Public Health England

NHS

Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening Programmes

Isle of Wight NHS Trust

19 June 2018

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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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Scope of visit

Service	Provider	Within the scope of this visit
Sickle cell and thalassaemia screening laboratory services	IOW NHS Trust	Yes
Infectious diseases screening laboratory services	IOW NHS Trust	Yes
Fetal trisomy screening – first trimester combined and quadruple screening laboratory services	Portsmouth Hospitals NHS Trust	No
Fetal anomaly screening to include first trimester and anomaly scans	IOW NHS Trust	Yes
Newborn infant physical examination	IOW NHS Trust	Yes
Newborn bloodspot screening laboratory services	Portsmouth Hospitals NHS Trust	No
Newborn hearing screening programme	Portsmouth Hospitals NHS Trust	Yes
Child health records department	IOW NHS Trust	Yes

Executive summary

Antenatal and newborn 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 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 quality assurance visit to the Isle of Wight NHS Trust antenatal and newborn screening service held on 19 June 2018.

Quality assurance purpose and approach

Quality assurance (QA) aims to maintain national standards and promote 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:

- routine monitoring data collected by the NHS screening programmes
- data and reports from external organisations
- evidence submitted by the provider(s), commissioner and external organisations
- information collected during a pre-review visit to the Isle of Wight NHS Trust on 10 April 2018
- information shared with the south east regional SQAS as part of the visit process

Local screening service

The Isle of Wight NHS Trust (IOW) provides NHS hospital services for a population of approximately 140,000 residents of the island. The island has defined borders with little movement to or away from the area.

Between April 2016 and March 2017, 1,321 women booked for maternity care and the trust recorded 1,154 births. The local pregnant population is characterised as 93% white British and 2.8% from outside the European Union, predominantly Asian; the remainder of the population is from the European Union (trust annual report data 2016 to 2017). The mean maternal age is 29 years.

The screening service is commissioned by and on behalf of NHS England (Wessex).

Maternity and screening services are provided at IOW and the site provides consultant and low risk midwifery led care.

Services at IOW include:

- maternity services in the acute hospital
- analysis of sickle cell and thalassaemia screening samples and infectious diseases screening samples
- maternity ultrasound services, excluding fetal medicine specialist services
- level 2 neonatal unit
- newborn infant physical examination
- child health records department

Delivery of the screening service involves interdependencies with other providers for parts of the pathway, and the following services are outside the scope of this report:

- analysis and risk calculation of combined and quadruple screening samples provided at Portsmouth Hospitals NHS Trust
- analysis of samples for newborn blood spot screening provided at Portsmouth Hospitals NHS Trust
- fetal medicine and prenatal diagnostic services provided by University Hospital Southampton NHS Foundation Trust
- newborn hearing screening provided by Portsmouth Hospitals NHS Trust

Findings

Immediate concerns

The QA visit team identified no immediate concerns.

High priority

The QA visit team identified 8 high priority findings as summarised below:

- the sickle cell and thalassaemia and infectious diseases screening laboratories have lost their accreditation
- there is no technical expertise for screening in the sickle cell and thalassaemia screening laboratory
- there are issues with identification of the antenatal screening cohort
- there is no clear distinction between screening and additional clinical testing which is offered to women within the fetal anomaly screening programme

- screen positive confirmatory results are received by telephone from the reference laboratory and reported to maternity services prior to receipt of a documented result
- combined screening results are not validated by the screening laboratory when the sonographer calculates the risk due to fetal demise of a twin
- there are inadequate tracking arrangements to ensure the timely referral into treatment service for screen-positive babies following newborn infant physical examination
- newborn bloodspot screening results are sent in bulk via Royal Mail rather than using an electronic transfer

Shared learning

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

- overall reduction in avoidable repeat rates for newborn bloodspot screening through implementation of dedicated clinics
- quarterly screening newsletter which is circulated to all members of staff within maternity and includes screening updates and actions or shared learning identified at local screening governance meetings
- the maternity Facebook page which is used to provide screening information for women
- clear arrangements for sending sickle cell and thalassaemia screening samples away to an external laboratory in the event of analyser failure which includes a service-level agreement stipulating adherence to the turnaround times of the programme

Recommendations

The following recommendations are for the provider to action unless otherwise stated.

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1	Regain laboratory accreditation	Laboratory handbooks	6 months	High	CPA/UKAS ISO 15189 certificate
2	Commissioner to consider options for commissioning accredited laboratory services in the event that the IOW accreditation remains suspended	Laboratory handbooks	12 months	High	CPA/UKAS ISO 15189 certificate Service level agreement with external provider (if required)
3	Document the commissioning pathway for screening issues and risk	Section 7a service specification no 15 to 21	6 months	Standard	Ratified escalation pathway and governance structure chart
4	The commissioner should finalise and ratify the terms of reference for the programme board to reflect its functions	Section 7a service specification no 15 to 21	6 months	Standard	Ratified terms of reference for programme board

No.	Recommendation	Reference	Timescale	Priority	Evidence required
5	The commissioner should ensure signed contracts are in place with all providers (and subcontractors)	Section 7a service specification no 15 to 21	6 months	Standard	Service level agreements and sub contracts
6	Revise the terms of reference for the trust screening board	Section 7a service specification no 15 to 21	6 months	Standard	Updated and ratified terms of reference which includes: • senior oversight • standing agenda items • lines of escalation to trust board level
7	Formalise internal meetings for: • sonography • child health information service • newborn hearing screening programme	Section 7a service specification no 15 to 21	6 months	Standard	Terms of reference Agenda and minutes Action plans
8	Formalise the organisational accountability structure for antenatal and newborn screening service to include escalation of risks and incidents	Section 7a service specification no 15 to 21 Managing Safety Incidents in NHS Screening Programmes	6 months	Standard	Organisational structure chart

No.	Recommendation	Reference	Timescale	Priority	Evidence required
9	Revise the template for risk assessment within the screening laboratories to ensure alignment to the requirements of the national programmes	Programme handbooks	6 months	Standard	Revised risk assessment template
10	Update all policies and standard operating procedures related to screening to ensure compliance with national service specifications and national programme guidance including incident management policies	Section 7a service specification no 15 to 21 Programme handbooks and standards	6 months	Standard	Ratified policies and standard operating procedures for each screening programme
11	Formalise maternity and sonography audits	Section 7a service specification no 15 to 21	12 months	Standard	Audit schedule Audit reports Action plans
12	Revise the turnaround time audit report to ensure compliance with sickle cell and thalassaemia (SCT) programme standards	NHS SCT Screening Programme: Handbook for antenatal laboratories SCT standards	6 months	Standard	Audit report showing compliance with required turnaround times

No.	Recommendation	Reference	Timescale	Priority	Evidence required
13	Revise the template for vertical audit within the screening laboratories to ensure alignment with the requirements of the national programmes	NHS SCT Screening Programme: Handbook for antenatal laboratories	6 months	Standard	Revised audit templates
14	Complete a user survey to gather views from women and stakeholders regarding the screening services provided	Section 7a service specification no 15 to 21	12 months	Standard	User survey Action plan

Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
15	Revise the staffing structure to ensure that there is technical expertise for screening in the sickle cell and thalassemia (SCT) screening laboratory	NHS SCT Screening Programme: Handbook for antenatal laboratories	3 months	High	Staffing structure
16	Ensure job descriptions are revised or developed for key staff	Section 7a service specification no 15 to 21	6 months	Standard	Ratified job descriptions including elements of screening responsibility

No.	Recommendation	Reference	Timescale	Priority	Evidence required
17	Undertake a staffing review to ensure resilience and contingency for: • screening coordinator • screening support sonographer • newborn hearing screening programme local manager	Section 7a service specification no 15 to 21	6 months	Standard	Staffing review Risk assessment and action plan
18	Ensure all staff involved in the screening pathway complete the training requirements	Section 7a service specification no 15 to 21	6 months	Standard	Training log for staff Training needs analysis and related action plan

No.	Recommendation	Reference	Timescale	Priority	Evidence required
19	Ensure best use is made of Viewpoint (maternity ultrasound IT system)	Section 7a service specification no 16 and 17 NHS Fetal Anomaly Screening Programme Handbook for ultrasound practitioners (April 2015) Fetal Anomaly Screening Programme - Programme handbook June 2015	6 months	Standard	Ratified policy or standard operating procedure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
20	Implement a replacement schedule for ultrasound equipment to provide resilience within the ultrasound screening service	Section 7a service specification no 16 and 17 NHS Fetal Anomaly Screening Programme Handbook for ultrasound practitioners (April 2015) Fetal Anomaly Screening Programme - Programme handbook June 2015	6 months	Standard	Replacement schedule for ultrasound equipment

Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority	Evidence required
21	Ensure all women that have been referred for antenatal care have been booked	Section 7a service specification no 15 to 18	6 months	High	Audit outcomes and action plan Risk assessment Ratified policy

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority	Evidence required
22	Revise the consent process to ensure that there is a clear distinction between screening and clinical testing for fetal anomalies	Section 7a service specification no 16 and 17 NHS Fetal Anomaly Screening Programme Handbook for ultrasound practitioners (April 2015) Fetal Anomaly Screening Programme - Programme handbook June 2015	3 months	High	Information for parents Ratified policy to include the process for gaining consent for screening and additional clinical testing Documentation of consent
23	Amend the trust website to ensure the correct screening information is presented	Section 7a service specification no 15 to 21 Programme handbooks and standards	6 months	Standard	Updated website

Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
24	Revise the request form to ensure that the family origin questionnaire meets the requirements of the programme	NHS Sickle Cell and Thalassaemia Screening Programme: Handbook for antenatal laboratories	6 months	Standard	Revised request forms compliant with national programme minimum data fields
25	Implement auditable electronic reporting of incomplete family origin questionnaires, rejected samples and screen positive results	NHS Sickle Cell and Thalassaemia Screening Programme: Handbook for antenatal laboratories	6 months	Standard	Ratified standard operating procedure

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
26	Audit the receipt of confirmatory screening results by telephone from the reference laboratory	NHS Screening Programme Infectious Diseases in Pregnancy Screening Programme Handbook for Laboratories 2016-17	3 months	High	Audit and address the findings
27	Revise the request form to remove rubella screening request	NHS Screening Programme Infectious Diseases in Pregnancy Screening Programme Handbook for Laboratories 2016-17	12 months	Standard	Revised request forms compliant with national programme minimum data fields

No.	Recommendation	Reference	Timescale	Priority	Evidence required
28	Implement an auditable electronic reporting of rejected samples and screen positive results	NHS Screening Programme Infectious Diseases in Pregnancy Screening Programme Handbook for Laboratories 2016-17	6 months	Standard	Ratified standard operating procedure

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
29	Implement the validation of risk calculations (using nuchal translucency only) by the laboratory for first trimester screening	Section 7a service specification no 16 NHS Fetal Anomaly Screening Programme Handbook for ultrasound practitioners (April 2015) Fetal Anomaly Screening Programme − Programme handbook June 2015	3 months	High	Confirmation of validation of results Ratified standard operating procedure

Newborn hearing screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
30	Allow the child health information service (CHIS) access to SMaRT 4 Hearing (S4H) to enable screening data to be transferred	Section 7a service specification no 20	6 months	Standard	Confirmation at programme board that CHIS has gained access to S4H

Newborn and infant physical examination

No.	Recommendation	Reference	Timescale	Priority	Evidence required
31	Extend the tracker for developmental dysplasia of the hips to include all screen positive results for the other conditions following the newborn and infant physical examination in a timely way to ensure each baby enters treatment services	Section 7a service specification no 21 Newborn and Infant Physical Examination: Programme handbook	3 months	High	Ratified policy to reflect tracking of screen positive cohort Tracker

Newborn blood spot screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
32	Request the electronic upload of results from the newborn bloodspot screening (NBS) laboratory to child health information service	Section 7a service specification no 19	3 months	High	Request submitted to newborn bloodspot screening laboratory through contractual route Information governance risk to be added to the trust risk register in the short term
33	Implement the use of Public Health England (PHE) template letters for screening results sent to parents	NBS programme guidance and standards	6 months	Standard	Adaptation of the PHE template letters for the local child health information service

Next steps

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

SQAS will work with commissioners for 12 months to monitor activity and progress in response to the recommendations following the final report. SQAS will then send a letter to the provider and the commissioners summarising the progress and will outline any further action needed.