



Public Health
England

Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening Programmes Plymouth Hospitals NHS Trust

26 September 2017

Public Health England leads the NHS Screening Programmes

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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 4 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 new-born screening quality assurance covers the identification of eligible women and babies and the relevant tests undertaken by each screening programme. It includes acknowledgement of the referral by 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 quality assurance visit of the Plymouth Hospitals NHS Trust screening service held on 26 September 2017.

Quality assurance purpose and approach

Quality assurance (QA) aims to maintain national standards and encourage continuous improvement in antenatal and newborn (ANNB) 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 data collected by the NHS screening programmes
- data and reports from external organisations
- evidence submitted by the provider, commissioner and external organisations
- information shared with the south west regional SQAS as part of the visit process

Local screening service

Plymouth Hospitals NHS Trust provides services for a local population of around 260,000 people. Over 86% of the eligible population for antenatal and newborn screening is characterised as white British with an age range of 13 to 53. The 2015 to 2016 annual report describes a changing ethnic population which includes a large non-European student cohort, and migrant and refugee women.

Local screening services are commissioned by North, East and West Devon Clinical Commissioning Group on behalf of NHS England South (South West).

Services provided by Plymouth Hospitals NHS Trust include:

- the maternity service
- laboratory services for sickle cell and thalassaemia and infectious disease screening

- the sonography service for trisomy screening and the 18 to 20+6 week fetal anomaly scan
- the newborn hearing screening service
- the child health information service

Delivery of this screening service involves interdependencies with other providers for parts of the pathway. Analysis of samples for trisomy screening is provided by Royal Devon and Exeter Hospitals NHS Foundation Trust for first trimester screening and by the Wolfson Institute of Preventative Medicine for second trimester screening. Confirmatory testing for infectious diseases screening is undertaken by the Public Health England laboratory in Bristol and for sickle cell and thalassaemia screening at Kings College Hospital NHS Foundation Trust. Newborn blood spot screening samples are analysed at North Bristol NHS Trust. Interfaces between Plymouth Hospitals NHS Trust and these services were included as part of this review.

Findings

This is the first QA visit to this service. Antenatal and newborn screening is a well led patient focused service with a strong ethos for continuous quality improvement across the screening pathways. Screening services are delivered by a team who are highly motivated and who work well across all disciplines. The commitment to address areas falling short of standards, maintain patient safety and drive programme quality is clearly evident.

Immediate concerns

The QA visit team identified no immediate concerns.

High priority

The QA visit team identified 3 high priority findings as summarised below:

- scans for first trimester trisomy screening are being performed by staff who do not hold the minimum qualification as recommended by the fetal anomaly screening programme
- the required e-learning modules have not been completed by sonographers performing scans for first trimester trisomy screening
- the current United Kingdom accreditation certificate (UKAS) for the infectious diseases laboratory does not include assessment of the new analyser

Shared learning

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

- the production of a monthly newsletter for staff which includes key themes identified from incidents or where the service is failing to meet the requirements of the screening specifications or standards
- contingency measures in the absence of key members of the screening team for the maternity service includes the use of a screening handbook which outlines all of the operational procedures performed by the team
- there is an ongoing comprehensive training package in place for existing hearing screeners
- the IT links between the laboratory and maternity services contribute to the checking processes to ensure all women complete screening. This reduces the burden of manual data collection
- linkage of the maternal and paternal screening results within the sickle cell and thalassaemia screening laboratory
- good evidence of risk assessment and internal quality checks within the infectious diseases screening laboratory
- clear processes documented within standard operating procedures for the child health information service
- ongoing audit within the sonography department to assess the effectiveness of detecting abnormalities at the 18 to 20+6 week fetal anomaly scan

Recommendations

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1	Ensure all key stakeholders are represented at each programme board meeting	Service specifications 15 to 21	12 months	Standard	Terms of reference to reflect membership Minutes of programme board demonstrating attendance of key stakeholders
2	Formalise the role of screening support sonographer for first trimester trisomy screening	Service specification 16	3 months	Standard	Job description produced with the role clearly defined Time is allocated within the role to allow all the functions to be fulfilled
3	Ensure that there is appropriate clinical oversight of the newborn blood spot screening service within Plymouth Hospitals NHS Trust	Service specifications 19	6 months	Standard	Named consultant clinical lead identified for the screening programme and function included in job plan

4	Establish an internal screening group within Plymouth Hospitals NHS Trust to ensure effective clinical oversight and governance of the antenatal and newborn screening services	Service specifications 15 to 21	3 months	Standard	Terms of reference to include membership, nominated clinical leads for each screening programme, governance arrangements and reporting lines to the trust board, frequency of meetings, review of risks and escalation of issues to the commissioners and to the screening quality assurance service
5	Produce terms of reference for the multidisciplinary team meeting	Service specifications 15 to 19 & 21	6 months	Standard	Terms of reference
6	Produce terms of reference for the newborn hearing screening local governance (operational) group to reflect its functions	Service specification 20	6 months	Standard	Terms of reference
7	Implement a process to ensure incidents in NHS screening programmes entered onto the trust incident reporting system are reported to the screening team	Managing Safety Incidents in NHS Screening Programmes	6 months	Standard	Standard operating procedure for identification, investigation and management of incidents in NHS screening programmes

8	Review and update the screening guidelines to address the gaps identified and ensure compliance with current national guidance and expected failsafe mechanisms	Service specifications 15 to 21	12 months	Standard	Revised guidelines which are benchmarked against NHS screening programme service specifications and standards on an annual basis
9	Review guidelines and consolidate the standard operation procedures for the hearing screening service	Service specification 20	12 months	Standard	Updated guidelines and standard operating procedures
10	Document agreed audits of the antenatal and newborn screening programmes on an audit schedule	Service specifications 15 to 21	12 months	Standard	Audit schedule
11	Complete a user survey to gather views about the antenatal and newborn screening pathways	Service specifications 15 to 21	12 months	Standard	Outcome of survey and action plan are discussed at programme board

Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
12	Ensure sonographers involved in fetal anomaly screening hold the minimum qualifications as recommended in the national service specifications	Service specification 16 and 17	6 months	High	All staff hold the minimum qualification

No.	Recommendation	Reference	Timescale	Priority	Evidence required
13	Ensure all staff involved in undertaking trisomy screening complete the required e-learning modules	Service specification 16 FASP: Handbook for ultrasound practitioners April 2015	6 months	High	Training records for staff

Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority	Evidence required
14	Implement a process for the generation of NHS numbers for babies in the case of a failure of the maternity IT system	Service specifications 19, 20 & 21	6 months	Standard	Standard operating procedure with roles and responsibilities clearly outlined
15	Ensure the NIPE SMART IT system is checked on a daily basis to fully utilise the failsafe function of the system	Service specification 21	6 months	Standard	Standard operating procedure/user guide for managing the tracking process with roles and responsibilities clearly outlined
16	Update the bereavement checklist to ensure a documented process is in place to inform all relevant services when a baby dies	Service specifications 19, 20 & 21	6 months	Standard	Updated bereavement checklist (including updating the baby's status as deceased on the screening IT systems)

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority	Evidence required
17	Monitor compliance with the plan to meet the acceptable level for the key performance indicator for ST2	Service specification 18	12 months	Standard	Submission of KPI data for ST2 which meets acceptable level
18	Revise the paper request form for infectious disease screening to meet minimum data fields specified by the national programme	Service specification 15 Infectious Diseases in Pregnancy Screening Programme Handbook for Laboratories 2016 to 2017	6 months	Standard	Revised request forms compliant with national programme minimum data fields

Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
19	Undertake a risk assessment within the sickle cell and thalassaemia laboratory for screening pathway	Service specification 18 SCT: Handbook for antenatal laboratories September 2017	12 months	Standard	Documented process with all risks identified and mitigations implemented

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
20	Ensure accreditation process is in place for the equipment used within the microbiology laboratory for infectious disease screening samples	Service specification 15 Infectious Diseases in Pregnancy Screening Programme Handbook for Laboratories 2016-2017	6 months	High	United Kingdom accreditation service certificate

No.	Recommendation	Reference	Timescale	Priority	Evidence required
21	Implement and monitor a plan to meet the acceptable level for the key performance indicator for infectious diseases in pregnancy screening ID2 - timely assessment of women with hepatitis B	Service specification 15	6 months	Standard	Submission of KPI data ID2 which consistently meets acceptable level

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
22	Discontinue the offer of screening for trisomy 18 as part of quadruple test	Service specification 16	3 months	Standard	Revised guideline and request form
23	Ensure women have access to a private area for counselling within the sonography department	Service specification 16	12 months	Standard	Facilities review ensures women have access to a private area for counselling

Newborn hearing screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
24	Implement and monitor a plan to meet the acceptable level for the key performance indicator NH2 – time from screening outcome to attendance at an audiological assessment appointment	Service specification 20	6 months	Standard	Submission of KPI data NH2 which consistently meets acceptable level

No.	Recommendation	Reference	Timescale	Priority	Evidence required
25	Investigate the high referral rate from screening to diagnostic audiological assessment (quality standard 3)	Newborn Hearing Screening Programme Standards 2016 to 2017	6 months	Standard	Data for quality standard 3 that consistently meets the acceptable level

Newborn blood spot screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
26	Monitor the plan to meet newborn blood spot standard 3 – the proportion of blood spot cards received by the laboratory with the baby's NHS number on a barcoded label	NHS Newborn Blood Spot Screening Programme Standards 2017 to 2018	12 months	Standard	Submission of standard 3 which consistently meets acceptable level
27	Implement and monitor a plan to meet the acceptable level for the key performance indicator NB4 – babies eligible for newborn blood spot screening who have a conclusive result recorded on the child health information system at ≤ 21 calendar days of notifying the CHR of movement in	Service specification 19	6 months	Standard	Action plan that is agreed and monitored at the programme board meeting Submission of key performance data for NB4

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 after the report is published. 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.