Public Health England

NHS

Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening Programmes
King's College Hospital NHS Foundation Trust

27 and 28 March 2019

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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 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. PHE advises the government and the NHS so England has safe, high quality screening programmes that reflect the best available evidence and the UK NSC recommendations. PHE also develops standards and provides specific services that help the local NHS implement and run screening services consistently across the country.

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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 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 King's College Hospital NHS Foundation Trust screening service held on 27 and 28 March 2019.

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 Public Health England (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, commissioners and external organisations
- information shared with the London SQAS as part of the visit process

Local screening service

King's College Hospital NHS Foundation Trust (KCHFT) is one of London's largest teaching hospitals, primarily serving the boroughs of Southwark, Bromley, Lambeth and Lewisham. In October 2013 the trust acquired Princess Royal University Hospital (PRUH), Orpington Hospital and some services at Queen Mary's Hospital (QMH) and Beckenham Beacon.

A full range of maternity and screening services are provided at the King's College Hospital site (KCH) and PRUH. Antenatal clinics are held at Beckenham Beacon, Orpington Hospital and Queen Mary's Hospital (QMH). The trust also has community services in the Bexley area.

The Fetal Medicine Research Institute, previously known as the Harris Birthright Centre, is based at KCH. It is the largest fetal medicine unit in England, caring for over 10,000 women each year. It has an on-site fetal anomaly screening laboratory and offers first trimester Down's syndrome, Edwards' syndrome and Patau's syndrome screening (combined test) to women booked at KCH. Women from Bexley and Bromley who book at PRUH can choose to have first trimester screening scans completed at QMH or KCH.

Viapath laboratory services for sickle cell and thalassaemia (SCT) and infectious diseases in pregnancy screening (IDPS) are within the trust. This public-private laboratory partnership is formed between KCHFT, Guy's and St. Thomas' NHS Foundation Trust and a commercial partner.

The Viapath specialist haematology laboratory (Red Cell Centre) is a national reference centre and the largest prenatal diagnosis laboratory for haemoglobinopathies in Europe. It is a second line testing laboratory for newborn bloodspot screening and completes genetic screening of transfused newborn babies.

Screening provided by external services include:

- first trimester screening scans – provided at QMH by Dartford and Gravesham NHS Trust
- second trimester biochemistry screening (quadruple test) for women booked at KCH – Wolfson Institute of Preventative Medicine
- combined and quadruple tests for women booked at PRUH who choose to be scanned at QMH – Wolfson Institute of Preventative Medicine
- prenatal diagnostic services for Down's syndrome, Edwards' syndrome and Patau's syndrome – Regional Genetics Laboratory at Guys and St Thomas' NHS Trust
- inconclusive IDPS sample testing – PHE Colindale laboratory
- SCT counselling for at-risk women and couples – Wooden Spoon House (WSH) sickle cell and thalassaemia centre for women booked at KCH
- newborn bloodspot laboratory screening services – south east (SE) Thames Regional Newborn Screening Service
- newborn hearing screening – south east London (SEL) newborn hearing screening programme (NHSP)
- child health services – SEL Child Health Information Service (CHIS) hub

Antenatal and newborn screening services are commissioned by and on behalf of NHS England London (NHSEL).

Findings

This is the first quality assurance visit to the trust. The service is delivered by a team of dedicated staff who are committed to quality improvement. There is evidence of good working relationships between staff across the screening programmes.

Immediate concerns

The QA visit team identified no immediate concerns.

High priority

The QA visit team identified 10 high-priority findings summarised into the themes below:

1. Trust oversight and governance of service level agreements with Dartford and Gravesham NHS Trust and the Wolfson Institute of Preventative Medicine is not well demonstrated.
2. A risk assessment has not been completed for the planned transfer of SCT counselling into maternity services (KCH).
3. Potential risks associated with the proposed changes to south east London pathology services have not been assessed.
4. The varied first trimester screening scan model across the trust should be reviewed to make sure best outcomes are achieved for women.
5. The lack of linkage between PRUH and KCH laboratory systems impacts on the timeliness of reporting SCT results.
6. Leadership and governance of KCH fetal anomaly screening laboratory service is unclear.
7. There is no direct referral process for SCT counselling and prenatal diagnosis at the KCH site.
8. The laboratory reporting of screen positive SCT results is not timely.
9. There is no process for notifying the screening teams of babies born to hepatitis B positive women at the KCH site.
10. The Fetal Anomaly Screening Programme (FASP) cut off for combined test screening is not used by the KCH fetal anomaly screening laboratory resulting in inconsistency and inequity in the management of higher chance results for women across the trust.

Shared learning

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

- there is a structured and effective approach to addressing health and social inequalities
- women can access their records through a portal to BadgerNet (maternity IT system)
- laboratory training material for infectious diseases is comprehensive and informative
- learning from screening incidents is shared through regular handover briefings
- health visitors and paediatric nurses are invited to attend newborn blood spot (NBS) screening training sessions
- SEL NHSP are involved in the provision of mandatory training
- SEL NHSP was cited as a best performer in the national PHE survey report ‘Time from attendance at an audiological appointment (NHSP standard 5): learning from best performing sites’, December 2017
- KCH screening coordinator represents London screening coordinators at the national newborn bloodspot failsafe solution user group. The group has worked on several improvement projects which include developing criteria to trigger alerts

Recommendations

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1	NHSEL should work with the trust to make sure sub-contracting arrangements are appropriately managed and comply with national screening standards	2	12 months	High	Confirmation at trust screening steering group (TSSG) of contract monitoring and compliance to national screening standards
2	Complete a risk assessment for the transfer of SCT counselling to maternity services	4	6 months	High	Risk assessment and action plan submitted to TSSG Action plan completion monitored by TSSG
3	CCG commissioners should work with the trust to process map and develop a risk mitigation plan to manage proposed changes to south east London pathology services	1, 4,16, 17, 18	12 months	High	Risk mitigation plan submitted to TSSG
4	Update TSSG terms of reference (TOR) to include representation from all relevant areas of each screening programme and remit of working groups	1 - 7	6 months	Standard	Amended TOR approved by TSSG Minutes of meetings
5	Combine all open actions into a single ANNB screening quality improvement plan and update as new actions arise	1 - 7	6 months	Standard	Quality improvement plan submitted to and monitored by TSSG

No.	Recommendation	Reference	Timescale	Priority	Evidence required
6	CCG commissioners should work with the trust to review and risk assess the first trimester screening scan model across the trust	2, 12	6 months	High	Risk assessment and action plan submitted to TSSG
7	Implement an action plan for the linkage of PRUH and KCH laboratory systems	1, 4,17, 18	12 months	High	System interface confirmed to TSSG
8	Complete a gap analysis of the KCH biochemistry laboratory service against United Kingdom Accreditation Service (UKAS) and FASP quality assurance requirements and produce an action plan	2, 12, 13, 14	3 months	High	Completed gap analysis and action plan submitted to TSSG Confirmation of monthly data submissions to NCARDRS
9	Develop screening guidelines and standard operating procedures (SOPs) for all programmes in line with national guidance	1 to 8	6 months	Standard	Ratified guidelines available for all screening programmes New or revised guidelines/SOPs submitted to TSSG for approval
10	Develop a trust wide audit schedule of all ANNB screening programmes	1 to 7	12 months	Standard	Completed audits submitted to the TSSG Action plans to address any identified gaps
11	Extend user satisfaction surveys to include all ANNB screening programmes	1 to 7	12 months	Standard	Outcome of surveys and actions taken discussed TSSG

Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	See recommendation 6				
	See recommendation 8				
12	Make sure staff providing SCT counselling for at risk women and couples meet national training requirements	4	6 months	Standard	NHS screening programme accredited genetic risk assessment and counselling module or equivalent completed
13	Develop job descriptions for screening support sonographer and deputy roles that clarify responsibilities and cover arrangements	2, 3, 12, 15	6 months	Standard	Job descriptions submitted to TSSG Evidence of protected time within the work rota
14	Clarify responsibilities of neonatal nurses identified as NBS screening links for the neonatal units	5	6 months	Standard	NBS guidelines describing roles and responsibilities submitted to TSSG
15	Identify a neonatal lead with overall responsibility for clinical oversight and governance of neonatal newborn screening programmes within the neonatal units	5 to 7	6 months	Standard	Confirmation to TSSG of a named neonatal lead
16	Make sure the trust is represented at FASP national training events	2, 3	6 months	Standard	Confirmation of attendance to TSSG
17	Review with IT the potential for remote access to laboratory results for community midwives	1, 4	12 months	Standard	Review outcome and action plan submitted to TSSG
18	Develop a business plan for access to Viewpoint at QMH and the implementation of an updated version at PRUH and KCH	2, 3	6 months	Standard	Business plan submitted to TSSG

Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority	Evidence required
19	Develop an IT solution to allow streamlined and weekly tracking of each woman through the screening pathways to make sure screening is offered, tests are performed and results are received	1 to 4	12 months	Standard	Revised, streamlined and weekly tracking process documented in SOP and submitted to TSSG

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority	Evidence required
20	Implement a direct referral process for SCT counselling and prenatal diagnosis (KCH)	4	6 months	High	Guideline or SOP submitted to TSSG

Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	See recommendation 7				
	See recommendation 19				
21	Implement a laboratory process for obtaining Family Origin Questionnaire (FOQ) information on all SCT samples	4, 18	6 months	Standard	Guideline or SOP submitted to TSSG
22	Implement a tracking process for cross-site sample transfer	4, 18	6 months	Standard	Guideline or SOP submitted to TSSG
23	Improve the timeliness for laboratory reporting of screen positive SCT results	4, 18	6 months	High	Guideline or SOP submitted to TSSG

Infectious diseases in pregnancy

No.	Recommendation	Reference	Timescale	Priority	Evidence required
24	Implement a tracking process for cross-site and external sample transfer	1, 14	6 months	Standard	Guideline or SOP submitted to TSSG
25	Make sure women declining IDPS are re-offered screening by 20 weeks gestation by an IDPS multi-disciplinary team member	16	6 months	Standard	Guideline submitted to TSSG

No.	Recommendation	Reference	Timescale	Priority	Evidence required
26	Implement a process to notify screening teams of women screened on delivery/postnatal wards	16	6 months	Standard	Guideline or SOP submitted to TSSG
27	Implement a process to notify the KCH screening team of babies born to hepatitis B positive women	16	6 months	High	Guideline submitted to TSSG

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	See recommendation 1				
	See recommendation 6				
	See recommendation 8				
	See recommendation 18				
28	Make sure FASP cut-off is used for combined test screening (KCH fetal anomaly screening laboratory)	2, 12	6 months	High	Guideline submitted to TSSG Documented evidence of decision process submitted to TSSG if decision to operate outside of national guidance is maintained

No.	Recommendation	Reference	Timescale	Priority	Evidence required
29	Revise local information on women's screening choices to make sure terminology used is inclusive and consistent	2,12	6	Standard	Revised documents submitted to TSSG

Newborn hearing screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
30	NHSP letters to parents should be updated with current national screening data	6	6 months	Standard	Revised letters submitted to TSSG

Newborn and infant physical examination

No.	Recommendation	Reference	Timescale	Priority	Evidence required
31	Identify neonatal leads with responsibility for monitoring newborn and infant physical examination (NIPE) screening completion in the neonatal units	7	6	Standard	NBS guidelines describing roles and responsibilities submitted to TSSG
32	Make sure all babies identified with developmental dysplasia of the hips at PRUH are referred and undergo hip ultrasound within 2 weeks of birth	7, 11	3 months	Standard	Improvement in key performance indicator (KPI) NP2

Newborn blood spot screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	See recommendation 14				

Next steps

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

SQAS will work with NHSEL 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 NHSEL summarising the progress made and will outline any further action(s) needed.

Appendix A: References

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3. Service specification number 17:NHS Fetal Anomaly Screening Programme: 18^{+0} to 20^{+6} week fetal anomaly scan (2018 to 2019) https://www.england.nhs.uk/wp-content/uploads/2017/04/Gateway-ref-07838-180913-Service-specification-No.-17-NHS-FASP-Fetal-anomaly-scan.pdf

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14. NHS Fetal Anomaly Screening Programme: Laboratory Quality Assurance Evidence Requirements July 2018
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