Public Health England

NHS

Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening Programmes

Royal Surrey County Hospital NHS Foundation Trust

22 May 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	Berkshire Surrey Pathology Services – Frimley Park Hospital	No
Infectious diseases screening laboratory services	Berkshire Surrey Pathology Services – St Peter's Hospital	No
Fetal trisomy screening – first trimester combined screening laboratory services (biochemistry)	Royal Devon and Exeter NHS Foundation Trust	No
Fetal trisomy screening – first trimester combined screening (risk calculation)	Royal Surrey County Hospital NHS Foundation Trust	Yes
Fetal trisomy screening – second trimester quadruple screening laboratory services	Wolfson Institute of Preventative Medicine (Barts and the London School of Medicine and Dentistry)	No
Fetal anomaly screening to include first trimester and anomaly scans	Royal Surrey County Hospital NHS Foundation Trust	Yes
Newborn infant physical examination	Royal Surrey County Hospital NHS Foundation Trust	Yes
Newborn bloodspot screening laboratory services	South West Thames Newborn Blood Spot Screening Laboratory	No
Newborn hearing screening programme	Kingston Hospital NHS Foundation Trust	No
Child health records department	Children and Family Health Surrey	No

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 of the Royal Surrey County Hospital NHS Foundation Trust antenatal and newborn screening service held on 22 May 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 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 regional SQAS as part of the visit process

Local screening service

The Royal Surrey County Hospital NHS Foundation Trust (RSCH) provides NHS hospital services for a population of around 320,000 people living in Guildford and the surrounding area.

Maternity and screening services are provided at RSCH and the site provides consultant led and low risk midwifery led care. There is a birth centre beside the main delivery suite.

Between April 2016 and March 2017, RSCH booked 3,389 women and recorded 2,978 births. The local pregnant population is reported as 71% white British, 19.1% European, 5.8% Asian, 1.3% black and 2.1% other. The maternal age range was 17 to 52 years and the mean maternal age was 34 years (Trust annual report data 2016/2017).

Services at RSCH include:

- maternity services in the acute hospital
- ultrasound and risk assessment for first trimester Down's syndrome, Edwards' syndrome and Patau's syndrome screening and the 18+0 to 20+6 fetal anomaly scan
- in-house fetal medicine
- level 1 neonatal unit
- newborn hearing screening
- newborn infant physical examination

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

- analysis of sickle cell and thalassaemia screening samples and infectious diseases screening samples at Berkshire Surrey Pathology Services (BSPS)
- analysis of the biochemical markers for first trimester screening for Down's syndrome, Edwards' syndrome and Patau's syndrome screening provided by the Royal Devon and Exeter NHS Foundation Trust
- analysis of the biochemical markers for second trimester screening for Down's syndrome provided by the Wolfson Institute of Preventative Medicine, Barts and the London School of Medicine and Dentistry
- analysis of samples for newborn blood spot screening provided by South West Thames Newborn Bloodspot Screening Laboratory
- child health records department provided by Children and Family Health Surrey (previously Virgin Care up to 31 March 2017)
- newborn hearing screening led by Kingston Hospital NHS Trust

Findings

Immediate concerns

The QA visit team identified 2 immediate concerns. A letter was sent to the chief executive on 23 May 2018, asking that the following items be addressed within 7 days:

- the measurement of nuchal translucency is taken despite women declining combined screening for fetal trisomies
- risks have been calculated when women have declined part of the combined screening test

A response was received within 7 days which assured the QA visit team that the identified risk had been mitigated and no longer posed an immediate concern.

High priority

The QA visit team identified 9 high priority findings as summarised below:

- accountability and responsibility for the combined screening pathway is not clearly defined
- there is no risk assessment of the first trimester screening pathway including the risk calculation element
- there is a lack of adequate training and competency assessment to ensure that all staff responsible for the calculation of risk are competent to undertake the process
- there is no reconciliation to ensure completeness of the antenatal screening cohort
- there are inadequate tracking arrangements to ensure completion of antenatal screening tests
- there is no clear distinction between screening and additional clinical testing which is offered to women within the fetal anomaly screening programme
- combined screening samples are not tracked from community areas to the laboratory to ensure results are received in a timely way
- there is no evidence that screen positive syphilis cases requiring referral to fetal medicine services before 26 weeks gestation is undertaken (if treatment is required during the current pregnancy)

Shared learning

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

- access to screening for women attending the early pregnancy unit
- the orientation programme, the midwife sonographer development programme and subsequent tracking of e-learning for sonographers
- an extensive image audit package for sonographers at RSCH - all audits are recorded in a single audit workbook for each sonographer
- a competency document for sonography equipment which is used to ensure that staff are proficient in their use of machinery within the department
- competency of midwifery NIPE practitioners undertaking the role which includes extensive training and the requirement to complete 6 examinations per month
- the use of an exemption form when babies are too unwell to complete NIPE
- training sessions for newborn bloodspot screening provided annually by the LCO and staff are expected to complete a competency process prior to working in the community

Recommendations

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

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1.1	Clarify the accountability and responsibility for the combined screening pathway	1	3 months	High	Service level agreement Ratified policy
1.2	Undertake a risk assessment of the first trimester screening pathway including risk calculation process in both maternity and sonography	6 10 to 12	3 months	High	Completed risk assessment and action plan
1.3	Clarify and revise the internal commissioning arrangements with the Wolfson Institute of Preventative Medicine to ensure that the service provided meets the NHS fetal anomaly screening programme (FASP) recommendations	10 to 12	6 months	Standard	Commissioning arrangements to be provided to the trust antenatal and newborn screening governance group
1.4	Revise the collection of key performance indicator (KPI) ST2 (conclusive result for sickle cell and thalassaemia by 10+0 weeks gestation) data to comply with national guidance	3 7	6 months	Standard	KPI submission

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1.5	Revise the organisational accountability structure for antenatal and newborn screening service to include escalation routes for governance and performance issues within the sonography service	1 6 10 to 12	6 months	Standard	Organisational structure chart to include sonography department
1.6	Revise the terms of reference for the trust screening board to include lines of escalation to trust board level	1	6 months	Standard	Updated and ratified terms of reference
1.7	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	1 to 2 4 to 12 14	6 months	Standard	Ratified policies and standard operating procedures for each screening programme
1.8	Document the commissioning escalation pathway for screening issues and risks	1 4 to 5	6 months	Standard	Ratified escalation pathway and governance structure chart
1.9	Update the terms of reference for the regional antenatal and newborn screening board to include representation of the newborn hearing screening programme	1 13	6 months	Standard	Updated and ratified terms of reference

Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
2.1	Provide appropriate training for the screening team and sonography staff who are responsible for the process of risk calculation of first trimester screening to ensure full understanding of the role	10 to 12	3 months	High	Training material and a register to ensure that all staff have completed the training
2.2	Ensure job descriptions are revised for: • antenatal care support worker • senior advanced neonatal nurse practitioner (NIPE lead)	1	6 months	Standard	Ratified job descriptions including elements of screening responsibility

Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority	Evidence required
3.1	Ensure that all women that have been referred for antenatal care have been booked	1	6 months	High	Audit Risk assessment Ratified policy

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority	Evidence required
4.1	Discontinue the measurement of nuchal translucency when women decline combined screening	1 10 to 12	7 days	Immediate	Standard operating procedure Audit
4.2	Train all staff responsible for the risk calculation element of the combined screening pathway to ensure that risks are only calculated for conditions consented for by the woman	1 10 to 12	7 days	Immediate	Standard operating procedure Audit
4.3	Revise the consent process to ensure that there is a clear distinction between screening and clinical testing for fetal anomalies	1 10 to 12	3 months	High	Information for parents Ratified policy to include the process for gaining consent for screening and additional clinical testing Documentation of consent
4.4	Track the booked cohort to ensure all those accepting screening complete testing within timescales stipulated by local policy	1 to 2 6 to 12 14	3 months	High	Audit

No.	Recommendation	Reference	Timescale	Priority	Evidence required
4.5	Introduce a process in the maternity service for communication of screening results once a woman has miscarried or had termination of pregnancy	1 9	6 months	Standard	System implemented Ratified trust screening policies describing pathway
4.6	Amend the trust website to ensure the correct screening information is presented	1 9 10 to 12	6 months	Standard	Updated website

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
5.1	Revise the pathway for syphilis screen positive women who have received treatment in the current pregnancy, to ensure that they are referred to fetal medicine by 26 weeks gestation	1 9	3 months	High	Ratified policy Included in tracker of screen positives

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
6.1	Track the combined screening bloods to ensure results are obtained for all samples taken	1 11 to 12	3 months	High	Ratified policy or standard operating procedure Tracker

No.	Recommendation	Reference	Timescale	Priority	Evidence required
6.2	Prevent the calculation of risk for fetal trisomies when the pregnancy is outside the nationally recommended gestational parameters	10 to 12	6 months	Standard	Request changes to software Confirmation of successful change to software
6.3	Develop and implement a process to suppress the original results of the biochemistry when superseded by a new sample to prevent errors in the risk calculation	10 to 12	6 months	Standard	Request changes to software Confirmation of successful change to software If not possible, implement a manual process in collaboration with the laboratory

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.