NHS

Screening Programmes

Fetal Anomaly

Fetal Anomaly Screening Programme

Standards

2015-16

About the NHS Screening Programmes

NHS Screening Programmes identify apparently health people who may be at increased risk or a disease or condition, enabling earlier treatment and better informed decisions. They are implemented on the advice of the UK National Screening Committee (UK NSC), which oversees screening policy in all four nations, and works with the different implementation bodies to support delivery.

Public Health England (PHE) is responsible for the NHS Screening Programmes. PHE is an executive agency of the Department of Health and works to protect and improve the nation's health and wellbeing, and reduce health inequalities.

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Contents

1. Introduction

This document presents the revised national standards for the Fetal Anomaly Screening Programme (FASP).

These revised standards replace the following documents and unless stated specifically within the document has an implementation date of April 2015:

- Antenatal Screening - Working standards for Down's syndrome screening 2007
- 18^{+0} to 20^{+6} weeks fetal anomaly scan - National standards and guidance for England 2010

FASP aims to support health professionals and commissioners in providing a high quality fetal anomaly screening programme. This involves the development and regular review of quality standards against which data is collected and reported annually. The standards provide a defined set of measures that providers have to meet to ensure local programmes are safe and effective.

Quality assurance (QA) is the process of checking that these standards are met and encouraging continuous improvement. QA covers the entire screening pathway; from identifying who is eligible to be invited to screening, through to referral and treatment where required/appropriate.

2. The NHS Fetal Anomaly Screening Programme (FASP)

The UK National Screening Committee (UK NSC) has responsibility for setting screening policy. It recommends that all eligible pregnant women in England are offered screening to assess the risk of the baby being born with Down's (Trisomy 21/T21), Edwards' (Trisomy 18/T18) and Patau's (Trisomy 13/T13) syndromes or a number of fetal anomalies (structural abnormalities of the developing fetus).

FASP has responsibility for implementing this policy. It is a complex programme delivered by a range of different organisations working together. There are two service specifications (No. 16 and No. 17) for the NHS providers available as part of the public health functions exercised by NHS England: gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016.

FASP aims to ensure that there is equal access to uniform and quality assured screening across England and that women are provided with high quality information so they can make an informed choice about their screening options and pregnancy choices. Some women may choose not to be screened at all, or accept screening for some conditions and it is important that this choice is respected. The screening policy is to offer screening to assess the risk of the baby being born with Down's, Edwards'/Patau's syndromes.

The test of choice for both singleton and twin pregnancies is first trimester combined screening. Women can choose:

- not to have screening
- to have screening for T21 and T18 / T13
- to have screening for T21 only
- to have screening for T18 / T13 only

The first scan usually takes place between 10 to 14 weeks and includes a blood sample taken to test for T21 and/or T18 / T13, with a second scan for fetal anomalies between $18+^{0}$ to 20^{+6} weeks. The timing of the scans allows for further diagnostic tests if required and ensures women have time to consider decisions about continuing their pregnancy.

The second scan is designed to identify abnormalities which may indicate the baby might die shortly after birth, conditions that may benefit from treatment before birth, to plan delivery in an appropriate hospital/centre and/or to optimise treatment after the baby is born.

3. Format of the standards

The format of screening standards has been revised. Development of this format has been an iterative process, based on work with providers, users, English screening programmes and quality assurance teams. The changes were made to ensure stakeholders have access to:

- reliable and timely information about the quality of the screening programme
- data at local, regional and national level
- quality measures across the screening pathway without gaps or duplications
- a consistent approach across screening programmes
- any burden of data collection is proportionate to the benefits gained

4. Scope and terminology - process standards

The scope is standards that assess the screening process and allow for continuous improvement. This enables providers and commissioners to identify where improvements are needed.

To clarify what is measured each process standard has three parts:

- objective: the aim of the standard
- criteria: what is being assessed
- measure: two thresholds (acceptable and achievable) are specified. These thresholds, definitions and reporting levels are approved by the UK NSC Data Analysts Quality Assurance (DAQA) group.
    - o the **acceptable threshold** is the lowest level of performance which programmes are expected to attain to ensure patient safety and programme effectiveness. All programmes are expected to exceed the acceptable threshold and to agree service improvement plans that develop performance towards an achievable level. Programmes not meeting the acceptable threshold are expected to implement recovery plans to ensure rapid and sustained improvement.
    - o the **achievable threshold** represents the level at which the programme is likely to be running optimally; screening programmes should aspire towards attaining and maintaining performance at this level.

Example: using a standard that assesses coverage for the Newborn and Infant Physical Examination:

- objective: to maximise timely coverage in those who want the screen
- criteria: the proportion screened by 72 hours
- measure: the acceptable and achievable levels set for the population screened are 95% and 99% respectively

Exclusions

There are two types of standards are not included here:

- structural standards: these describe the structure of the programme and must be fully met. Examples of structural standards are "provision of information to all participants" and "a screening laboratory must be accredited". Structural standards are included in screening service specifications and monitored through commissioning and other quality assurance routes. The service specifications should be reviewed by providers and commissioners to ensure structural standards are met by all screening programmes.
- outcome standards: outcomes of the screening pathway are influenced by screening as well as factors beyond the screening programme. Assessment of screening outcomes is currently under review by the operations team of Public Health England.

5. Screening Pathway

QA of screening programmes covers the entire screening pathway; from identifying who is eligible to be invited to screening, through to referral and treatment where required/appropriate. The standards therefore, are based on ten themes that assess the whole pathway:

1. identify population
2. inform
3. coverage/uptake
4. test
5. diagnose
6. intervention/treatment
7. outcome
8. minimising harm
9. staff: education and training
10. commissioning/governance

6. Relationship between standards and key performance indicators (KPIs)

KPIs are a subset of standards that are collated and reported quarterly compared to annual reporting for standards. There are 2-3 KPIs per programme. The KPIs focus on areas of particular concern. Once a KPI consistently reaches the achievable level, the KPI will revert to being a standard and allow entry of another KPI to focus on additional areas of concern or a change to the threshold of the existing standard to promote continuous improvement.

7. Reporting standards

Standards will be reported annually unless they are also a key performance indicator in which case they are reported on quarterly and annual figures are aggregated. A template and process for annual reporting will be developed by DAQA. Data should be collated between two and three months after fiscal year (March-April) end with a submission deadline of 30 June. Responsibility for reporting is as follows:

Responsibility	FASP standards
Local providers- maternity units, ultrasound departments, screening laboratories, tertiary fetal medicine centres	1 2 5 6 (currently a KPI) 7 8 (a) and (b)
National systems- data will be reported nationally	3 4 9 (a), (b), (c), (d)

8. Revising standards

It is anticipated that standards will be reviewed in line with the service specifications on an annual basis.

9. Other resources to support providers and commissioners

This document focuses on process standards to enable providers and commissioners to continuously improve the quality of the screening programme.

Additional FASP operational guidance is included in the following documents which are accessible online: fetalanomaly.screening.nhs.uk/publications:

- Screening programme handbook
- Ultrasound practitioner's handbook
- Handbook for laboratories

10. FASP Standards

FASP Standard 1	Coverage and identifying population (T21/T18/T13 screening)
Rationale	This standard is needed to provide assurance that screening is offered to everyone who is eligible and each individual accepting screening has a conclusive screening result. **Thresholds have not been set for this standard.**
Objective	To maximise timely T21/T18/T13 screening (first trimester screening) in the eligible population who are informed and wish to participate in the screening programme.
Criteria	The proportion of pregnant women eligible for first trimester combined screening for T21 and T18/T13 for whom a conclusive screening result is available at the day of report.
Definitions	eligible women | tested women | women who decline Eligible women is the total number of pregnant women booked for antenatal care during the reporting period **excluding** women who miscarry, opt for termination or transfer out between booking and testing (ie prior to testing), and women who book later than 14 weeks and 1 day of pregnancy. Tested women is the total number of eligible women for whom a completed screening result was available from the first trimester (T21/T18/T13) screening on the day of report. Women who decline is the total number of eligible women who are offered screening and make an informed choice not to take up screening- clear reporting of women who decline screening is required as a measure of informed choice. Booking is the point at which a pregnant woman first sees a midwife to book for maternity care. At the booking appointment the midwife assesses and documents the woman's medical and previous pregnancy history in a maternity record (which should be an auditable information system but may be a paper-based record where appropriate information systems have not been implemented).
Performance thresholds	**Thresholds have not been set for this standard**. FASP supports informed choice for women. This standard enables service providers to be assured that all eligible women are offered the opportunity to enter the screening pathway, should they wish to.
Mitigations	This standard requires matched cohort data. This ensures women do not miss the offer of screening and if they wish to have screening, it is completed. There is no intention to report this standard by percentage for each maternity service but is being introduced to enable and promote failsafe processes.
Reporting	Reporting focus: Maternity service Data source: Maternity information system (may be IT or manual systems) ***At a local level, units need to review these data and account for eligible women who neither decline nor were tested.***
Equity impact	Review of this standard at a local level will indicate if specific groups do not enter, complete the screening pathway or do not access services within optimal timescales. Equity impact assessments and the NHS England Equality Delivery Scheme are tools to improve equity of access.

FASP Standard 2	Coverage and identifying population (18^{+0} to 20^{+6} fetal anomaly ultrasound)
Rationale	This standard is needed to provide assurance that screening is offered to everyone who is eligible and each individual accepting screening has a conclusive screening result.
Objective	To maximise timely fetal anomaly ultrasound screening in the eligible population who are informed and wish to participate in the screening programme.
Criteria	The proportion of pregnant women eligible for fetal anomaly screening for whom a conclusive screening result is available within the designated timescale.
Definitions	tested women / eligible women — expressed as a percentage Tested women (numerator) is the total number of eligible women for whom a completed screening result was available from the 18^{+0} to 20^{+6} week fetal anomaly scan on the day of report, **including** women who required a single further scan by 23 weeks to complete the screening examination if the image quality of the first examination is compromised by one of the following: • increased maternal body mass index (BMI) • uterine fibroids • abdominal scarring • sub-optimal fetal position Eligible women (denominator) is the total number of pregnant women booked for antenatal care during the reporting period **excluding** women who miscarry, opt for termination or transfer out between booking and testing (ie prior to testing), and women who book later than 23^{+0} weeks of pregnancy. Booking is the point at which a pregnant woman first sees a midwife to book for maternity care. At the booking appointment the midwife assesses and documents the woman's medical and previous pregnancy history in a maternity record (which should be an auditable information system but may be a paper-based record where appropriate information systems have not been implemented).
Performance thresholds	**Acceptable:** ≥90% **Achievable:** ≥95%
Mitigations	This standard requires matched cohort data and follow up of any missing cohort to ensure women are not missed.
Reporting	Reporting focus: Maternity service Data source: Ultrasound information systems
Equity impact	Review of this standard at a local level will indicate if specific groups do not enter, complete the screening pathway or do not access services within optimal timescales. Equity impact assessments and the NHS England Equality Delivery Scheme are tools to improve equity of access.

<table>
<tr><th>FASP Standard 3</th><th>The test performance (T21/T18/T13 screening)</th></tr>
<tr><td>Rationale</td><td>This standard is needed to monitor the performance of the screening strategy at a national level.</td></tr>
<tr><td>Objective</td><td>To maximise performance of the screening test and timely reporting.</td></tr>
<tr><td>Criteria</td><td>Test performance.</td></tr>
<tr><td>Definitions</td><td>
<table>
<tr><td>Number of screening tests with risks above the cut-off</td><td rowspan="2">expressed as a percentage</td></tr>
<tr><td>Total number of screening tests in the reporting period</td></tr>
</table>

FASP defines the national cut off set at 1 in 150 at term for both first and second trimester screening tests. A woman with a risk of 1 in 150, or greater (1 in 2 – 1 in 150), of having a pregnancy affected by T21, T18/T13 in the first trimester or T21 only in the second trimester will be considered to be in the ‘higher risk’ group and offered an invasive test.
For women having screening using the combined test, dependant of their screening choice, up to two risks will be reported:
• a risk for T21 and a risk for T18/T13
• a risk for T21 only or T18/T13 only

Excludes increased nuchal translucency (NT) measurement only –FASP policy stipulates all women who accept first trimester screening must have all components of the screening test completed- NT and biochemistry: fetalanomaly.screening.nhs.uk/publications
</td></tr>
<tr><td>Performance thresholds</td><td>
<table>
<tr><th rowspan="2">Screening strategy</th><th colspan="2">Thresholds</th></tr>
<tr><th>Acceptable</th><th>Achievable</th></tr>
<tr><td>T21</td><td colspan="2">Standardised DR 85%</td></tr>
<tr><td></td><td>Standardised SPR 1.8-2.5%</td><td>Standardised SPR 1.9-2.4%</td></tr>
<tr><td>T18/T13</td><td colspan="2">Standardised DR 80%</td></tr>
<tr><td></td><td>Standardised SPR 0.1-0.2%</td><td>Standardised SPR 0.13%-0.17%</td></tr>
<tr><td>T21/T18/T13</td><td>Standardised SPR 1.8-2.5%</td><td>Standardised SPR 1.9-2.4%</td></tr>
<tr><td rowspan="2">Quadruple (T21)</td><td colspan="2">Standardised DR 80%</td></tr>
<tr><td>Standardised SPR 2.5-3.5%</td><td>Standardised SPR 2.7-3.3%</td></tr>
</table>
DR- Detection rate SPR- Screen positive rate

Both crude and maternal age standardised screen positive rates will be presented. Ranges as specified reflect the need to maintain the SPR close to the national programme target. A screen positive rate below the range maybe associated with a lower than expected detection rate. A screen positive rate above the range maybe associated with a higher invasive testing rate.
</td></tr>
<tr><td>Mitigations</td><td></td></tr>
<tr><td>Reporting</td><td>Reporting focus: National

Data source: Data collected and reported nationally via Down’s syndrome Screening Quality Assurance Support Service (DQASS).</td></tr>
<tr><td>Equity impact</td><td>Review of this standard will indicate if the screening test is doing harm ie higher than expected screen positive rate.</td></tr>
</table>

FASP Standard 4	The test performance (18+0 to 20+6 fetal anomaly ultrasound)
Rationale	This standard is needed to monitor the performance of the screening strategy.
Objective	To maximise performance of the screening test and timely reporting.
Criteria	Test performance.
Definitions	<table><tr><td>Affected cases with an abnormal cardiac scan finding</td><td rowspan="2">expressed as a percentage</td></tr><tr><td>Affected cases from the screened population</td></tr></table> The numerator and denominator include those completing fetal anomaly scan from 18+0 to 23+0 weeks of pregnancy. The numerator and denominator excludes congenitally corrected Transposition of the Great Arteries (TGA). Affected cases are fetuses/babies with a confirmed diagnoses of one or more of the following serious cardiac anomalies occurring in isolation: • Transposition of the Great Arteries (TGA) • Atrioventricular Septal Defect (AVSD) • Tetralogy of Fallot (TOF) • Hypoplastic left heart syndrome (HLHS)
Performance thresholds	**Acceptable:** Detection rate (DR) ≥ 50% for each serious cardiac anomaly listed above.
Mitigations	Data are reported at least one year in arrears to allow for active postnatal ascertainment of cardiac anomalies, which are more likely to be screen negative cases. The use of isolated cases reduces the bias possible by variation in the presences of co-existing non cardiac anomalies which improve detection rates.
Reporting	Reporting focus: National Data source: NCARDRS Providers are responsible for reporting affected cases born at their trust and those diagnosed or screened at their trust (if born elsewhere). All affected cases to be notified by NHS Trusts to National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) as for other structural and chromosomal anomalies. Data items on dates and cardiac findings of fetal anomaly scans, repeat scans, expected date of delivery, date of booking to be completed/validated by relevant trust of booking/ screening. Detection rates will be reported separately for each of the four cardiac anomalies.
Equity impact	Review of this standard at a local level will indicate if specific groups do not enter, complete the screening pathway or do not access services within optimal timescales. Equity impact assessments and the NHS England Equality Delivery Scheme are tools to improve equity of access.

FASP Standard 5	The test turnaround time (T21/T18/T13 screening)
Rationale	This standard is needed to monitor the performance of the screening strategy.
Objective	To maximise performance of the screening test and timely reporting.
Criteria	Screening test turnaround time.
Definitions	Number of results reported within three working days of sample receipt / Total number of T21/T18/T13 samples received by the laboratory in the reporting period — expressed as a percentage
Performance thresholds	**Acceptable:** ≥97% of T21/T18/T13 screening results are reported within three working days of sample receipt in the laboratory. **Achievable:** ≥99% of T21/T18/T13 screening results are reported within three working days of sample receipt in the laboratory.
Mitigations	Denominator excludes initial samples received that are not fit for analysis and a repeat sample is requested as this standard is a measure of the laboratory's performance.
Reporting	Reporting focus: laboratory Data source: laboratory
Equity impact	Review of this standard at a local level will indicate if specific groups do not enter, complete the screening pathway or do not access services within optimal timescales. Equity impact assessments and the NHS England Equality Delivery Scheme are tools to improve equity of access.

FASP Standard 6	Minimising harm (T21/T18/T13 screening)
Rationale	To minimise delays in reporting results due to incomplete/ inaccurate completion of screening request forms.
Objective	To minimise potential harms in those screened and in the population.
Criteria	Completion of the screening request forms to enable timely screening.
Definitions	completed laboratory request forms / submitted laboratory request forms — expressed as a percentage Completed laboratory request forms (numerator), is the number of submitted laboratory request forms with completed data for all of the following fields at the initial request: • sufficient information for the woman to be uniquely identified • woman's correct date of birth • maternal weight • family origin • smoking status • ultrasound dating assessment in millimetres, with associated gestational date Submitted laboratory request forms (denominator) is the total number of request forms for Down's syndrome screening submitted to the laboratory within the reporting period during the recommended timeframe for analysis of 10^{+0} weeks' to 20^{+0} weeks' gestation (inclusive).
Performance thresholds	**Acceptable:** ≥97% request forms including complete data prior to screening analysis, submitted to the laboratory within the recommended timeframe of 10^{+0} to 20^{+0} weeks' gestation. **Achievable:** 100% request forms including complete data prior to screening analysis, submitted to the laboratory within the recommended timeframe of 10^{+0} to 20^{+0} weeks' gestation.
Mitigations	All services should aim for completion of all laboratory request forms. The 'acceptable' threshold above reflects the possibility that some women may not wish to supply their family origin or smoking status. This standard measures only laboratory requests submitted within the recommended timeframe for analysis, and not subsequent or repeat requests.
Reporting	Reporting focus: Maternity service Data source: Down's syndrome screening laboratory or ultrasound department as appropriate. This standard is currently a KPI.
Equity impact	Review of this standard at a local level will indicate if specific groups do not enter, complete the screening pathway or do not access services within optimal timescales. Equity impact assessments and the NHS England Equality Delivery Scheme are tools to improve equity of access.

FASP Standard 7	Time to intervention (T21/T18/T13 screening)
Rationale	To provide assurance that individuals with screen positive results are referred in a timely manner and receive timely intervention where appropriate.
Objective	To ensure timely intervention where appropriate.
Criteria	Timely communication of screen positive results.
Definitions	Number of women with higher risk results offered an appointment within three working days / Total number of higher risk results reported in the reporting period — expressed as a percentage Denominator includes higher risk results for first trimester combined screening and T21 quadruple screening in the second trimester. FASP defines the national cut off set at 1 in 150 at term for both first and second trimester screening tests. A woman with a risk of 1 in 150, or greater (1 in 2 – 1 in 150), of having a pregnancy affected by T21, T18/T13 in the first trimester or T21 only in the second trimester will be considered to be in the 'higher risk' group and offered an invasive test. For women having screening using the combined test, dependant of their screening choice, up to two risks will be reported: • a risk for T21 and a risk for T18/T13 • a risk for T21 only or T18/T13 only
Performance thresholds	**Acceptable:** ≥97% of women with a higher risk result should be offered the opportunity to discuss the results and further management options within three working days of the result being reported to the maternity unit. **Achievable:** ≥99% of women with a higher risk result should be offered the opportunity to discuss the results and further management options within three working days of the result being reported to the maternity unit.
Mitigations	This standard counts the offer of an appointment within the specified timeframe ie not attendance at that appointment. Offer is defined as direct contact with the woman – providers should be able to demonstrate that reasonable efforts were made to contact the woman and where contact was not possible this should be explained in the mitigations. Data for each maternity service may be small and therefore would be aggregated and reported as regional/national figures.
Reporting	Reporting focus: Maternity service Data source: Maternity information systems (may be IT or manual systems).
Equity impact	Review of this standard at a local level will indicate if specific groups do not enter, complete the screening pathway or do not access services within optimal timescales. Equity impact assessments and the NHS England Equality Delivery Scheme are tools to improve equity of access.

<table>
<tr><th>FASP Standard 8 (a, b)</th><th>Time to intervention (18+0 to 20+6 fetal anomaly ultrasound)</th></tr>
<tr><td>Rationale</td><td>To provide assurance that individuals with screen positive results are referred in a timely manner and receive timely intervention where appropriate.</td></tr>
<tr><td>Objective</td><td>To ensure timely intervention where appropriate.</td></tr>
<tr><td>Criteria</td><td>Timely referral (local and tertiary as clinically appropriate) when an abnormality is suspected or confirmed.</td></tr>
<tr><td>Definitions</td><td>(a) Local referral
<table><tr><td>Number of women with a suspected/confirmed abnormality seen within three working days</td><td rowspan="2">expressed as a percentage</td></tr><tr><td>Total number of women with a suspected /confirmed abnormality identified in reporting period</td></tr></table>Excludes women with a suspected or confirmed fetal anomaly where the referral is to a tertiary fetal medicine centre (as clinically appropriate as per local pathway).

(b) Tertiary referral
<table><tr><td>Number of women with a suspected/confirmed abnormality seen within five working days</td><td rowspan="2">expressed as a percentage</td></tr><tr><td>Total number of women with a suspected /confirmed abnormality identified in reporting period</td></tr></table>Excludes women with a suspected or confirmed fetal anomaly where the referral is to an obstetric ultrasound specialist locally (as clinically appropriate as per local pathway).</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: ≥97% of women with a suspected or confirmed fetal anomaly should be seen by an obstetric ultrasound specialist locally within three working days of the referral being made.

Acceptable: ≥97% of women with a suspected or confirmed fetal anomaly should be seen by a fetal medicine sub specialist in a tertiary fetal medicine centre within five working days of the referral being made.</td></tr>
<tr><td>Mitigations</td><td>In cases where women are referred to a tertiary fetal medicine centre, good communication and feedback to the referring unit/clinician is necessary to enable local units to report on this standard.

A single repeat scan must be offered and completed by 23+0 weeks gestation in cases where the image quality of the first examination is compromised by one of the following:
• increased maternal body mass index (BMI)
• uterine fibroids
• abdominal scarring
• sub-optimal fetal position

The woman should be rescanned on the same day or offered a new appointment according to local clinical assessment. If first examination is sub-optimal and the sonographer is suspicious of a possible fetal abnormality, a second opinion should be sought.

Where an adequate assessment of the fetal anatomy remains compromised after the repeat scan, the woman should be informed that the screening is incomplete and this should be documented.</td></tr>
<tr><td>Reporting</td><td>Reporting focus: Maternity service

Data source: Maternity unit/ultrasound department/ tertiary centre.</td></tr>
<tr><td>Equity impact</td><td>Review of this standard at a local level will indicate if specific groups do not enter, complete the screening pathway or do not access services within optimal timescales. Equity impact assessments and the NHS England Equality Delivery Scheme are tools to improve equity of access.</td></tr>
</table>

<table>
<tr><th>FASP Standard 9 (a, b, c, d)</th><th>Diagnose (T21/T18/T13 screening and 18+0 to 20+6 fetal anomaly ultrasound)</th></tr>
<tr><td>Rationale</td><td>To provide assurance of timely information to enable ongoing decisions/ actions.</td></tr>
<tr><td>Objective</td><td>To maximise timely reporting of diagnostic results.</td></tr>
<tr><td>Criteria</td><td>Test turnaround times (QFPCR)
Test turnaround times (Karyotype)</td></tr>
<tr><td>Definitions</td><td>(a)
<table><tr><td>Number of QFPCR results reported within three calendar days of sample receipt</td><td rowspan="2">expressed as a percentage</td></tr><tr><td>Number of samples received for QFPCR testing where the indication for genetic testing is a high risk T21/T18/T13 screening result issued within the reporting period</td></tr></table>T21/T18/T13 high risk screening result is defined as a result from combined screening for T21 and/or T18/T13 or from quadruple testing for T21 using national cut off.
(b)
<table><tr><td>Number of karyotype results reported within 14 calendar days of sample receipt</td><td rowspan="2">expressed as a percentage</td></tr><tr><td>Number of samples received for karyotype testing where the indication for genetic testing is a high risk T21/T18/T13 screening result issued within the reporting period</td></tr></table>T21/T18/T13 high risk screening result is defined as a result from combined screening for T21 and /or T18/T13 or from quadruple testing for T21 using national cut off.
(c)
<table><tr><td>Number of QFPCR results reported within three calendar days of sample receipt</td><td rowspan="2">expressed as a percentage</td></tr><tr><td>Number of samples received for QFPCR testing where the indication for genetic testing is a suspected / confirmed abnormality detected from the 18- 20+6 fetal anomaly ultrasound scan undertaken within the reporting period</td></tr></table>(d)
<table><tr><td>No. of karyotype results reported within 14 calendar days of sample receipt</td><td rowspan="2">expressed as a percentage</td></tr><tr><td>Number of samples received for karyotype testing where the indication for genetic testing is a suspected / confirmed abnormality detected from the 18- 20+6 fetal anomaly ultrasound scan undertaken within the reporting period</td></tr></table>All denominators above excludes samples referred for genetic testing where the only indication for testing is an increased nuchal translucency.
FASP policy stipulates all women who accept first trimester screening must have all components of the screening test completed- NT and biochemistry: fetalanomaly.screening.nhs.uk/publications</td></tr>
<tr><td>Performance thresholds</td><td>Acceptable: 90% of rapid aneuploidy QFPCR/FISH results should be reported within three calendar days of sample receipt in the laboratory.
Acceptable: 90% of karyotype results should be reported within 14 calendar days of sample receipt in the laboratory.</td></tr>
<tr><td>Mitigations</td><td>Thresholds are set at 90% to allow for a number of samples where a result is not possible to give a diagnostic result due to slow growing cultures where, for example, insufficient sample was received by the laboratory for processing or sub-optimum samples (eg maternal cell contamination).</td></tr>
</table>

Mitigations	All laboratories should endeavour to maintain adequate reporting times. It is recognised that the changes to reporting time measurement from working days to calendar days may affect the ability of some laboratories to meet all the expected turnaround times immediately. Therefore it is recommended that the reporting times stated are implemented by April 2016 ***[General Genetic Laboratory Reporting Recommendations' (2015) Association for Clinical Genetic Science, A member of the British Society for Genetic Medicine].***
Reporting	Reporting focus: National Data source: Association for Clinical Genetic Science.
Equity impact	Review of this standard at a local level will indicate if specific groups do not enter, complete the screening pathway or do not access services within optimal timescales. Equity impact assessments and the NHS England Equality Delivery Scheme are tools to improve equity of access.

Glossary

The glossary defines terms that are consistent across NHS screening programmes. The scope of each defined term as it applies to a particular screening programme is detailed separately for each screening programme.

A broken underline indicates that a term is used according to its definition in this glossary. Where terms from the glossary are used without a broken underline, their common English meaning can be assumed; except where context determines otherwise. Definitions include all forms of the defined term; so 'tested' and 'testing' refer to the definition of 'test'.

accept

A response to an offer which indicates that a screening subject is willing to proceed with a screening encounter.

acceptance of offer

The proportion of those offered screening who accept the offer.

Low acceptance of offer might indicate that:

i) the offer is not being communicated or delivered effectively (no response); and/or

ii) screening is not deemed necessary or desirable by an entitled population (declined)

affected case

An individual in whom the condition being screened for is present.

booking

The point at which a pregnant woman first sees a midwife to book for maternity care. At the booking appointment the midwife assesses and documents the woman's medical and previous pregnancy history in a maternity record (which should be an auditable information system but may be a paper-based record where appropriate information systems have not been implemented).

communication

An interchange that the subject is capable of understanding and acting upon. This may be in a variety of formats including verbal and/or written.

coverage

The proportion of those eligible for screening who are tested.

Coverage is a measure of the delivery of timely screening to an eligible population. Low coverage might indicate that:

i) not all eligible people have been offered screening

ii) those offered screening are not accepting the test; and/or

iii) those accepting the test are not being tested

day of report

The day on which data to support an audit or performance return are collated.

Usually there will be a time lag between the end of the reporting period and the day of report to allow for the completion of processes being measured and the collation of report data.

decline

A response to an offer which indicates that a screening subject does not wish to proceed with the screening test or pathway.

detection rate (DR)

The proportion of affected individuals with a positive screening result.

eligible

The population that is entitled to an offer of screening.

The criteria for eligibility may be administrative, demographic, clinical, or any combination of these, and may take into account individual circumstances such as time of presentation to the screening service.

Glossary

matched cohort data

The numerator must be a subset of the denominator .

offer

A formal communication made by the screening service, giving a specific subject a realisable opportunity to be tested within an effective timeframe.

An offer or invitation will only count as an offer if:

i) it reaches the subject

ii) the subject is capable of understanding and acting upon it

iii) the screening service has the capacity to realise it; and

iv) it offers an opportunity of testing within an effective timeframe

population

The population that meets the general criteria for inclusion within a screening programme.

The criteria for inclusion within a screening programme may be administrative, demographic, clinical, or any combination of these. Not everyone in the total population is likely to be eligible for screening (for example, those who present later than it would be possible to test).

refer

The process of securing further diagnosis / specialist assessment following a screen positive test.

The date of referral is the first realisable assessment date offered by an appropriate specialist unit to a screening subject following a screen positive result. Allocation to a pending list or a referral subsequently cancelled by the specialist unit is not a referral.

reporting period

The defined time period over which activities should be included in an aggregate audit or performance return.

A reporting period can relate to any specified period but for routine reports is usually quarterly or annual.

Most screening processes occur over a period of days or weeks, to allow a scan or sample to be assessed. In such cases, a single point in the process (such as the screening encounter) should be used to determine whether the process falls within a particular reporting period.

result

A formal and completed assessment of the risk of a condition being screened for in a subject, following a screening encounter.

Usually a result will be screen positive or screen negative. Insufficient and unassessable indicate a failure to obtain a result, and are not themselves results.

screen negative/ lower risk

An indication following a test that the condition being screened for is low-risk / not suspected in a subject.

screen positive/ higher risk

An indication following a test that the condition being screened is high-risk / suspected in a subject.

screen positive rate

The proportion of individuals with a screen positive result.

screening

Testing people who do not have or have not recognised the signs or symptoms of the condition being tested for, either with the aim of reducing risk of an adverse outcome, or with the aim of giving information about risk.

subject

An eligible individual for screening.

test

A screening encounter/event leading to the determination of a conclusive result.

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