Public Health England

NHS

Screening Quality Assurance visit report

NHS Fetal Anomaly Screening Programme Medway Foundation Trust

18 May 2017

Public Health England leads the NHS Screening Programmes

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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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Executive summary

Antenatal and newborn screening quality assurance (QA) covers the identification of eligible women and babies and the relevant tests undertaken by each screening programme. It includes acknowledgement of the referral to treatment or diagnostic services as appropriate (for individuals/families with screen-positive results), or the completion of the screening pathway.

The findings in this report relate to the QA visit of the Medway Foundation Trust fetal anomaly screening service held on 18 May 2017.

Purpose and approach to quality assurance (QA)

QA aims to maintain national standards and promote continuous improvement in antenatal and newborn screening. This is to ensure that all eligible people have access to a consistent high quality service wherever they live.

QA visits are carried out by the PHE screening quality assurance service (SQAS).

The evidence for this report comes from the following sources:

- routine monitoring of data collected by the NHS screening programmes
- data and reports from external organisations
- evidence submitted by the provider(s), commissioner and external organisations
- information shared with the regional SQAS as part of the visit process

Description of local screening service

Medway Foundation Trust (MFT) serves the local population of Medway and Swale. In 2015/16, 5827 women booked for maternity care and there were 5131 deliveries (annual report data). In 2015/16, 78.1% of women booking for maternity care were white British. The mean maternal age at booking was 30 years old. The acute service is provided at Medway Maritime Hospital, Gillingham, Kent. Screening programmes are commissioned by the Public Health Commissioning Team (PHCT) Kent, Surrey and Sussex.

The fetal anomaly screening services at MFT include:

- obstetric led and midwifery led services, co-located with a birth centre for low risk women
- a fetal medicine unit on site providing ultrasound services and invasive prenatal testing

- a one stop clinic for assessment and risk (OSCAR) includes first trimester ultrasound scan and the analysis of biochemical markers as part of the combined screening risk calculation on site
- a combined screening service which is part of a larger laboratory network. The lead laboratory service is provided by Kings College Hospital, London

Findings

Immediate concerns

The QA visit team did not identify any immediate concerns.

High priority

The QA visit team identified high priority findings as summarised below:

- formalise the governance arrangements including meetings for the laboratory network
- ensure biochemistry testing for the combined screening programme is included within the scope of the United Kingdom Accreditation Service ISO 15189 application
- engage with Public Health Commissioning Team (PHCT) and the Screening QA Service (SQAS) with the reconfiguration of laboratory services
- ensure incidents are reported and managed in accordance with PHE guidance
- ensure the laboratory has responsibility for all aspects of internal quality assurance
- upgrade viewpoint software to ensure that only conditions consented have a risk calculated
- change the risk calculation to ensure that the risk cut off is greater than or equal to 1:150 at term

Shared learning

The QA visit team identified several areas of practice for sharing, including:

- strong commitment to audit demonstrating compliance against national fetal anomaly screening programme (FASP) standards
- yearly client satisfaction surveys
- one stop clinic for assessment and risk providing women-centred care and completion of the screening pathway for the majority of women in one appointment

- 99.7% of samples analysed and reported within three working days with the majority of samples completed within one hour of receipt in the laboratory
- 100% compliance with completion of information fields in Viewpoint
- face to face communication of screening results by a sonography practitioner, supported by fetal medicine consultant and specialist midwives
- immediate access to invasive prenatal testing as required

Table of consolidated recommendations

Governance and leadership

No.	Recommendation	Timescale	Priority *	Evidence required
1.1	Formalise the governance and contracting arrangements of the laboratory network	3 months	High	Service level agreement with lead laboratory (King's College Hospital, London) Formal contract between two organisations which is signed off at board level Governance structure including identification of an executive lead for the network Documented contingency agreement and standard operating procedure demonstrating compliance with the network (including documentation that the process has been tested)
1.2	Ensure biochemistry testing for the combined screening programme is included within the scope of the United Kingdom Accreditation Service ISO 15189 application	3 months	High	Application to UKAS demonstrating that combined screening is included in scope Gap analysis and monitoring for achieving accreditation Evidence of accreditation for the lead laboratory within the network

No.	Recommendation	Timescale	Priority *	Evidence required
1.3	Engage with the Public Health Commissioning Team (PHCT) and the Screening QA Service (SQAS) with the reconfiguration of laboratory services	3 months	High	Inclusion of SQAS and PHCT in the laboratory reconfiguration plan for screening services Terms of reference for meeting Agenda and minutes with representation from PHCT and SQAS
1.4	Ensure that all stakeholders within the screening programme identify, report and manage incidents and serious incidents as per the PHE guidance	3 months	High	Ratified trust wide incident management policy which reflects the PHE Managing Safety Incidents in NHS Screening Programmes guidance (October 2015)
1.5	Ensure the laboratory has responsibility for software updates, changing median equations and implementing changes suggested by DQASS under the direction of the laboratory biochemistry director at the lead site within the network	6 months	High	Standard operating procedure with responsibility defined written in collaboration with and aligned to processes within the lead laboratory
1.6	Implement formal network meetings to ensure oversight of the service	3 months	High	Terms of reference for laboratory network meetings Agenda and minutes

No.	Recommendation	Timescale	Priority *	Evidence required
1.7	Ensure Medway Foundation Trust (MFT) data is coded separately from lead laboratory data submitted to Down's Syndrome Quality Assurance Service (DQASS) to ensure MFT data is accurately identifiable	6 months	Standard	Data submission containing MFT data separated from the lead laboratory data Agreement within the network and documentation within a service level agreement or standard operating procedure of the process of data submission to DQASS and implementation of any changes required
1.8	Ensure all aspects of the first trimester screening test are enrolled into the national external quality assurance scheme (NEQAS)	6 months	Standard	Biochemistry, multiples of the median and risk calculation to be included

Fetal anomaly screening

No.	Recommendation	Timescale	Priority *	Evidence required
2.1	Upgrade viewpoint software to ensure that only conditions consented have a risk calculated	3 months	High	Screen shots of the system demonstrating compliance Confirmation of upgrade and version number System testing Training logs

No.	Recommendation	Timescale	Priority *	Evidence required
2.2	Change the risk calculation to ensure that the risk cut off is greater than or equal to 1:150 at term	3 months	High	Screen shots of system demonstrating compliance Reference to risk calculation at term within the DQASS report System testing Training logs

Next steps

The screening service provider is responsible for developing an action plan in collaboration with the commissioners to complete the recommendations contained within this report.

SQAS will work with commissioners to monitor activity/progress in response to the recommendations made for a period of 12 months following the issuing of the final report. After this point, SQAS will send a letter to the provider and the commissioners summarising the progress made and will outline any further action(s) needed.