



Public Health
England

Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening
Programmes Birmingham Women's and
Children's NHS Foundation Trust

3 and 4 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/families with screen-positive results), or the completion of the screening pathway.

The findings in this report relate to QA visit of Birmingham Women's and Children's NHS Foundation Trust screening service held on 3 and 4 July 2017.

Purpose and approach to quality assurance

QA aims to maintain national standards and promote continuous improvement in antenatal and newborn screening. This method is to ensure that all eligible people have access to a consistently 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 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 shared with the SQAS (West Midlands) as part of the visit process

Description of local screening service

Birmingham Women's and Children's NHS Foundation Trust was launched in February 2017 creating the first single specialist trust for women and children in England. It is a merger between Birmingham Women's Hospital and Birmingham Children's Hospital. The Trust delivers antenatal and newborn screening programme services to a population of over 50, 000 women and babies. The maternity service operates from Birmingham Women's Hospital, Edgbaston.

From 2015 to 2016, 8466 women booked for care and there were 8351 births. 68% of women booking for maternity care were white British.

Birmingham Women's and Children's NHS Foundation Trust provide a full range of antenatal and newborn screening services, including:

- sickle cell and thalassaemia and infectious disease screening

- analysis of samples for first-trimester screening for Down's, Edwards' and Patau's syndromes and the second-trimester quadruple screen for Down's syndrome
- sonography services for first-trimester screening and the 18 to 20+6 week fetal anomaly scan
- fetal medicine centre and prenatal diagnostic services
- laboratory services based at Birmingham Children's Hospital for the analysis of newborn blood spot screening samples
- newborn hearing screening

The following clinical commissioning groups work together across the Birmingham and Solihull area:

- NHS Birmingham Cross City clinical commissioning group
- NHS Birmingham South Central clinical commissioning group
- NHS Birmingham South Central clinical commissioning group

NHS Birmingham South Central clinical commissioning group are the lead commissioners of maternity services for Birmingham Women's and Children's NHS Foundation Trust. NHS England Midlands and East (West Midlands) commission the antenatal and newborn screening services.

Findings

Immediate concerns

The QA visit team identified no immediate concerns.

High priority

The QA visit team identified 5 high priority findings as summarised below:

- the pregnancy ultrasound scan service is challenged by increasing activity and constrained capacity. As a result, the implementation of fetal anomaly screening programme standards were delayed. The trust has now fully implemented the 3 vessel trachea view as part of the fetal anomaly ultrasound scan. Whilst both capacity and workforce are on the trust's risk register, and a business continuity plan in place, further monitoring of the service is needed to ensure sustainably.
See recommendation 1
- there is no joint trust steering group to oversee the antenatal and newborn screening programmes. The separate sub-groups are presented at the directorate clinical improvement group and perinatal risk group. At the time of the QA visit, the newborn screening sub-group did not include child health records

or the newborn hearing programmes. The newborn sub-group does not have a designated senior lead for all newborn screening programmes.

See recommendation 2

- the new combined trust is moving to a single laboratory operating model. They are in the process of documenting the operational relationships between the two hospitals (eg allocation of testing/calibration work, transfer of samples between locations, movement of technical staff and equipment and centralised reporting arrangements). Birmingham Women's Hospital laboratories have temporarily withdrawn from the laboratory United Kingdom accreditation scheme until the documentation and integration is complete. Detailed accreditation and mitigation plans are now required to provide assurance and manage current service risks.

See recommendation 3

Key performance indicator acceptable thresholds are not being met for 4 out of 14 indicators. This includes:

- ST2 (timeliness of haemoglobinopathy testing) - $\geq 50.0\%$ standard has not been achieved although some progress has been made from 9% in 2015 to 38.7% in 2017
- NH2 (hearing test within 4 weeks of referral) - $\geq 90\%$ standard not achieved in 3 out of the last 4 quarters. **See recommendation 4**
- there is no annual process to benchmark service provision against the antenatal and newborn screening standards and service specifications requirements. The screening service should review all current quality standards to identify gaps and areas for future development. **See recommendation 5**

Shared learning

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

- monthly newborn screening meetings between the maternity and neonatal directorates where the newborn blood spot audits are presented, issues identified and discussed to improve NBS performance
- service changes are made in response to user views. For example, pop up clinics to gain user feedback and a call buzzer system implemented in clinics
- the NIPE screening service has established a closed Facebook group which facilitates shared learning between clinicians
- production of a 'lessons of the week' staff bulletin on screening programmes

Table of consolidated recommendations

Governance and Leadership

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
1	Monitor the effectiveness of the ultrasound business and continuity plan and ensure actions are completed	Screening service specifications 2017-18 (2-3)	Ongoing	H	<p>Business continuity plan monitored by the trust screening steering group, clinical radiology and screening programme board</p> <p>Risk register reviewed and updated monthly by the trust</p> <p>Exception reports produced and monitored by the trust screening steering group and screening programme board</p>
2	Arrangements should be made to integrate the newborn and antenatal screening programme trust governance arrangements	Screening service specifications 2017-18 (1-7)	3 months	H	<p>Joint trust steering screening group</p> <p>Revised terms of reference and membership of the trust screening steering group</p>

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
3	<p>The new laboratory operating model should document the operational arrangements and responsibilities between the Birmingham Women’s Hospital and Birmingham Children’s Hospital</p> <p>Production of mitigation and integration plans to be shared with commissioners</p> <p>Plans should address the implications of the new operating model including the voluntary withdrawal from the United Kingdom accreditation scheme register</p> <p>Agree a completion date with commissioners</p>	<p>Laboratory Handbook (13,14,17)</p>	<p>1 month</p>	<p>H</p>	<p>Mitigation and integration action plan produced that is agreed and monitored by the screening programme board</p> <p>New operating model in place with documented relationships between the two hospitals</p> <p>United Kingdom accreditation scheme assessment and completion date agreed by commissioners</p>

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
4	<p>Produce key performance indicator improvement plans</p> <p>Agree plans with commissioners and trust screening steering group to address improving performance data</p>	<p>Screening service specifications 2017-18 (all antenatal and newborn screening)</p>	<p>Ongoing</p>	<p>H</p>	<p>Improvement plans produced for FA1, ST2, NH2</p> <p>Plans reviewed and updated at trust screening steering group (TSSG) and the screening programme board</p> <p>Improvement plans produced for NB4 reviewed and updated at the screening programme board</p> <p>Acceptable standards for FA1, ST2, NH2 and NB4 met</p>

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
5	<p>Put in place an annual process to benchmark service provision against the antenatal and newborn screening standards and service specifications requirements</p> <p>Agree plan with commissioners to address any service gaps</p>	<p>Screening service specifications 2017-18 (all antenatal and newborn screening)</p>	<p>Ongoing</p>	<p>H</p>	<p>Process agreed at the screening programme board</p> <p>Copy of benchmarking exercise for NHS screening service specification 2017-18 presented to board</p> <p>Action plan produced to meet service gaps for approval by trust steering screening group and screening programme board</p>
6	<p>Monitor the sustainability and transformation plans with commissioners</p>	<p>National Maternity Review: Better births (25)</p>	<p>Ongoing</p>	<p>S</p>	<p>Sustainability and transformation plans including modelling and workforce plans shared and monitored at the screening programme board</p>

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
7	Revise the commissioner programme board terms of reference to reflect the integration between Birmingham Woman's Hospital and Birmingham Children's Hospital	Programme board terms of reference 2017	3 months	S	Revised copy of commissioner programme board terms of reference that include Birmingham Women's and the Children's NHS Foundation Trust
8	Ensure the provision of permanent failsafe officer post to maintain screening failsafe activities	Trust annual report 2015-2016 Screening service specifications 2017-18 (1-7)	6 months	S	Reviewed service and action plan produced Action plan shared with the trust steering screening group and programme board
9	Put in place an annual process to ensure the newborn hearing service level agreement is renewed	Screening service specifications 2017-18 (6)	1 month	S	Service level agreement signed by provider and trust for 2017/2018
10	Make sure child health records department reports to screening programme board on performance, issues and risks	Trusts programme board minutes Screening service specifications 2017-18 (23)	3 months	S	Minutes from programme board demonstrates child health records department attendance or reports on performance, issues and risks

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
11	Include the 'Managing safety incidents in NHS screening programmes guidance' in integrated trust risk management policy	PHE guidance 'Managing safety incidents in NHS Screening Programmes' (1 March 2015. Updated 4 September 2017) (8)	6 months	S	Updated and ratified trust risk management policy
12	Make sure trust antenatal and newborn screening guidelines and policies include reference to current national guidance and are audited for compliance	Screening service specifications 2017-18 (all newborn screening)	6 months	S	Updated trust guidelines and policies to include monitoring tables, schedule for audit of antenatal and newborn screening programmes
13	A schedule of screening audits should be agreed annually with commissioners and completed as agreed	Screening service specifications 2017-18 (all antenatal and newborn screening)	6 months	S	The audit schedule and completed audits should be presented to the programme board and action plans put in place as required

Infrastructure

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
14	Put a plan in place to ensure that staff attendance at trust mandatory antenatal and newborn screening training meets the trust target of 85%	Trust mandatory training policy	6 months	S	<p>Plan presented to the programme board and trust steering screening group</p> <p>Trust training needs analysis and NHS e-learning monitored by staff line managers and updated to ensure accurate compliance data</p> <p>Non-compliance action plan produced and monitored by the senior line managers</p>

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
15	Make sure all appropriate staff involved in the screening pathway complete training requirements as identified by the screening service training needs analysis	Screening service specifications 2017-18 (all antenatal and newborn screening) National Maternity Review: Better births (25)	6 months	S	Training needs analysis to include all appropriate staff involved in the screening pathway
16	Ensure new roles and functions for child health records are reflected in current job descriptions	Screening service specifications 2017-18 (23)	6 months	S	Updated job descriptions
17	Produce a laboratory IT action plan to mitigate current IT screening risks arising from the transition of former IT systems to a new integrated system Action plan agreed and timescales agreed by commissioners	Screening service specifications 2017-18 (all antenatal and newborn screening)	6 months	S	Updated IT strategy Mitigation action plan produced and monitored by the programme board

Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
18	Implement an auditable process to identify and track samples from antenatal clinic to the laboratory	Screening service specifications 2017-18 (1-4)	6 months	S	Standard operating procedure for managing the tracking process with roles and responsibilities clearly outlined

Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
19	Implement an auditable process to identify and track each baby (movers in – within the UK and/or abroad) eligible for screening from offer to screening result	Screening service specifications 2017-18 (5-7, 23)	6 months	S	Submission of KPI data-NB4 Standard operating procedure for managing the tracking process with roles and responsibilities clearly outlined
20	Implement a process for notifying deceased babies to all key stakeholders	Screening service specifications 2017-18 (5-7)	6 months	S	Standard operating procedure for the notification of deceased babies with roles and responsibilities clearly defined

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
4					

Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
4 and 17					

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
21	Make sure that the laboratory standard operating procedure includes the follow up for repeat sample requests	NHS Infectious disease in pregnancy laboratory handbook 2016-17 (14)	6 months	S	Amended standard operating procedure that contains sample pathways

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
22	Put arrangements in place to meet compliance against fetal anomaly screening standards 8a and 8b	Fetal anomaly programme standards April 2015 (18)	6 months	S	<p>Audit of compliance completed and presented to trusts screening programme board</p> <p>Performance data shows compliance with standard 8a and 8b</p>

Newborn hearing screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
23	<p>Take further action to improve NH2 KPI performance</p> <p>Review the current action plan and agree changes with commissioners</p> <p>Undertake an audit of NH2 breaches and implement an action plan to address findings</p>	<p>Screening service specifications 2017-18 (20)</p>	6 months	S	<p>Audit undertaken and an updated action plan in place</p> <p>The action plan is monitored at the trust screening steering group (TSSG) and screening programme board</p> <p>Acceptable standard for NH2 met</p>

Newborn and infant physical examination

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
24	<p>Utilise the national recording and reporting system NIPE SMaRT to its full capacity</p>	<p>Screening service specifications 2017-18 (1-7)</p>	6 months	S	<p>NIPE SMaRT used to produce KPI data referral letters and record outcome for positive screening tests</p>

Newborn blood spot screening

No.	Recommendation	Reference	Timescale	Priority *	Evidence required
25	<p>Review and revise the current action plan to improve the use of barcoded labels and NB3 performance</p> <p>Agree updated plan and completion date with commissioner</p>	Standards for Newborn blood spot screening April 2017 (22)	Ongoing	S	<p>Action plan monitored by screening programme board</p> <p>Acceptable standard for NB3 met</p>

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.

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.