Public Health England

NHS

Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening Programmes East Lancashire Hospitals NHS Trust

9 and 10 November 2016

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 four 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/families with screen-positive results), or the completion of the screening pathway.

The findings in this report relate to the quality assurance (QA) visit of the East Lancashire Hospitals NHS Trust (ELHT) screening service held on 9 and 10 November 2016.

Purpose and approach to quality assurance (QA)

Quality assurance 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 (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 SQAS North as part of the visit process
- Key Performance Indicators (KPIs) for the period quarters 1 to 4, 2015 to 2016

Description of local screening service

East Lancashire Hospitals NHS Trust (ELHT) provides all six antenatal and newborn screening programmes across three principle sites: Burnley (Lancashire Women's and Children's Centre at Burnley hospital site), Blackburn and Rossendale, along with a number of clinic venues in the community.

During 2015 to 2016, 7212 women booked for delivery. Total deliveries recorded (including live births/stillbirths) were 6457. The infant mortality rate is higher than the England average, within the top 105 in England [4]. 65% of expected infant deaths in the first year of life are due to genetic, chromosomal or congenital abnormalities [5].

NHS England North (Lancashire) are the lead commissioner for antenatal and newborn screening. Commissioning arrangements are in place with NHS East Lancashire CCG

and Blackburn with Darwen CCG for the Maternity Payment Pathway (MPP) [6]. East Lancashire Hospital Trust is within the Lancashire and South Cumbria footprint for the Sustainability and Transformation Plan - 5 Year Forward View.

East Lancashire Hospitals NHS Trust (ELHT) provides the following parts of the antenatal and newborn screening pathway:

- Sickle Cell and Thalassaemia Screening Programme (SCT) laboratory, is designated a high prevalence Trust for SCT.
- Infectious Diseases in Pregnancy Screening Programme (IDPS) laboratory
- offer of pre-natal diagnosis with referral pathway into tertiary centres
- mid pregnancy scan for Fetal Anomaly Screening (FASP) at Burnley, Blackburn and Rossendale sites
- Newborn Infant Physical Examination (NIPE) is provided at all birth sites including home deliveries

Services that interface with ELHT:

- antenatal Down's, Edward's and Patau's syndrome screening risk assessment is provided by the Screening Laboratory situated within Bolton NHS Foundation Trust
- Newborn Blood Spot (NBS) Screening sample analysis is provided by the Manchester Newborn Blood Spot Screening laboratory at Central Manchester Foundation Trust
- pathways are in place for pre-natal diagnosis and post-natal care at the tertiary referral centre at St Mary's Hospital Manchester (Central Manchester Foundation Trust) and Liverpool Women's Hospital, joint with Cardiology at Alder Hey Children's Hospital
- Newborn Hearing Screening Programme (NHSP) for the East Lancashire Site is co-terminus with the population served by ELHT
- Child Health Records Department (CHRD) is hosted by Blackpool Teaching Hospitals NHS Trust

Findings

This is the first QA visit to this service. This antenatal and newborn screening service is a woman and family focussed service with a strong ethos for quality improvement. It is delivered by a team which is motivated and works well across all disciplines. The commitment to address areas falling short of standards, maintain patient safety and drive programme quality was clearly evident.

Immediate concerns

The QA visit team identified no immediate concerns.

High priority

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

- no evidence of a Trust ANNB Screening Programme Oversight Group
- no process for appropriate sign off of data before it leaves the Trust
- failure to manage screening safety incidents according to national guidance
- failure to manage and escalate risk appropriately
- no overarching SOP in the laboratories for antenatal screening process
- no provision of an antenatal IT system that can provide auditable cohort data, no auditable systems to track all babies eligible for NIPE
- failure to report accurately on KPI ST3 and NP2 (completion of Family Origin Questionnaire and referral of screen positives)
- health visiting (HV) does not ensure offer of NHSP for babies under 3 months moving in
- no system in place to audit referrals of screen positives for NIPE
- trust does not send NBS samples directly to NBS laboratory, but adds internal quality control

Shared learning

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

- active monitoring to ensure women identified as hepatitis B positive attend referral, evidenced by 100% attendance
- promotion of early booking and flexibility of antenatal care for ethnically diverse population that consistently exceeds the acceptable standards
- active management across the newborn programme to ensure completion of pathway
- the NIPE clinical lead presents an annual audit of all screen positive outcomes to clinical staff
- the NHSP team have developed new ways of making the screening offer more acceptable, convenient, and family friendly
- microbiology laboratory audit TATs for reporting screen positives to the multi-disciplinary team
- use of pictoral aids by midwives to support informed consent
- health visiting service monitoring of delivery of NBS results by the HV within an effective timeframe
- actively seeking and sharing user feedback via a Facebook group
- consistent action on staff training, prioritisation of update attendance and provision of new training materials

Table of consolidated recommendations

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
1	Formalise the SLA with Preston Haematology to ensure business continuity	12	12 months	S	SLA and business continuity plan
2	Establish a Trust Antenatal and Newborn Screening Programme Oversight Group with representation from all key stakeholders	9, 10, 11, 12, 13, 14, 15	3 months	H	Terms of reference, minutes of meeting monitor attendance
3	Develop an agreed process for sign off of data leaving East Lancashire Hospital Trust	9, 10, 11, 12, 13, 14, 15	3 months	H	Assurance of accurate data submissions. Trust ANNB Oversight Group ratification of data
4	Ensure compliance with Managing Safety Incidents in NHS Screening Programmes	8	3 months	H	Appropriate reporting and management of incidents
5	Assurance that risks to the antenatal and newborn screening are captured on the Trust Risk Register	9, 10, 11, 12, 13, 14, 15	3 months	H	Risk register example with evidence of escalation and management.
6	Review and update all policies, guidelines and operating procedures in line with service specifications and standards	9, 10, 11, 12, 13, 14, 15	6 months	S	Updated policies, guidelines and operating procedures ratified and available to staff

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
7	Laboratories to develop an overarching protocol that includes managing samples sent away, turnaround times, and reporting of incidents	9, 12, 16, 17,	6 months	S	Screening specific operating procedure ratified and available to staff
8	Develop and implement an annual audit schedule including all antenatal and newborn screening programmes	9, 10, 11, 12, 13, 14, 15	6 months	S	Annual audit schedule Audit examples from antenatal and new born screening programmes
9	Review accesibility to translation services and take action to to address any gaps	9, 10, 11, 12, 13, 14, 15	6 months	S	Translation service accessibility review with action plan monitored through antenatal and newborn oversight group.
10	Complete an annual user satisfaction survey and take action to address findings	9, 10, 11, 12, 13, 14, 15	6 months	S	Outcome from feedback reported. Action plan monitored through antenatal and newborn oversight group

Infrastructure

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
11	Screening Midwives to undertake the approved genetic risk and counselling course	18	12 months	S	Satisfactory completion of the accredited training
12	To provide assurance that EMIS Child Health Information Systems module meets the Child Health Service Specification	7	12 months	S	Assurance of benchmarking process from commissioner

Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
13	Progress implementation of the planned antenatal IT system	9, 10, 11, 12, 13, 14, 15	12 months	H	Demonstrable ability to report against all key performance indicators and antenatal and newborn screening standards

Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
14	Audit compliance with newborn key performance indicators and develop an action plan to ensure babies eligible for newborn and infant physical examination complete screening within 72 hours and referrals into treatment are timely	15, 24, 25	3 months	H	Audit activity demonstrates compliance with newborn key performance indicators. Action plan monitored via oversight group

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
15	Undertake annual equity audit and develop an action plan to address any findings	9, 10, 11, 12, 13, 14,15	12 months	S	Findings from equity audits actioned

Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
16	Review the early booking pathway to ensure achievable threshold of key performance indicator for sickle cell and thalassaemia is met	12, 18	12 months	S	Continued improvement of key performance indicator for sickle cell and thalassaemia (ST2), to reach the achievable threshold of ≥75%
17	Progress implementation of an electronic family origin questionnaire	16, 18	12 months	S	Action plan and progress reported through ANNB OG
18	Laboratory to record receipt of incomplete family origin questionnaires so that key performance indicator for sickle cell and thalassaemia (ST3) is accurately reported	16, 18	3 months	H	Accurate reporting of key performance indicator ST3

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
19	Develop a process for reporting screening results that includes notifying women for whom a pregnancy ends early	9, 27, 28	6 months	S	Updated process ratified. Evidence of compliance seen
20	Virology Laboratory to work collaboratively with maternity services to remove barriers to implementation of electronic requesting	9, 17	12 months	S	System of electronic requesting in place with associated failsafe and reporting benefits
21	Laboratory to develop an analytical protocol in biochemistry and put in place a process protocol for virology.	9, 17	6 months	S	Auditable protocols in place
22	Develop a protocol that documents the process for women who present in labour with no results	9, 17, 28	3 months	S	Protocol ratified
23	Child Health Records Department to develop protocol that documents the process for capturing all babies in receipt of hepatitis B immunisation	7, 9, 28	6 months	S	Documented process and compliance monitored

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
24	Progress the planned pilot site agreement for electronic requesting in collaboration with the Bolton Down's Syndrome screening Laboratory, to meet 100% compliance with key performance indicator FA1	10, 19, 29	12 months	S	FA1 achievable threshold met consistently
25	Review the fetal anomaly ultrasound pathway to identify a process for reporting key performance indicator FA2 and ensure women who accept the offer of this scan, complete the scan within the correct timeframe	10, 20, 29	3 months	S	Action plan in place to monitor progress. Ability to report FA2

Newborn hearing screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
26	Child Health Records Department to record results of newborn hearing screening undertaken in line with national child health information systems service specification	7, 14, 22,	12 months	S	Audit of effective capture of newborn hearing screening results for the defined population
27	Update the health visiting service protocol to include the offer of hearing screening to babies without a valid screening result under 3 months of age	14, 22	3 months	H	Revised protocol ratified and audited for compliance

Newborn and infant physical examination

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
28	Ensure processes are in place to submit accurate data to meet key performance indicator NP2 acceptable threshold and annual reporting of all newborn and infant physical examination screen positives is accurate and timely	15, 24, 25	6 months	H	Accurate data submission and improvement in key performance indicator NP2 to acceptable threshold

Newborn blood spot screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
29	Obtain and send samples directly to the newborn blood spot laboratory without internal quality control as detailed in the guidelines	32	3 months	H	Updated protocol in line with guidance; change in practice

I = Immediate
H= High
S = Standard

Next steps

East Lancashire Hospitals NHS Trust is responsible for developing an action plan to ensure completion of 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 following the issuing of the final report. 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.