We are committed to equality and diversity. These standards are intended to support improvements in healthcare for everyone, regardless of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation, socio-economic status or any other status. Suggested aspects to consider and recommended practice throughout the standards should be interpreted as being inclusive of everyone living in Scotland. We have assessed these standards for likely impact on the nine equality protected characteristics as stated in the Equality Act 2010. A copy of the impact assessment is available on request from the Healthcare Improvement Scotland Equality and Diversity Advisor.

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www.healthcareimprovementscotland.org
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Introduction

Background to the pregnancy and newborn screening standards
Screening is offered to groups of the population to identify people who may be at an increased chance of a particular condition. Pregnancy screening is offered to help women make informed choices about their health and the health of their unborn baby during pregnancy. Newborn screening is offered to facilitate parents and carers to make informed choices about the health of their newborn baby. It is important that informed decisions are made in partnership with healthcare professionals at the respective stage of the screening programme.\(^1\) Information on pregnancy and newborn screening, including national information produced by NHS Health Scotland, is provided to women throughout their pregnancy and following the birth of the baby.

Fetal anomaly screening
The objective of this screening programme is to offer fetal anomaly screening to all pregnant women in Scotland to provide them with information and support to facilitate an informed choice to be made around their pregnancy and child’s health.

Appropriate healthcare professionals should provide women with timely opportunities to discuss benefits, limitations and implications associated with this screening, prior to the procedures, to provide support and facilitate women in making informed choices.\(^2\)

Women’s choices and decisions should always be respected and relevant support should be offered and signposted.\(^1,3-8\)

The fetal anomaly programme is in two parts, with both screening and diagnostic components.\(^2\)

Policy context
National Services Division (NSD) has an ongoing role in the national multidisciplinary groups which monitor and evaluate the pregnancy and newborn screening programmes. Healthcare Improvement Scotland supports NHSScotland’s screening programmes through developing new and, where appropriate, revising existing standards. A request to revise the Clinical Standards for Pregnancy and Newborn Screening (October 2005) was received from the Scottish Government and NSD in summer 2016.

NSD has developed and published a set of Key Performance Indicators (KPIs)\(^9\) to document progress in areas that have been identified within the pregnancy and newborn screening programme as requiring additional support.

These standards should be read alongside other relevant legislation, standards and guidance such as the KPIs mentioned above.

Scope of the standards
These standards apply to fetal anomaly screening in pregnancy and cover:

- trisomy screening – eligibility and coverage
• trisomy screening – test performance
• trisomy screening – referral to further testing
• fetal anomaly screening – eligibility and coverage
• fetal anomaly screening – test performance
• fetal anomaly screening – referral to further testing and/or management and support, and
• reporting of prenatal diagnostic testing.

These fetal anomaly screening standards should be read alongside the general standards for pregnancy and newborn screening:

• Standard 1: Leadership and governance
• Standard 2: Information and support

Information relating to the development of the pregnancy and newborn screening standards can be found in Appendix 1 of the general standards.

The full suite of pregnancy and newborn screening standards is available on the Healthcare Improvement Scotland website (www.healthcareimprovementscotland.org).

Format of the standards
All our standards follow the same format. Each standard includes:

• a statement of the level of performance to be achieved
• a rationale providing reasons why the standard is considered important
• a list of criteria describing the required structures, processes and outcomes
• what to expect if you are a person receiving care
• what to expect if you are a member of staff, and
• what the standards mean for organisations, including examples of evidence of achievement.

Within the standards, all criteria are considered ‘essential’ or ‘required’ in order to demonstrate the standard has been met.

Terminology
Wherever possible, we have incorporated generic terminology which can be applied across all health and social care settings.

The terms ‘woman’, ‘women’ and ‘individual’ are used within the standards to refer to all individuals with a female Community Health Index (CHI) number.

The term ‘eligible women’ refers to women who are invited for pregnancy screening.

The first antenatal contact can be defined as the first appointment with the midwife or hospital.
Quality of care approach

The pregnancy and newborn screening standards are a key component in supporting the pregnancy and newborn screening programme in quality assurance of its services. Monitoring and improving performance against these standards, at a local and national level, aims to improve the quality of the pregnancy and newborn screening programme.

External quality assurance (EQA) of screening programmes is delivered using Healthcare Improvement Scotland’s 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 quality of care approach emphasises the importance of regular open and honest self-evaluation using the Quality Framework as a basis, combined with other relevant data and intelligence including the performance against these standards. Any outcomes from the quality assurance activity will be risk based and set in the context of the programme capacity for improvement. Further information on this approach is available on the Healthcare Improvement Scotland website (www.healthcareimprovementscotland.org).

Implementation

Healthcare Improvement Scotland develops and publishes national standards to support organisations and health professionals in providing a high quality pregnancy and newborn screening programme. The implementation of these standards is for local determination.
Summary of standards

**Standard 1:** All eligible pregnant women are offered trisomy screening no later than 20+0 weeks gestation.

**Standard 2:** Trisomy screening in pregnancy is safe, effective and person centred, and results are reported in a timely manner.

**Standard 3:** Referral to further testing, following a higher chance trisomy screen result, is timely and person centred.

**Standard 4:** All eligible women are offered an ultrasound scan to identify major structural fetal anomalies in the second trimester.

**Standard 5:** Fetal anomaly screening scans are safe, effective and person centred, and results are reported in a timely manner.

**Standard 6:** Referral for further testing and/or management and support of fetal anomaly screening is timely and person centred.

**Standard 7:** NHS boards provide timely reporting of prenatal diagnostic results to facilitate informed choice about ongoing management, information and support.
Pregnancy and newborn screening: fetal anomaly standards

Standard 1: Trisomy screening – eligibility and coverage

**Standard statement**

All eligible pregnant women are offered trisomy screening no later than 20+0 weeks gestation.

**Rationale**

Trisomy screening is offered to everyone who is eligible and each individual accepting screening has a conclusive screening result.\(^\text{11}\) The trisomy screening programme looks for specific chromosomal anomalies, primarily for Down’s syndrome, but others may be identified in line with national policy.\(^\text{2, 11}\)

Evidence notes that first trimester screening is the most accurate screening test as it has a higher detection rate. Fetal chromosomal anomalies can be present at any maternal age and can happen by chance or be inherited.\(^\text{11-13}\)

Women who attend an antenatal appointment before 20+0 weeks gestation should be offered trisomy screening in line with national policy.\(^\text{11, 12, 14}\)

Person-centred information on the screening tests should be provided to women (and their partners) in advance of offering trisomy screening to allow them an opportunity to make an informed decision about whether they would like to take part in trisomy screening.\(^\text{1, 14, 15}\)

Women should be fully informed, involved and supported, with their decisions and choices respected, regardless of the personal views of the healthcare professional.\(^\text{1, 12, 15}\)

**Criteria**

1.1 NHS boards have systems and protocols for timely and person-centred trisomy pregnancy screening, which include:

- offering trisomy screening at the most appropriate stage in pregnancy
- methods of recording the decision to accept or decline the offer of screening
- timescales and methods for communication of results of screening
- the opportunity to discuss with women their results, further management, further testing and/or support, and
- processes for follow-up diagnostic testing.

1.2 All eligible women receive information about trisomy screening at the first antenatal contact with the midwife or hospital service.

1.3 Information about trisomy screening is given to women 48 hours in advance of the screening test.
1.4 The decision to accept or decline trisomy screening is recorded and shared appropriately.

<table>
<thead>
<tr>
<th>What does the standard mean for the individual participating in pregnancy screening?</th>
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<tbody>
<tr>
<td>• Women will be offered gestationally-appropriate trisomy screening.</td>
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<td>• Women will receive information:</td>
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<td>- in a style and format appropriate to their needs at least 48 hours before the screening test.</td>
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<tr>
<td>- providing an overview of the screening process, and</td>
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<td>- outlining the benefits and implications associated with screening to enable the woman to make an informed choice.</td>
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<tr>
<td>• Women will be offered a discussion about trisomy screening with the midwife to facilitate an informed choice.</td>
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<tr>
<td>• Once an informed choice has been made, this will be supported and respected by healthcare professionals.</td>
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<th>What does the standard mean for staff?</th>
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<tr>
<td>• Staff can demonstrate knowledge of:</td>
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<tr>
<td>- eligibility criteria for offering trisomy screening</td>
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<tr>
<td>- the patient pathway for trisomy screening, and</td>
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<tr>
<td>- how individuals can opt in and opt out of the trisomy screening process.</td>
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<tr>
<td>• Staff will record and share the woman’s decision on trisomy screening appropriately.</td>
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<tr>
<td>• Staff will provide information and support to women which is sensitive to their needs and respects their choices.</td>
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<th>What does the standard mean for the NHS board?</th>
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<tr>
<td>• The NHS board will:</td>
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<tr>
<td>- have an effective system in place to offer and provide eligible women with trisomy screening at the appropriate time in their pregnancy, and</td>
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<tr>
<td>- monitor the screening pathway of trisomy screening to ensure it is effective, timely and person centred.</td>
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<tr>
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<td>• Protocols for eligibility and invitation to the pregnancy screening service.</td>
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<tr>
<td>• Evidence that any woman who wishes to have screening completes the pathway unless there is a clinical reason why this could not be achieved.</td>
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</table>
Standard 2: Trisomy screening – test performance

Standard statement
Trisomy screening in pregnancy is safe, effective and person centred, and results are reported in a timely manner.

Rationale
The performance of the screening test and timely reporting will be monitored.

Women who present between 11+2 and 14+1 weeks gestation will be offered the combined test, this includes a nuchal translucency (NT) scan and a blood test.\textsuperscript{1, 14} Healthcare professionals use the information gathered from this test to identify the chance of trisomy pregnancies.\textsuperscript{12-14}

Women who present later, or where a NT measurement cannot be obtained, will be offered the quadruple test, which is performed between 14+2 and 20+0 weeks gestation.\textsuperscript{14} Healthcare professionals use the information gathered from this test to identify the chance of trisomy pregnancies.\textsuperscript{12-14}

Where a higher chance result is received, women should be given timely and appropriate information and support, with the offer of further and/or diagnostic testing.\textsuperscript{1, 11} Women who participate in trisomy screening should be informed of how and when they will receive their results. Rapid reporting minimises anxiety and allows follow-up testing (if requested) to be carried out as early as possible.

Criteria

2.1 All women who participate in screening receive a trisomy screening result in line with national guidance.

2.2 NHS boards have systems and protocols for trisomy screening, which include:
   \begin{itemize}
   \item timescales and methods for communication of results
   \item opportunities for women to discuss their results, further management and/or further testing, and
   \item processes for follow-up diagnostic testing.
   \end{itemize}

2.3 All requests for screening are submitted to the laboratory with a completed request form and a sample taken in the correct gestational window.

2.4 All laboratory request forms have all fields completed accurately and legibly.

2.5 Initial trisomy screening results are issued to the maternity service within 3 working days of receipt of the sample at the laboratory.
2.6 Women with a higher chance trisomy screen result are:

- informed about the result within 3 working days of the result being received from the laboratory
- provided with an opportunity to attend an appointment to discuss the result with medical or midwifery staff within 2 working days of being informed, and
- given information and support in a style and format that is appropriate to their needs.

**What does the standard mean for the individual participating in pregnancy screening?**

- Women will:
  - be offered the nationally agreed screening test
  - have a high quality and accurate trisomy screening test
  - receive the results within the agreed timescale
  - feel supported and be aware of support groups available, and
  - have their choices and decision-making supported and respected.
- Women will be offered a discussion about trisomy screening with the medical or midwifery staff to facilitate an informed choice and this will be supported and respected.
- Once an informed choice has been made, this will be supported and respected by healthcare professionals.

**What does the standard mean for staff?**

- Staff can demonstrate knowledge of:
  - the trisomy being screened for
  - eligibility criteria for trisomy screening
  - the patient pathway for trisomy screening
  - how further information and support can be obtained, and
  - options following a higher chance result.
- Staff will provide information and support to women which is sensitive to their needs and respects their choices.

**What does the standard mean for the NHS board?**

- The NHS board will have a primary and failsafe mechanism in place to ensure that results (both higher chance and lower chance) are received for all women who consent to screening.
<table>
<thead>
<tr>
<th>Practical examples of evidence of achievement (NOTE: this list is not exhaustive)</th>
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<tr>
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<td>• Demonstrate adherence to national protocols for the pregnancy trisomy screening programme.</td>
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<td>• Evidence that any woman who wishes to have trisomy screening completes the pathway unless there is a clinical reason why this could not be achieved.</td>
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<tr>
<td>• Quality assurance of all aspects of trisomy screening process.</td>
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</table>
Standard 3: Trisomy screening – referral to further testing

**Standard statement**
Referral to further testing, following a higher chance trisomy screen result, is timely and person centred.

**Rationale**
All pregnant women with a higher chance trisomy screen result are offered a high quality, timely referral.\(^{11}\)

Provision of good information enables informed choices to be made and helps minimise and reduce anxiety and concern.\(^{1}\) When discussing results, it is important that healthcare professionals provide sensitive, impartial, research-based and relevant information.\(^{12}\)

It is highly important that healthcare professionals discuss the results with women, providing them with support and information to enable them to make informed decisions about further and/or diagnostic testing.\(^{11, 14}\)

Where prenatal diagnostic (PND) testing is offered, discussion should include information so that women are aware of the purpose, benefits, limitations and implications of undergoing the test.\(^{3}\)

All decisions and choices about further and/or diagnostic testing made by women should be respected and supported by healthcare professionals.\(^{11, 14, 15}\) All decisions should be recorded and shared appropriately.

**Criteria**

3.1 Women with a higher chance trisomy screen result who wish to undergo further testing are given the opportunity to:

- discuss the results and further management options with medical or midwifery staff within 3 working days of the result being received from the laboratory, and
- have an appointment within 3 working days of the discussion with a specialist.

3.2 All women with a higher chance trisomy screen result are provided with relevant information and support appropriate to their needs.

**What does the standard mean for the individual participating in pregnancy screening?**

- Women will:
  - receive a timely offer of further investigation when appropriate
  - feel supported and be made aware of support groups available, and

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\(^{1}\) Provision of good information enables informed choices to be made and helps minimise and reduce anxiety and concern.

\(^{11}\) All pregnant women with a higher chance trisomy screen result are offered a high quality, timely referral.

\(^{12}\) It is highly important that healthcare professionals discuss the results with women, providing them with support and information to enable them to make informed decisions about further and/or diagnostic testing.

\(^{3}\) Where prenatal diagnostic (PND) testing is offered, discussion should include information so that women are aware of the purpose, benefits, limitations and implications of undergoing the test.

\(^{11, 14}\) All decisions should be recorded and shared appropriately.

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*Pregnancy and Newborn Screening: Fetal Anomaly Standards – March 2019*
- have a discussion about further testing with an appropriate healthcare professional to allow an informed choice to be made and this will be respected and supported.
- Once an informed choice has been made, this will be supported and respected by healthcare professionals.

**What does the standard mean for staff?**

- Staff can demonstrate knowledge of:
  - undertaking referral and provision of results for trisomy screening in line with competency frameworks
  - the diagnostic pathway, and
  - working within national guidance.
- Staff will provide information and support to women that is sensitive to their needs and respect their choices.

**What does the standard mean for the NHS board?**

- The NHS board will have processes and care pathways in place to ensure timely referral and management.

**Practical examples of evidence of achievement** *(NOTE: this list is not exhaustive)*

- Monitoring reports detailing completion of the trisomy screening pathway within an agreed defined reporting period.
- Evidence that any woman who wishes to have screening completes the pathway unless there is a clinical reason why this could not be achieved.
- Audit of quality assurance of trisomy screening.
- Details of support or further information offered to women referred for further testing.
Standard 4: Fetal anomaly screening – eligibility and coverage

**Standard statement**

All eligible women are offered an ultrasound scan to identify major structural fetal anomalies in the second trimester.

**Rationale**

Fetal anomaly screening is offered to all eligible pregnant women and each individual accepting screening will receive a screening result. The optimal gestational window for completing the fetal anomaly ultrasound scan is 18 weeks + 0 days to 20 weeks + 6 days of pregnancy.

The aim of the fetal anomaly scan is to identify fetal structural anomalies or conditions which may shorten or affect a baby’s life. Antenatal ultrasound scans enable healthcare professionals to identify fetal structures, plan treatment before and after birth, and enable a planned delivery in an appropriate hospital/centre.\textsuperscript{14, 16}

Information on fetal anomaly screening, including the range of anomalies that might be suspected or identified, should be provided to women (and their partners). This will allow individuals the opportunity to make an informed decision about whether they would like to take part in fetal anomaly screening. Women should be informed of the limitations of fetal anomaly screening and that detection rates vary by the type of fetal anomaly, increased body mass index (BMI) and fetal position.\textsuperscript{14, 16}

Women who consent to fetal anomaly screening should be advised that all significant findings seen on the scan will be reported and shared with them.\textsuperscript{14} This information should be provided at the first antenatal contact to allow the individuals to make an informed decision on whether they should accept fetal anomaly screening or not.

When making decisions and informed choices, women and their partners, where appropriate, should be fully involved and supported, with their decisions and choices respected by healthcare professionals.\textsuperscript{1, 3, 12, 15} All decisions should be recorded and shared appropriately.\textsuperscript{3}

**Criteria**

4.1 NHS boards have systems and processes in place to identify and offer all eligible women a fetal anomaly ultrasound scan at the appropriate stage of their pregnancy.

4.2 All eligible women receive information about the fetal anomaly ultrasound scan at least 48 hours before the first antenatal contact.

4.3 All eligible women are given the opportunity to discuss all prenatal diagnostic testing for fetal anomaly and the decision to accept or decline screening and/or referral options are recorded and shared appropriately.
4.4 All women, who choose to undergo screening, will start the fetal anomaly ultrasound scan pathway between 18 weeks + 0 days to 20 weeks + 6 days of pregnancy.

4.5 Women, who start screening between 18 weeks + 0 days to 20 weeks + 6 days of pregnancy and require a second ultrasound scan to finish the screening examination, will complete the pathway by 23 weeks of pregnancy.

What does the standard mean for the individual participating in pregnancy screening?

- Women will be offered screening for fetal anomalies at the appropriate time during their pregnancy.
- Women will receive information:
  - in a style and format appropriate to their needs
  - providing an overview of the screening process
  - outlining the benefits and implications associated with screening to enable the woman to make an informed choice, and
  - at least 48 hours before the first antenatal contact.
- Women will have a discussion about fetal anomaly screening with the medical or midwifery staff to facilitate an informed choice.
- Once an informed choice has been made, this will be supported and respected by healthcare professionals.

What does the standard mean for staff?

- Staff can demonstrate knowledge of:
  - eligibility criteria for the fetal anomaly screening
  - the patient pathway for fetal anomaly screening, and
  - how individuals can opt in and opt out of the fetal anomaly screening process.
- Staff will provide information and support to women that is sensitive to their needs and facilitates the woman to make an informed choice.

What does the standard mean for the NHS board?

- The NHS board will:
  - have an effective system in place to invite eligible women for fetal anomaly screening at the appropriate time in their pregnancy
  - monitor the screening pathway for fetal anomaly screening to ensure it is timely, and
  - offer women an opportunity to complete the screening pathway within the agreed time frames.
### Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

- Monitoring reports detailing completion of the fetal anomaly screening pathway within an agreed defined reporting period.
- Protocols for eligibility and invitation to the pregnancy screening service.
- Demonstrate adherence to national protocols for the pregnancy fetal anomaly screening programme.
- Evidence that any woman who wishes to have screening completes the pathway unless there is a clinical reason why this could not be achieved.
Standard 5: Fetal anomaly Screening – test performance

**Standard statement**
Fetal anomaly screening scans are safe, effective and person centred, and results are reported in a timely manner.

**Rationale**
Pregnant women who accept fetal anomaly screening receive a high quality and accurate fetal anomaly ultrasound scan and timely results.

Ultrasound equipment and peripherals used for fetal anomaly screening must meet a minimum equipment specification as identified in national guidance.\(^{17}\)

In addition to women receiving information on the purpose of the ultrasound scan at the first antenatal contact, the sonographer should also outline the purpose of the ultrasound scan, limitations and benefits at the start of the appointment.\(^ {14}\)

Where the screening examination is incomplete, or image quality is compromised due to high maternal BMI, uterine fibroids, abdominal scarring or sub-optimal fetal position, a further ultrasound examination (prior to 23 weeks’ gestation) should be offered to complete the screening examination.

If an anomaly is detected or suspected during the fetal anomaly ultrasound scan there should be a clear pathway for onward timely referral.\(^ {1, 3, 12, 14}\)

It is essential that women have the opportunity to discuss their results with the appropriate healthcare professional. Support and information, including written information about the fetal anomaly or anomalies should be provided to enable women to make an informed decision about further testing and all further options.\(^ {1, 12}\)\(^ {14}\)

The effectiveness of fetal anomaly screening, including screen positive rate (SPR) and detection rate (DR), should be audited and reported in line with national protocol.

**Criteria**

5.1 During the fetal anomaly ultrasound scan, undertaken between 18 weeks + 0 days to 20 weeks + 6 days of pregnancy, the following is carried out in line with national guidance:

- the main structures are assessed
- pre-defined fetal anatomical sections are identified and imaged
- measurements are undertaken to assess fetal growth velocity in line with nationally approved charts and tables
- images are captured, stored and archived, and
- where appropriate, permanent electronic records of all fetal anomaly scans are stored.
5.2 If the sonographer suspects a possible fetal anomaly, a second opinion is sought from another healthcare professional, documented and shared appropriately.

5.3 Where an adequate assessment of the fetal anatomy remains unachievable after the repeat scan, the woman is advised that the screening is incomplete, and this should be recorded.

5.4 Details of detected fetal anomalies and screen positive results are recorded electronically to provide data for audit purposes.

5.5 Ultrasound equipment and peripherals used for fetal anomaly screening should meet a minimum equipment specification as identified in national guidance.

5.6 All women who accept fetal anomaly screening receive a fetal anomaly screening result as identified in national guidance.

5.7 All women receive their ultrasound scan results on the day of the ultrasound scan.

5.8 The NHS board has protocols and systems in place to follow up babies found to have structural anomalies at birth.

### What does the standard mean for the individual participating in pregnancy screening?

- Women will:
  - have a high quality and accurate fetal anomaly ultrasound scan
  - receive the results within agreed timescales, and
  - be offered a repeat ultrasound scan, where appropriate.

### What does the standard mean for staff?

- Staff can demonstrate knowledge of:
  - eligibility criteria for the fetal anomaly screening
  - the patient pathway for fetal anomaly screening, and
  - what is being screened for during fetal anomaly screening.

- Staff will provide information and support to women which is sensitive to their needs and respects their choices.

### What does the standard mean for the NHS board?

- The NHS board will:
  - have an effective system in place to invite eligible women for fetal anomaly screening at the appropriate time in their pregnancy
  - identify pregnant women who have been missed from fetal anomaly screening, and
  - have a planned preventative maintenance, quality assurance and rolling replacement schedule in place for all screening equipment and peripherals.
### Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

- Monitoring reports detailing completion of the fetal anomaly screening pathway within an agreed and defined reporting period.
- Demonstrate adherence to national protocols for fetal anomaly ultrasound scan.
- Evidence that any woman who wishes to have screening completes the pathway unless there is a clinical reason why this could not be achieved.
- Audit of quality assurance of fetal anomaly ultrasound scans.
- All ultrasound scan reports and images should be able to be uploaded on an auditable electronic reporting system in order to provide minimum auditable data.
- Audit of structural anomalies.
- Record of ultrasound practitioners’ training and ongoing clinical professional development (CPD).
Standard 6: Fetal anomaly screening – referral to further testing and/or management and support

**Standard statement**
Referral for further testing and/or management of fetal anomaly screening is timely and person-centred, and support is provided.

**Rationale**
Women with screen positive results are referred in a timely manner and receive timely intervention where appropriate.\textsuperscript{11}

If there is a suspicion of a fetal anomaly at the ultrasound scan, a second opinion should be sought.\textsuperscript{11,14} Women should be informed of the nature of the suspected anomaly at the time of the ultrasound scan.\textsuperscript{3,14}

NHS boards should provide a timely referral for women with a suspected or confirmed fetal anomaly, including further specialist review; counselling; a second ultrasound, where appropriate; and/or further testing, for example amniocentesis and chorionic villus sampling (CVS), as indicated by the anomaly detected.\textsuperscript{11,14,18}

Where prenatal diagnostic testing is indicated, discussion will include information so that the woman and their partner, where appropriate, is aware of the purpose, benefits, limitations and implications of undergoing a diagnostic test.\textsuperscript{3}

**Criteria**

6.1 Where a fetal anomaly is suspected or confirmed, an appointment will be offered with a local or tertiary specialist team for assessment, information, counselling and further care.

6.2 Women with a suspected or confirmed fetal anomaly will be seen by an obstetric ultrasound specialist within 3 working days of the referral being made.

6.3 Women with a suspected or confirmed fetal anomaly will be seen by a fetal medicine sub-specialist, or geneticist if appropriate, in a tertiary fetal medicine centre within 5 working days of the referral being received.

6.4 Women with a suspected or confirmed fetal anomaly will be seen within 5 working days if the local specialist also suspects or confirms fetal anomaly AND this requires referral to a tertiary centre.

6.5 Women with a suspected or confirmed fetal anomaly will be seen within 3–5 working days for the offer of further screening/diagnostic testing to be made.
### What does the standard mean for the individual participating in pregnancy screening?

- **Women will:**
  - receive a timely offer of further investigation when appropriate
  - feel supported and be made aware of support groups available, and
  - have a discussion about further testing with an appropriate healthcare professional to allow an informed choice to be made and this will be respected and supported.

- Once an informed choice has been made, this will be supported and respected by healthcare professionals.

### What does the standard mean for staff?

- **Staff can demonstrate knowledge of:**
  - undertaking referral and provision of results for fetal anomaly screening in line with competency frameworks
  - the diagnostic pathway, and
  - working within national guidance.

- **Staff will provide information and support to women that is sensitive to their needs and respect their choices.**

### What does the standard mean for the NHS board?

- The NHS board will have processes and care pathways in place to ensure timely referral and management for tertiary referral for specialist assessment.

### Practical examples of evidence of achievement *(NOTE: this list is not exhaustive)*

- Monitoring reports detailing completion of the fetal anomaly screening pathway within an agreed and defined reporting period.
- Audit of quality assurance of fetal anomaly ultrasound scans.
- Details of support or further information for women referred for further testing.
- Evidence that any woman who wishes to have screening completes the pathway unless there is a clinical reason why this could not be achieved.
Standard 7: Reporting of prenatal diagnostic testing

Standard statement
NHS boards provide timely reporting of prenatal diagnostic results to facilitate informed choice about ongoing management, information and support.

Rationale
Where screening has identified an anomaly, and prenatal diagnostic testing is offered to obtain more information, it is important that a discussion takes place with the woman and their partner, where appropriate, to highlight the purpose of the tests and to outline their benefits and limitations.³

Where a suspected fetal anomaly is confirmed, the woman and their partner, where appropriate, should be offered the opportunity to discuss the results, including the implications for the baby, management options for the pregnancy and delivery of the baby, and onward care.³

It is good practice that reporting of prenatal diagnostic testing results should be timely in order to reduce the duration of anxiety in women. Communication of results should be discussed and agreed with the individual at the time of prenatal diagnostic testing and their preferred method of communication used when reporting the results.¹⁹

Once the woman and their partner, where appropriate, receive the results they should be given support, time and opportunity to make informed decisions about their care and/or treatment.¹

Criterion
7.1 Where a diagnostic test has been performed:

- rapid aneuploidy quantitative fluorescent polymerase chain reaction (QFPCR) results are reported within 3 calendar days of sample receipt in the laboratory, and
- karyotype or microarray results are reported within 14 calendar days of sample receipt in the laboratory.

What does the standard mean for the individual participating in pregnancy screening?

- Women will receive results from prenatal diagnostic testing in a timely manner.
- Once an informed choice has been made, this will be respected by healthcare professionals.

What does the standard mean for staff?

- Staff can demonstrate knowledge of:
  - undertaking referral and provision of results in line with professional competency frameworks, and
  - working within local and national guidance.
<table>
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<th>What does the standard mean for the NHS board?</th>
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<tr>
<td>• The NHS board will have:</td>
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<td>- processes and care pathways in place to ensure timely referral and management of tertiary referral for specialist assessment, and</td>
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<td>- systems in place to monitor outcomes following prenatal diagnostic testing.</td>
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<th>Practical examples of evidence of achievement (NOTE: this list is not exhaustive)</th>
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<tr>
<td>• Monitoring reports detailing completion of the screening pathway within an agreed and defined reporting period.</td>
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<td>• Monitoring reports of diagnostic testing and pregnancy outcomes.</td>
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References


