Public Health England

NHS

Screening Quality Assurance visit report

NHS antenatal and newborn screening programmes

Whittington Health NHS Trust

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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Contents

Scope of this report

	Covered by this report?	If 'no', where you can find information about this part of the pathway
Underpinning functions		
Coverage	Yes	
Workforce	Yes	
IT and equipment	Yes	
Commissioning	Yes	
Leadership and governance	Yes	
Pathway		
Cohort identification	Yes	
Invitation and information	Yes	
Testing	Yes	First trimester Down's, Edwards' and Patau's syndromes screening and second trimester Down's syndrome screening: The Wolfson Institute visit 6 December 2017 Newborn blood spot screening laboratory: Great Ormond Street Hospital for Children NHS Foundation Trust visit 10 September 2014
Results and referral	Yes	
Diagnosis	Yes	
Intervention/treatment	Yes	

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/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 Whittington Health NHS Trust screening service held on 20 March 2018.

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 Public Health England (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 NHS England (London) commissioners on 15 March 2018 and Child Health Information Services (CHIS), North East London Foundation Trust on13 March 2018
- information shared with the London regional SQAS as part of the visit process

Local screening service

Whittington Health NHS Trust is an integrated care organisation situated in north central London. The trust serves a local population of 500,000 in the borough of Islington and Haringey, and surrounding areas including Barnet, Enfield, Camden and Hackney. The trust provides the full range of antenatal, labour, birth, postnatal and neonatal care. All ANNB screening programmes are offered.

In the financial year 2016 to 2017, 4,654 women were booked for antenatal care at the trust and 3,685 babies were born. Antenatal counselling services for SCT are provided by Camden and Islington sickle cell and thalassaemia centre, part of Whittington Health NHS Trust. Laboratory services for infectious diseases in pregnancy screening (IDPS)

and sickle cell and thalassaemia (SCT) screening are provided by the trust. Samples are sent to PHE Colindale for infectious disease confirmatory testing. Laboratory services for first trimester Down's, Edwards' and Patau's syndromes screening and second trimester screening for Down's syndrome are provided by the Wolfson Institute of Preventive Medicine. Great Ormond Street Hospital (GOSH) newborn screening laboratory provides the screening service for the newborn blood spot (NBS) screening programme. Newborn hearing screening is provided by Whittington Health NHS Trust.

Findings

This was the first ANNB QA visit to Whittington Health NHS Trust. During the visit there was a clear willingness to learn and develop practice.

Immediate concerns

The QA visit team identified 2 immediate concerns. A letter was sent to the chief executive on 23 March 2018 asking that the following items be addressed within 7 days relating to the SCT counselling service:

- the antenatal SCT counselling service lacks resilience for the following reasons:
  - the staff that currently provide this service aren't in substantive posts
  - the staff that currently provide this service haven't undertaken the genetic risk assessment and counselling module as per the NHS public health functions agreement 2017 to 2018 − www.england.nhs.uk/wp-content/uploads/2017/06/service-specification-18.pdf
  - the guideline for the processes undertaken by this service is currently in draft and requires more detail and clarity of responsibilities prior to ratification
- the antenatal SCT counselling service reported that in some cases they are interpreting maternal mean cell haemoglobin (MCH) and family origin questionnaire (FOQ) results to identify women at risk of alpha zero thalassaemia and determine if the father of the baby should be screened; this is because the laboratory currently recommends father testing for all women with an MCH less than 23pg − as per the NHS Sickle Cell and Thalassaemia Screening Programme handbook for laboratories, this interpretation and reporting should be undertaken by the laboratory in line with the algorithms within the guidance − www.gov.uk/government/uploads/system/uploads/attachment_data/file/656094/Antenatal_Laboratory_Handbook.pdf
  (this risk is further impacted by the lack of approved training completion as stated above)

A response from the trust was received and where possible immediate actions have been taken. This has partially mitigated the immediate risks within the programme.

An action plan has been submitted which details how the concerns identified will continue to be addressed within agreed timescales.

High priority

The QA visit team identified 12 high priority findings as summarised below:

- there is a lack of clarity in relation to roles and responsibilities across the team and in some areas escalation and governance routes are unclear; this means that any action plans developed in response to incident investigations, performance deficits and improvement projects are not always effectively monitored
- policies, protocols and standard operating procedures need updating to reflect current national programme guidance
- there is currently no complete failsafe process in place for NIPE and for the remaining programmes the failsafe requires strengthening to make sure screening is offered and undertaken in a timely manner and reoffered where needed
- timely offer of intervention following a positive screening result would be improved by the introduction of a process whereby the laboratory notifies SCT results to the relevant screening team

Shared learning

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

- midwives have an iPad which enables community access to the maternity system and electronic results
- all areas interviewed on the visit day reported access to face to face and telephone interpreters; the hearing screening service has access to a dual telephone handset
- the maternity unit has a designated counselling room solely available for the screening team
- the SCT counselling service has access to the maternity IT system and documents all appointments and outcomes for other maternity staff to view
- corporate oyster cards are allocated to hearing screeners to encourage and allow movement of staff between north central London hearing screening sites; this has improved the service coverage

Recommendations

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

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1	Make sure the NHS service level agreement (SLA) for fetal anomaly screening complies with national policy, guidance and NHS service specifications	2, 18, 19	12 months	Standard	SLA in place for maternity services accessing **fetal anomaly screening programme (FASP)** screening laboratory services
2	Update the Trust Screening Steering Group (TSSG) terms of reference (ToR) to reflect its functions, accountability and reporting arrangements and escalation routes	1-7	3 months	Standard	Updated ToR presented and agreed at the TSSG Includes organogram demonstrating escalation routes.
3	Make sure all action plans created following incident investigations, performance deficits and improvement projects are monitored effectively in the TSSG until they are completed	1-23	6 months	High	Updated TSSG ToR includes responsibility to monitor action log Escalation where required is included within TSSG minutes
4	Update antenatal and newborn screening guidelines and standard operating procedures (SOP) in line with national guidance	1-7, 11-23	9 months	Standard	Updated guidelines and SOPs ratified and presented at the TSSG

No.	Recommendation	Reference	Timescale	Priority	Evidence required
5	Update relevant local policies to include reference to managing screening incidents in accordance with 'Managing Safety Incidents in NHS Screening Programmes' (2017)	8, 9	6 months	Standard	Updated ratified policy approved at the TSSG Audit of performance against the guidelines scheduled
6	Include screening audits in the maternity audit schedule	1-7	6 months	Standard	Completed audits, with action plans presented at the TSSG TSSG ToR updated to reflect responsibility for reviewing ANNB screening audits
7	The SCT and IDPS laboratories should include a vertical audit of an antenatal sample in the annual audit schedule	12,13	6 months	Standard	Audits scheduled in laboratory annual audit schedule Completed audits presented at TSSG
8	**Complete a user survey to gather views about the antenatal and newborn screening pathways**	1-7	12 months	Standard	Completed survey, with findings and action plan presented at the TSSG

Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
9	Review and document roles and responsibilities, including deputising arrangements, within the antenatal and newborn screening programmes	1-5, 7	6 months	High	Updated job descriptions for the screening team
10	Make sure all ANNB failsafe processes are captured within the failsafe policy	1-5	6 months	Standard	Ratified failsafe policy presented at the TSSG
11	Make sure administrative and failsafe support for the screening pathways is in line with the national service specifications	1-5, 7	9 months	Standard	Confirmation to the TSSG that administration support for all ANNB programmes is in place
12	Review the SCT counselling service for pregnant women to make sure there is resilience within the service	4	3 months	High	Confirmation at the TSSG there is substantive cover in place Completion of the action plan submitted by the trust in response to the immediate concerns letter
13	Make sure the SCT counsellors complete the genetic risk assessment and counselling course	4	6 months	High	Completion of the genetic risk assessment and counselling course confirmed at the TSSG

No.	Recommendation	Reference	Timescale	Priority	Evidence required
14	**Make sure all staff involved in the screening pathway complete the relevant training requirements**	1-23	12 months	Standard	a) Present training compliance data at TSSG b) Confirmation at the TSSG screening presentation includes all ANNB screening programmes

Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority	Evidence required
15	Implement a weekly process for tracking each woman through the FASP pathway to make sure screening is offered, tests are performed and results are received	3,10	6 months	Standard	Implemented tracking and failsafe process detailed within ratified failsafe policy and presented at the TSSG Submission of KPI data for FA2
16	**Make sure all women who miscarry or terminate their pregnancy receive their results**	1,4	6 months	Standard	Confirmation at the TSSG of amended guideline to reflect practice

Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority	Evidence required
17	Make sure the neonatal unit (NNU) has access to the Newborn Blood Spot Failsafe Solution (NBSFS) to support accurate cohort identification and monitoring	5	6 months	Standard	Confirmation at the TSSG that the NNU have access to NBSFS and are supporting the monitoring process
18	Implement a weekly process to identify and track each screen positive baby through the Newborn Infant Physical Examination (NIPE) screening pathway from referral to being seen	7,10,21	6 months	Standard	Confirmation via TSSG that failsafe process in place Ratified SOP for process presented at the TSSG
19	Implement a documented process to inform the newborn screening programmes of birth notification errors so that relevant failsafe systems are updated	5-7	12 months	Standard	Ratified SOP for the notification of birth notification errors with roles and responsibilities clearly outlined presented at the TSSG
20	Update the bereavement checklist to include informing the newborn screening programmes to enable update of the Northgate failsafe systems	5-7	6 months	Standard	Ratified SOP for the notification of deceased babies with roles and responsibilities clearly outlined presented at the TSSG

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority	Evidence required
21	Update the links to NHS screening programmes information on the trust website	1-7	3 months	Standard	Confirmation of updated links to the TSSG

Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
22	Make sure the laboratory interprets and reports all SCT results in line with national guidance	12	1 month	High	Confirmation at the TSSG that the laboratory is reporting all results in line with recommended practice
23	Make sure the laboratory completes the planned gap analysis against the SCT standards and handbook for antenatal laboratories	11, 12	6 months	Standard	Completed gap analysis and action plan presented at the TSSG
24	Implement a weekly failsafe process to confirm that the laboratory has notified all screen positive SCT results to the screening team	1, 4, 12, 13	3 months	High	Failsafe process implemented and confirmed at the TSSG
25	Implement a checking process in the SCT laboratory to make sure repeat samples are received	12	9 months	Standard	Ratified SOP presented at the TSSG
26	Make sure the SCT service confirms directly with the woman the identity of the father of the baby for all women referred to their service	4	3 months	High	Guideline updated to include this process and ratified document presented at the TSSG

No.	Recommendation	Reference	Timescale	Priority	Evidence required
27	Implement a process to make sure women who miscarry or terminate their pregnancy are informed of their screen positive result to allow appropriate management	4	6 months	High	Guideline updated to includes this process and ratified document presented at the TSSG
28	Revise and monitor the improvement plan for KPI ST2	4, 10, 11	3 months	Standard	Action plan agreed and monitored at the TSSG KPI ST2 acceptable threshold met and improvement sustained
29	Review the data collection process for KPI ST3 make sure it is in line with current KPI guidance	4, 10, 11	6 months	Standard	Confirmation at the TSSG of review and outcome.

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
30	Implement a weekly failsafe process to confirm that the laboratory has notified all screen positive IDPS results to the screening team	1, 4, 12, 13	3 months	High	Failsafe process implemented and confirmed at the TSSG
31	Implement a tracking system for samples sent to the PHE Colindale laboratory	13, 15	6 months	Standard	SOP submitted to the TSSG
32	Make sure the full process for women who decline the initial offer of IDPS screening (HIV, hepatitis B and/or syphilis) is clearly documented within the Maternal Antenatal Screening Tests guideline	1	6 months	Standard	Updated ratified guideline presented at the TSSG

No.	Recommendation	Reference	Timescale	Priority	Evidence required
33	Clarify the criteria for urgent IDPS testing and test turnaround times for HIV, hepatitis B and syphilis	1	3 months	High	Updated ratified guideline presented at the TSSG

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
34	Implement a failsafe process to make sure all women who are eligible for and accept the quadruple test receive the result	2, 19	6 months	High	Relevant guideline updated with the quadruple screening pathway and presented at the TSSG
35	Audit the reasons for low performance in FASP standard 8a, and develop an improvement plan based on the findings	3, 19	6 months	Standard	Audit findings and improvement plan presented and monitored at the TSSG

Newborn hearing screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
36	Audit the reasons for increased referral rates to audiology; KPI NH2 and develop an improvement plan based on the findings	6, 10, 22	6 months	Standard	Audit findings presented at the TSSG

Newborn and infant physical examination

No.	Recommendation	Reference	Timescale	Priority	Evidence required
37	Implement NIPE SMaRT to make sure accurate cohort identification and effective failsafe pathways are in place	7,10,21	12 months	High	Implementation of NIPE SMaRT

Newborn blood spot screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
38	Revise and monitor the improvement plan for KPI NB2	5,10,23	6 months	Standard	Improvement plan reviewed and monitored at the TSSG

Next steps

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

SQAS will work with commissioners for 12 months to monitor activity and progress in response to the recommendations following the final report. SQAS will then send a letter to the provider and the commissioners summarising the progress and will outline any further action needed.