



Public Health  
England

# **Screening Quality Assurance visit report**

**NHS Antenatal and Newborn Screening  
Programmes Chesterfield Royal Hospital  
NHS Foundation Trust**

21 and 22 May 2018

## About Public Health England

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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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# Contents

About Public Health England	2
About PHE Screening	2
Scope of this report	4
Executive summary	6
Recommendations	9

## Scope of this report

	<b>Covered by this report?</b>	<b>If 'no', where you can find information about this part of the pathway</b>
<b>Underpinning functions</b>		
<b>Uptake and coverage</b>	Yes	
<b>Workforce</b>	Yes	
<b>IT and equipment</b>	Yes	
<b>Commissioning</b>	Yes	
<b>Leadership and governance</b>	Yes	
<b>Pathway</b>	Yes	
<b>Cohort identification</b>	Yes	
<b>Invitation and information</b>	Yes	
<b>Testing</b>	Yes	Sheffield Teaching Hospitals NHS Foundation Trust for Down's syndrome, Edwards' syndrome and Patau's syndrome screening QA Report February 2015 Sheffield Children's NHS Foundation Trust for newborn blood spot screening QA report February 2015
<b>Results and referral</b>	Yes	Sheffield Children's NHS Foundation Trust for newborn blood spot

		screening QA report February 2015 Sheffield Teaching Hospitals NHS Foundation Trust for Down's syndrome, Edwards' syndrome and Patau's syndrome screening QA Report February 2015
<b>Diagnosis</b>	Yes	
<b>Intervention/ treatment</b>	Yes	Sheffield Children's NHS Foundation Trust for newborn blood spot screening QA report February 2015 Sheffield Teaching Hospitals NHS Foundation Trust for Down's syndrome, Edwards' syndrome and Patau's syndrome screening QA Report February 2015

## 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 Chesterfield Royal Hospital NHS Foundation Trust screening service on 21 and 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 Public Health England screening quality assurance service (PHE 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 collected during pre-review visits
- information shared with the East Midlands regional SQAS as part of the visit process

### Local screening service

Chesterfield Royal Hospital NHS Foundation Trust offer all 6 antenatal and newborn screening programmes.

In 2016 to 2017, there were 3,086 women booked for delivery and there were 2,933 babies born.

The Trust provides laboratory services for sickle cell and thalassaemia screening and infectious diseases in pregnancy screening.

Down's syndrome, Edwards' syndrome and Patau's syndrome screening is provided by Sheffield Teaching Hospitals NHS Foundation Trust. Sheffield Children's NHS Foundation Trust provides newborn blood spot screening laboratory services.

Child health information services are provided by NHS Arden and Greater East Midlands Commissioning Support Unit.

Clinical genetics services are provided by Sheffield Children's NHS Foundation Trust.

NHS England (Midlands & East - North Midlands) is the lead commissioner for the antenatal and newborn screening programmes. Maternity services are commissioned by North Derbyshire, Hardwick and Erewash CCGs.

## Findings

This is the second antenatal and newborn screening programmes QA visit to Chesterfield Royal Hospital NHS Foundation screening services. The first visit took place in March 2014

At the time of this visit there were 3 outstanding recommendations from the initial visit, these related to:

- lack of a Trust operational steering group
- archiving ultrasound images from screening in association with the reports
- updating newborn screening guidelines

The visiting team commented that the service was delivered by an enthusiastic staff who were open to sharing information and service improvement.

## Immediate concerns

No immediate concerns were identified by the QA visit team.

## High priority

The QA visit team identified 4 high priority findings as summarised below:

- there is no Trust operational steering group to provide clinical oversight to antenatal and newborn screening programmes - this is an outstanding recommendation from the last QA visit
- 3 out of 4 ultrasound machines in use are showing signs of image deterioration
- when a pregnancy is 'at risk' of a significant haemoglobin disorder there is a lack of staff who are trained in an approved counselling course

- the teams providing newborn bloodspot screening and newborn hearing screening were not notified promptly when a baby dies, which increases the risk that parents could be contacted inappropriately

## Shared learning

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

- good evidence of feedback to staff and learning from incidents through community and clinic meetings and via newsletters and staff e mail updates
- evidence of an audit plan with a number of screening audits undertaken since 2016
- sharing of the Newborn Hearing Screening Programme (NHSP) user survey with maternity colleagues and other stakeholders through 'you said, we did' notice boards
- clear and effective hepatitis B pathway in place, developed by NHS England to make sure all babies who require vaccination complete the pathway



## Recommendations

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

### Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1	Make sure there are commissioning arrangements in place for newborn hearing screening, provision of invasive testing services and infectious diseases screening referral laboratories (for confirmatory testing)	Service specifications Nos. 15, 16 and 20	6 months	Standard	Commissioning/and subcontracting arrangements documented and confirmed at the programme board
2	<p>Review the programme board to make sure:</p> <ul style="list-style-type: none"> <li>the terms of reference reflect the current function</li> <li>the minutes accurately record attendance and the names and roles of those attending</li> <li>comments are attributed to the person and organisation they represent</li> <li>performance reports are integrated into the minutes</li> <li>the membership and invitation to attend includes all programme stakeholders</li> <li>review the location of the programme board to make sure senior leaders can attend to provide assurance on the key aspects of the local programmes</li> </ul>	<p>Service specification</p> <p>PHE Review of Centre Screening and Immunisation Functions</p>	6 months	Standard	<p>Revised terms of reference</p> <p>Revised meeting minutes</p>

No.	Recommendation	Reference	Timescale	Priority	Evidence required
3	Establish new working arrangements to enable closer public health leadership and oversight of screening quality, failsafe and service provision. These arrangement should directly link into the programme board governance arrangements	Service specification  PHE Review of Centre Screening and Immunisation Functions	6 months	Standard	Working arrangements documented and confirmed at the programme board
4	Review staffing in the screening team to make sure there is: <ul style="list-style-type: none"> <li>• appropriate failsafe and administrative support</li> <li>• adequate cover to manage the screening programmes</li> <li>• timely reporting and response to requests for information</li> </ul>	Service specifications Nos. 15 to 21	6 months	Standard	Deputy, cover and administrative roles and responsibilities are identified in job descriptions and in screening pathways

No.	Recommendation	Reference	Timescale	Priority	Evidence required
5	Establish a Trust operational screening group to make sure there is clinical oversight and governance of the antenatal and newborn screening services.	Service specifications Nos. 15 to 21	9 months	High	<p>Terms of reference, which includes:</p> <ul style="list-style-type: none"> <li>• membership</li> <li>• the Trust director responsible for the antenatal and newborn screening programmes</li> <li>• clinical leads for each programme</li> <li>• governance and reporting lines to the Trust board</li> <li>• frequency of meetings</li> <li>• review of risks and escalation of issues within the Trust, to commissioners and the screening quality assurance service</li> </ul> <p>Minutes of 3 meetings which demonstrate quoracy and effective terms of reference</p>

No.	Recommendation	Reference	Timescale	Priority	Evidence required
6	<p>Develop or update screening guidelines and standard operating procedures (SOPs) to reflect programme standards for:</p> <ul style="list-style-type: none"> <li>• first and second trimester fetal anomaly screening</li> <li>• ultrasound scanning in fetal anomaly screening</li> <li>• sickle cell and thalassaemia screening (SCT)</li> <li>• infectious diseases in pregnancy screening (IDPS)</li> <li>• newborn hearing screening programme (NHSP)</li> <li>• newborn blood spot screening (NBS)</li> <li>• Child Health Record Department (CHRD) pathways</li> </ul>	<p>Service specifications Nos. 15 to 20</p>	<p>12 months</p>	<p>Standard</p>	<p>Updated and guidelines ratified to:</p> <ul style="list-style-type: none"> <li>• include a failsafe to identify lost Fetal Anomaly Screening Programme (FASP) samples quickly</li> <li>• include pathways for notifying positive results and unsuitable samples to screening coordinator and deputy</li> <li>• who to contact in the screening coordinator's absence</li> <li>• include in NHSP guideline that home visits should be risk assessed</li> <li>• include a SOP for receipt and bulk upload of results to the electronic patient record</li> <li>• include the day of sample for NBS is day 5</li> <li>• include review dates in CHRD SOPs</li> <li>• be recorded in the programme board minutes as published</li> <li>• be reviewed annually</li> <li>• be uploaded onto Q-Pulse</li> </ul>

No.	Recommendation	Reference	Timescale	Priority	Evidence required
7	Audit the antenatal and newborn screening records to demonstrate compliance with antenatal and newborn screening guidelines	Service specifications Nos. 15 to 21	9 months	Standard	Audit repeated and completed by March 2019  Summary of the audit findings and action plan monitored at programme board
8	The Screening and Immunisation Team should lead the development of a screening inequalities action plan. The plan should: <ul style="list-style-type: none"> <li>• be linked into the Derbyshire Maternity Transformation Programme Board</li> <li>• look at the women who do not access early maternity care to reduce inequalities in access to screening</li> </ul>	Service specification Nos. 15-18  Guidance for NHS Commissioners on equality and health inequality duties 2015  NHS Accessible Information standard and specification	9 months	Standard	Summary of audit, findings and action plan monitored at programme board
9	There should be an audit schedule for the sickle cell and thalassaemia screening laboratory  This should include an audit of the pathway from receipt of sample in the laboratory to issuing of result	SCT laboratory handbook	6 months	Standard	Audit schedule  Summary of audits, findings and action plan monitored at programme board

No.	Recommendation	Reference	Timescale	Priority	Evidence required
10	Complete a user survey for ultrasound services to gather views about the antenatal and newborn screening pathways to improve standards	Service specifications Nos. 16 and 17	9 months	Standard	Summary of survey findings and evidence of actions taken monitored at programme board

## Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
11	Update the screening support sonographer (SSS) and deputy SSS job descriptions to include the functions of the role and include protected time to undertake them	Service specification No 16  FASP Handbook for ultrasound practitioners April 2015	6 months	Standard	Revised job descriptions

No.	Recommendation	Reference	Timescale	Priority	Evidence required
12	<p>Make sure all laboratory staff involved in the screening pathways complete the training requirements</p> <p>Update the sickle cell and thalassemia laboratory training competencies to include:</p> <ul style="list-style-type: none"> <li>• communication with the screening coordinator or deputy</li> <li>• the system to identify when testing of the baby's father is required</li> </ul> <p>Update the microbiology laboratory training competencies to include the antenatal screening pathway</p>	<p>Service specifications No. 15 and 18</p> <p>SCT Lab handbook</p> <p>IDPS lab handbook</p>	9 months	Standard	<p>Completed training logs presented to programme board for all involved staff</p> <p>Updated training competencies</p>
13	<p>Undertake a risk assessment of the continued use of ultrasound machines where pixilation of images has been noted to make sure the machines are capable of producing images of appropriate diagnostic quality</p>	<p>Service specification No 16</p> <p>FASP Handbook for ultrasound practitioners April 2015</p>	1 month	High	<p>Completed risk assessment is shared with commissioners for review in contracting processes</p> <p>Image quality monitoring and machine replacement progress reported through the programme board</p>

### Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority	Evidence required
14	Provide a link to NHS Choices for information about antenatal and newborn screening on the Trust website	Service specifications Nos. 15 to 21	3 months	Standard	Link available on the website

### Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority	Evidence required
15	Review the NIPE pathway to make sure that each baby who is not examined with the 72 hour timeframe is accounted for	Service specification No. 21	6 months	Standard	Review and actions required presented to the screening programme board  All eligible babies accounted for  The reasons for delayed examinations are given in the explanatory notes
16	Implement a process for notifying key stakeholders about deceased babies (including updating the baby's status as deceased on the screening IT systems)	Service specifications Nos. 19, 20, 21	3 months	High	Standard operating procedure for the notification of deceased babies with roles and responsibilities clearly outlined in both CHRD and hospital SOP  CHRD deceased baby SOP includes a list of who should be informed



No.	Recommendation	Reference	Timescale	Priority	Evidence required
17	Review KPI NB4 (coverage: movers in) to make sure that the eligible population (denominator) and the number of tested babies (numerator) are correctly reported	NBS standard 1b	6 months	Standard	KPI NB4 data accurately reported and supporting comments by CHRD explain why eligible babies were not screened

Invitation, access and uptake – see recommendations 6, 7 and 14

### Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
18	Implement and monitor a plan to meet KPI ST3 (completion of family origin questionnaire)	Service specification No. 18 SCT standard 3	9 months	Standard	Action plan that is agreed and monitored by programme board Submission of KPI data - ST3
19	Develop a standard operating procedure for samples sent away for confirmatory testing which covers: <ul style="list-style-type: none"> <li>tracking samples</li> <li>monitoring and reporting turnaround times</li> <li>following up outstanding results</li> </ul>	Service specification No. 18	6 months	Standard	Standard operating procedure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
20	<p>Undertake a risk assessment and implement failsafes for the processing of sickle cell and thalassemia samples to include:</p> <ul style="list-style-type: none"> <li>• when a sample is sent for testing, it is received, tested and a result issued with the specified turnaround time</li> <li>• information missing from FOQs are followed up promptly and do not delay a screening result being issued</li> <li>• repeat sample requests are received</li> </ul>	<p>Service specification No. 18</p> <p>SCT standard 4</p>	6 months	Standard	<p>Risk assessment and action plan that is agreed and monitored by programme board</p> <p>Audit of turnaround times</p> <p>The failsafes should be documented in a standard operating procedure</p>
21	Revise reports to meet recommended formats	<p>Service specification No 18</p> <p>SCT laboratory handbook</p>	6 months	Standard	Revised reports meet programme recommended formats
22	Implement and monitor a plan to meet screening test turnaround times	<p>Service specification No. 18</p> <p>SCT antenatal laboratory handbook</p> <p>SCT standard 4</p>	6 months	Standard	Action plan that is agreed and monitored by programme board

No.	Recommendation	Reference	Timescale	Priority	Evidence required
23	Make sure that women who have an 'at risk' pregnancy are only counselled by appropriately trained staff	Service specification No. 18	3 months	High	Pathway identifies counselling arrangements including absence cover

### Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
24	Develop a standard operating procedure for the screening pathway from receipt of sample in the laboratory to issuing of result and includes specimen storage	Service specification No. 15	6 months	Standard	Standard operating procedure
25	Monitor the test turnaround times for IDPS samples sent to reference laboratory to make sure they meet the acceptable standard	Service specification No.15 IDPS standard 4	9 months	Standard	Summary of turnaround times and action plan if needed monitored by programme board

### Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
26	Include the SSS and deputy in the membership of the perinatal meeting	Service specification No. 17	3 months	Standard	Revised membership and minutes show attendance

## Newborn hearing screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
27	Hearing screeners must use the translator required field in SMART4Hearing (S4H) information system	Service specification No. 20  NHSP operational guidance	3 months	Standard	NHSP trained to use S4H translator required field
28	Make sure the screening manager has full access rights to S4H	Service specification No. 20  NHSP operational guidance	3 months	Standard	The team manager has access rights to all S4H modules
29	Implement and monitor a plan to meet: <ul style="list-style-type: none"> <li>• KPI NH1 (coverage)</li> <li>• KPI NH2 (timely assessment for referrals)</li> </ul>	Service specification No. 20  NHSP standard 1 & 5	6 months	Standard	Action plan that is agreed and monitored by programme board  KPIs NH1 and NH2 are met
30	Implement and monitor an improvement plan that develops performance towards an achievable rate for standard 2 AOAE1	NHSP standard 2	6 months	Standard	Action plan that is agreed and monitored at programme board

## Newborn and infant physical examinations - see recommendations 6 and 15

### Newborn blood spot screening

No.	Recommendation	Reference	Timescal	Priority	Evidence required
31	Investigate the data supplied by the laboratory for standard 3 (use of barcoded labels) standard 4 (taking sample on day 5) and standard 5 (timely receipt of sample into laboratory) to make sure standards are met	NBS standards 3, 4 and 5	9 months	Standard	Summary of the audit findings and action plan monitored at programme board
32	Make sure result letters are sent by CHRD to all parents including where one result is suspected or the baby is too old for cystic fibrosis screening	Service specification No. 19	9 months	Standard	Letters reviewed by programme board and system in place to send them

## 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.