



Public Health
England

Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening
Programmes
Brighton and Sussex University Hospitals
NHS Trust

24 and 25 April 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 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 Brighton and Sussex University Hospitals NHS Trust screening service held on 24 and 25 April 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 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 shared with the south east regional SQAS as part of the visit process

Local screening service

Brighton and Sussex University Hospitals NHS Trust (BSUH) provides maternity services to the local population in and around Brighton and Hove, Mid-Sussex and the western part of East Sussex. The trust primarily serves a population of over 539,500 people (CQC report January 2019).

The trust provides maternity care across two sites, the Royal Sussex County Hospital in Brighton and the Princess Royal Hospital in Haywards Heath.

The trust also provides antenatal and ultrasound services at Hove Polyclinic.

BSUH has a level 3 surgical neonatal unit (Trevor Mann Unit) at the Royal Sussex County Hospital which provides specialist care for babies born from 23 weeks gestation and a level 1 neonatal unit at the Princess Royal Hospital.

Between April 2017 and March 2018, 5932 women booked for maternity care and the trust recorded 5285 births. The local pregnant population is characterised as:

- 73.87% white British
- 14.11% other white ethnic background
- 5.11% Asian
- 0.81% Chinese
- 1.67% black
- 2.12% mixed race
- 1.25% other ethnic background

1.06% of women were recorded as ethnicity unknown. The mean age at booking for maternity care was 31.56 years (all data submitted with pre-visit evidence data for 1 April 2017 to 31 March 2018). The screening service is commissioned by and on behalf of NHS England South East (Kent, Surrey and Sussex).

Services at BSUH include:

- maternity services provided across two sites – Royal Sussex County Hospital in Brighton and Princess Royal Hospital in Haywards Heath
- maternity clinic and ultrasound services at Hove Polyclinic
- analysis of sickle cell and thalassaemia screening samples at Princess Royal Hospital in Haywards Heath
- analysis of infectious diseases screening samples at Royal Sussex County Hospital in Brighton
- analysis and calculation of result for combined screening samples provided at Royal Sussex County Hospital in Brighton
- maternity ultrasound services at both hospital sites and at Hove Polyclinic
- fetal medicine specialist services (FM) at Royal Sussex County Hospital in Brighton
- level 3 neonatal intensive care unit (NICU) situated at Royal Sussex County Hospital, Brighton which accepts babies from 23 weeks gestation and level 1 neonatal unit at Princess Royal Hospital
- newborn and infant physical examination (NIPE) and newborn bloodspot screening (NBS) which are performed at both hospital sites and in the community
- newborn hearing service which is a hospital-based programme offered at both hospital sites
- child health information service which is provided by Sussex Community NHS Foundation Trust

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 calculation of result for quadruple screening samples provided by the Wolfson Institute of Preventive Medicine at Barts and The London School of Medicine and Dentistry
- analysis of samples for newborn blood spot screening provided at South East Thames Newborn Screening Laboratory at Guy's and St Thomas' NHS Foundation Trust
- prenatal diagnostic tests (mainly chorionic villus sampling – CVS) provided at Harris Birthright Centre, Kings College Hospital NHS Foundation Trust, London

Findings

Immediate concerns

The QA visit team identified 2 immediate concerns. A letter was sent to the chief executive (or equivalent) on Friday 26 April 2019 asking that the following items were addressed within 7 days.

1. The microbiology laboratory was not reporting confirmed screen positive results directly to the designated lead (women's health advisor/local antenatal and newborn screening co-ordinator) in accordance with the national service specification and guidance. Failure to do so can result in avoidable delays to treatment for pregnant women who have infectious diseases such as HIV, hepatitis B and syphilis. This has potential critical consequences for women and unborn babies.
2. The trust was delivering training for midwifery examiners as part of the newborn and infant physical examination (NIPE) programme that is not university accredited. Until recently, NIPE examinations have been undertaken by paediatricians or GPs. NIPE examinations by midwives, nurses or health visitors are now strongly encouraged. However, these practitioners must be competent to undertake all elements of the newborn examination. National guidance is for midwives to successfully undertake a university accredited 'examination of the newborn' programme of study and undergo a locally agreed competency assessment by a practising NIPE examiner.

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

High priority

The QA visit team identified 10 high-priority findings, as summarised:

- there is a lack of clarity regarding the governance arrangements and accountability for screening at senior trust level
- the screening steering board within the trust meets infrequently, lacks key stakeholder participation and the governance arrangements are unclear

- the maternity information system is not fit for purpose for antenatal and newborn screening
- the infectious diseases screening laboratory has had its UKAS accreditation suspended
- the cohort of women who refer to the maternity services is not reconciled against the booked cohort to ensure all women are identified in a timely way
- there are inadequate tracking arrangements to ensure the timely referral into treatment services for screen positive women within the fetal anomaly screening programme
- there is insufficient time for the screening support sonographer to complete vital aspects of her role in relation to internal quality assurance of the service
- there are inadequate tracking arrangements to ensure the timely referral into treatment services for screen positive babies following the newborn and infant physical examination
- manual transcription of birth demographics, including the NHS number from the birth notification application (BNA) into the trust IT systems – poses a risk of transcription and therefore identification errors
- the child health information service is not always informed of deceased babies in a timely way

Shared learning

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

- the 'message of the week' newsletter has shared learning following screening incidents which includes a shared document 'Support for Staff Involved in Incidents'
- the child health information service has exemplary standard operating procedures and business continuity plans
- there is evidence of collaborative working between health visitors and the child health information service with opportunities for health visitors to spend time in the department
- use of a rotational post in the infectious diseases in pregnancy screening (IDPS) laboratory service ensures the service can be supported if one of the permanent posts holders is not available

Recommendations

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

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1	Strengthen and clarify the governance arrangements and accountability for screening at senior trust level	Section 7a service specification No. 15 to 21	3 months	High	Reinstate high level screening board meetings Terms of reference Agenda, minutes and action plans
2	Revise the internal antenatal and newborn screening steering meeting to ensure clear governance and escalation process are established, adequate stakeholder representation and increase frequency	Section 7a service specification No. 15 to 21	3 months	High	Updated terms of reference to include: increase in number of meetings per year representation from all stakeholders Agenda and minutes Action plans

No.	Recommendation	Reference	Timescale	Priority	Evidence required
3	Regain infectious diseases in pregnancy screening (IDPS) laboratory accreditation	Laboratory handbooks	6 months	High	UKAS ISO 15189 certificate
4	Commissioner to consider options for commissioning accredited laboratory services if the BSUH accreditation remains suspended	Laboratory handbooks	12 months	High	UKAS ISO 15189 certificate
5	Identify a clinical lead for the antenatal screening programmes	Section 7a service specification No. 15 to 18	6 months	Standard	Governance structure Role and responsibilities defined
6	Formalise newborn hearing screening operational meetings	Newborn Hearing Screening Programme (NHSP) operational guidance	6 months	Standard	Terms of reference Agenda Minutes and action plan
7	Manage all screening patient safety incidents and serious incidents in accordance with 'Managing Safety Incidents in NHS Screening Programmes'	Managing Safety Incidents in NHS Screening Programmes	6 months	Standard	All staff trained in incident reporting Incident reports presented to programme board
8	Ensure oversight and approval of key performance indicator (KPI) data by the directorate lead prior to national submission	Section 7a service specification No. 19	6 months	Standard	Authorised submission of child health information service (CHIS) data from directorate lead or deputy

No.	Recommendation	Reference	Timescale	Priority	Evidence required
9	Update all policies and standard operating procedures related to screening to ensure compliance with national service specifications and national programme guidance	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 including: maternity sonography newborn hearing screening child health information service laboratory
10	Update / amend relevant local policies to include reference to managing screening incidents in accordance with 'Managing Safety Incidents in NHS Screening Programmes'	Managing Safety Incidents in NHS Screening Programmes	6 months	Standard	Policy ratified at programme board
11	Ensure signed contracts are in place for any sub-contracted services with adequate oversight by the public health commissioning team	Section 7a service specification No. 15 to 21	6 months	Standard	Service level agreements and sub contracts
12	Revise the service level agreement (SLA) for the fetal anomaly screening programme (FASP) network to ensure compliance with the FASP laboratory handbook 2018	FASP laboratory handbook	6 months	Standard	Service level agreements

No.	Recommendation	Reference	Timescale	Priority	Evidence required
13	Evaluate and revise the pathway for sickle cell and thalassaemia (SCT) samples sent away during laboratory failure/downtime to ensure compliance with standard 4 (turnaround times)	SCT handbook for antenatal laboratories	6 months	Standard	Audit Action plan
14	Ensure that the infectious diseases screening laboratory has an SLA with an external accredited laboratory in the event of laboratory failure/downtime	IDPS handbook for laboratories	6 months	Standard	Service level agreements
15	Collate and report combined screening turnaround time data within the fetal anomaly screening programme (FASP) laboratory	NHS fetal anomaly screening programme handbook for ultrasound practitioners (2015)	6 months	Standard	Annual data return
16	Improve achievement against key performance indicators (KPI) :- NP1 (newborn infant physical examination coverage) NP2 (referral of babies with suspected developmental dysplasia of hips) NB2 (newborn bloodspot screening avoidable repeat rate) NB4 (newborn bloodspot screening for movers in)	Section 7a service specification No. 15 to 21 Screening programme standards Key performance indicators: NHS screening programmes	12 months	Standard	KPI data meeting the acceptable thresholds

No.	Recommendation	Reference	Timescale	Priority	Evidence required
17	Complete a user survey to gather views about the antenatal and newborn screening pathways	Section 7a service specifications No. 15 to 21	12 months	Standard	Outcome of survey is discussed at programme board
18	Undertake screening specific audits to demonstrate compliance with national programme requirements	Section 7a service specifications No. 15 to 21	12 months	Standard	Audit Action plan Shared learning

Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
19	Assess and mitigate the risk of supplying an unaccredited training course for newborn infant physical examination (NIPE) screeners	Section 7a service specifications No. 21	7 days	Immediate	Risk assessment Action plan Entry on trust risk register
20	Ensure that all midwifery examiners of the newborn have completed a university accredited course	Section 7a service specifications No. 21	6 months	High	Confirmation of university accreditation Tracker of training completion
21	Modernise the maternity information system to meet the requirements of the NHS screening programmes	Section 7a service specifications No. 15 to 21	12 months	High	Screenshots of new system showing compliance with screening pathway requirements

No.	Recommendation	Reference	Timescale	Priority	Evidence required
22	Undertake a workforce review to ensure resilience within the sickle cell and thalassaemia (SCT) screening laboratory	Section 7a service specifications No. 18	6 months	Standard	Workforce review Action plan
23	Undertake a workforce review of ultrasound department reception staff at Princess Royal Hospital and Royal Sussex County Hospital to ensure appropriate cover and prevent sonographers having to carry out reception duties	Section 7a service specifications No. 15 to 21	6 months	Standard	Workforce review Action plan
24	Ensure capacity for the newborn hearing screening programme (NHSP) local manager to fulfil all aspects of her role	Section 7a service specifications No. 20	6 months	Standard	Attendance at local, regional and national events Audit

No.	Recommendation	Reference	Timescale	Priority	Evidence required
25	Ensure adequate time is available for the screening support sonographers to complete all aspects of the role	<p>Section 7a service specification No. 16</p> <p>NHS fetal anomaly screening programme handbook for ultrasound practitioners (2015)</p>	6 months	Standard	<p>Quarterly nuchal translucency (NT) and crown rump length (CRL) audits for all sonographers participating in first trimester screening</p> <p>Track completion of training</p> <p>Monitor Down's Syndrome Screening Quality Assurance Support Service (DQASS) reports for sonographers</p> <p>Induction resources in accordance with FASP handbook</p>
26	<p>Ensure job descriptions are revised for:</p> <p>screening specialist midwife and deputy newborn and infant physical examination (NIPE) lead</p> <p>maternity support worker</p> <p>screening support sonographer</p> <p>child health information service (CHIS) staff with responsibility for managing the failsafe systems</p>	Section 7a service specifications No. 15 to 21	6 months	Standard	Ratified job descriptions including elements of screening responsibility and contingency planning.

No.	Recommendation	Reference	Timescale	Priority	Evidence required
27	Appoint a failsafe clerk	Section 7a service specifications No. 15 to 21 Programme specific Checks and Audits documents	6 months	Standard	Failsafe clerk appointed Job description to cover screening failsafe and tracking
28	Maximise the functionality of the Viewpoint ultrasound reporting IT system to reduce the risk of error through manual transcription of data standardise the units of measurement used standardise audits document accept or decline for first trimester screening	Section 7a service specifications No. 16 and 17	6 months	Standard	Electronic data transfer of scan measurements into viewpoint Standard operating procedure for audit
29	Long term project to review how the Viewpoint system can be used to make the screening process more efficient and assist with audit and failsafe.	Section 7a service specifications No. 16 and 17	12 months	Standard	Multidisciplinary group be set up with defined objectives for monitoring the use of Viewpoint

No.	Recommendation	Reference	Timescale	Priority	Evidence required
30	Ensure there is a capital replacement programme for Automated Auditory Brainstem Response (aABR) equipment	Section 7a service specifications No. 20 Newborn Hearing Screening Programme (NHSP) operational guidance	6 months	Standard	aABR equipment to be replaced as required
31	Review and revise the IT infrastructure within the SCT laboratory to reduce the number of manual processes and risk of errors	SCT handbook for antenatal laboratories	12 months	Standard	Risk assessment Action plan

Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority	Evidence required
32	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

Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority	Evidence required
33	Risk assess the manual transcription of birth demographics including the NHS number from the birth notification application (BNA) into the trust IT systems	Section 7a service specifications No. 19 to 21	3 months	High	Risk assessment Action plan
34	Develop a process for the allocation of NHS numbers for newborn cohort in the event of a maternity IT system failure	Section 7a service specifications No. 19 to 21	6 months	Standard	Collaborative process developed for the allocation of NHS numbers between maternity and CHIS Standard operating procedure
35	Develop a process for managing errors with birth demographics including the NHS number in the birth notification application and all linked IT and national failsafe systems	Section 7a service specifications No. 19 to 21	6 months	Standard	Collaborative process developed for the allocation of NHS numbers between maternity and relevant stakeholders Standard operating procedure
36	Allow access to the national newborn failsafe systems to staff working within the neonatal unit	Section 7a service specifications No. 19 to 21	6 months	Standard	Standard operating procedure demonstrating that staff in neonatal unit are utilising the system to ensure completion of the screening pathways

No.	Recommendation	Reference	Timescale	Priority	Evidence required
37	Ensure babies details are transferred in and out on the national newborn failsafe systems in a timely way	Section 7a service specifications No. 19 to 21	6 months	Standard	Standard operating procedure demonstrating contingency for the NIPE lead

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority	Evidence required
38	Develop a process to inform the child health information service (CHIS) of deceased babies in a timely way	Section 7a service specifications No. 19 to 21	3 months	High	Standard operating procedure
39	Amend the trust maternity website to ensure the correct screening information is presented	Section 7a service specifications no 15 to 21	12 months	Standard	Amended trust maternity website

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
40	Reinstate the reporting of confirmed screen positive results to the designated lead for infectious diseases in a timely way	Section 7a service specifications no 15 Medical laboratories – Requirements for quality and competence (ISO 15189:2012)	7 days	Immediate	Standard operating procedure Audit
41	Report all infectious diseases in pregnancy screening (IDPS) rejected samples and declines to the designated lead in accordance with national guidance	NHS Screening Programme Infectious Diseases in Pregnancy Screening Programme Handbook for Laboratories 2016-17	6 months	Standard	Standard operating procedure Audit
42	Identify antenatal screening samples at each critical point within the infectious diseases in pregnancy screening (IDPS) screening laboratory	Section 7a service specifications No. 15	6 months	Standard	Completed annual data return
43	Audit the use of the carbonated booking form to ensure clear consent or decline is obtained prior to testing	Section 7a service specifications No. 15	6 months	Standard	Audit Action plan

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
44	Ensure acknowledgement by the screening team of screen positive results from the fetal anomaly screening programme (FASP) laboratory to close the loop in the pathway	Section 7a service specifications No. 16	6 months	Standard	Tracker
45	Implement a process of reviewing and reporting all unexpected abnormalities at birth	Section 7a service specifications No. 16 and 17	6 months	Standard	Ratified policy Audit Report to the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS)

Newborn and infant physical examination

No.	Recommendation	Reference	Timescale	Priority	Evidence required
46	Track all screen positives from the newborn and infant physical examination (NIPE) to ensure timely access to treatment and that the outcome is recorded	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

No.	Recommendation	Reference	Timescale	Priority	Evidence required
47	Offer newborn and infant physical examination (NIPE) screen to all preterm babies as soon as their condition allows	Section 7a service specification No. 21 Newborn and Infant Physical Examination: Programme handbook	6 months	Standard	Standard operation procedure

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 and 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.