold risk	The value at which a diagnostic test is considered to be appropriate.
thyroid (gland)	A gland in the neck which secretes the hormone thyroxine, which is important in the development of a baby's brain and controls the body's metabolic rate.
thyroxine	A hormone which controls the body's metabolic rate.
treponema pallidum	The bacterium causing syphilis.
trimester	Three months, ie one third of the length of a pregnancy.
Trust	See NHS Trust.
ultrasound	An image created by the use of sound waves above the audible range of the human ear. It is useful in the confirmation of pregnancy, the determination of fetal size and wellbeing.
Universal Newborn Hearing Screening (UNHS) Programme	A national hearing screening programme, which aims to implement a hearing screen for all newborn babies.
viral antigen	Part of a virus that the body regards as foreign or potentially dangerous and against which it produces an antibody.

virus	A very simple sub-microscopic organism which can cause disease and is only able to reproduce inside the living cells of a host.
working days	Monday to Friday inclusive.
window period	The period between the onset of an infection and the ability to make the diagnosis of the condition.

You can read and download this document from our website.
We can also provide this information:

- by email
- in large print
- on audio tape or CD
- in Braille, and
- in community languages.

NHS Quality Improvement Scotland

Edinburgh Office
Elliott House
8-10 Hillside Crescent
Edinburgh EH7 5EA

Phone: 0131 623 4300
Textphone: 0131 623 4383

Email: comments@nhshealthquality.org
Website: www.nhshealthquality.org

Glasgow Office
Delta House
50 West Nile Street
Glasgow G1 2NP

Phone: 0141 225 6999
Textphone: 0141 241 6316

