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England

Protecting and improving the nation's health

Screening Quality Assurance visit report

**NHS Antenatal and Newborn Screening
Programmes Milton Keynes University
Hospital NHS Foundation Trust**

23 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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Published September 2020

PHE publications

gateway number: GW-1552

PHE supports the UN

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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 or 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 Milton Keynes University Hospital NHS Foundation Trust screening service held on 23 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:

- 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 visit to look at antenatal cohort tracking and failsafe processes
- information shared with the Midlands and East Screening QA Service (SQAS) as part of the visit process

Local screening service

Milton Keynes University Hospital NHS Foundation Trust offers all 6 NHS antenatal and newborn screening programmes. The full range of antenatal, intrapartum and postnatal care is provided at 1 site, Milton Keynes University hospital. In 2018 to 2019 there were 4,031 bookings and 3,592 deliveries.

The lead commissioner for Milton Keynes University Hospital NHS Foundation Trust maternity services is NHS Milton Keynes Clinical Commissioning Group. NHS England and NHS Improvement (East of England) commissions antenatal and newborn screening in line with NHS England section 7a service specifications.

Oxford University Hospitals NHS Foundation Trust provides the laboratory services for screening for Down's syndrome, Edwards' syndrome and Patau's syndrome as well as analysis of newborn blood spot screening samples.

Milton Keynes University Hospital NHS Foundation Trust provides the laboratory testing for:

- infectious diseases in pregnancy screening
- sickle cell and thalassemia screening

United Kingdom Accreditation Service assesses both ISO 15189:2012 requirements and the screening QA requirements as an integrated process. The interfaces between the laboratory and the trust were included in the QA visit day discussions and will be included in this report.

Newborn hearing screening is provided by Milton Keynes University Hospital NHS Foundation Trust.

Child health information services are provided by Hertfordshire Community NHS Trust. The interfaces between child health information services and the trust were included in the visit day discussions and are included in this report.

Findings

This is the second QA visit to the antenatal and newborn screening programmes at Milton Keynes University Hospitals NHS Foundation Trust. The first visit took place in April 2016. There were 10 recommendations outstanding 12 months after this visit and a letter giving the details of these was sent to the chief executive and commissioners.

The current visit identified several high priority findings that must be addressed to deliver a consistent, high quality antenatal and newborn screening service.

Structures and processes for internal governance of screening programmes are not well developed and strategic oversight of the screening programmes was not evident. The visiting team is not assured that risks, incidents and non-compliance issues are being escalated to senior management within the trust.

The trust does not report and manage screening incidents in line with national guidance.

There are several screening programme standards and key performance indicators that are not being met.

Immediate concerns

The QA visit team identified no immediate concerns.

High priority

The QA visit team identified 8 high priority findings which were:

- there was a concern about the lack of strategic oversight and governance of the screening programmes, including the non-achievement of key performance indicators and standards
- the management of safety incidents within NHS screening programmes did not follow national guidance
- there was no evidence that the internal antenatal and newborn screening steering group escalate performance concerns, risks and other issues upwards as necessary
- there did not appear to be timely processes in place to make sure that all eligible women and babies who had been offered screening had completed the pathway
- there was no evidence of ongoing training and education for staff involved in screening, except for newborn hearing screening staff
- there was no evidence that services had been tailored to meet the needs of the population
- audits and user surveys were not completed or used to inform service improvements
- women who miscarry or terminate their pregnancies do not receive their screening results unless they are screen positive

Recommendations

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

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1.	Improve internal risk and governance arrangements to make sure there are clear lines of accountability, pathways for escalation of risks/concerns, and regular monitoring of the quality of antenatal and newborn screening programmes by trust governance	Service specifications 15 to 21	6 months	High	<p>Governance structure showing how antenatal and newborn screening links to trust governance, including performance reporting and escalation of issues</p> <p>Minutes from trust governance meetings demonstrate escalation of screening performance issues, risks and incidents</p> <p>Inclusion of antenatal and newborn screening in the trust maternity strategy</p>
2.	The provider and commissioners should work together to undertake a health equity audit and develop an action plan to identify and reduce	Service specifications 15 to 21	12 months	High	Summary of the audit and findings presented and discussed at the programme board

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	inequalities	Guidance for NHS Commissioners on equality and health inequality duties 2015			Action plan to address any identified inequalities
3.	Update the terms of reference for the internal antenatal and newborn screening steering group to reflect the functioning of the group and reporting / escalation to trust governance	Service specifications 15 to 21	6 months	High	<p>Updated terms of reference show accurate timings of meetings, function of group and reporting to trust governance</p> <p>Minutes demonstrate discussion of risks, issues, incidents and performance, and relevant actions taken to escalate</p> <p>Documented evidence of performance reports to trust governance</p>
4.	Make sure that the relevant staff have the necessary skills and training to effectively report and investigate screening safety incidents in line with the 'Managing Safety Incidents in NHS Screening Programmes' guidance	Managing safety incidents in NHS screening programmes	6 months	High	<p>Evidence of timely reporting of incidents to commissioners and the Screening QA Service</p> <p>Confirmation that training in incident management</p>

No.	Recommendation	Reference	Timescale	Priority	Evidence required
					<p>and root cause analysis has been completed</p> <p>Final incident reports that demonstrate timely and effective incident investigations, action planning and sharing of lessons learned</p> <p>Completion of 'Managing safety incidents in NHS screening programmes' e-Learning</p>
5.	Revise screening guidelines to make sure that they meet national guidance and reflect internal processes, and implement a process for regular review	Service specifications 15, 16, 17 18,19 and 21	12 months	Standard	<p>Ratified updated guidelines</p> <p>Documented process for regular review of guidelines</p>
6.	Implement an audit cycle of the antenatal and newborn screening programmes, including action taken following audit findings	Service specifications 15 to 21	12 months	Standard	<p>Audit cycle in place</p> <p>Findings from audit presented at internal antenatal and newborn screening steering group and the programme board</p> <p>Evidence of actions taken to address findings</p>

No.	Recommendation	Reference	Timescale	Priority	Evidence required
7.	Complete a user survey to gather views about the antenatal and newborn screening pathways and make sure findings are used to improve services	Service specifications 15 to 21	12 months	High	Evidence of completion of user surveys and actions taken to address findings

Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
8.	Make sure the job descriptions for the screening team cover both the antenatal and newborn screening programmes	Service specifications 15 to 21	6 months	Standard	Updated job descriptions showing coordination of antenatal and newborn screening programmes
9.	Implement a training programme for all staff involved in the screening pathway	Service specifications 15, 16, 17, 18, 19, 21	6 months	High	Evidence of implementation of a training programme
10.	Demonstrate that ultrasound staff have completed training as specified in national guidance	Service specification 16 and 17 NHS Fetal anomaly screening programme: ultrasound practitioners handbook	3 months	Standard	Training records presented to internal antenatal and newborn screening steering group Minutes showing confirmation that training has been completed
11.	Make sure the risk of not updating the ultrasound software Viewpoint has	Service specification	3 months	Standard	Entry onto risk register

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	been reviewed, raised with trust governance and mitigations are in place	16 and 17			Evidence of mitigation and escalation of risk to trust governance Updates at programme board

Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority	Evidence required
12.	Use the maternity IT system to identify the antenatal cohort to allow accurate tracking of the eligible population	Service specifications 15 to 18	12 months	Standard	Updated tracking system using the eligible population from the maternity IT system Updated standard operating procedure for identifying the eligible population
13.	Implement a weekly process for tracking each woman through the screening pathway to make sure that screening is offered, screening tests are performed, and results are received within recommended timescales	Service specifications Nos. 15, 16, 17 and 18 NHS population screening: checks and audits for failsafe	3 months	High	Screen shot of tracking (failsafe) system Standard operating procedure for managing the tracking process with roles and responsibilities clearly outlined

No.	Recommendation	Reference	Timescale	Priority	Evidence required
14.	Make sure the data submitted for key performance indicator FA2 (coverage – ultrasound) is accurate	Service specification 17	6 months	Standard	Eligible population that matches data submitted by the maternity service Women who are excluded from the data are accounted for
15.	Develop an effective system of referring all eligible pregnant women with diabetes to the eye screening team	Service specification 22	6 months	Standard	Updated standard operating procedure and guideline showing defined roles and responsibilities

Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority	Evidence required
16.	Implement and monitor a plan to meet key performance indicator NP1 (coverage) and improve service resilience	Service specification 21	3 months	Standard	Action plan monitored at antenatal and newborn screening programme board Actions taken to improve service resilience reported to trust governance
17.	Demonstrate routine achievement of the acceptable level for all national screening standards and KPIs that are not currently achieved	Service specifications 15 to 21	12 months	Standard	Submission of data that shows consistent achievement of the acceptable standards

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority	Evidence required
18.	Make sure all women who miscarry or terminate their pregnancy who have had screening tests receive their results	NHS Infectious diseases in pregnancy screening programme handbook	6 months	High	Confirmation that letters are being sent to women who have been screened and that guideline is being followed

Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
19.	Confirm that the process for fast tracking women who are known to be screen positive sickle cell and/or thalassaemia is followed	Service specifications 18 NHS Sickle cell and thalassaemia screening handbook	6 months	Standard	Antenatal screening guideline shows 'fast track' process for known at risk women Communication with midwifery staff booking women for antenatal care Audit of known carriers shows that they were fast tracked

No.	Recommendation	Reference	Timescale	Priority	Evidence required
20.	Update the current pathology request form and electronic request form to make sure it is in line with the latest version of the family origin questionnaire	Service specification 18	3 months	Standard	Updated booking request form and eCare request
21.	Implement and monitor a plan to meet key performance indicator ST2 (timeliness – results by 10 weeks)	Service specification No. 18 NHS Sickle cell and thalassaemia screening programme standard 2	3 months	Standard	Action plan that is agreed and monitored by the programme board
22.	Implement and monitor a plan to meet key performance indicator ST3 (completion of family origin questionnaire)	Service specification No. 18 NHS Sickle cell and thalassaemia screening programme standard 3	3 months	Standard	Action plan that is agreed and monitored by the programme board

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
23.	Make sure all women who are hepatitis B positive are seen within 10 days to discuss their results	<p>NHS Infectious diseases in pregnancy screening programme standard 5b</p> <p>NHS Infectious diseases in pregnancy screening programme checks and audits</p> <p>Antenatal and newborn national audit protocol 2019 to 2022</p>	12 months	Standard	<p>Completion of national audit for standard 5b</p> <p>Action plan to achieve the standard and reaudit if needed</p> <p>Findings of audit discussed at internal antenatal and newborn screening steering group</p> <p>Monitoring achievement of standard at programme board</p>
24.	Make certain that all babies who are eligible for hepatitis B immunisation are given the first dose of vaccine or immunoglobulin within 24 hours and this is recorded clearly in the notes	NHS Infectious diseases in pregnancy screening programme standard 7a	6 months	Standard	<p>Ongoing review of all babies at internal antenatal and newborn screening steering group</p> <p>Annual data return reviewed at the</p>

No.	Recommendation	Reference	Timescale	Priority	Evidence required
					programme board

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
25.	Complete an image review every 3 months, in line with national guidance	Service specification 16 NHS Fetal anomaly screening programme: handbook for ultrasound practitioners	6 months	Standard	Confirmation that image reviews are taking place to programme board Evidence of image reviews taking place every 3 months monitored at internal antenatal and newborn screening steering group Escalation to trust governance if reviews are not taking place
26.	Make sure that all women who consent to quadruple screening complete the screening pathway	Service specification 16	6 months	Standard	Failsafes in place to track all women Updated standard operating procedure
27.	Review cases where women referred to the tertiary centre are not seen within 5 days and take action with tertiary centre to achieve timely appointments	NHS Fetal anomaly screening programme standard 8b	6 months	Standard	Completion of national audit for standard 8b Monitoring achievement of standard at programme board

No.	Recommendation	Reference	Timescale	Priority	Evidence required
					<p>Action plan to meet standard if not achieved</p> <p>Escalation to trust governance if any concerns raised with the provider of tertiary care</p>
28.	Implement an effective system to report physical conditions to the national congenital and rare disease register, including those found after birth	Service specification 17	12 months	Standard	<p>Standard operating procedure for reporting ratified</p> <p>Evidence of implementation of effective electronic system</p>
29.	Confirm that information leaflets given to women attending for fetal anomaly screening are up to date and in line with national guidance	Service specification 17	6 months	Standard	<p>Confirmation that current national leaflets are being used documented at internal antenatal and newborn screening steering group</p> <p>Updated local information</p>
30.	Make sure there is a local process for women found to have a twin pregnancy or 'vanished twin' so they are counselled by appropriately trained staff	NHS Fetal anomaly screening programme: laboratory	6 months	Standard	Updated guideline and standard operating procedure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
		handbook			
31.	Make sure that data submitted for key performance indicator FA2 (18+0 to 20+6 fetal anomaly ultrasound coverage) is accurate and that all eligible women are accounted for	NHS Fetal anomaly screening programme standard 2	6 months	Standard	Data submitted is accurate and accounts for the eligible population

Newborn hearing screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
32.	Make sure the risk factor recording sheet is completed before hearing screening takes place in the neonatal intensive care unit	NHS Newborn hearing screening programme: operational guidance	12 months	Standard	Confirmation that the risk factor recording sheet is completed by the relevant staff before screening takes place

Newborn and infant physical examination

No.	Recommendation	Reference	Timescale	Priority	Evidence required
33.	Implement and monitor a plan to consistently meet key performance indicator NP2 (developmental dysplasia of the hips)	Service specification 21 NHS Newborn infant physical examination	3 months	Standard	Action plan that is agreed and monitored by the programme board

No.	Recommendation	Reference	Timescale	Priority	Evidence required
		screening programme standards			
34.	Make sure outcomes for standard 2 (abnormalities of the eye), standard 3 (developmental dysplasia of the hips), standard 4 (developmental dysplasia of the hips – risk factors) and standard 5 (bilateral undescended testes) are recorded on Smart4NIPE	Service specification 21 NHS Newborn infant physical examination screening programme standards 2, 3, 4 and 5	12 months	Standard	Action plan to record outcomes on SMaRT4NIPE is agreed and monitored by the programme board Documented evidence that trust oversight is in place

Newborn blood spot screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
35.	Implement and monitor a plan to meet standard 3 (use of barcoded labels), standard 5 (sample received within 3 days) and standard 6 (avoidable repeats)	Service specification 19 NHS Newborn blood spot screening programme standard 3, 5 and 6	3 months	Standard	Action plans monitored at antenatal and newborn screening programme board Documented evidence that trust oversight is in place

Next steps

The screening service provider is responsible for developing an action plan in collaboration with the commissioners to complete the recommendations contained in 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.