



Public Health
England

Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening Programmes Luton and Dunstable University Hospital NHS Foundation Trust

12 and 13 July 2017

Public Health England leads the NHS Screening Programmes

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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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Executive summary

Antenatal and newborn screening quality assurance (QA) 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 and families with screen-positive results), or the completion of the screening pathway.

The findings in this report relate to the QA visit of the Luton and Dunstable University Hospital NHS Foundation Trust screening service held on 12 and 13 July 2017.

Purpose and approach to quality assurance

QA aims to maintain national standards and promote continuous improvement in antenatal and newborn 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.

The evidence for this report comes from the following sources:

- routine monitoring of 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 East Midlands regional screening QA service as part of the visit process

Description of local screening service

Luton and Dunstable University Hospital NHS Foundation Trust offers all 6 antenatal and newborn screening programmes. Antenatal and postnatal care is provided at Luton and Dunstable University Hospital NHS Foundation Trust.

From 2015 to 2016, 6,367 women were booked for delivery and there were 5,342 births (1).

Luton and Dunstable University Hospital NHS Foundation Trust provide laboratory services for the infectious diseases in pregnancy and sickle cell and thalassaemia screening programmes.

Regional laboratory services for Down's, Edwards' and Patau's syndromes screening are provided by Birmingham Women's and Children's Hospital NHS Foundation Trust. Great Ormond Street Hospital for Children NHS Foundation Trust provides newborn blood spot screening laboratory services.

Cambridge Community Services NHS Trust (CCS) provide newborn hearing screening services.

NHS England (Midlands and East - Central Midlands) is the lead commissioner for the antenatal and newborn screening programmes. Co-commissioning arrangements are in place with Luton Clinical Commissioning Group.

Findings

This is the first QA visit to this service.

Immediate concerns

The QA visit team identified no immediate concerns.

High priority

The QA visit team identified 11 high priority findings summarised below:

- resources for antenatal sonography should be reviewed to ensure that PHE requirements are met (see recommendations 3 and 17)
- the Trust's incident policies need updating to reflect 'Managing safety incidents in NHS Screening Programmes' national guidance and embedded in practice (see recommendation 4)
- a risk assessment should be completed for laboratory aspects of sickle cell and thalassaemia screening (see recommendation 5)
- the processes for antenatal samples sent to reference labs need to be strengthened (see recommendation 6)
- the haematology laboratory audit schedule needs updating (see recommendation 12)
- communication and collaboration between the newborn hearing screening team and maternity service should be improved (see recommendation 13)
- better connectivity and interfaces between all the different IT systems would support cohort tracking and data accuracy (see recommendations 18 and 27)
- preparations for haematology laboratory UK Accreditation Service (UKAS) assessment should include mapping screening services against relevant ISO standards (see recommendation 31)

- aliquots of infectious diseases in pregnancy screening samples should be stored for at least 2 years (see recommendation 33)

Shared learning

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

- collaborative, responsive working between NHS England, screening QA service and Luton and Dunstable University Hospital NHS Foundation Trust
- Datix reporting system includes 'screening' as a locality which facilitates review and identification of screening safety incidents
- Luton and Dunstable University Hospital NHS Foundation Trust completed a review of antenatal and newborn screening against the service specifications and standards in May 2017. Action plans are in progress to address gaps in service provision
- as part of the induction, process maternity staff are supernumerary and work for 1 week in all maternity clinical areas including clinics, fetal medicine, screening and community. So that they are aware of antenatal and newborn screening programmes
- user feedback for the maternity aspects of screening informs service delivery and there are a variety of ways to seek feedback
- improvements in the proportion of women who have a sickle cell and thalassaemia screening result by 10 weeks gestation from 14% in 2010/11 quarter 3 to 61.4% in 2016/17 quarter 4
- the proportion of women who book early for their maternity care has increased following a comprehensive equity audit and action plan
- all fetal anomaly screening scans were completed within the required timeframe during 2016/17 quarter 3
- the acceptable standard for newborn blood spot avoidable repeats (NB2) is met (3). The Trust continue to work towards the achievable level. For example, the maternity screening team have made a template tool to show the size of sample required which all sample takers can attach to their ID badge lanyards

Table of consolidated recommendations

The recommendations are listed in the order that they appear in the report.

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
1	Ensure that all stakeholders who contribute to the screening pathways participate in the NHS England screening programme board	Service specifications (4-10)	6 months	S	Meeting notes demonstrate representation from the microbiology and haematology laboratories
2	Revise documentation for the NHS England screening programme board to ensure that all issues and risks that affect the screening pathways are recorded clearly	Service specifications (4-10)	6 months	S	Meeting notes Risk register
3	Ensure sufficient time and resource allocation for the screening support sonographer and deputy to perform the specified supervision and support functions	Service specification (5) Programme handbook (11)	3 months	H	Screening support sonographer and deputy have dedicated time to meet role requirements

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
4	Revise the Luton and Dunstable University Hospital NHS Foundation Trust incident policy to reflect 'Managing safety incidents in NHS Screening Programmes'. Ensure the policy and the guidance it contains is known to staff and embedded in local practice	National guidance (12)	3 months	H	Ratified policies meet requirements described in national guidance
5	Complete risk assessment process and documentation for the laboratory aspects of sickle cell and thalassaemia screening	Service specification (7) Laboratory handbook (13)	3 months	H	Relevant documentation available on Q-Pulse system: Uploaded risk assessment, completed audits, service logs, validation and verification data and internal quality control checks to the Q-Pulse system
6	Complete laboratory risk assessment for antenatal screening samples that are sent to reference and regional laboratories and implement tracking systems	Laboratory handbook (13)	3 months	H	Relevant documentation available on Q-Pulse system: Laboratory sample tracking process in place for sickle cell and thalassaemia, infectious diseases in pregnancy and combined and quadruple screening test samples

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No.	Recommendation	Reference	Timescale	Priority *	Evidence required
7	Update the laboratory standard operating procedure for sickle cell and thalassaemia screening	Service specification (7) Laboratory handbook (13)	6 months	S	Standard operating procedure ratified and uploaded to Q-Pulse
8	Update the microbiology laboratory standard operating procedures for quality control and quality assurance and the internal disaster management plan	Service specification (4) Laboratory handbook (14)	6 months	S	Standard operating procedure and plan ratified and uploaded to Q-Pulse
9	Update the newborn blood spot screening guidelines to improve accessibility and ease of use for all staff	Programme standards (15) Programme guidelines (16)	6 months	S	Ratified guidelines include pathways that allow clear step by step guidance for all staff
10	Ensure the Trust screening steering group maintains appropriate membership, meets regularly and takes action to improve the performance and quality of the screening programmes	Service specifications (4-10)	6 months	S	Terms of reference, agendas and meeting notes demonstrate regular meetings, appropriate membership and improvement action eg actions are followed up and screening incidents are reviewed

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
11	Develop an action plan which includes a repeat audit of maternity notes	Service specifications (4-10)	12 months	S	Audit schedule. Action plan progress presented at screening programme board
12	Update the haematology audit schedule and ensure audits are completed	Service specification (7) Laboratory handbook (13)	3 months	H	Relevant documentation available on Q-Pulse system
13	Improve communication and collaboration between the newborn hearing screening team and maternity service	Service specification (9)	3 months	H	Newborn hearing screening team included in membership of Trust screening steering group and relevant 'Better Births' work streams. Systematic process to identify babies who are eligible for newborn hearing screening
14	Ensure that sonographers participate in relevant multi-disciplinary review meetings	Service specifications (5, 6)	6 months	S	Meeting notes
15	Develop ways to capture user feedback about the antenatal ultrasound screening service or include it in other mechanisms used to capture feedback about the screening programmes	Service specifications (5, 6)	12 months	S	User feedback mechanisms implemented and audit action plans facilitated to improve services

Infrastructure

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
16	Review service provision for the newborn physical examination to ensure that there are enough midwife NIPE examiners to support the screening programme. So that at least 95% of eligible babies are examined within 72 hours (NP1)	Service specification (10) Programme handbook (17)	6 months	S	Plan to increase number of midwife NIPE examiners identifies: <ul style="list-style-type: none"> • details of university which midwives will attend • the number of midwives who will complete the examination of the newborn module • funding
17	Complete a risk assessment to identify the impact of the recently adopted care bundle on antenatal ultrasound screening service provision	Service specifications (5, 6)	3 months	H	Completed risk assessment and mitigation of any identified risks
18	Review and monitor the connectivity and interfaces between all the different IT systems used for antenatal and newborn screening programmes at the Trust to improve cohort tracking and data accuracy	Key Performance Indicators (3) Service specifications (4-10, 19)	6 months	H	Project plan prepared and business case presented for consideration during 2017/18. Assurance that all women complete the screening pathways

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
19	Complete plans to replace laboratory equipment	Service specifications (4, 7)	12 months	S	Procurement process for antenatal screening laboratory analysers complete
20	Define the time interval for maintenance of haematology laboratory analysers	Service specification (7)	6 months	S	Relevant documentation available on Q-Pulse system
21	Formalise business continuity plans for the haematology and microbiology laboratories. The plans should detail: <ul style="list-style-type: none"> • minimum staffing levels required to deliver laboratory aspects of the screening pathways • maintenance of turnaround times so that at least 90% of sickle cell and thalassaemia screening samples are reported within 3 working days 	Service specifications (4, 7) Laboratory handbooks (13, 14)	6 months	S	Business continuity plans uploaded to laboratory quality management system. Risk assessment details minimum staffing requirements. Acceptable threshold for sickle cell and thalassaemia standard 4 met.
22	Implement quality assurance testing of ultrasound machines by sonographers	Service specifications (5, 6) Guidelines (18)	3 months	S	Records of testing maintained and available as appropriate
23	Provide suitable equipment for antenatal screening scans	Service specifications (5, 6)	3 months	S	Ultrasound couches and paper roll holders replaced

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
24	Identify authorised users to run reports from e-learning for Healthcare	Service specifications (4-8, 10)	6 months	S	Accurate records for maternity staff and sonographers completion of antenatal and newborn screening e-learning modules available
25	Ensure all sonographers who undertake antenatal screening scans are registered users of the e-learning for Healthcare website	Service specifications (5, 6) Programme handbook (11)	6 months	S	Records of completion of e-learning modules available

Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
26	Assess the impact of population changes on services that provide antenatal and newborn screening	Service specifications (4-10)	12 months	S	Completed review and action plan to address impact on screening services
27	Develop processes with the laboratories to make sure that screening is offered, performed and results are received for every woman and data collection is facilitated	Service specifications (4, 7)	6 months	H	Accurate data submissions which account for all eligible women

Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
28	Issue personal child health records to families at birth	Service specification (10)	6 months	S	Personal child health record issued at birth. Birth details, newborn physical examination and first dose of the hepatitis B immunisation schedule recorded in personal child health record
29	Improve communication about newborn screening tests and make sure that the newborn hearing screening team are included in communication when a baby has died	Service specifications (9, 17, 40)	3 months	S	Newborn screening tests recorded in maternity care records and discharge summary. End of life pathways include communications with the newborn hearing screening team and cover arrangements for weekends and bank holidays

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
30	Improve information for women wishing to book for maternity care so that it is easily accessed from the hospital website, along with translation services and information about antenatal and newborn screening	Service specifications (4-7)	6 months	S	User feedback informs website design. Website is accessible to women and includes information about screening programmes

Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
31	Map screening services against ISO standards to prepare for haematology laboratory UKAS visits	Service specification (7)	3 months	H	Service mapping against relevant ISO standards
32	Take action so that all biological fathers (where the women is found to be a carrier of a haemoglobin variant) are offered screening in every pregnancy	Service specification (19) Standards (20)	3 months	S	Action plan agreed and monitored by programme board. Audit report demonstrates all women and relevant fathers are offered screening in every pregnancy

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
33	Store aliquots of infectious diseases in pregnancy screening samples for at least 2 years	Laboratory handbook (14)	3 months	H	Standard operating procedure ratified and uploaded to QPulse. Samples stored for at least 2 years
34	Set up systems in the laboratory to identify antenatal samples so that a result is available for at least 95% of infectious diseases in pregnancy screening samples within 8 working days of sample receipt	Standards (21)	12 months	S	Laboratory data reporting details antenatal screening samples. Acceptable threshold for standard 4 met
35	Record HIV screen positive results in maternity care records so they are easy to understand	Clinical guidance (42)	6 months	S	HIV screen positive results recorded explicitly in maternity care records with women's consent
36	Take action so that all women who are screen positive for syphilis or Hepatitis B are seen by the multi-disciplinary team within 10 working days	Standards (21)	3 months	S	Action plan agreed and monitored by programme board. Acceptable threshold for standards 5b and 5c met

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
37	Review current process for giving women information about the combined screening test before their ultrasound scan so they can make an informed choice	Service specification (5)	3 months	S	User feedback. Sonographer feedback. Report produced with action plan as appropriate
38	Record Down's, Edwards' and Patau's syndrome screening results in the maternity hand held care record	Service specification (5)	3 months	S	Notes audit demonstrates results recorded
39	Ensure that at least 97% of women with a high risk Down's, Edward's or Patau's syndrome screening result and/or suspected or confirmed scan abnormality have an appointment to discuss their results within 3 working days of the result being reported to maternity services	Standards (21)	6 months	S	Action plan agreed and monitored by programme board. Acceptable threshold for standards 7 and 8 met Annual data submission

Newborn and infant physical examination

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
40	Implement and monitor a plan to meet NP2 (timely assessment of developmental dysplasia of the hips)	Key performance indicators (3) Programme handbook (17)	3 months	S	Submission of KPI data- NP2 excludes babies with 'clicky hips' on examination who do not have risk factors

Newborn blood spot screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
41	Take action so that least 90% of blood spot cards include a barcoded label with the baby's NHS number	Standards (15)	6 months	S	Action plan agreed and monitored by programme board. Newborn Screening Laboratory Quarterly report. Annual data submission
42	Ensure that at least 90% of first blood spot samples are taken on day 5	Standards (15)	6 months	S	Action plan agreed and monitored by programme board. Newborn Screening Laboratory Quarterly report. Annual data submission
43	Make sure that at least 95% of blood spot samples are received by the laboratory within 3 working days	Standards (15)	6 months	S	Action plan agreed and monitored by programme board. Newborn Screening Laboratory Quarterly report. Annual data submission

*I = Immediate.
H= High.
S = Standard.

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.

The screening QA service will work with commissioners to monitor activity/progress in response to the recommendations made for a period of 12 months following the issuing of the final report. After this point, the screening QA service will send a letter to the provider and the commissioners summarising the progress made and will outline any further action(s) needed.