Public Health England

NHS

Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening Programmes

East Kent Hospitals University NHS Foundation Trust

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG
Tel: 020 7654 8000 www.gov.uk/phe
Twitter: @PHE_uk Facebook: www.facebook.com/PublicHealthEngland

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.

www.gov.uk/phe/screening Twitter: @PHE_Screening Blog: phescreening.blog.gov.uk
For queries relating to this document, please contact: phe.screeninghelpdesk@nhs.net

Published January 2019
PHE publications
gateway number: GW-75

PHE supports the UN
Sustainable Development Goals

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 East Kent Hospitals University NHS Foundation Trust (EKHUFT) screening service held on 9 and 10 October 2018.

This is the second quality assurance visit to the antenatal and newborn screening service at EKHUFT. The service was previously visited in September 2014. 18 of the 33 recommendations made following the first visit remain outstanding and have been identified in the main body of the report.

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 collected during pre-review visits to East Kent Hospitals University NHS Foundation Trust
- information shared with the South East regional SQAS as part of the visit process

Local screening service

The East Kent Hospitals University NHS Foundation Trust (EKHUFT) is one of the largest hospital trusts in England, with 6 hospitals and community clinics serving the local population of Canterbury, Margate, Deal, Folkestone, Dover and Ashford with a population in the region of around 795,000 people. The Trust serves a population living across a large geographical area, in excess of 800 square miles.

Between April 2016 and March 2017, 7720 women booked for maternity care and the trust recorded 6783 births. The local pregnant population is characterised as 76.6% white British, 8.9% other white ethnic background, 2.8% Asian, 0.9% black and 0.7% mixed race. 10.1% of women were recorded as ethnicity unknown. The mean age was 28.5 years (annual report 2015/16). The screening service is commissioned by and on behalf of NHS England South East (Kent, Surrey and Sussex).

Maternity and screening services are provided at EKHUFT and the site provides consultant and low risk midwifery led care.

Services at EKHUFT include:

- maternity services provided across 2 sites; Queen Elizabeth the Queen Mother (QEQM) Hospital in Margate and William Harvey Hospital (WHH) in Ashford
- maternity day care services offered at Buckland Hospital in Dover and at Kent and Canterbury Hospital in Canterbury
- analysis of sickle cell and thalassaemia screening samples at QEQM Hospital in Margate
- analysis of infectious diseases screening samples at WHH in Ashford
- maternity ultrasound services offered at all maternity sites as well as at the Royal Victoria Hospital in Folkestone and the Victoria Hospital in Deal
- fetal medicine specialist services (FM) provided at QEQM Hospital and WHH
- neonatal intensive care unit (NICU) situated in the WHH which accepts babies from 23 weeks gestation and the NICU in QEQM Hospital which accepts babies from 30 weeks gestation
- newborn and infant physical examination (NIPE) and newborn bloodspot screening (NBS) which is performed at all sites and in the community
- newborn hearing service which is a hospital based programme at QEQM Hospital and WHH, with outpatient clinics held in Canterbury and Buckland on a weekly basis for babies who require a further screen or have moved into the area

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 risk calculation of combined and quadruple screening samples provided by the King George Screening Laboratory (Barking, Havering and Redbridge University Hospitals NHS Trust)
- analysis of samples for newborn blood spot screening provided at South East Thames Newborn Screening Laboratory (Guy’s and St Thomas’ NHS Foundation Trust)
- Child health records department (CHRD) managed by Kent Community Health NHS Trust (KCHT), based in Folkestone

Findings

Immediate concerns

Whilst there were no additional immediate concerns raised as part of the QA visit, substantial risks have recently been identified within the antenatal and newborn screening programmes at EKHUFT. These are being addressed as part of serious incident investigations and management processes (PHE incident reference numbers 000208, 000121, 095251-332, 093102-952 and 000167).

High priority

The QA visit team identified 13 high priority findings as summarised below:

- the governance arrangements for screening are unclear
- the antenatal screening steering group has not met in the past year and does not have a senior chairperson
- there is a repetitive theme to incidents suggesting that changes required as a result of incident investigation have not been fully embedded
- the cohort of women who refer to the maternity service is not reconciled against the booked cohort to ensure all women are identified in a timely way
- there are inadequate tracking arrangements to ensure completion of antenatal screening tests
- there is inadequate confirmation of syphilis screen positive results before release to the maternity service
- there is no clear distinction between screening and additional clinical testing which is offered to women within the fetal anomaly screening programme
- women are not offered choice with regard to trisomy screening
- women consenting to combined and quadruple screening do not receive screen negative results within 2 weeks
- women do not receive quadruple screening at the earliest opportunity
- 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

Shared learning

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

- the sickle cell and thalassaemia (SCT) laboratory has devised a bespoke database to collect quarterly statistics and to pre-populate the annual data return
- the maternity service and SCT laboratory review the newborn blood spot screen positive outcomes to close the loop in the pathway
- the SCT laboratory reports rejected samples to the maternity service to facilitate prompt follow up and to ensure a second sample is received
- the maternity app (MOMA) implemented in October 2018 provides information for women during pregnancy and the postnatal period
- the newborn hearing screening programme (NHSP) senior screener has recently received an award for the production of a training tool to support objective structured clinical examination (OSCE)

Recommendations

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

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1	Ensure clear governance arrangements are in place for screening services at EKHUFT	Section 7a service specification no 15-21	3 months	High	Trust governance structure and escalation chart Maternity governance structure to include screening services Radiology governance structure to include screening services
2	Reinstate the screening steering group to include newborn screening in the membership and ensure the meeting is chaired by a senior member of the department	Section 7a service specification no 15-21	3 months	High	Revised terms of reference Agenda Minutes

No.	Recommendation	Reference	Timescale	Priority	Evidence required
3	Ensure completion of action plans resulting from serious incidents and screening safety incidents and share learning amongst healthcare professionals involved in screening	Managing Safety Incidents in NHS Screening Programmes NHS England Serious Incident Framework (2015)	3 months	High	Completion of action plans Dissemination of shared learning at programme boards, through trust mechanisms and at study days
4	Revise the monthly performance report for the sonography service to include actions required	Section 7a service specification no 16 - 17	6 months	Standard	Performance report and action log
5	Embed culture of screening incident reporting to the public health commissioning team and screening quality assurance service	Managing Safety Incidents in NHS Screening Programmes	6 months	Standard	Incidents reported by all screening stakeholders at EKHUFT

No.	Recommendation	Reference	Timescale	Priority	Evidence required
6	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 – 21 Programme handbooks and standards	6 months	Standard	Ratified policies and standard operating procedures for each screening programme
7	Formalise internal meetings for: • sonography • newborn hearing screening programme	Section 7a service specification no 16, 17 and 20	6 months	Standard	Terms of reference Agenda and minutes Action plans
8	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 – 21	6 months	Standard	Service level agreements and sub contracts
9	Document the commissioning escalation pathway for screening issues and risks	Section 7a service specification no 15 – 21	6 months	Standard	Ratified escalation pathway and governance structure chart

No.	Recommendation	Reference	Timescale	Priority	Evidence required
10	Improve achievement against key performance indicators (KPI): • FA1 (completion of the laboratory request form) • NB2 (newborn bloodspot avoidable repeat rate) • NH2 (referral to audiological services within 4 weeks) • NP2 (referral of babies to ultrasound services within 2 weeks of age with confirmed or suspected developmental dysplasia of the hips)	Section 7a service specification no 15 – 21 Screening programme standards Key performance indicators: NHS screening programmes	6 months	Standard	KPI data meeting the acceptable thresholds
11	Revise the collection of key performance indicator (KPI) FA2 (completion of fetal anomaly scan) and ST2 (conclusive result for SCT by 10 weeks gestation) to comply with national guidance	Section 7a service specification no 16 Screening programme standards Key performance indicators: NHS screening programmes	6 months	Standard	KPI submission

No.	Recommendation	Reference	Timescale	Priority	Evidence required
12	Revise the turnaround time audit report to ensure compliance with sickle cell and thalassaemia (SCT) programme standards	NHS SCT Screening Programme: Handbook for antenatal laboratories SCT standards	6 months	Standard	Audit report showing compliance with required turnaround times
13	Undertake a client satisfaction survey specific to antenatal and newborn screening pathways	Section 7a service specifications no 15 - 21	12 months	Standard	Completion of user satisfaction survey and feedback at screening group meetings
14	Schedule antenatal and newborn screening audits on a yearly basis	Section 7a service specifications no 15 - 21	12 months	Standard	Maternity audit schedule
15	Formalise audits and ensure that the outcomes of screening audits inform changes in practice: • to include audit of the high quadruple screening rate	Section 7a service specifications no 15 - 21	12 months	Standard	Audit reports and subsequent changes agreed by screening governance group

No.	Recommendation	Reference	Timescale	Priority	Evidence required
16	Undertake a risk assessment of the sickle cell and thalassaemia (SCT) screening pathway within the laboratory	NHS SCT Screening Programme: Handbook for antenatal laboratories UKAS ISO 15189: laboratory quality assurance evidence requirements	6 months	Standard	Risk assessment and action plan

Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
17	Ensure adequate time is available for the screening support sonographers to complete all aspects of the role	Section 7a service specification no 16 NHS fetal anomaly screening programme handbook for ultrasound practitioners (2015)	3 months	High	Quarterly nuchal translucency (NT) and crown rump length (CRL) audits for all sonographers participating in first trimester screening Track completion of training Monitor Down's Syndrome Screening Quality Assurance Support Service (DQASS) reports for sonographers Induction resources to cover screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
18	Ensure job descriptions are revised for: • local screening coordinator (LCO) • screening support midwives • newborn and infant physical examination (NIPE) lead • newborn hearing screening programme (NHSP) local manager and administrative clerk	Section 7a service specifications no 15 - 21	6 months	Standard	Ratified job descriptions including elements of screening responsibility
19	Appoint a failsafe clerk	Section 7a service specifications no 15 – 21 Programme specific Checks and Audits documents	6 months	Standard	Failsafe clerk appointed Job description to cover screening failsafes and tracking
20	Monitor compliance of screening mandatory training	Section 7a service specifications no 15 - 21	6 months	Standard	Tracking of e-learning completion Tracking attendance at mandatory training sessions

No.	Recommendation	Reference	Timescale	Priority	Evidence required
21	Ensure screening support midwives undertake the Genetic Risk Assessment and Counselling module	Section 7a service specification no 18	12 months	Standard	Certificate of completion

Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority	Evidence required
22	Ensure equitable access for women referring for maternity care	Section 7a service specifications no 15 - 21	3 months	High	Map process of referral across EKHUFT Equity audit of referral process
23	Embed new process of online referral into maternity services to ensure complete cohort is identified	Section 7a service specifications no 15 - 18	6 months	Standard	Ratified policy and standard operating procedure Tracking Monitoring Audit

Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority	Evidence required
24	Allow the child health information service (CHIS) access to SMaRT 4 Hearing (S4H) to enable screening data to be transferred	Section 7a service specification no 20	6 months	Standard	Confirmation at programme board that CHIS has gained access to S4H
25	Develop a process to amend birth notification errors and allocate NHS numbers in the event of system failure	Section 7a service specifications no 19 - 21	6 months	Standard	Ratified policy or standard operating procedure
26	Ensure access to NIPE Screening Management and Reporting Tool (SMaRT) at weekends in order to escalate the need for screening to be completed within 72 hours of birth	Section 7a service specifications no 15 – 21 Programme standard Programme handbook	6 months	Standard	Improvement in key performance indicator NP1 Ratified policy or standard operating procedure

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority	Evidence required
27	Revise the consent process to ensure that there is a clear distinction between screening and clinical testing for fetal anomalies	Section 7a service specifications no 16 -17 Programme handbooks	3 months	High	Information for parents Ratified policy to include the process for gaining consent for screening and additional clinical testing Documentation of consent
28	Track the booked cohort to ensure all those accepting screening complete testing for sickle cell and thalassaemia, infectious diseases in pregnancy and fetal anomalies within timescales stipulated by PHE guidance	Section 7a service specifications no 15 – 18 Programme standards Programme handbooks	3 months	High	Ratified policy Trackers and spreadsheets Audit

No.	Recommendation	Reference	Timescale	Priority	Evidence required
29	Offer choice to women in relation to first trimester screening for trisomy 21, trisomy 13 and trisomy 18	Section 7a service specifications no 16 Programme standard Programme handbooks	3 months	High	Ratified policy Blood request form
30	Introduce a process in the maternity service for communication of screening results once a woman has miscarried or had a termination of pregnancy	Section 7a service specifications no 15 and 18	6 months	Standard	System implemented Ratified trust screening policies describing pathway
31	Implement a process to follow up women and babies when they do not attend for screening	Section 7a service specifications no 15 - 21	6 months	Standard	Ratified policy
32	Amend the trust website to ensure the correct screening information is presented	Section 7a service specifications no 15 - 21	12 months	Standard	Updated website

Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
33	Devise an antenatal specific laboratory request form for SCT screening	UKAS ISO 15189: laboratory quality assurance evidence requirements	6 months	Standard	Antenatal specific request form compliant with national programme minimum data fields
34	Revise and strengthen the pathway to ensure that all at risk couples are identified and referred at booking	Programme handbook	6 months	Standard	Ratified policy

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
35	Review the performance of the Espline test for syphilis and ensure absolute confirmation of results prior to release to maternity services	NHS Screening Programme Infectious Diseases in Pregnancy Screening Programme Handbook for Laboratories 2016-17	3 months	High	Audit Confirmation that syphilis screen positive samples will be referred to the reference laboratory until rapid plasma reagin (RPR) test is available in house

No.	Recommendation	Reference	Timescale	Priority	Evidence required
36	Devise an antenatal specific laboratory request form for infectious diseases in pregnancy screening (IDPS)	NHS Screening Programme Infectious Diseases in Pregnancy Screening Programme Handbook for Laboratories 2016-17 UKAS ISO 15189: laboratory quality assurance evidence requirements	6 months	Standard	Antenatal specific request form compliant with national programme minimum data fields
37	Revise the pathway for the follow up of women who decline IDPS at booking to ensure compliance with PHE guidance	Section 7a service specifications no 15 Programme handbook	6 months	Standard	Ratified policy

No.	Recommendation	Reference	Timescale	Priority	Evidence required
38	Revise the screen positive trackers for women diagnosed with an infectious disease to demonstrate all aspects of the pathway are complete	Section 7a service specifications no 15 Programme handbook Programme standards	6 months	Standard	Screen positive tracker

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
39	Undertake quadruple screening at the ultrasound appointment when head circumference is greater than 101mm	Section 7a service specifications no 16 Programme handbook	3 months	High	Ratified policy Quadruple screening tracker
40	Ensure all women accepting screening receive their combined or quadruple screening results within 2 weeks	Section 7a service specifications no 16	3 months	High	Ratified policy Audit

No.	Recommendation	Reference	Timescale	Priority	Evidence required
41	Implement an electronic auditable spreadsheet for the tracking of screen positive results and abnormalities detected at ultrasound scan to ensure completion of the pathway	Section 7a service specifications no 16 and 17	3 months	High	Auditable electronic tracker Ratified policy or standard operating procedure
42	Clarify and revise the internal commissioning arrangements with the King George Screening Laboratory to ensure that the service provided meets the NHS fetal anomaly screening programme (FASP) recommendations	Section 7a service specifications no 16 Programme handbooks	6 months	Standard	Commissioning arrangements to be provided to the trust antenatal and newborn screening governance group
43	Embed the process of reporting all unexpected abnormalities at birth	Section 7a service specifications no 16 and 17	6 months	Standard	Ratified policy Audit

Newborn and infant physical examination

No.	Recommendation	Reference	Timescale	Priority	Evidence required
44	Extend the tracker for developmental dysplasia of the hips to include all screen positive results for the other conditions following the newborn and infant physical examination in a timely way to ensure each baby enters treatment services	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

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.