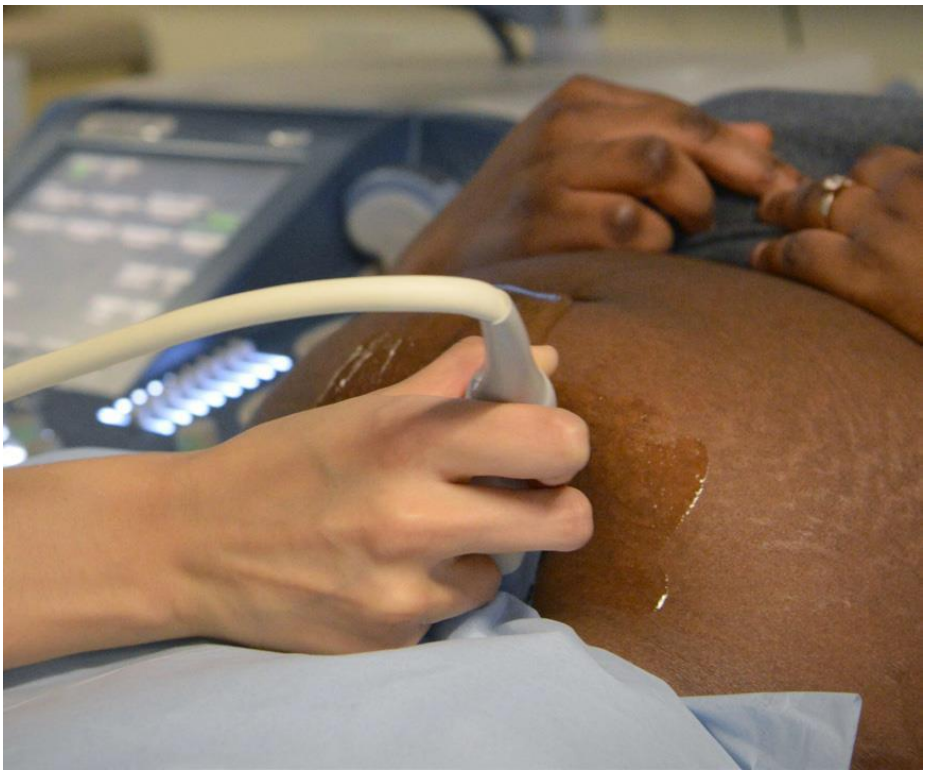
Public Health England

NHS

NHS Fetal Anomaly Screening Programme

Standards Data Report April 2015 to March 2016



Public Health England leads the NHS Screening Programmes

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

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About PHE Screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

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Contents

Executive summary

This is the first published annual standards data report for the NHS Fetal Anomaly Screening Programme (FASP). The aim of the report is to feedback performance against the national standards. Data is presented by financial year (1 April to 31 March) unless stated otherwise.

Dependent on the standard, data was returned by maternity units; biochemical screening laboratories; diagnostic laboratories and national teams such as the Down's syndrome quality assurance support service (DQASS).

There is no report against Standard 4 for 2015 to 2016 as the National congenital anomaly and rare diseases registration service (NCARDRS) was still expanding the registration service across all areas of England and training and implementation of the additional 3 vessel and trachea view to the examination of the fetal heart was not complete across England.

As expected with a new process of reporting there was some variation across England in reporting and completeness of data returns. This can be seen in the table below:

Table 1. Completeness of data returns

Standard	Source	Number of expected returns	Number of submissions (% of returns)	Number of accepted submissions (% of submissions)
Standard 1	Maternity Units	144	106 (74%)	54 (51%)
Standard 2	Maternity Units	144	106 (74%)	39 (37%)
Standard 3	Down's Quality Assurance Support Service (DQASS)	National submission		
Standard 4	NCARDRS	Not currently collected		
Standard 5	Screening Laboratories	21	12 (57%)	12 (100%)
Standard 6 (KPI)	Maternity Units	144	142 (99%)	142 (99%)
Standard 7	Maternity Units	144	106 (74%)	94 (89%)
Standard 8a	Maternity Units	144	106 (74%)	54 (51%)

Standard 8b	Maternity Units	144	106 (74%)	57 (54%)
Standard 9a	Diagnostic Laboratories	18	14 (78%)	14 (100%)
Standard 9b	Diagnostic Laboratories	18	15 (83%)	15 (100%)
Standard 9c	Diagnostic Laboratories	18	12 (67%)	12 (100%)
Standard 9d	Diagnostic Laboratories	18	15 (83%)	15 (100%)

The main issues reported for non-submission or partial submission of data were:

- lack of adequate reporting and IT systems in place to collect and report data, for example maternity systems are not necessarily designed to interface with other systems such as laboratories
- unable to define exclusions and split exclusion categories
- unable to provide matched cohort data
- misunderstanding of the data requirements
- reporting of partial data e.g. Q1 – Q3 only in the case of Standard 2 coverage of the fetal anomaly scan

Data was not included in the analysis for Standards 1 and 2 that relate to coverage of screening for Down's, Edward's/ Patau's syndromes in the first trimester and the fetal anomaly scan if:

- providers were unable to account for 3 or more exclusion criteria
- data was clearly non-matched cohort data

A large proportion of returns for standards 8a and 8b were excluded as the data did not conform to the definition. It was not possible to effectively account for women where this occurred. NHS FASP has revised the definitions and submission template for these standards to make it clearer for providers

The recommendations from the analysis of the data for 2015 to 2016 are set out in Table 2 below:

Table 2. Recommendations

Standard Number	Recommendation	Responsibility	Timescales
1a	Pilot a key performance indicator for this standard to facilitate more timely identification of missed screening by quarterly reporting. Lessons learnt from the pilot will be shared to support development of data collection and collation processes in other providers, particularly in relation to identifying the population of women eligible for screening and, where accepted, tracking the women to assure receipt of result.	FASP	April 2017 - December 2017
1b	Work with provider IT and audit departments to set up manageable systems for cross-referencing and correlating data that allows women who have accepted the offer of screening for Down's, Edwards'/Patau's syndromes to be "tracked" to confirm completion of screening. This process must ensure that all women are accounted for, including those who decline the offer of screening.	Maternity Providers	March 2018
2a	Publish a guidance document detailing the lessons learnt from the KPI pilot.	FASP	December 2017
2b	Work with provider IT and audit departments to set up manageable systems for cross-referencing and correlating data that allows women who have accepted the offer of fetal anomaly ultrasound screening to be "tracked" to confirm completion of screening. This process must ensure that all women are accounted for, including those who decline the offer of screening.	Maternity Providers	March 2018

3	Providers and commissioners should regularly review their DQASS reports at programme boards and address the recommended actions	Maternity Providers/Public Health Commissioners/ Screening & Immunisation Teams	Ongoing
5	Work should be undertaken directly with laboratories to understand reasons for non-submission of data to improve future returns	Screening & Immunisation teams/Regional SQAS	April 2018
6	Providers should review local performance and processes to ensure all required data fields are completed on requests for screening	Maternity Providers	April 2018
7	Implement local referral pathways for women with higher risk screening results for Down's, Edwards' and Patau's syndromes to enable timely intervention	Maternity Providers	April 2018
8a,b	Clarify the definitions to support improvement in the accuracy of the submitted data will be undertaken for the 2016/17 FASP data submission template and KPIs	FASP National screening programmes/KPI data team	April 2018

8c	Put measures in place to accurately report data for these standards	Maternity providers	April 2018
9a	Seek advice from the screening evidence team regarding the possibility of a review of policy regarding use of Karyotype versus micro-array	FASP	April 2018

Introduction

The NHS Fetal Anomaly Screening Programme (FASP) offers screening to all eligible pregnant women in England to assess the risk of the baby being born with Down's, or Edwards'/Patau's syndromes or a number of fetal anomalies (structural abnormalities of the developing fetus).

FASP aims to ensure there is equal access to uniform and quality-assured screening across England and women are provided with high quality information so they can make an informed choice about their screening and pregnancy options. Education and training resources are available for staff covering all stages of the process, from informing women of test availability, through to understanding and supporting their decisions.

FASP supports health professionals and commissioners in providing a high quality fetal anomaly screening programme. This involves developing and regular review of screening standards and key performance indicators against which data is collected and reported.

The standards provide a defined set of measures that providers have to meet to ensure local programmes are safe and effective. NHS FASP published a set of revised standards in April 2015.

Table 3. Standards

Standard	Definition
1	Coverage and identifying population (Down's (T21), Edwards'/Patau's (T18/T13) syndrome screening)
2	Coverage and identifying population (18^{+0} to 20^{+6} fetal anomaly ultrasound)
3	Test performance (T21/T18/T13 screening)
4	Test performance (18^{+0} to 20^{+6} fetal anomaly ultrasound)
5	Test turnaround time (T21/T18/T13 screening)
6	Minimising harm (T21/T18/T13 screening)
7	Time to intervention (T21/T18/T13 screening)
8	Time to intervention (18^{+0} to 20^{+6} fetal anomaly ultrasound)
9	Diagnose (T21/T18/T13 screening and 18^{+0} to 20^{+6} fetal anomaly ultrasound)

Standards are reported annually unless they are also a key performance indicator (KPI) in which case they are reported quarterly and annual figures are aggregated where data were provided for all 4 quarters.

Two thresholds (acceptable and achievable) are specified for each standard except Standard 1 coverage and identifying population (T21 and T18/13) screening.

Thresholds are not set for standard 1 as FASP supports informed choice for women. This standard enables service providers to be assured that all eligible women are offered the opportunity of screening and where this offer is accepted that women complete the screening pathway.

These thresholds, definitions and reporting levels are approved by the Public Health England Screening Data Group (PHE SDG). The SDG is a divisional group where quality assurance and programme teams come together to look at the data and intelligence needs of the screening programmes and to agree changes that drive continuous quality improvement.

- 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.

- 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.

Data is presented by financial year (1 April to 31 March) unless stated otherwise. The year ‘2015/16’, for example, refers to the financial year ‘1 April 2015 to 31 March 2016’.

Methodology

A process and data submission template to support reporting against the standards is in place. Data submission is requested in April each year with a deadline of 30 June. Data received after the deadline is identified as a non-submission and is not included in the report. Null submissions are noted and accepted. Responsibility for reporting is as follows:

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

Standard 4 on the test performance (18^{+0} to 20^{+6} fetal anomaly ultrasound) is not reported for 2015/16 for two reasons:

- NCARDRS was still expanding the registration service across all areas of England
- training and implementation of the additional 3 vessel and trachea view to the examination of the fetal heart was not complete across England

NCARDRS are expected to achieve full reporting across England by 2018/19.

Data was reviewed by the NHS FASP data manager, and clarifications on unclear submissions were sought directly from the person submitting the data. Table 3 demonstrates the data sources and returns received, identifying:

- expected number of returns per standard
- returns received
- returns accepted

The main issues reported for non-submission or partial submission of data were:

- lack of adequate reporting and IT systems in place to collect and report data, for example maternity systems are not necessarily designed to interface with other systems such as laboratories
- unable to define exclusions and split exclusion categories
- unable to provide matched cohort data
- misunderstanding of the data requirements
- reporting of partial data e.g. Q1 – Q3 only in the case of Standard 2 coverage of the fetal anomaly scan

Data was not included in the analysis for Standards 1 and 2 that relate to coverage of screening for Down's, Edward's/ Patau's syndromes in the first trimester and the fetal anomaly scan if:

- providers were unable to account for 3 or more exclusion criteria
- data was clearly non-matched cohort data

NHS FASP will take the following actions to improve the methodology for the data collection for 2016/17:

- revise the data dictionary to clarify the definitions of key data fields
- revise definitions of the standards to improve understanding of the data requirements
- amend the data template to support the actions above and align with other antenatal programmes to support consistency in the reporting required
- collaborate with the 2 other antenatal screening programmes (the NHS Sickle Cell and Thalassemia and NHS Infectious Diseases in Pregnancy Screening Programmes); national Screening Quality Assurance Service (SQAS) and national data team to deliver a set of regional data reporting workshops to support improved knowledge and understanding of the reporting and data requirements for the NHS screening programmes data submissions for standards and KPIs.

Results

Table 1. Completeness of data returns

Standard	Source	Number of expected returns	Number of submissions (% of returns)	Number of accepted submissions (% of submissions)
Standard 1	Maternity Units	144	106 (74%)	54 (51%)
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Standard 9c	Diagnostic Laboratories	18	12 (67%)	12 (100%)
Standard 9d	Diagnostic Laboratories	18	15 (83%)	15 (100%)

Standard 1 Coverage and identifying the population (T21/T18/T13 screening)

Numerator	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
Denominator	Eligible women: Total number of pregnant women booked for antenatal care during the reporting period

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.

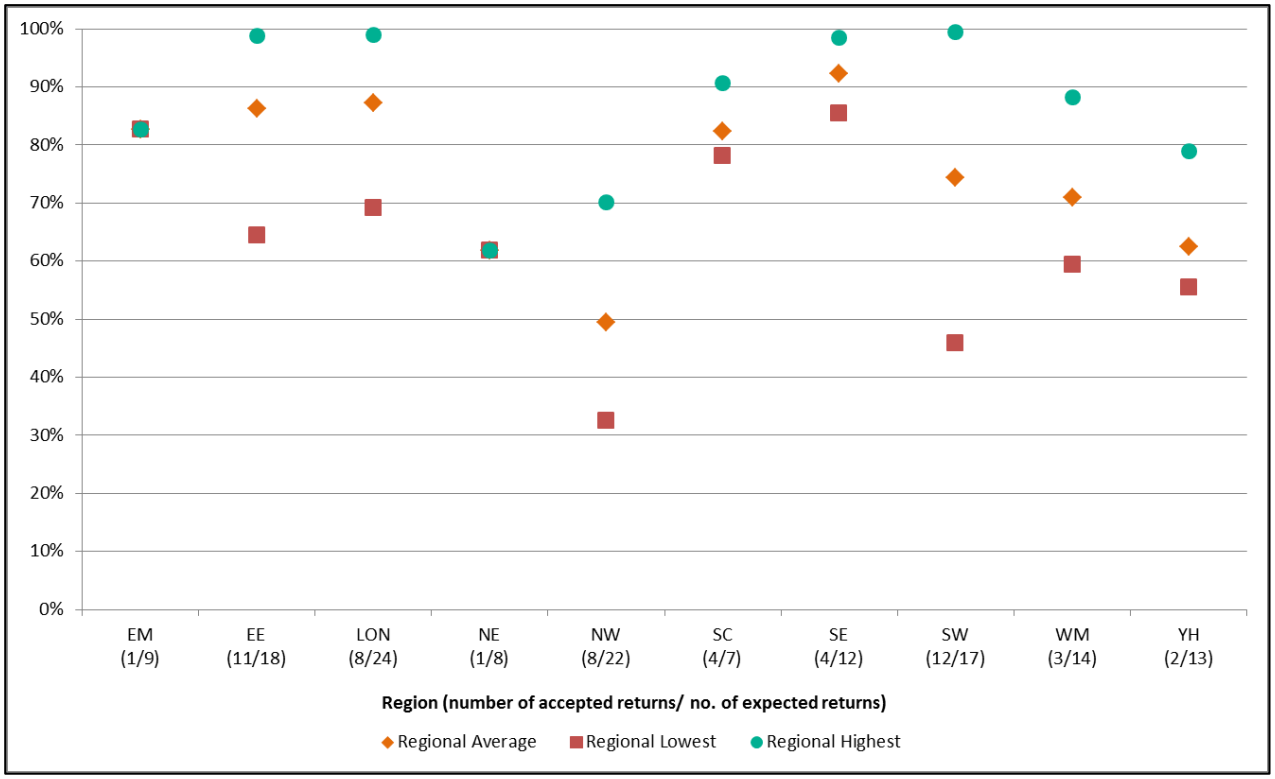
Thresholds are not set for this standard. FASP supports informed choice for women and the current screening policy offers women the choice:

- not to have screening
- to have screening for Down's syndrome and Edwards'/Patau's syndromes
- to have screening for Down's syndrome only
- to have screening for Edwards'/Patau's syndrome screening only

This standard requires matched cohort data. This ensures women do not miss the offer of screening and, if they wish to have screening, that it is completed. There is no intention to report this standard by maternity service. It was introduced to enable and improve the integrity of the screening pathway by monitoring and tracking women from offer to completion of screening.

It is evident from screening incidents that there are a number of 'missed' screening events across England. This particularly relates to the interface between the combined and quadruple screening pathway, that is, where women who are unable to complete combined screening, and are referred for quadruple test but are not tested and do not receive a screening result. See the PHE screening blog written about this.

Figure1. Percentage of eligible women for whom a completed screening result was available from the first trimester (T21/T18/T13) screening on the day of report



The data submitted identifies a wide variation in completed screening rates both across and within the regions of England. Caution should be taken in the interpretation of the data in figure 1 due to the inconsistency in data returns across regions. We cannot draw any national conclusions from the data due to data quality issues.

Providers need to make sure:

- the population of women eligible for the offer of screening are identified
- all women who are offered and accept screening in their service do receive a screening result.

Recommendations

Number	Recommendation	Responsible	Timescale
1a	Pilot a key performance indicator for this standard to facilitate more timely identification of missed screening by quarterly reporting. Lessons learnt from the pilot will be shared to support development of data collection and collation processes in other providers, particularly in	FASP	April 2017 - December 2017

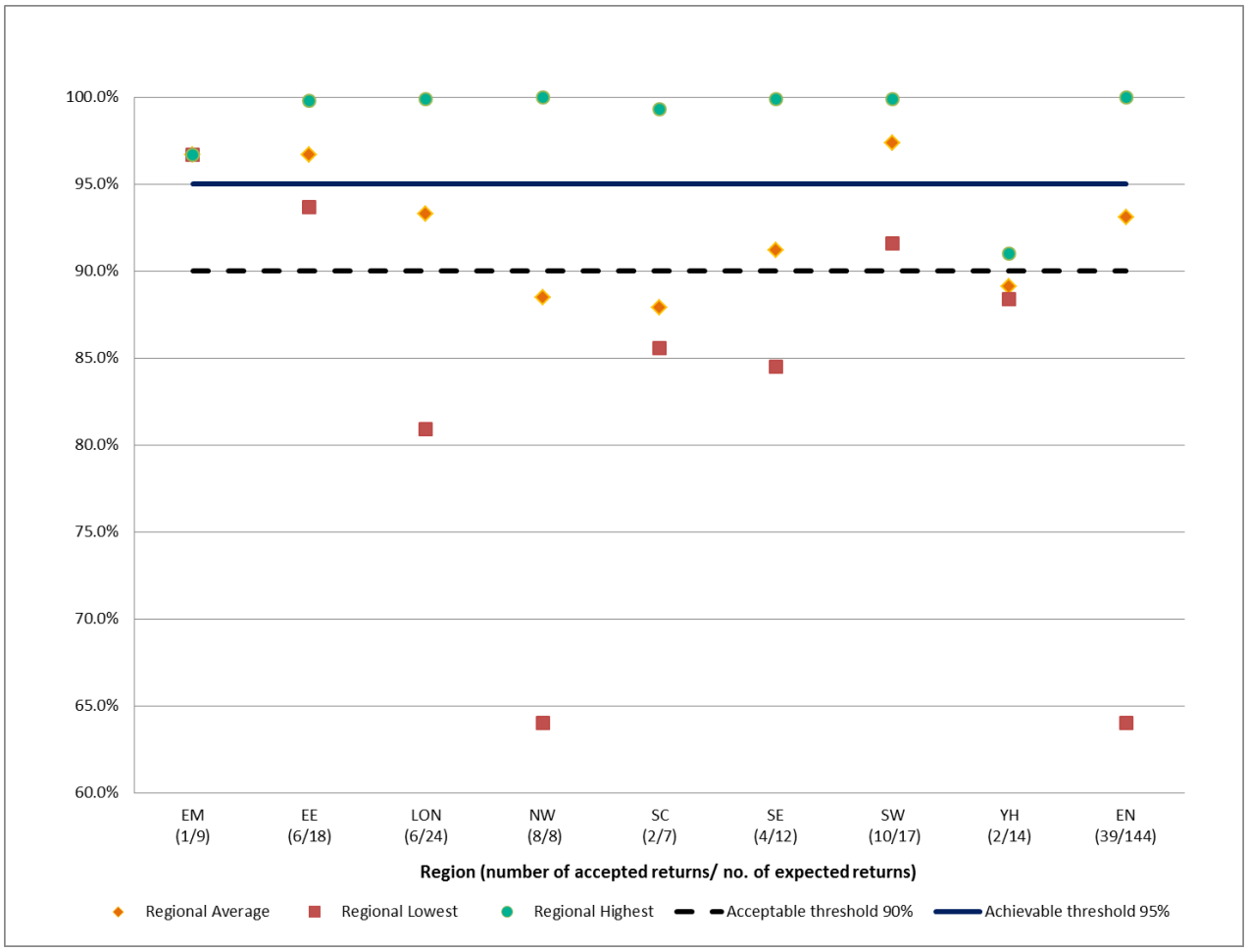
	relation to identifying the population of women eligible for screening and, where accepted, tracking the women to assure receipt of result.		
1b	Work with provider IT and audit departments to set up manageable systems for cross-referencing and correlating data that allows women who have accepted the offer of screening for Down's, Edwards'/Patau's syndromes to be "tracked" to confirm completion of screening. This process must ensure that all women are accounted for, including those who decline the offer of screening.	Maternity Providers	March 2018

Standard 2 Coverage and identifying the population (18^{+0} to 20^{+6} fetal anomaly ultrasound)

Numerator	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
Denominator	Eligible women: Total number of pregnant women booked for antenatal care during the reporting period

The purpose of collecting data against this standard is to maximise timely fetal anomaly ultrasound screening in the eligible population who are informed and wish to participate in the screening programme and to make sure women who accept screening for the 11 auditable conditions offered by the FASP screening pathway complete screening in a timely manner (by 23^{+0} weeks of pregnancy).

Figure 2. Percentage 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



A number of providers were unable to submit data against this standard. To report against this standard, collaboration is required between a number of health professionals and departments, such as maternity, ultrasound, or radiology services. Data may sit on a number of different information systems with no direct interface. Support from provider IT and audit departments and professionals is therefore required to set up manageable systems for cross-referencing and correlating data that allows women who have accepted screening to be "tracked" to confirm completion of screening is also needed.

Of the data submitted, 6 of the 9 regions have services that are unable to meet the acceptable threshold of 90%. Therefore they cannot be assured that women who have accepted the offer of screening have completed screening for the 11 auditable conditions offered as part of the 18^{+0} to 20^{+6} week fetal anomaly scan.

This standard became a KPI in April 2016 and will therefore be reported on a quarterly basis from April 2016. Due to the potential time lag between early booking and ultrasound scanning, the complete cohort of women cannot be accounted for until 2 quarters later meaning women booking in quarter 1 may not complete screening until quarter 3. Data is reported as follows:

- April to June (Q1) is reported by December 31 (Q3)
- July to September is reported by March 31 (Q4)
- October to December is reported by June 30 (Q1)
- January to March is reported by September 30 (Q2)

Recommendations

Number	Recommendation	Responsible	Timescale
2a	Publish a guidance document detailing the lessons learnt from the KPI pilot.	FASP	December 2017
2b	Work with provider IT and audit departments to set up manageable systems for cross-referencing and correlating data that allows women who have accepted the offer of fetal anomaly ultrasound screening to be "tracked" to confirm completion of screening. This process must ensure that all women are accounted for, including those who decline the offer of screening.	Maternity Providers	March 2018

Standard 3 Test performance (T21/T18/T13)

Numerator	Number of screening tests with risks above the cut-off
Denominator	Total number of screening tests in the reporting period

Table 4. Test performance data reported by DQASS.

FASP annual data 2015-16	Total
Number of tests performed	508,900
Number of tests in 1st trimester (combined test)	437,748
Number of Integrated test*	795
Number of tests in 2nd trimester (quadruple test)	70,357
Number of women at high risk	13,920
Standardised screen positive rate	2.2%

**This relates to data submitted to DQASS with a risk result which do not conform to the recommended combination of biochemical markers, ultrasound measurements or screening timeframes used in the national screening strategies of either first trimester combined or quadruple tests. Laboratories should remove these data prior to submission to DQASS as they are not performed as part of the NHS screening pathway*

This standard is needed to:

- monitor the performance of the screening strategy at a national level
- maximise performance of the screening test and timely reporting.

There are 21 screening laboratories in England providing first and/or second trimester screening for Down's, Edwards' and Patau's syndromes to the Down's syndrome quality assurance screening support service (DQASS).

The first trimester combined test uses 2 biochemical markers from maternal blood and paired measurements from the ultrasound scan, crown rump length (CRL) and nuchal translucency (NT). The second trimester quadruple test uses 4 biochemical markers from maternal blood.

Various factors, including maternal weight, gestational age, ethnicity and maternal smoking affect these markers. These factors require standardisation by laboratories to ensure risk calculations are as accurate as possible.
The latest DQASS audit showed an improvement in this standardisation process, leading to a more effective and equitable programme and ultimately fewer women being offered unnecessary invasive tests.

Number	Recommendation	Responsible	Timescale
3a	Providers and commissioners should regularly review their DQASS reports at programme boards and address the recommended actions	Maternity Providers/Public Health Commissioners/ Screening & Immunisation Teams	Ongoing

Standard 4 Test performance (18^{+0} to 20^{+6} fetal anomaly ultrasound)

There is no data reported for Standard 4 this year as this requires a national submission from NCARDRS.

Standard 4 on the test performance (18^{+0} to 20^{+6} fetal anomaly ultrasound) is not reported for 2015/16 for two reasons:

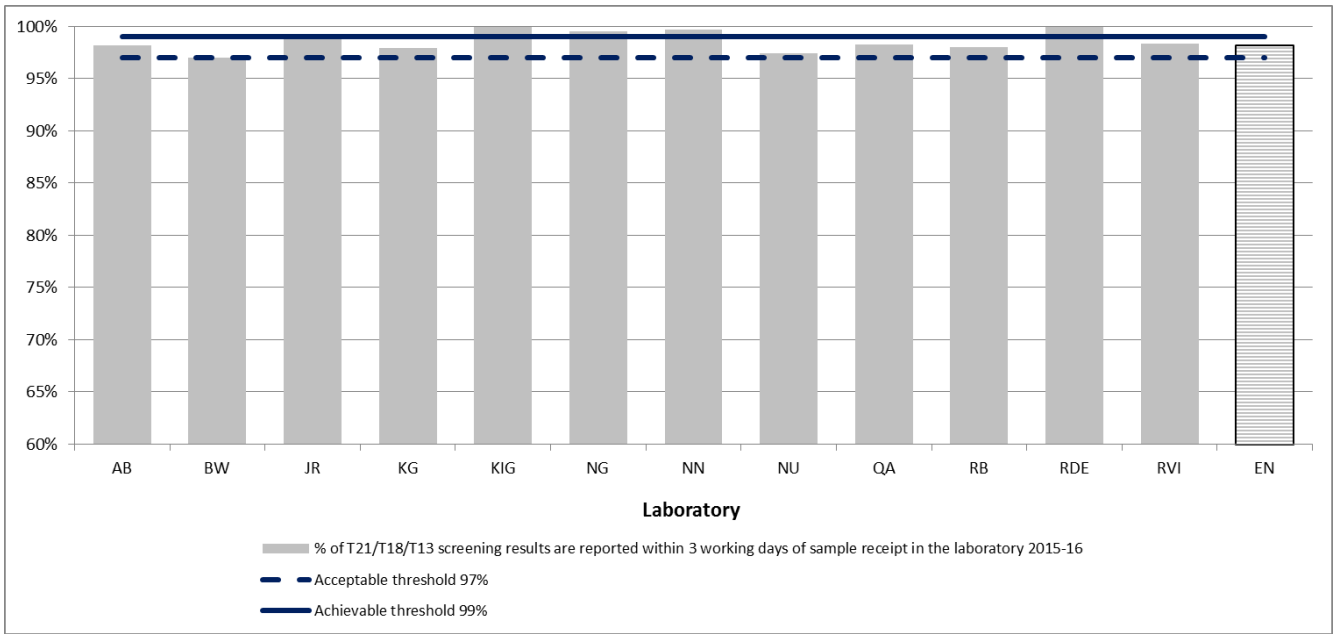
- NCARDRS were still expanding the registration service across all areas of England
- training and implementation of the additional 3 vessel and trachea view to the examination of the fetal heart was not complete across England

  NCARDRS are expected to achieve full reporting across England by 2018/19.

Standard 5 The test turnaround time (T1/T18/T13 screening)

Numerator	Number of results reported within 3 working days of the sample receipt
Denominator	Total number of T21/T18/T13 samples received by the laboratory in the reporting period

Figure 3. Percentage of T21/T18/T13 screening results reported within 3 working days of sample receipt in the laboratory



In this first year of reporting:

- 12 of the 21 laboratories providing screening for Down's, Edwards' and Patau's syndromes submitted data
- all laboratories submitting data met the acceptable threshold of 97% of reporting results within 3 working days of the sample receipt
- 4 laboratories also met the achievable threshold of ≥99%.

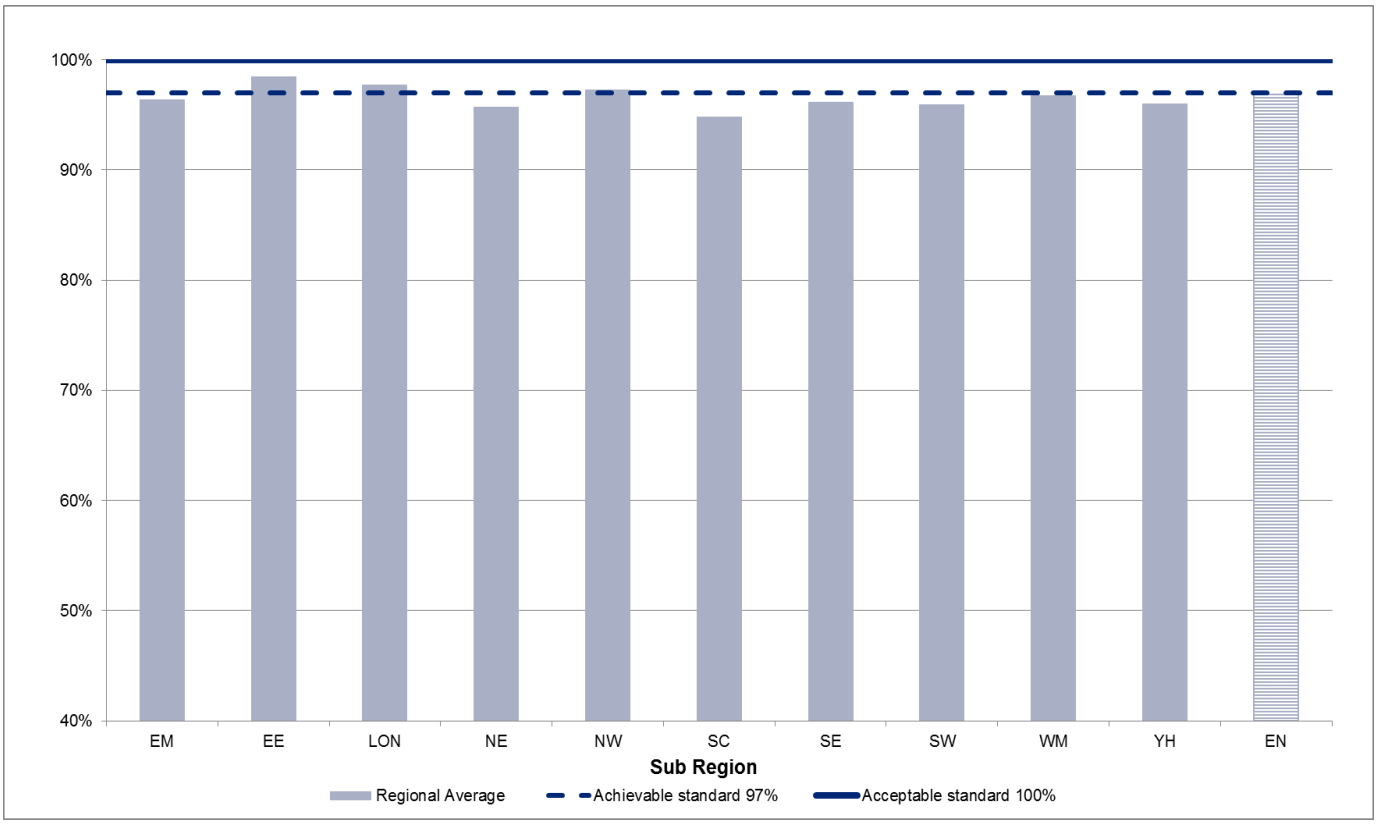
Recommendations

Number	Recommendation	Responsible	Timescale
5	Work should be undertaken directly with laboratories to understand reasons for non-submission of data to improve future returns	Screening & Immunisation teams/Regional SQAS	April 2018

Standard 6 Minimising harm – completed request forms (T21/T18/T13 screening)

Numerator	Number of completed laboratory request forms
Denominator	Number of submitted laboratory request forms

Figure 4. Percentage of completed laboratory request forms



The purpose of this standard is to minimise delays in reporting results due to incomplete or inaccurate completion of screening request forms and to minimise potential harms in those screened and in the population.

This standard is reported quarterly as a KPI. The data presented here is collated from the submitted quarterly returns:

- national performance of FA1 in 2015 to 2016 is 96.8%, showing a slight improvement compared with the previous year (96.6% in 2014 to 2015).
- the annual performance in 2015 to 2016 ranged from 95.7% in the South region, to 97.7% in the London region.
- out of 142 providers that submitted data for all 4 quarters in the year, overall for 2015 to 2016, 89 providers met the acceptable threshold of 97.0%.

Overall trend for England 2015 to 2016

Q1	Q2	Q3	Q4	Trend
96.3	97.0	97.0	96.9	

There is a need to consider shared learning opportunities as presented in the PHE screening blog at: https://phescreening.blog.gov.uk/2016/06/29/shared-learning-mask-helps-improve-kpi-performance-for-fetal-anomaly-screening/

Recommendation

Number	Recommendation	Responsible	Timescale
6	Providers should review local performance and processes to ensure all required data fields are completed on requests for screening	Maternity Providers	April 2018

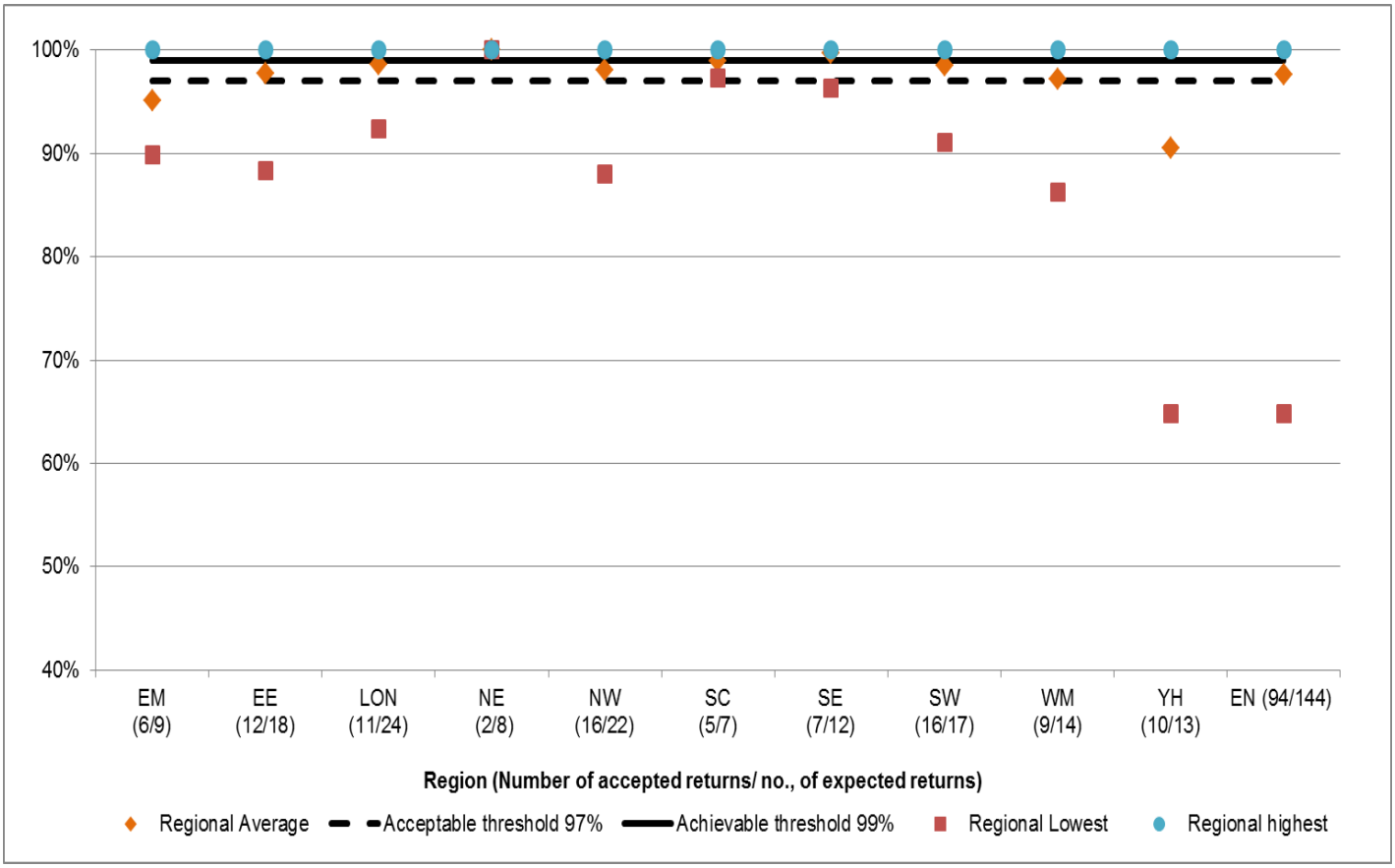
Standard 7 Time to intervention (T21/T18/T13 screening)

Numerator	Number of women with higher risk results offered an appointment within 3 working days
Denominator	Number of women with higher risk results reported in the reporting period

The purpose of this standard is to provide assurance that individuals with a higher risk result are referred in a timely manner and receive timely intervention where appropriate.

Services are required to report this data as it a long standing standard, since 2007.Therefore it was expected that the data return and performance would have been higher than received.

Figure 5. Percentage of women with higher risk results offered an appointment within 3 working days



There was variation in performance across and within the regions. Of those providers who did submit, a number performed below the acceptable threshold.

Recommendations

Number	Recommendation	Responsible	Timescale
7a	Implement local referral pathways for women with higher risk screening results for Down's, Edwards' /Patau's syndromes to enable timely intervention	Maternity Providers	April 2018

Standard 8 Time to intervention (18^{+0} to 20^{+6} fetal anomaly ultrasound)

A large proportion of submissions for received for 8a and 8b reported a 'shared' denominator between the local and tertiary unit, counting women attending the alternative option (either local or tertiary unit) as an exclusion which makes it difficult to account for women effectively. These returns were accepted providing the exclusions and numerator did not exceed the denominator. 11 submissions were discounted as they shared both a numerator and denominator and therefore the data reported for 8a contradicted the data reported for 8b.

8a. Local Referral

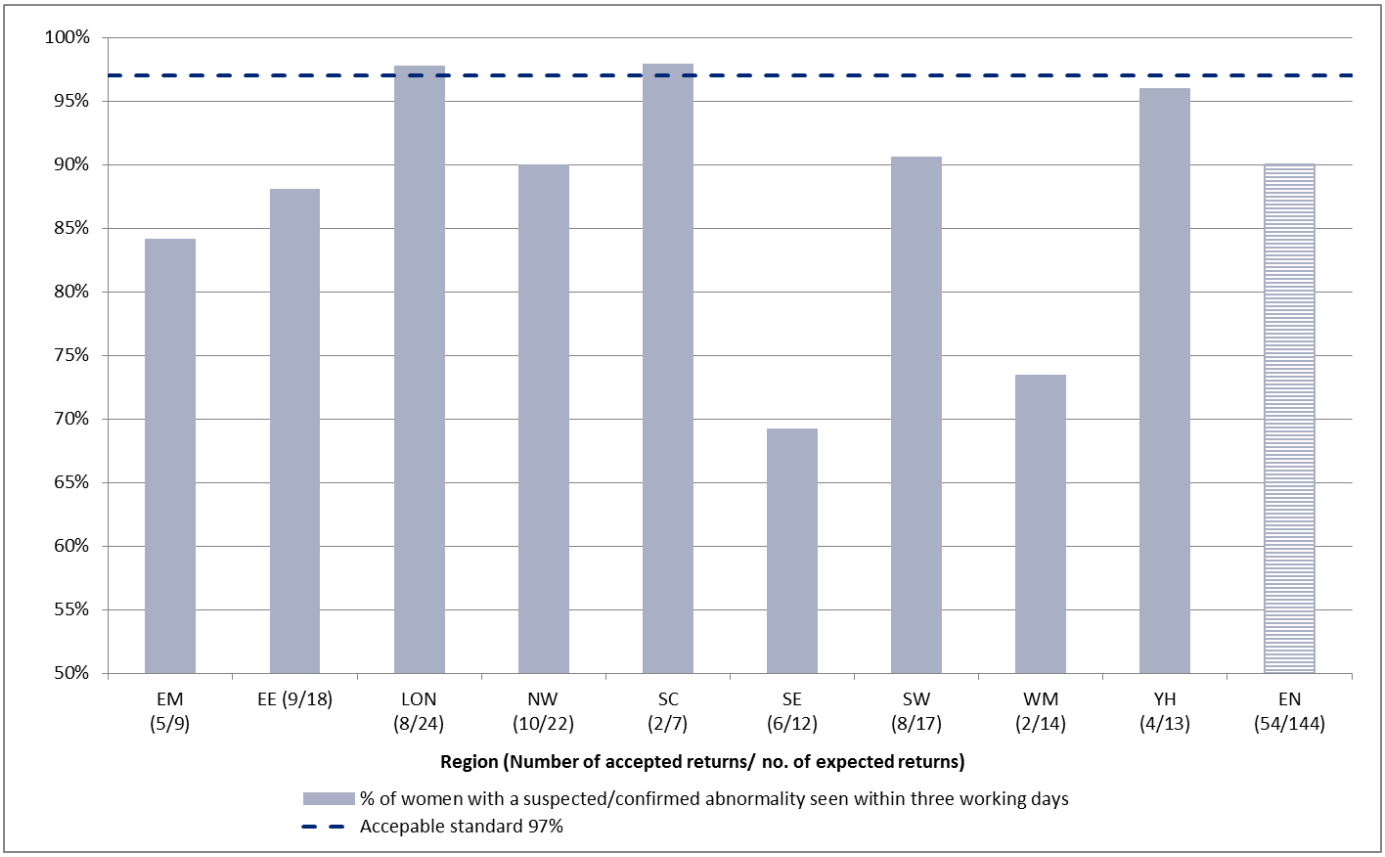
Numerator	Number of women with a suspected/confirmed abnormality seen within 3 working days
Denominator	Total number of women with a suspected /confirmed abnormality identified in reporting period

Standard 8a measures the performance of service providers where referral in-house is required when an anomaly is suspected from the 18^{+0} to 20^{+6} week fetal anomaly scan and further investigation is required.

The purpose of this standard is to provide assurance that individuals with screen positive results are referred in a timely manner and receive timely intervention where appropriate.

The acceptable threshold is set at ≥ 97% of women with a suspected or confirmed fetal anomaly should be seen by an obstetric ultrasound specialist locally within 3 working days of the referral being made.

Figure 6 Percentage of women with a suspected/confirmed abnormality seen within 3 working days



This threshold was met in 3 areas, London, South Central and Yorkshire & Humber. South East and West Midlands areas reported that only 69.2% and 73% of women were offered appointments within this timeframe respectively.

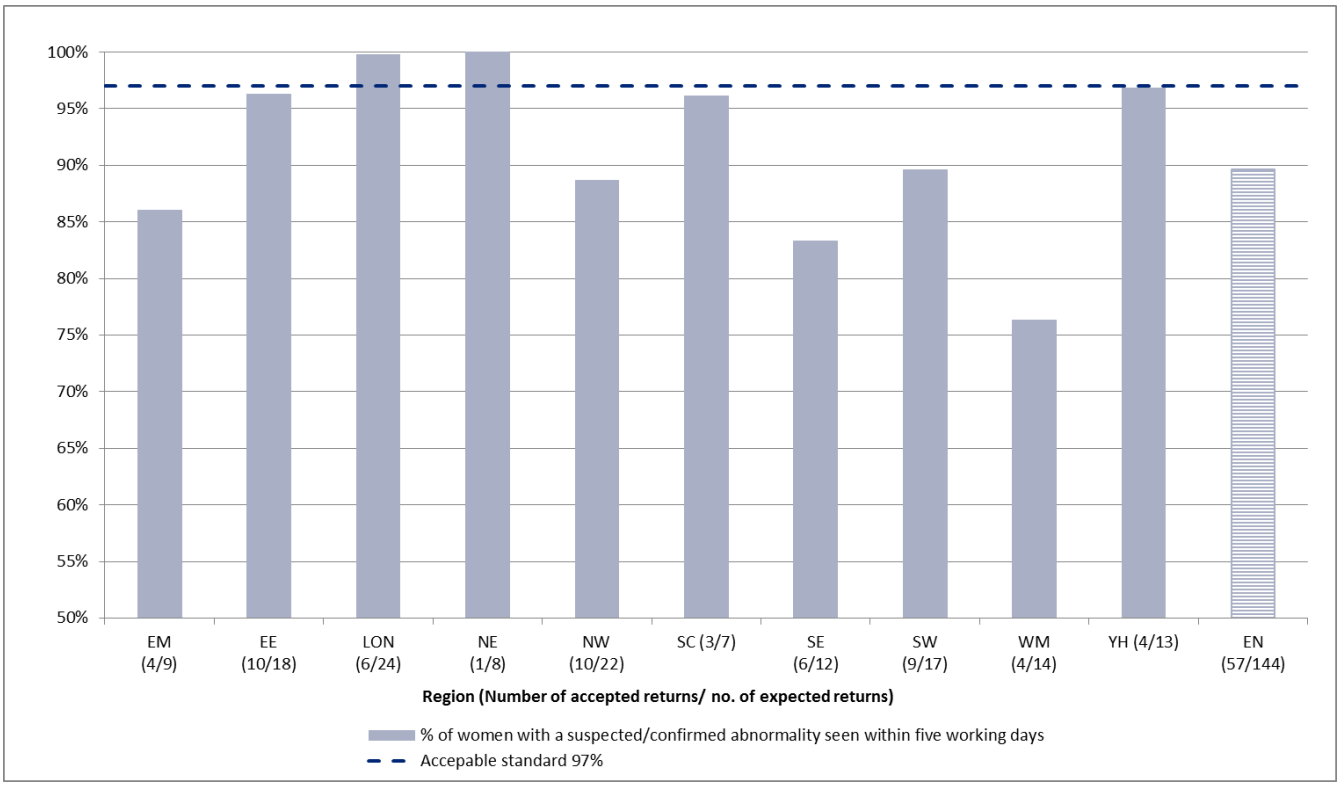
8b. Tertiary referral

Numerator	Number of women with a suspected/confirmed abnormality seen within 5 working days
Denominator	Total number of women with a suspected /confirmed abnormality identified in reporting period

Standard 8b measures the performance of service providers where referral to a tertiary fetal medicine service is required where an anomaly is suspected from the 18^{+0} to 20^{+6} week fetal anomaly scan and further investigation is required.

The acceptable threshold is set at ≥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 5 working days of the referral being made.

Figure 7. Percentage of women with a suspected/confirmed abnormality seen within 5 working days



The acceptable threshold was met in 2 areas: London and the North East (although in the North East only 1 of 8 provider units submitted data). West Midlands reported the lowest percentage of women (76%) being offered an appointment within the required 5 working days.

Recommendations

Number	Recommendation	Responsible	Timescale
8a,b	Clarify the definitions to support improvement in the accuracy of the submitted data will be undertaken for the 2016/17 FASP data submission template and	FASP National screening programmes/KPI data team	April 2017

	KPIs.		
8c	Put measures in place to accurately report data for these standards	Maternity providers	April 2018

Standards 9 a and b Diagnose (T21/T18/T13 screening)

	Standard 9a	Standard 9b
Numerator	Number of QFPCR (Quantitative Fluorescence-Polymerase Chain Reaction) results reported within 3 **working** days of sample receipt	Number of karyotype results reported within 14 **calendar** days of sample receipt
Denominator	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	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

The purpose of this standard is to provide assurance of timely reporting of diagnostic results to enable ongoing information, discussions, and pregnancy management options.
Standards 9a and 9b measure the turnaround times for results from either QFPCR or Karyotype following a higher risk screening result for Down's, Edwards'/Patau's syndromes.

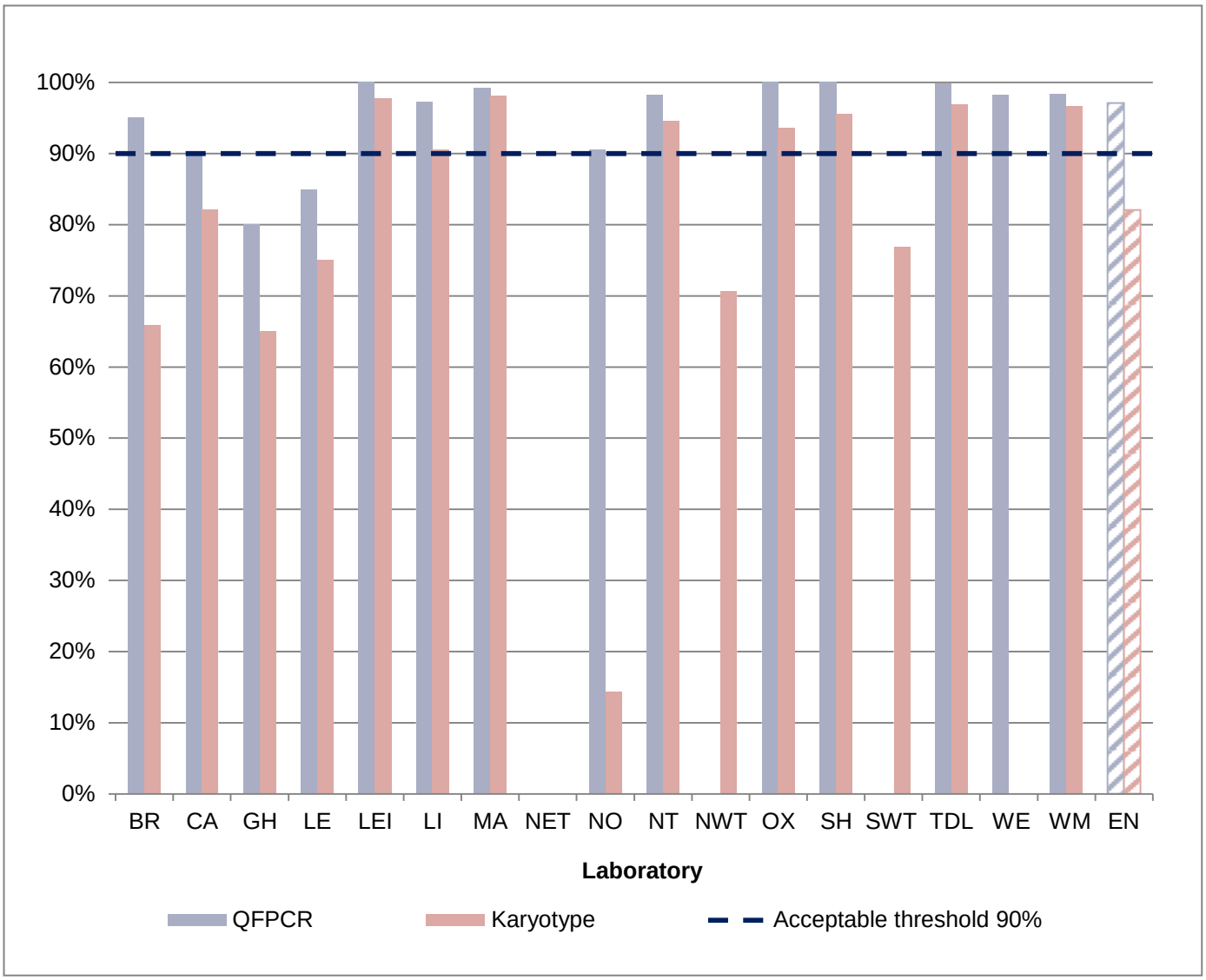
The thresholds for this standard are:

- 9a (QFPCR) - 90% of rapid aneuploidy QFPCR/FISH results should be reported within 3 calendar days of sample receipt in the laboratory
- 9b (Karyotype)- 90% of karyotype results should be reported within 14 calendar days of sample receipt in the laboratory

The data identifies some variation in the performance of laboratories and it should be noted that one laboratory did not submit data in time for inclusion in the report:

- most laboratories (12/14) meet the threshold for reporting of QFPCR of 3 working days
- Guys Hospital and Leicester laboratories perform below this threshold for 2015-2016 with 80% and 85% respectively
- the performance in reporting Karyotype results is more mixed with 8/15 laboratories meeting or exceeding the 90% acceptable threshold of reporting results within 14 working day
- an increasing number of diagnostic laboratories report that they are more likely to perform a micro-array than Karyotype. It should however be noted that the FASP standards and service specification for the screening programme still recommend Karyotype.

Figure 8. Percentage of QFPCR and karyotype results reported within 3 working days (QFPCR) and 14 working days (karyotype) of sample receipt following screening for Down's, Edwards' and Patau's syndromes



Standard 9 c and d Diagnose and (18^{+0} to 20^{+6} fetal anomaly ultrasound)

	Standard 9c	Standard 9d
Numerator	Number of QFPCR results reported within 3 **working** days of sample receipt	No. of karyotype results reported within 14 **calendar** days of sample receipt
Denominator	Number of samples received for QFPCR testing where the indication for genetic testing is a suspected /confirmed abnormality detected from the 18^{+0} to 20^{+6} fetal anomaly ultrasound scan undertaken within the reporting period	Number of samples received for karyotype testing where the indication for genetic testing is a suspected/ confirmed abnormality detected from the 18^{+0} -20^{+6} fetal anomaly ultrasound scan undertaken within the reporting period

Standards 9c and 9d measure the turnaround times for results for either QFPCR or Karyotype following a suspected fetal anomaly from the 18^{+0} to 20^{+6} week fetal anomaly scan.
The thresholds for this standard are:

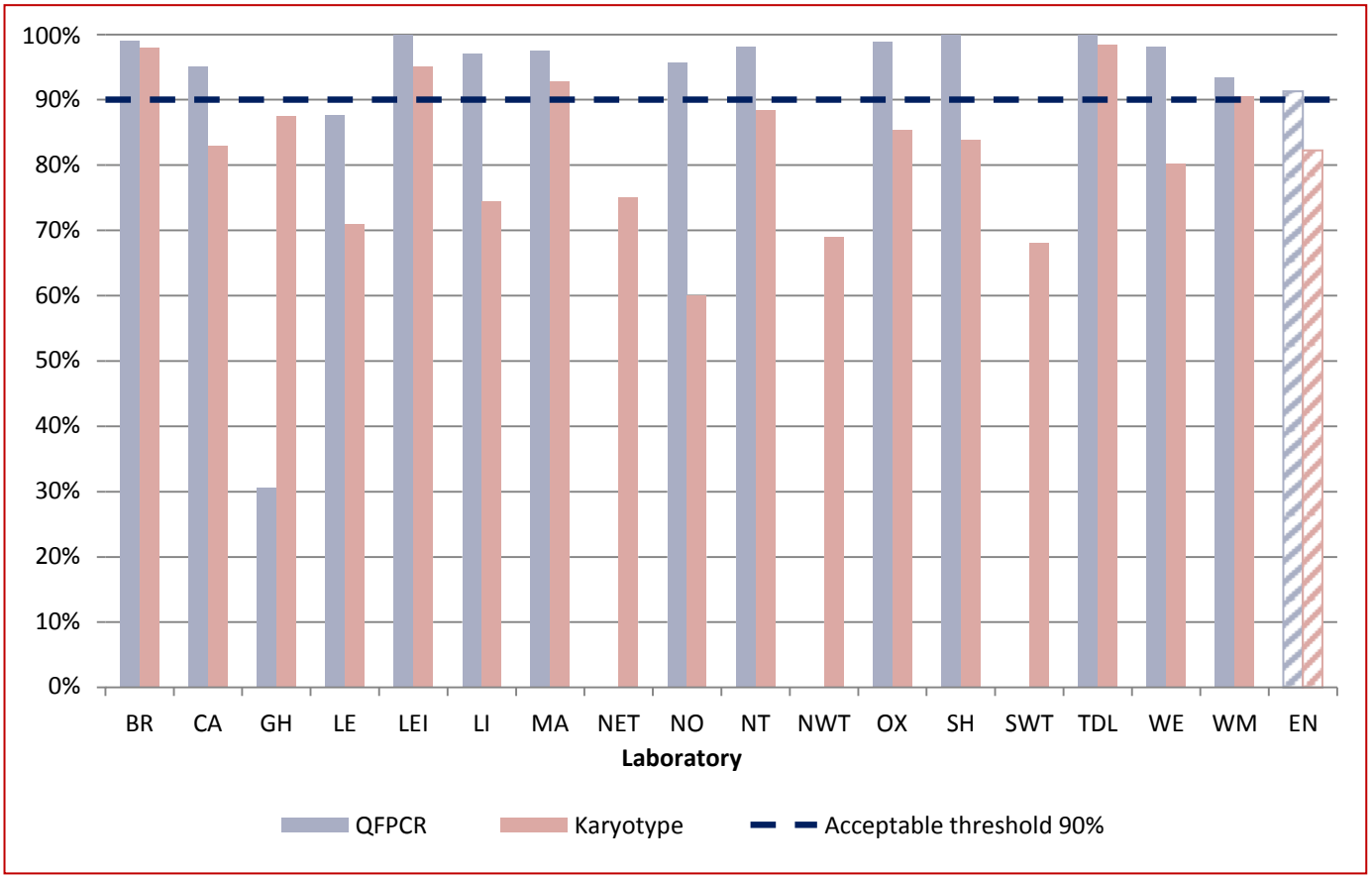
- 9c / QFPCR - 90% of rapid aneuploidy QFPCR/FISH results should be reported within 3 calendar days of sample receipt in the laboratory
- 9d / Karyotype - 90% of karyotype results should be reported within 14 calendar days of sample receipt in the laboratory

Most laboratories (10/12) meet the threshold for reporting of QFPCR in 3 working days:

- Leicester reported performance just below this threshold at 88%
- Guys Hospital report performance of only 30% of samples reported within 3 working days for 2015-2016.

The performance in reporting Karyotype results is more mixed with only 4/15 laboratories meeting or exceeding the 90% acceptable threshold of reporting results within 14 working days. Performance in reporting results within 14 working days ranges from 60% in Norwich to 88% in North Thames.

Figure 9. Percentage of QFPCR and karyotype results reported within 3 working days (QFPCR) and 14 calendar days (karyotype) of sample receipt following fetal anomaly scan



Recommendations

Number	Recommendation	Responsible	Timescale
9a	Seek advice from the screening evidence team regarding the possibility of a review of policy regarding use of Karyotype versus micro-array	FASP	April 2018

Table 5. Abbreviations glossary

Region	Initials	Laboratory	Initials	Organisation Name	Initials
East Midlands	EM	Addenbrookes NHS Hospital	AB	Bristol	BR
East of England	EE	Birmingham Women's Hospital	BW	Cambridge	CA
London	LON	John Radcliffe Hospital	JR	Guys Hospital, GSTS	GH
North East	NE	Kettering General Hospital	KG	Leeds	LE
North West	NW	King George Hospital	KIG	Leicester	LEI
South Central	SC	Norfolk & Norwich NHS Trust	NN	Liverpool	LI
South East	SE	Northern General Hospital	NG	Manchester	MA
South West	SW	Nottingham University Hospital	NU	NE Thames, Great Ormond Street	NET
West Midlands	WM	Queen Alexandra Hospital	QA	Norwich	NO
Yorkshire and Humber	YH	Royal Bolton Hospital	RB	Nottingham	NT
England	EN	Royal Devon and Exeter Hospital	RDE	NW Thames, Northwick Park Hospital	NWT
		Royal Victoria Infirmary	RVI	Oxford	OX
		England	EN	Sheffield Diagnostic Genetics Service	SH
				SW Thames Genetics Laboratory, St Georges	SWT
				TDL Genetics, The Doctors Laboratory	TDL
				Wessex Regional Laboratory, Salisbury	WE
				West Midlands, Birmingham Women's Hospital	WM