



Public Health  
England

Protecting and improving the nation's health

# Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening  
Programmes The Queen Elizabeth  
Hospital, Kings Lynn, NHS Foundation  
Trust

15 January 2020

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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 the Queen Elizabeth Hospital, Kings Lynn, NHS Foundation Trust screening service held on 15 January 2020.

### 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(s), commissioner and external organisations
- information shared with the Midlands and East regional SQAS as part of the visit process

### Local screening service

The Queen Elizabeth Hospital, Kings Lynn, NHS Foundation Trust offers all NHS antenatal and newborn screening programmes. The maternity unit provides antenatal, intrapartum and postnatal care. There is a level 2 neonatal intensive care unit.

In 2018 to 2019, 2627 women were booked for maternity care at the Queen Elizabeth Hospital, Kings Lynn, with 2195 deliveries recorded by the trust (including live and still births).

Antenatal and newborn screening services interface with the following external providers:

- Eastern Pathology Alliance – laboratory services for infectious diseases in pregnancy screening and sickle cell and thalassaemia screening, combined test for Down's syndrome, Edwards' syndrome and Patau's syndrome for the fetal anomaly screening programme
- Cambridge University Hospital Foundation Trust laboratory – quadruple test for fetal anomaly screening samples and regional bloodspot laboratory
- Provide UK – Child information Service (CHIS)

The screening and immunisation team, Public Health England Midlands and East, (East), is the lead commissioner for the antenatal and newborn screening programmes. Co-commissioning arrangements are in place with West Norfolk Clinical Commissioning Groups (CCG) and NHS England Specialised commissioning.

## Findings

This was the second antenatal and newborn screening programmes QA visit to the Queen Elizabeth Hospital, Kings Lynn, NHS Foundation Trust. The first QA visit took place in April 2016. The action plan has been closed with no outstanding recommendations.

## Immediate concerns

The QA visit team identified no immediate concerns.

## High priority

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

- there is not a defined governance process for the management and monitoring of compliance against screening standards or action plans
- there is not a failsafe mechanism for the fetal anomaly screening ultrasound scan process
- known carriers of sickle cell and thalassaemia are not fast tracked
- the screening request form used for infectious diseases in pregnancy and sickle cell and thalassaemia screening does not reflect national guidance
- the consent processes for fetal anomaly and newborn hearing screening are not being delivered as specified in the screening guidance
- there is not a designated clinical lead for the newborn and infant physical examination screening programme

## Themes

The QA visit identified 16 standard priority findings, summarised below:

- it was not clear if the trust meets the accessible information standard or the needs of women defined in equality legislation as having protected characteristics
- feedback from user surveys is not used to inform and improve the screening service
- the screening support sonographer does not have designated time to perform the role
- there is not a structured programme of training and updates for the screening coordinators and staff performing the newborn and infant physical examination screening test
- the trust does not have multidisciplinary processes to provide clinical oversight or feedback to sonographers.
- 9 of the 16 standard recommendations relate to the newborn hearing screening programme. There was a lack of assurance in the following:
  - meeting population needs and use of interpreting services
  - entry of data into the national SMaRT4Hearing IT system
  - job descriptions
  - compliance against screening standards 2 and 4 and key performance indicator NH2
  - identification of the eligible population for babies moving into the area under 3 months of age
  - the competency framework does not reflect national guidance

## Shared learning

The QA visit team identified a maintained focus on training and support for the delivery of newborn blood spot screening. This has resulted in consistently meeting national standard and key performance indicator NB2 (avoidable repeat rate).

## Recommendations

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

### Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1	The commissioners and provider should work together to undertake a health equity audit and develop an action plan to identify and reduce screening inequalities in underserved and protected population groups	NHS screening programmes service specifications 15 to 21 (2018 to 2019)  Guidance for NHS commissioners on equality and health inequality duties 2015  NHS Accessible Information standard and specification	12 months	Standard	Summary of the audit and findings presented at the antenatal and newborn screening Programme Board  Action plan(s) presented to the Programme Board to address any identified inequalities

No.	Recommendation	Reference	Timescale	Priority	Evidence required
2	The commissioners and provider to implement a process for the regular reporting and monitoring of all antenatal and newborn screening standards	<p>NHS screening programmes service specifications 15 to 21 (2018 to 2019)</p> <p>All antenatal and newborn screening standards</p>	6 months	Standard	<p>National screening standards as a standing item on the antenatal and newborn screening Programme Board agenda</p> <p>Action plans presented to the Programme Board to address any identified gaps</p>
3	Improve internal risk and governance arrangements to make sure there are lines of accountability and regular monitoring of the quality and integrity of antenatal and newborn screening programmes	<p>NHS screening programmes service specifications 15 to 21 (2018 to 2019)</p>	6 months	High	<p>Revised terms of reference for the local screening group demonstrating divisional team involvement, reporting arrangements and board level oversight. (Maternity department, obstetric radiography department and newborn hearing screening service)</p> <p>Inclusion of antenatal and newborn screening in the trust maternity</p>

No.	Recommendation	Reference	Timescale	Priority	Evidence required strategy
					<p>A process for monitoring actions from incidents audit, user feedback surveys and gap analysis included in a local policy</p> <p>Revised documents ratified via local governance processes and presented to the Programme Board</p> <p>Evidence of cross divisional processes to communicate risks, and screening related information between Audiology, Radiology and Women and Children's services</p>

### Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
4	Complete a user survey to gather views about the antenatal and newborn screening pathways and use findings to inform service delivery	NHS screening programmes service specifications 15 to 21 (2018 to 2019)	12 months	Standard	<p>Summary of findings presented at the antenatal and newborn screening Programme Board</p> <p>Action plan(s) presented</p>



No.	Recommendation	Reference	Timescale	Priority	Evidence required
					to the Programme Board to address any identified changes in service delivery required
5	Make sure the functions of the Screening Support Sonographer (SSS) are in place within ultrasonography, including protected time for image audit	NHS screening programmes service specification No.17 (2018 to 2019)  FASP Programme Handbook	3 months	Standard	Evidence of dedicated SSS hours agreed through local governance structure and reported at screening Programme Board
6	Make sure job descriptions for the newborn hearing screening manager and audiology services manager reflect newborn hearing screening programme operational guidance	Newborn hearing screening programme (NHSP) operational guidance 2016	6 months	Standard	Revised job descriptions agreed through local governance structure  Reported in the minutes of the local antenatal and newborn screening group and Programme Board
7	Make sure there is an ongoing educational programme for screening coordinators and staff performing the newborn and infant physical examination screening	NHS screening programmes service specifications 15 to 21 (2018 to 2019)	6 months	Standard	Revised training needs analysis that includes screening coordinators and staff performing the newborn and infant physical examination screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
					<p>Mechanisms to monitor ongoing competency for NIPE practitioners</p> <p>Process agreed through local governance structure</p> <p>Reported in the minutes of the local antenatal and newborn screening group and Programme Board</p> <p>Training included in the screening annual report</p>
8	Update the newborn hearing screening competence framework to reflect national guidance	Newborn hearing screening programme (NHSP) operational guidance (2019)	6 months	Standard	<p>Updated newborn hearing screening competence framework ratified and published</p> <p>Reported in the minutes of the local antenatal and newborn screening group and Programme Board</p>

### Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority	Evidence required
9	Improve failsafe processes for the fetal anomaly screening test	Fetal Anomaly screening standards (2018)  NHS screening programmes service specification. No.17 (2018 to 2019)	3 months	High	Revised failsafe process included in a standard operating procedure  Ratified via local governance processes and presented to Programme Board

### Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority	Evidence required
10	Make sure Child Health Information Services notify the hearing screening team of babies who move into the area under 3 months of age	NHS screening programmes service specification. No.20 (2018 to 2019)	6 months	Standard	Revised process ratified via local governance processes and presented to the Programme Board

## Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority	Evidence required
11	Make sure that the model used for translators/interpreters complies with national guidelines and update the relevant standard operating procedure accordingly	<p>NHS screening programmes service specifications 15 to 21 (2018 to 2019)</p> <p>The Equality Act 2010</p> <p>The NHS Constitution for England October 2015</p> <p>Advice and guidance on the health needs of migrant patients for healthcare practitioners</p>	6 months	Standard	<p>Review the process and changes to be reflected in the local policy ratified via local governance processes and presented to the Programme Board</p> <p>Compliance audit presented to Programme Board</p>

## Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
12	Update the family origin questionnaire to reflect the latest version (version 4)	NHS Sickle Cell and Thalassaemia Screening Programme. Handbook for Laboratories 2017  NHS screening programmes service specifications 18 (2018 to 2019)	3 months	High	Revised form ratified through local governance processes and reported at the Programme Board
13	Formalise the sickle cell and thalassaemia fast track pathway for known carriers at the point of referral or booking appointment in line with national programme guidance and service specifications	NHS screening programmes service specifications 18 (2018 to 2019)	3 months	High	Agreed fast track pathway presented to the Programme Board  Local guideline updated and ratified to reflect change  Minutes of local screening meeting demonstrate monitoring of the new process

### Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
14	Update the infectious diseases in pregnancy screening request form to reflect screening standards	<p>Infectious diseases in pregnancy screening programme: laboratory handbook (2016 to 2017)</p> <p>NHS screening programmes service specifications 15 (2018 to 2019)</p>	6 months	High	Revised form ratified through local governance processes and reported at the Programme Board

### Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
15	Revise the Down's syndrome, Edwards' syndrome and Patau's syndrome screening pathway for women with a twin pregnancy to facilitate informed choice	<p>NHS Fetal Anomaly Screening Programme</p> <p>Down's syndrome, Edwards' syndrome and Patau's</p>	3 months	High	Revised guidelines ratified via local governance processes and presented to the Programme Board

No.	Recommendation	Reference	Timescale	Priority	Evidence required
		syndrome screening Handbook for Laboratories (2018)			
16	Improve clinical oversight arrangements by implementing multidisciplinary processes to maintain the quality of the entire fetal anomaly screening pathway	NHS screening programmes service specification No.17 (2018 to 2019)	12 months	Standard	Process change described in local guideline  Ratified via local governance process and presented to the Programme Board

### Newborn hearing screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
17	Implement and monitor a plan to consistently meet the acceptable level for key performance indicator NH2 (timely assessment for referrals)	Newborn hearing screening standards valid for data collected from 1 April 2018  NHS screening service specification No. 20 (2018 to 2019)	12 months	Standard	Improvement plan agreed and monitored by the antenatal and newborn screening Programme Board  Submission of data that shows consistent achievement of the acceptable standard
18	Implement and monitor a plan to meet newborn hearing screening standard 2 (well babies who do not	Newborn hearing screening	12 months	Standard	Improvement plan agreed and monitored by the antenatal and

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	show a clear response in both ears at automated otoacoustic emission 1 (AOAE1))	standards valid for data collected from 1 April 2018  NHS screening service specification No. 20 (2018 to 2019)			newborn screening Programme Board  Submission of data that shows consistent achievement of the acceptable standard
19	Implement and monitor a plan to meet newborn hearing screening standard 4 (time from screening outcome to offered appointment for diagnostic audiological assessment) the acceptable level was not met	Newborn hearing screening standards valid for data collected from 1 April 2018  NHS screening service specification No. 20 (2018 to 2019)	12 Months	Standard	Improvement plan agreed and monitored by the antenatal and newborn screening Programme Board  Submission of data that shows consistent achievement of the acceptable standard
20	Improve the process for the offer of newborn hearing screening and consent to make sure this is recorded on the SMaRT4Hearing IT system	Newborn hearing screening programme (NHSP) operational guidance 2019  NHS screening	3 months	High	Process change described in local guideline  Ratified via local governance process and presented to the Programme



No.	Recommendation	Reference	Timescale	Priority	Evidence required
		service specification No. 20 (2018 to 2019)			Board
21	Improve timeliness of data entry into SMaRT4Hearing to make sure data is complete	Newborn hearing screening programme (NHSP) operational guidance 2019  NHS screening service specification No. 20 (2018 to 2019)	3 months	Standard	Process change described in local guideline  Ratified via local governance process and presented to the Programme Board  Data reports presented to the local screening meeting

### Newborn and infant physical examination

No.	Recommendation	Reference	Timescale	Priority	Evidence required
22	Implement and monitor a plan to consistently meet the acceptable level for key performance indicator NP2 (timely assessment of DDH)	Newborn and infant physical examination programme standards (2018)  NHS screening service	12 months	Standard	Improvement plan agreed and monitored by the antenatal and newborn screening Programme Board  Submission of data that shows consistent achievement of the

No.	Recommendation	Reference	Timescale	Priority	Evidence required
		specification No. 21 (2018 to 2019)			acceptable standard
23	Appoint a clinical lead to support the newborn and infant physical examination screening programme	NHS screening service specification No. 21 (2018 to 2019)	3 months	High	Evidence of appointment via local governance process  Report to Programme Board
24	Implement a process to record outcomes for all screened conditions using SMaRT4NIPE	NHS screening programmes service specifications 21 (2018 to 2019)	12 months	Standard	National reporting from SMaRT4NIPE showing outcome data  Data consistently presented to the local screening meeting and Programme Board

### Newborn blood spot screening

No recommendations were identified in this section

## 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.