Healthcare Improvement Scotland | Evidence
Advice, guidance and intelligence

# Pregnancy screening:

Draft standards for:

- Down's syndrome, Edwards' syndrome and Patau's syndrome
- Mid-pregnancy ultrasound

July 2024

NHS SCOTLAND

We are committed to advancing equality, promoting diversity and championing human rights. These standards are intended to enhance improvements in health and social care for everyone, regardless of their age, disability, gender identity, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation, socioeconomic status or any other status. Suggested aspects to consider and recommended practice throughout these standards should be interpreted as being inclusive of everyone living in Scotland.

We carried out an equality impact assessment (EQIA) to help us consider if everyone accessing health and social care services will experience the intended benefits of these standards in a fair and equitable way. A copy of the EQIA is available on request.

Healthcare Improvement Scotland is committed to ensuring that our standards are up-to-date, fit for purpose and informed by high-quality evidence and best practice. We consistently assess the validity of our standards, working with partners across health and social care, the third sector and those with lived and living experience. We encourage you to contact the standards and indicators team at his.screeningstandards@nhs.scot to notify us of any updates that might require consideration.

**Healthcare Improvement Scotland**

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**www.healthcareimprovementscotland.org**

# Contents

# Introduction

## Background

During pregnancy, people are offered a range of screening tests, ultrasound scans and health checks.[1, 2] The aim of pregnancy screening is to:

- enable early identification of screened conditions and offer care options
- support informed decisions about pregnancy
- support women and, where appropriate their partners, to plan care and support if this is required.

The national pregnancy and newborn screening programme covers a range of screening tests for specific conditions. These standards relate to screening during pregnancy for:[3]

- Down's syndrome, Edwards' syndrome or Patau's syndrome
- Eleven conditions screened for at the mid-pregnancy scan including, spina bifida and cardiac conditions, see Table 1 below.

## Who the standards are for

These standards are for women/pregnant people who are eligible to take part in the national pregnancy screening programme. Throughout the standards, the term women/pregnant woman is used but includes any person who is pregnant including transgender and non-binary people.

NHS boards are responsible for implementing these standards to deliver pregnancy screening services for women within their locality.

The screening tests covered in these standards are for singleton and twin pregnancies. Multiple pregnancies greater than twins are not part of the national programme. However, healthcare staff will discuss the options available for a women's pregnancy, in line with clinical guidance for triplet and higher pregnancies.

The table below provides an overview of the national pregnancy screening programme tests covered in these standards. It includes the type of test, timing of tests and eligibility criteria. Further information on the range of screening tests, their eligibility and limitations is available from NHS Inform.

## Table 1: National pregnancy screening tests covered by these standards

| What conditions does the screen look for* | Type of test | Eligibility – who is offered the screening test and when |
|---|---|---|
| **First line screening** (also known as first trimester combined screening test or primary screening test) | | |
| • Down's syndrome<br>• Edwards' syndrome<br>• Patau's syndrome | Maternal blood test and ultrasound scan to measure nuchal translucency | Pregnant women with singleton and twin pregnancies between $11^{+2}$ weeks to $14^{+1}$ weeks of pregnancy |
| **First line screening** (also known as second trimester quadruple screening or primary screening test) | | |
| • Down's syndrome | Maternal blood test | Pregnant women with singleton and twin pregnancies between $14^{+2}$ week to $20^{+0}$ weeks of pregnancy. |
| **Second line screening:** (also known as Non Invasive Prenatal Testing (NIPT) or secondary screening test) | | |
| • Down's syndrome<br>• Edwards' syndrome<br>• Patau's syndrome | Maternal blood test | Pregnant women with singleton and twin pregnancies with a higher chance result from the primary screen up to $21^{+6}$ weeks of pregnancy.<br>Exclusion criteria are available from NHS Inform website. |
| **Mid-pregnancy ultrasound scan** | | |
| • Anencephaly<br>• Open spina bifida<br>• Cleft lip<br>• Diaphragmatic hernia<br>• Gastroschisis<br>• Exomphalos<br>• Serious cardiac anomalies<br>• Bilateral renal agenesis<br>• Lethal skeletal dysplasia<br>• Edwards' syndrome<br>• Patau's syndrome | Ultrasound scan | Pregnant women with singleton and twin pregnancies between $18^{+0}$ weeks to $20^{+6}$ weeks of pregnancy.<br>A further ultrasound examination (up to 23 weeks of pregnancy) may be performed, if required to complete screen. |

*In line with the national screening programme[3]

## Information and resources

A key aim of the screening programme is to support pregnant women to make informed decisions about these screening tests and the care options they may wish to consider. Information should be provided in a format and language that suits their needs. Support should be provided to enable informed decisions with opportunities for questions. Care should be compassionate, understanding and non-judgemental. Women should always be respected and supported in their choices and decisions.[4]

The following resources and organisations are available to support women and their partners:

- Your pregnant! Scans and tests
- NHS Inform: Pregnancy screening
- Antenatal results and choices
- Down's syndrome Scotland
- SOFT UK

## Review of pregnancy screening standards

Healthcare Improvement Scotland published the pregnancy screening: fetal anomaly standards in 2019. In Autumn 2023, these standards were prioritised by the National Screening Oversight Board for review in 2024/25 to incorporate changes to the screening programme including updating terminology.

The changes to the programme include:[5]

- the expansion of first trimester screening for Down's syndrome to include screening for Edwards' syndrome and Patau's syndrome
- implementation of NIPT as second line test for pregnancies with a higher chance result from primary (known as first line) screening
- inclusion of twin pregnancies for combined first trimester screening for Down's syndrome, Edwards' syndrome and Patau's syndrome, and second trimester quadruple screening for Down's syndrome and NIPT as a second line screen for those pregnancies receiving a higher chance result from the primary screen.

These standards cover the screening pathway for the detection of some health (also known as fetal conditions) and chromosomal conditions during pregnancy.

Standards for other pregnancy and newborn screening tests will be reviewed at future date and can be found on the Healthcare Improvement Scotland website:

- Haemoglobinopathies in pregnancy
- Infectious diseases in pregnancy
- Newborn bloodspot screening
- Newborn hearing screening.

## Scottish pregnancy and newborn screening programme: governance

Pregnancy screening sits with the Scottish pregnancy and newborn screening programme. The Scottish pregnancy and newborn screening programme board is:

- accountable for the pregnancy screening pathway, screening assessment, diagnosis and referral
- responsible for monitoring the effectiveness of the programme, including the offer of gestationally appropriate screening options and performance against key performance indicators (KPIs).

NHS boards deliver pregnancy screening services for women within their locality. This includes:

- managing the care of pregnant women
- coordinating and booking screening appointments
- undertaking maternal blood tests and ultrasound scans
- informing women of the results from the screening tests
- provision of diagnostic testing
- provision of specialist referral or counselling including support.

Local NHS board laboratories and nationally commissioned laboratories undertake the screening test analysis.

## Key performance indicators

KPIs for pregnancy screening are developed, reviewed and monitored by the pregnancy and newborn quality performance and monitoring group. These standards should be read alongside the KPIs. The KPIs provide a retrospective assessment of the effectiveness of screening, evaluating quality and performance. KPIs also promote continuous improvement by highlighting areas that are underperforming.

Public Health Scotland reports data on aspects of the pregnancy and newborn screening programme.[6, 7]

## Health inequalities

The Scottish Equity in Screening Strategy 2023-26 aims to reduce inequalities across all the national screening programmes including pregnancy screening.[8] The strategy has highlighted gaps in inequalities data for the pregnancy screening programme. Work has been identified to improve national data from the pregnancy screening programme and include inequalities data.[6]

NHS boards should undertake work to understand the impact of inequalities on the coverage of women participating in pregnancy screening including any barriers.[4, 6, 9] This will support development of information resources and improve provision of care.[8, 10]

It is important that healthcare and screening service providers support women to make informed decisions about screening during their pregnancy. Easily accessible resources in an appropriate language and format, and access to specialist support organisations, will enable women to understand the information and make the decision that is right for them.[2, 11]

## Related guidance and policy

These standards should also be read alongside relevant legislation and guidance, including but not limited to:

- Adults with Incapacity (Scotland) Act 2000
- Health and Social Care Standards
- Healthcare Improvement Scotland: Congenital heart disease standards
- Healthcare Improvement Scotland: Core screening standards
- Healthcare Improvement Scotland: learning from adverse events framework
- National Services Scotland: A guide to national population screening in Scotland
- National health and wellbeing outcomes
- NHS Inform: Pregnancy screening
- NHS Scotland: Climate emergency and sustainability strategy 2022-2026
- NICE Antenatal Care guideline
- Public Health Scotland: Pregnancy screening for Down's syndrome, Edwards' syndrome and Patau's syndrome in Scotland
- Realising realistic medicine
- Scottish Government: Organisational duty of candour guidance
- Scottish Equity in Screening Strategy 2023-26

- Scottish Government: Scotland's public health priorities
- The United Nations Convention on the Rights of the Child (UNCRC).

## Scope of the standards

These standards ensure consistent and equitable approach to the provision and monitoring of the screening tests for Down's syndrome, Edwards' syndrome and Patau's syndrome, and the mid-pregnancy ultrasound examination in Scotland.[12] The standards cover:

- pregnancy screening: eligibility and information
- specialist support and care planning
- first line screening in pregnancy
- second line screening: non-invasive prenatal testing
- mid-pregnancy ultrasound scan
- prenatal diagnostic testing and reporting
- laboratory processes.

## Implementation

These standards have been developed by key stakeholders from across the pregnancy screening pathway. The standards support and inform organisational self-evaluation and improvement.

Implementation of these standards by the Scottish pregnancy and newborn screening programme and NHS boards will ensure the delivery of safe, effective and person-centred services across the pregnancy screening pathway.

These standards are a key component in supporting the Scottish pregnancy and newborn screening programme's approach to quality assurance. Monitoring performance against these standards, at a local and national level, aims to improve the quality of the programme.

External quality assurance (EQA) of screening programmes will be delivered using the Healthcare Improvement Scotland quality of care approach and the quality framework. This approach specifies how Healthcare Improvement Scotland will design and deliver EQA activity to support improvement in healthcare.

The approach emphasises the importance of regular, open and honest self-evaluation of programmes using the quality framework as a basis, combined with other relevant data and intelligence, including performance against these standards.

## Format of the standards

All Healthcare Improvement Scotland standards follow the same format. Each standard includes:

- an overarching standard statement
- a rationale explaining why the standard is important
- a list of criteria describing what is needed to meet the standard
- what the standard means if you are a person participating in pregnancy screening
- what the standard means if you are a member of staff
- what the standard means for NHS boards
- examples of what meeting the standard looks like in practice.

## Terminology

Wherever possible, we have incorporated used generic terminology which can be applied across the screening pathway. Details on the screening tests are provided in Table 1. The following terms are used throughout this document.

**Women/pregnant women**: anyone who is pregnant including transgender and non-binary people, who access services or receive care and support across the pregnancy screening pathway. This includes people with a CHI number as well as those not registered with a GP.

**Chromosomal condition:** chromosomes carry genes that determine how we develop. People usually have 46 chromosomes, 23 from the mother and 23 from the father. If babies have an extra full or partial chromosome in their cells, they'll have a chromosomal condition. If this is only in some of their cells, it may be called mosaicism. Down's syndrome, Edwards' syndrome and Patau's syndrome are chromosomal conditions.

**Failsafe** refers to processes designed to ensure that all aspects of the processes are safe and effective, and that there are appropriate mechanisms where an issue or adverse event occurs.

**High/higher chance result** indicates that the baby is more likely to have the condition or Down's syndrome, Edwards' syndrome or Patau's syndrome in line with national guidance.

**Partner** refers to an individual who shares the pregnancy with the person, or is associated with the person as part of a couple.

**Ultrasound scan** refers to a procedure that uses high-frequency sound waves to create an image of the unborn baby. Referred to in the standards as mid-pregnancy (ultrasound) scan.

# How to participate in the consultation process

We welcome feedback on the draft standards and will review every comment received. We are using different methods of consultation, including:

- targeted engagement with people who use services (and representatives) and service providers (including staff at the point of care)
- circulation of the draft standards to relevant professional groups, pregnancy screening staff and third sector organisations
- an online survey: https://www.smartsurvey.co.uk/s/5URY0E/

## Submitting your comments

Responses to the draft standards should be submitted using our online survey: https://www.smartsurvey.co.uk/s/5URY0E/.

The consultation closes on **Monday 19 August 2024 at 5pm**. If you would like to submit your comments using a different format, please contact the project team on his.screeningstandards@nhs.scot.

Please note, consultation comments will not be accepted after the closing date, or in an alternative format, unless previously agreed with the project team.

## Consultation feedback

Feedback on the draft standards will be reviewed and themed by the project team. The development group will reconvene following consultation to review feedback on the draft standards and agree on amendments to the standards.

A summary of the responses to the consultation will be made available on request from the project team at his.screeningstandards@nhs.scot.

The final standards will be published in Winter 2024.

# Summary of standards

**Standard 1: Pregnancy screening: eligibility and information**

All eligible women are offered pregnancy screening for chromosomal and health conditions.

**Standard 2: Specialist support and care planning**

NHS boards have processes and pathways for specialist support and care planning.

**Standard 3: First line screening in pregnancy**

NHS boards ensure first line screening is safe, effective and person-centred, with timely reporting of results.

**Standard 4: Second line screening: Non-invasive prenatal testing**

NHS boards ensure non-invasive prenatal testing is safe, effective and person-centred, with timely reporting of results.

**Standard 5: Mid-pregnancy ultrasound scan**

NHS boards ensure the mid-pregnancy ultrasound scan is safe, effective and person-centred, with timely reporting of results.

**Standard 6: Prenatal diagnostic testing and reporting**

NHS boards ensure prenatal diagnostic testing is safe, effective and person-centred, with timely reporting of results.

**Standard 7: Laboratory processes**

Laboratory services and processes for pregnancy screening are carried out in line with nationally recognised standards.

# Standard 1: Pregnancy screening: eligibility and information

**Standard statement**

All eligible women are offered pregnancy screening for chromosomal and health conditions.

**Rationale**

As part of the pregnancy screening programme, all eligible women are offered gestationally appropriate screening for:[3]

- Down's syndrome, Edwards' syndrome or Patau's syndrome
- Eleven conditions screened as part of the mid-pregnancy ultrasound scan.

This is provided by the woman's local NHS board maternity service. Women can be referred by their GP or self-refer to local maternity services.

Throughout pregnancy screening it is important that women, and their partners where appropriate, are provided with sufficient time to understand and discuss their needs and ongoing care. The principles of informed consent and shared decision making are central to supporting women who take part in screening. Consent should be obtained for all stages of screening and any ongoing care and support. It is important that women are informed they can withdraw from screening at any stage. Women should be informed about how they can take part in screening if they have previously chosen to withdraw.

The first antenatal appointment should identify the woman's preferred communication method for receiving information, support and results.[4, 11] Information should be provided at the first antenatal appointment and throughout the screening pathway. Information should be tailored to the person's needs, preferences and circumstances. This may include information provided in alternative formats, languages and easy read guides. Translation and interpreter services should be made available, including face to face and virtual options, as appropriate. It is good practice to review the woman's understanding of the process and her communication needs throughout the pathway, as this may change.[2]

NHS boards should ensure that staff are supported and appropriately trained in communicating the benefits and implications of screening, eligibility for screening, potential results and care options available. Women should be informed of the possibility of screening identifying incidental findings. Training should support staff to share results of screening using a person-centred and trauma informed approach.[13-16] Women should be respected and supported in their decisions. Referral to counselling and specialist support organisations should be made as appropriate.

The national pregnancy screening programme collects data on the performance of the programme, including coverage and outcomes.[6, 7] Women should be informed about the collection, storage, retention and sharing of data relating to screening. Consent should be obtained, where appropriate. NHS boards should ensure regular reporting through appropriate national databases and forums.

### Criteria

**1.1** NHS boards offer screening appointments to all eligible women at the appropriate stage of pregnancy in line with national guidance.

**1.2** To support informed decision making, women are provided with evidence informed, accessible and timely information, which covers:

- the conditions screened, the aim, benefits and limitations of screening, and possible incidental findings
- consent, that all screening tests are optional, and the person can withdraw at any point in the pathway
- how to opt into screening if the person initially declines, where eligible
- the timelines of when screening is offered
- options for women who are not eligible for screening including women with multiple pregnancies
- what results mean and when they will be received
- what happens if a repeat blood test or diagnostic testing is indicated.

**1.3** Where an early pregnancy scan shows the person is at a later stage of pregnancy and first trimester screening is not possible, the healthcare professional will provide information on which tests are available.

**1.4** NHS boards have systems and processes in place to ensure the woman's decision to accept or decline the offer of chromosomal or health conditions screening is recorded and shared appropriately.

**1.5** NHS boards ensure that the woman's preference for communication, including receiving results, is recorded and shared appropriately.

**1.6** Staff are trained and knowledgeable in the screening tests offered and eligibility criteria.

**1.7** NHS boards ensure results for screening are timely and shared appropriately with the woman and relevant healthcare professionals.

**1.8** Staff, relevant to their role and workplace setting, can:

- provide women with evidence informed, accessible and timely information
- support women to understand what the screening results mean and the women's options
- signpost women and partners to specialist counselling and support where required.

**1.9** NHS boards have systems and processes for clinical governance including:

- data monitoring, reporting and review in line with national pregnancy screening indicators, where appropriate
- monitoring, reporting and review of any incidents or adverse events in line with national guidance
- adherence to national pregnancy screening protocols
- adherence to these standards and the Healthcare Improvement Scotland core screening standards.

**1.10** NHS boards work in collaboration with national services to collect and share data as required to support national evaluation and research.

**1.11** Women are informed about the collection, storage, retention and sharing of any personal data, in line with national policies and following consent, where appropriate.

| What does the standard mean for the person taking part in pregnancy screening? |
| --- |
| • You will be offered screening at the right time in your pregnancy.<br>• You be provided with the relevant information about the screening test. This includes benefits, implications, potential options and timeframe for screening.<br>• Your decision to go ahead with or decline screening will be supported and respected. At all times during screening, you will be supported by compassionate and non-judgemental healthcare professionals.<br>• You will be given the time you need to discuss what screening means for you.<br>• You can withdraw from screening at any point. If you change your mind, you will be advised of your options.<br>• Your partner, where appropriate, will be offered information and support. |
| **What does the standard mean for staff?** |
| Staff:<br>• support women (and their partners, where appropriate) in informed decision making through providing compassionate, person-centred and trauma informed care<br>• signpost women (and their partners, where appropriate) to information, specialist organisations and other healthcare teams, where required<br>• are appropriately trained and knowledgeable in pregnancy screening including benefits and limitations, consent and eligibility criteria<br>• undertake regular training and continued professional development including mentoring and supervision. |

| What does the standard mean for the NHS board? |
| --- |
| NHS boards:<br>• have systems and processes to offer and provide timely, person-centred and trauma informed screening in line with national guidance and protocols<br>• have robust clinical governance arrangements for the delivery of pregnancy screening<br>• ensure the availability of appropriate, easily accessible and timely information and support<br>• have clear pathways of communication between the woman and multidisciplinary teams<br>• ensure staff have time, resources and training to support and care for women and their partners, where appropriate. |
| **Examples of what meeting this standard might look like** |
| • Evidence of information provided in alternative formats and languages.<br>• Evidence of support for people with additional communication needs, for example, people with sensory impairments.<br>• Signposting of women, and their partners where appropriate, in accessing information and support services including specialist third sector organisations.<br>• Evidence of the woman's involvement in decision making.<br>• Documented evidence of staff training including personal development plans, demonstration of mentoring and peer support.<br>• Demonstration of participation in data collection, audit and review at local, regional and national level.[6, 7, 17] |

# Standard 2: Specialist support and care planning

**Standard statement**

NHS boards have processes and pathways for specialist support and care planning.

### Rationale

When it is suspected or confirmed during pregnancy that a baby may have one of the conditions screened for, women, and their partners where appropriate, are provided with support. Women are informed about their baby's prognosis and options to enable informed decision making, effective planning and any further referral that may be required.

NHS boards should have or develop care pathways for women with a high/higher chance screening result or confirmed diagnosis in line with the national screening programme protocols and guidance. The pathways should include multidisciplinary and multiagency care planning, for example access or signposting to specialist support organisations, counselling or bereavement services. Specialist care is managed by local NHS boards.

Staff are appropriately trained and knowledgeable to provide women, and their partners where appropriate, with person-centred and trauma informed support. This should include all treatment and care options including if they chose to end the pregnancy.[13, 15, 18] Communication should be at a time and pace that is right for the woman and always compassionate, respectful and non-judgemental.

### Criteria

**2.1** NHS boards have processes and protocols in place for timely referral to specialist support and care following identification that the baby may have one of the conditions screened for.

**2.2** NHS boards have a designated multidisciplinary team with relevant training and expertise, including neonatology, fetal medicine and palliative care.

**2.3** Women, and where appropriate their partners, are signposted to specialist support organisations including peer support groups.

**2.4** Following confirmation of a baby with a health or chromosomal condition, NHS boards provide person-centred and trauma informed support to women, and where appropriate their partners, covering:

- the options for care and management of the condition during pregnancy
- planning for birth and ongoing care, where appropriate
- assessment for referral to appropriate services including perinatal mental health, clinical or practitioner psychology or wellbeing support
- information and support about options for ending a pregnancy including counselling
- referral for genetic counselling.

**2.5** NHS boards provide person-centred bereavement care for women, and where appropriate their partners, in line with national guidance and standards.[15, 18]

**2.6** Staff provide support and information in a range of formats and languages on anticipatory grief, grief and bereavement support.

**2.7** Staff have an individual wellbeing support plan.

| **What does the standard mean for the person taking part in pregnancy screening?** |
| --- |
| • You will be able to access specialist staff and services to support you.<br>• You will be supported by compassionate, respectful and non-judgemental and given the time to make your decision.<br>• You and your partner, where appropriate, will receive emotional wellbeing support and signposting to specialist support organisations. |

| What does the standard mean for staff? |
| --- |
| Staff:<br>• are appropriately trained and knowledgeable in care pathways following a diagnosis of a health or chromosomal condition<br>• undertake training and continued professional development in the provision of person-centred and trauma informed care and communication<br>• are provided with support to manage their own wellbeing<br>• signpost women (and their partners, where appropriate) to information, specialist support organisations and other healthcare teams, where required. |
| **What does the standard mean for the NHS boards?** |
| NHS boards:<br>• have systems and processes to offer and provide timely, person-centred and trauma informed specialist support and care planning, in line with national guidance and protocols<br>• ensure local care pathways for specialist referral and support are clear and accessible<br>• ensure staff are supported with their own health and wellbeing, including peer support and access to employee assistance. |
| **Examples of what meeting this standard might look like** |
| • Local referral pathways to specialist services.<br>• Signposting and referral to specialist support services.<br>• Standardised referral documentation with evidence of appropriate referrals.<br>• Demonstration of a person-centred and trauma informed approach to services delivery and design.[14]<br>• Provision of training and adherence to national guidance.[15, 18] |

# Standard 3: First line screening in pregnancy

**Standard statement**

NHS boards ensure first line screening is safe, effective and person-centred, with timely reporting of results.

## Rationale

First line screening is offered to eligible women, including women with twin pregnancies, to screen for Down's syndrome, Edwards' syndrome and Patau's syndrome. First line screening is offered in line with national screening policy.[19]

Women in their first trimester ($11^{+2}$ to $14^{+1}$ weeks gestation) are offered combined screening. This involves a maternal blood test and ultrasound scan measuring the baby's nuchal translucency. The blood test should be performed at the same time as the ultrasonography measurements are taken, where possible.

If a woman presents later, or the NT translucency cannot be assessed, a quadruple test for Down's syndrome only will be offered. This is carried out in the second trimester (from $14^{+2}$ to $20^{+0}$ weeks gestation). Women can still be screened for Edwards' syndrome and Patau's syndrome as part of the mid-pregnancy ultrasound scan.

Where there is a higher chance result from either the combined or quadruple testing, women will be offered non-invasive prenatal testing and/or diagnostic testing. As with all screening tests, women may decline further testing. Women will be supported in their choice.

Equipment and peripherals used for first line screening including ultrasound should comply with agreed standards.[20] To process a blood sample effectively, staff should ensure the laboratory request form is complete, accurate and legible. Laboratory processes are covered in standard 7.

NHS boards ensure systems and processes are in place for the monitoring of first line screening and reporting of results. Rapid and reliable reporting minimises anxiety and allows follow up testing to be performed at the earliest opportunity, if appropriate.

## Criteria

**3.1** NHS boards offer high-quality, safe and timely first line screening to all eligible women in line with national timelines, guidance and protocols.

**3.2** NHS boards have systems and processes in place for first line screening, which include:

- timescales and methods for communication of results
- opportunities for women to discuss their results
- processes for referral to second-line screening, diagnostic testing, specialist support and care planning
- adverse event and incident monitoring and review.

**3.3** Staff providing first line screening have access to training which covers:

- eligibility criteria in line with national guidance and protocols
- information about the tests available and the conditions screened
- how to understand and communicate the results
- the options for further testing and referral.

**3.4** Where NT measurement has not been obtained, women are offered a further opportunity to undertake an appropriate test within agreed national timelines.

**3.5** The maternal blood sample taken for the combined or quadruple test is:

- undertaken by appropriately trained and experienced healthcare professionals
- accompanied by a complete and accurate laboratory request form in line with agreed protocols
- carried out in an appropriate clinical environment that uses techniques and equipment including ultrasound that complies with national guidance and protocols.

**3.6** Where a sample has yielded an invalid result, local protocols are in place which cover:

- timely communication from the laboratory to the appropriate team
- communication with the woman, in the format requested, to discuss the next steps
- offer and timely provision of a repeat test, where appropriate.

**3.7** Women with a higher chance chromosomal screening result are:

- informed of the result in line with national timelines of the result being received from the laboratory
- provided with an opportunity to discuss the result with appropriately trained medical or midwifery staff
- provided with support and information in a language and format that is appropriate for their needs.

**3.8** Women with a higher chance result from first line screening are:

- supported to make an informed decision about participating in further testing, including if they choose to decline further screening
- offered non-invasive prenatal testing
- offered diagnostic testing.

**3.9** All results and outcomes from first line screening are recorded electronically as part of national and local data collection and review.

**3.10** Women with a lower chance screening result will be provided with the outcome by, or at, their next appointment.

| **What does the standard mean for the person taking part in pregnancy screening?** |
| --- |
| • You will be offered a screening test to help you make decisions about the care for you and your baby.<br>• You will be given information and support that is right for you. This includes information about available specialist support organisations and further referral.<br>• You will be able to discuss why the test has been offered and what the results may mean.<br>• You have the choice to have a blood test or not, and your decision will not affect any part of your care.<br>• You will be contacted as soon as possible if the test shows you have a higher chance result.<br>• If you have a higher chance result you will be given information and support that is right for you. This includes information about available specialist support organisations and if you will be referred for further tests. |
| **What does the standard mean for staff?** |
| Staff:<br>• understand and follow local and national protocols for first line screening including further testing or referral<br>• demonstrate knowledge and skills required in line with professional competency frameworks<br>• can provide and signpost to accurate information and support that is compassionate, respectful and non-judgemental to the choices of women. |

| What does the standard mean for the NHS boards? |
| --- |
| NHS boards:<br>• have systems and processes in place to provide first line screening including the timely communication of results in line with the national screening programme<br>• meets standards and requirements for safe and effective first line screening procedures<br>• have failsafe mechanisms in place to ensure that the results of first line screening are received in a timely manner by all participating women. |
| **Examples of what meeting this standard might look like** |
| • Evidence of staff qualifications, competencies and continued professional development.<br>• Audit demonstrating adherence to national guidelines, standards and protocols.<br>• Regular data collection and audit of chromosomal screening procedures.<br>• Demonstration of learning at national, local and regional levels of screening incidents and adverse events. |

# Standard 4: Second line screening: Non-invasive prenatal testing

**Standard statement**

NHS boards ensure non-invasive prenatal testing is safe, effective and person-centred, with timely reporting of results.

## Rationale

Non-invasive prenatal testing (NIPT) is a maternal blood test that is offered to eligible women when a previous screening test has shown a higher chance that the baby may have Down's syndrome, Edwards' syndrome or Patau's syndrome.

Staff should be trained in providing NIPT, eligibility criteria, results and options available.[21]

Women should be provided with information at the time of screening on the possible NIPT results along with eligibility for further or repeat testing.[22]

NHS boards should ensure systems and processes are in place for the monitoring of second line screening and reporting of results.

Laboratory processes are covered in standard 7.

## Criteria

**4.1** NHS boards ensure all eligible women are offered NIPT in line with nationally agreed timeframes, guidance and protocols. This includes:

- a screening appointment in a timely manner
- information about NIPT safety and accuracy in an appropriate language and format
- information on possible results, outcomes and further options
- when to expect the result
- providing sufficient time for women to consider their decision.

**4.2** Staff are appropriately trained and knowledgeable in:

- the benefits and limitations of the NIPT screening test
- when an NIPT screening test is offered
- providing accurate information about the NIPT test, results and options for further testing
- accurately completing the laboratory request form to ensure all essential information is included.

**4.3** NHS boards have systems and processes in place to monitor and review the screening test, including:

- NIPT sample taking including request for referral
- reporting of higher chance results and outcomes to local clinical lead
- accurate completion of laboratory forms
- adverse events and incidents.

**4.4** Women who receive an NIPT high chance result are:

- provided with time and opportunities to make decisions about their options
- supported to make informed decisions about diagnostic testing or no further testing
- provided with information about appropriate support organisations.

**4.5** Where no result has been obtained from NIPT, women are offered further testing in line with national protocols.

| **What does the standard mean for the person taking part in pregnancy screening?** |
| --- |
| • You will be offered a blood test (known as NIPT) where previous tests have indicated that your baby has a higher chance of having Down's syndrome, Edwards' syndrome or Patau's syndrome.<br>• You will be given information, support and the opportunity to discuss why a further blood test has been offered, when to expect the results and what the results may mean.<br>• You will be given the choice to have the blood test or not, and your healthcare professional will support you in your decision.<br>• If you have a higher chance result you will be given information and support that is right for you. This includes information about available specialist support organisations and if you will be referred for further tests. |

| What does the standard mean for staff? |
| --- |
| Staff:<br>• understand and follow local and national protocols for NIPT<br>• understand the possible NIPT results and respective care pathways including further testing or referral<br>• demonstrate knowledge and skills required for NIPT screening<br>• can provide and signpost to accurate information that is compassionate, respectful and non-judgemental to the choices of women<br>• understand their roles and responsibilities in clinical governance and adverse event reporting. |
| **What does the standard mean for the NHS boards?** |
| NHS boards:<br>• have processes and care pathways in place to ensure timely referral and management of women following a high chance result, including access to diagnostic test or specialist support and care planning<br>• demonstrate systems and processes are in place for monitoring the quality of NIPT and identify issues in a timely manner<br>• have failsafe mechanisms in place to ensure that the results of NIPT are received in a timely manner by all participating women. |
| **Examples of what meeting this standard might look like** |
| • Evidence of information offered to women and signposting to available support groups.<br>• Regular data collection and audit of NIPT.<br>• Documentation of discussions about diagnostic testing between healthcare professionals and women.<br>• Demonstration of learning at national, local and regional levels of screening incidents and adverse events. |

# Standard 5: Mid-pregnancy ultrasound scan

**Standard statement**

NHS boards ensure the mid-pregnancy ultrasound scan is safe, effective and person-centred, with timely reporting of results.

## Rationale

NHS boards are responsible for offering eligible women a mid-pregnancy ultrasound scan between $18^{+0}$ and $20^{+6}$ weeks of pregnancy. The scan checks the baby's health and development and eleven specific conditions.[1, 3]

NHS boards should provide high-quality, safe and timely ultrasound services undertaken by appropriately trained staff. Ultrasound services should be provided in suitable facilities and using equipment that complies with national standards and guidance.[20, 23]Support and education should be provided for obstetric sonographers who undertake screening as this can increase the rate of early detection and accuracy of diagnosis.

Women should be informed of the benefits and limitations of the mid-pregnancy scan. If one of the conditions is detected or suspected during the mid-pregnancy scan, a second opinion may be sought from another healthcare professional. The findings should be documented and shared appropriately with other healthcare professionals. Information from the scan supports care planning of pregnancy and timely onward referral, where required.

Women should be offered a further ultrasound examination (up to 23 weeks of pregnancy) to complete the screening examination if the image quality of the first examination is compromised. The quality of the first examination may be impacted by factors including increased maternal body mass index, uterine fibroids or position of the baby. Where another scan is required, this should be carried out on the same day where possible.

Where a repeat ultrasound scan is incomplete, the women should be informed. This should be recorded and shared appropriately.

## Criteria

**5.1** NHS boards ensure high-quality, person-centred and trauma informed mid-pregnancy ultrasound scan are offered to all eligible women.

**5.2** Women who opt for a mid-pregnancy ultrasound scan are:

- informed of factors that may impact the completion of the scan
- informed of the result on the same day
- provided with an opportunity to discuss the result with appropriately trained staff.

**5.3** Performance of the mid-pregnancy ultrasound scan complies with national guidance, including:

- assessment of the main fetal structures
- identification and image capture of pre-defined fetal anatomical sections
- measurement to assess fetal growth velocity.

**5.4** Staff undertaking a mid-pregnancy ultrasound scan:

- have relevant qualifications and continued professional development in line with national registration bodies and protocols[20]
- adhere to national guidance and clinical protocols
- are trained in person-centred and trauma informed communication
- participate in relevant local or national professional forums to share learning.

**5.5** If the sonographer suspects a possible health condition, a second opinion may be sought from another healthcare professional, with the findings documented and shared appropriately.

**5.6** Where the mid-pregnancy ultrasound scan is incomplete or inconclusive, staff:

- offer a repeat ultrasound on the same day or a further appointment prior to 23 weeks of pregnancy
- ensure information and relevant data is captured and recorded.

**5.7** Where the repeat mid-pregnancy ultrasound scan is incomplete, staff should inform the woman and document the outcome.

**5.8** Where the mid-pregnancy ultrasound scan either detects a condition, or there is a suspected condition, the woman will be:

- referred to a relevant specialist team for diagnostic or confirmatory testing in line with national protocols, where eligible
- provided with time and opportunity to make decisions about the next stage in the management of the condition
- provided with information to access specialist support organisations.

**5.9** Ultrasound services provide a safe and trauma informed environment with private consultation.

**5.10** NHS boards ensure that equipment and peripherals used for the mid-pregnancy ultrasound scan comply with national or regulatory equipment specification and infection prevention control.

**5.11** NHS boards have processes in place to support quality assurance and improvement of ultrasound services, which includes:

- local protocols for the storage, access and archiving of images and correspondence on an electronic system
- peer review of ultrasound scans
- regular monitoring of data and images for trends
- adverse events and incidents monitoring and review.

**5.12** Data on ultrasound outcomes are recorded, reviewed and monitored in line with national guidance.

| **What does the standard mean for the person taking part in pregnancy screening?** |
| --- |
| • You will be offered a mid-pregnancy ultrasound scan at the right time in your pregnancy.<br>• You will be given information, support and the opportunity to discuss why the mid-pregnancy scan has been offered. This will include the benefits and limitations of the scan.<br>• You will receive the results of your scan at the scan appointment.<br>• If your baby has a condition, you will receive information and support that is right for you. This includes information about available specialist support organisations and further referral.<br>• You will be offered another scan where appropriate. |
| **What does the standard mean for staff?** |
| Staff:<br>• demonstrate the knowledge and skills required to deliver safe, effective and person-centred mid-pregnancy screening<br>• are aware of the importance of timely reporting of results<br>• can provide person-centred information and support to women<br>• respect the choices made by women<br>• understand their roles and responsibilities in clinical governance and adverse event reporting. |

| What does the standard mean for the NHS board? |
| --- |
| NHS boards:<br>• have processes and protocols in place to ensure that mid-pregnancy scans are performed in accordance with national guidance<br>• ensure that mid-pregnancy scans are performed by appropriately trained and knowledgeable staff<br>• have planned preventative maintenance, quality assurance and a rolling replacement schedule in place for all ultrasound equipment and peripherals<br>• monitor, report and review data on performance of the mid-pregnancy scan<br>• have systems and processes in place for the appropriate communication of the mid-pregnancy scan results to other healthcare providers, with the consent of the woman. |
| **Examples of what meeting this standard might look like** |
| • Audit of outcomes and quality assurance of mid-pregnancy scans.<br>• Demonstrate use of electronic reporting systems for the storage images and mid-pregnancy scan reports, in accordance with GDPR.<br>• Evidence of appropriate information sharing between healthcare teams.<br>• Demonstration of learning at national, local and regional levels of screening incidents and adverse events. |

# Standard 6: Prenatal diagnostic testing and reporting

**Standard statement**

NHS boards ensure prenatal diagnostic testing is safe, effective and person-centred, with timely reporting of results.

## Rationale

NHS boards have responsibility for the provision of diagnostic or confirmatory testing where there is a high chance result of the baby having Down's syndrome, Edwards' syndrome, Patau's syndrome or one of the conditions screened for is suspected following the mid-pregnancy scan. Diagnostic testing can be offered to eligible women from 11 weeks of pregnancy.

The tests offered include chorionic villus sampling (CVS) (from 11 weeks of pregnancy) and amniocentesis (after 15 weeks of pregnancy). Information on diagnostic testing should include the purpose of the test and any implications for the women and the pregnancy, including the chance of miscarriage. Results of diagnostic testing should be shared with the women in line with national timelines.

NHS boards should ensure timely access for further specialist review, which includes person-centred information, support and counselling.

Staff should be appropriately trained in all aspects and outcomes of diagnostic testing.[24]

NHS boards should monitor and review on outcomes following prenatal diagnostic testing and communicate these appropriately with other healthcare providers.

## Criteria

**6.1** NHS boards ensure timely appointments for diagnostic or confirmatory testing are arranged and carried out at a local maternity unit or tertiary referral unit.

**6.2** NHS boards have systems and processes in place for diagnostic and confirmatory testing which include:

- timescales and methods for communication of results
- opportunities for women to discuss their results
- specialist support and care planning
- adverse event and incident monitoring and review.

**6.3** Women referred for prenatal diagnostic testing are:

- provided with information about the condition suspected and the diagnostic or confirmatory testing pathway in an appropriate language and format
- referred to a specialist team for further discussion, assessment, counselling and support
- given time and support to consider their decision.

**6.4** Results of the diagnostic testing are reported to women using an agreed method of communication, within agreed national timelines.

**6.5** Data on diagnostic testing outcomes are recorded, reviewed and monitored in line with national guidance.

**6.6** Staff are appropriately trained and knowledgeable in diagnostic testing and reporting.

| **What does the standard mean for the person taking part in pregnancy screening?** |
| --- |
| • You will be offered a further test (known as a diagnostic test) where previous tests have indicated that your baby has a high chance of a particular condition.<br>• You will be given information and support that is right for you. This includes information about available specialist support organisations and further referral.<br>• You will be able to discuss why the test has been offered and what the results may mean.<br>• You will be given the choice to have the test or not, and you will be supported by your healthcare professional in your decision.<br>• You will be given time to discuss your options and be supported in your decision. |

| What does the standard mean for staff? |
| --- |
| Staff:<br>• understand the diagnostic pathway including outcomes and specialist referral<br>• work within local and national protocols and guidance for diagnostic testing<br>• communicate results with compassion and in accordance with competency frameworks<br>• provide person-centred information and support to women, and respect their choices<br>• understand the importance of timely reporting of results following prenatal diagnostic testing<br>• understand their roles and responsibilities in clinical governance and adverse event reporting. |
| **What does the standard mean for the NHS board?** |
| NHS boards:<br>• have systems and processes to support safe, effective and high-quality diagnostic pathways including specialist referral<br>• ensure staff are appropriately trained and supported to take part in local and national learning forums<br>• collect, monitor and review outcomes of diagnostic testing<br>• have processes and care pathways in place to ensure timely reporting of results and referral for specialist assessment, if appropriate. |
| **Examples of what meeting this standard might look like** |
| • Audit of outcomes from prenatal diagnostic testing.<br>• Evidence of timely referral to specialist appointments within agreed timelines.<br>• Evidence of signposting to specialist support organisations and further resources.<br>• Evidence of completion of diagnostic pathways within agreed reporting timelines.<br>• Demonstration of learning at national, local and regional levels of screening incidents and adverse events (refer to core screening standards). |

# Standard 7: Laboratory processes

**Standard statement**

Laboratory services and processes for pregnancy screening are carried out in line with nationally recognised standards.

## Rationale

The laboratory processes and analyses maternal blood samples collected from first and second line screening.

Good clinical governance ensures that pregnancy screening tests are processed within an environment that can deliver high reliability and accuracy. Laboratories must comply with national and local guidance and be accredited with United Kingdom Accreditation Service (UKAS) to perform tests.

NHS boards should ensure laboratory staff have access to ongoing training, supervision and assessment to ensure all staff maintain professional accreditation, in line with national guidance.

## Criteria

**7.1** Laboratories involved in processing and analysing samples for the pregnancy screening programme maintain all necessary or required accreditations.

**7.2** Laboratories have a designated clinical lead and service manager with responsibility for the pregnancy screening laboratory processes.

**7.3** Screening samples are processed using equipment and techniques in line with national protocols and guidelines.

**7.4** All laboratory staff are trained to the required standards of competence and undertake regular training, supervision and assessment appropriate to their roles and responsibilities.

**7.5** All laboratory request forms are monitored and reviewed in accordance with agreed protocols.

**7.6** Results from first or second line screening are issued by the laboratory in line with national timelines.

**7.7** Where no result has been obtained for NIPT, laboratory staff will retest the original sample and issue a report.

**7.8** Where the retest of the original sample fails, the woman will be offered a repeat test.

**7.9** Laboratories involved in processing samples from pregnancy screening pathways demonstrate:

- participation in the relevant quality assurance and regulatory frameworks
- adherence to national standards and procedures for results reporting and monitoring quality, including adverse events management
- reporting against screening KPIs and result turnaround times
- procedures to detect, review and report on any issues relating to laboratory processes.

**7.10** Laboratory services work collaboratively with national screening governance groups, local maternity units and other relevant clinical departments to participate in multidisciplinary meetings and forums.

| **What does the standard mean for people?** |
| --- |
| • You can be confident that your screening test sample will be analysed in a timely manner by appropriately trained staff. |
| **What does the standard mean for staff?** |
| Staff:<br>• understand and work within the relevant national standards, protocols and guidance<br>• work collaboratively as part of the wider multidisciplinary team<br>• are supported to attended regular training, continued professional development and education. |
| **What does the standard mean for the NHS boards?** |
| NHS boards:<br>• ensure standards and requirements for safe and effective laboratory services are in place<br>• ensure laboratories maintain the relevant accreditation<br>• provide data monitoring in line with national and relevant audit returns<br>• review internal and external monitoring and quality reports to ensure quality and identify issues in a timely manner. |

| Examples of what meeting this standard might look like |
| --- |
| • Evidence of timely laboratory processes.<br>• Evidence of UKAS accreditation.<br>• Evidence of staff qualifications and continued professional development.<br>• Evidence of regular data collection, audit and review of laboratory processes.<br>• Demonstrate lessons learned from any incidents or adverse events. |

# Appendix 1: Development of the standards

Healthcare Improvement Scotland has established a robust process for developing standards which is informed by international standards development methodology.[25] This ensures they:

- are fit for purpose and informed by current evidence and practice
- set out clearly what people accessing services can expect
- are an effective quality assurance tool.

The standards have been informed by current evidence, best practice recommendations and developed by expert group consensus.

## Evidence base

A review of the literature was carried out using an explicit search strategy devised by an information scientist in Healthcare Improvement Scotland. Additional searching was done through citation chaining and identified websites, grey literature and stakeholder knowledge. Searches included Scottish Government, PHS, NICE, SIGN, NHS Evidence and Department of Health websites. This evidence was also informed equalities impact assessments.

## Standards development

A standards development group, chaired by Dr Lorna Rashid, Principal Clinical Scientist, NHS Lothian, was convened in April 2024 to consider the evidence and to review the 2019 pregnancy screening: fetal anomaly standards.

Membership of the development group is outlined in Appendix 2.

Each standard is underpinned by the views and expectations of healthcare staff, third sector representatives, people participating in screening and the public. Information for the revised standards will be gathered from several sources and activities.

## Consultation feedback and finalisation of standards

Following consultation, the standards development group will reconvene to review all comments received and make final decisions and changes. More information can be found in the consultation feedback report, which will be available on request following publication of the final standards.

## Quality assurance

All development group members are responsible for advising on the professional aspects of the standards. Clinical members of the development group advise on clinical aspects of the work. The chair has lead responsibility for formal clinical assurance and sign off on the technical and professional validity and acceptability of any reports or recommendations from the group.

All development group members make a declaration of interest at the beginning of the project. They also review and agree to the development group's terms of reference. More details will be available on request from his.screeningstandards@nhs.scot.

An editorial panel met in June 2024 to review and agree the pregnancy screening standards as a final quality assurance check prior to consultation. Membership of the editorial panel is outlined in Appendix 3.

The editorial panel ensures that:

- the standards are developed according to agreed Healthcare Improvement Scotland methodologies
- the standards document addresses the areas to be covered within the agreed scope
- any risk of bias in the standards development process will be minimised.

The standards were developed within the Operating Framework for Healthcare Improvement Scotland and the Scottish Government (December 2018), which highlights the principles of independence, openness, transparency and accountability. For more information about the direction and priorities of Healthcare Improvement Scotland, please visit: www.healthcareimprovementscotland.org/

# Appendix 2: Membership of the standards development group

| Name | Position | Organisation |
|---|---|---|
| Lorna Rashid (Chair) | Principal Clinical Scientist | NHS Lothian |
| Lesley Aitken | Senior Reviewer, Quality Assurance | Healthcare Improvement Scotland |
| Julie Anderson | Portfolio Manager – Screening Services | NHS National Service Scotland |
| Nicola Andrew | Deputy Head | East of Scotland Regional Genetic Service |
| David Baty | Consultant Clinical Scientist & Head of Laboratory | NHS Tayside |
| Catherine Calderwood | Programme Board chair for Pregnancy & Newborn Screening | NHS Lothian |
| Sarah Campbell | Senior Midwifery Manager | NHS Grampian |
| Michelle Clarke | Lead Midwife, Fetal Medicine | NHS Lanarkshire |
| Katie Dee | Public Health Consultant/Screening Coordinator | NHS Lothian |
| Sophie Dias Cavaco | Inspector, Quality Assurance | Healthcare Improvement Scotland |
| Jacqueline Dunlop | Principle Genetic Counsellor | NHS Tayside |
| Elaine Gardiner | Programme Lead MSc Medical Ultrasound / Diagnostic Imaging Lecturer | Glasgow Caledonian University |
| Jo Hughes | Head of Service Development | Down's Syndrome Scotland |

| Name | Position | Organisation |
|---|---|---|
| Lyn Hutchison | Senior Programme Manager | National Specialist and Screening Services Directorate (NSD) |
| Marieanne Ledingham | Consultant Obstetrician | NHS Greater Glasgow & Clyde |
| Karen McIntosh | Scottish Co-ordinator | Antenatal Results and Choices (ARC) |
| Antony Nicholl | Consultant Obstetrician | NHS Tayside |
| Jocelyn Reid | Lead Midwife Sonographer | NHS Highland |
| Tasmin Sommerfield | Scottish Clinical Advisor (Screening) | NHS National Service Scotland |
| Varshali Swadi | Professional Engagement and Development Lead | Down's Syndrome Scotland |
| Judith Tait | Principal Information Analyst | Public Health Scotland |

The standards development group were supported by the following members of Healthcare Improvement Scotland's standards and indicators team:

- Stephanie Kennedy – Administrative Officer
- Carolyn Roper – Project Officer
- Jen Layden – Programme Manager
- Fiona Wardell – Team Lead

# Appendix 3: Membership of the standards editorial panel

| Name | Position | Organisation |
|---|---|---|
| Jo Hughes | Head of Service Development | Down's Syndrome Scotland |
| Lyn Hutchison | Senior Programme Manager | National Specialist and Screening Services Directorate (NSD) |
| Jen Layden | Programme Manager | Healthcare Improvement Scotland |
| Safia Qureshi | Director of Evidence and Digital | Healthcare Improvement Scotland |
| Lorna Rashid | Standards development group chair<br>Principal Clinical Scientist | NHS Lothian |
| Fiona Wardell | Team Lead, Standards and Indictors | Healthcare Improvement Scotland |

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