Public Health England

NHS

Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening Programmes

Imperial College Healthcare NHS Trust

8 and 9 November 2017

Public Health England leads the NHS Screening Programmes

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Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG
Tel: 020 7654 8000 www.gov.uk/phe Twitter: @PHE_uk
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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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Prepared by: Screening QA Service (London).
For queries relating to this document, please contact: phe.screeninghelpdesk@nhs.net

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About this publication

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Amendment history

Version	Date	Author	Description
0.1	10/12/2017	A.Fiddler	First draft
0.2	20/12/2017	A.Fiddler	Comments incorporated from Modupe Omonijo and Valerie Armstrong
0.3	21/12/2017	A.Fiddler	Comments incorporated from Jan Yates
0.4	15/01/2018	A. Fiddler	Revised following factual accuracy review from providers and commissioners

Review/approval

Version	Date	Requirement	Signed
Final	22/01/2018	Approved for final version release	Valerie Armstrong

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 laboratory services : Birmingham Women's and Children's NHS Foundation Trust – Quality Assurance (QA) report July 2017 Newborn bloodspot screening laboratory services: Epsom and St Helier University Hospitals NHS Trust – QA report 8 February 2017 Great Ormond Street hospital for Children NHS Trust – QA report 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 Imperial College Healthcare NHS Trust screening service held on 8 and 9 November 2017.

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 a pre-review visit to North West London Child Health Services, Health Intelligence on 7 November 2017
- information shared with the London regional SQAS as part of the visit process

Local screening service

Imperial College Healthcare NHS Trust provides the full range of antenatal, labour, birth, postnatal and neonatal care across 2 sites based at St Mary's hospital and Queen Charlotte's and Chelsea hospital. All ANNB screening programmes are offered at both sites.

In financial year 2016/17, 11,686 women were booked for antenatal care at the Trust with 9,158 babies born. Sickle cell and thalassaemia and infectious diseases laboratory services are all provided within the Trust. Newborn bloodspot laboratory services are provided by Epsom and St Helier University Hospitals NHS Trust and Great Ormond Street hospital for Children NHS Trust. Trisomy screening laboratory services are provided by Birmingham Women's and Children's NHS Foundation Trust. Newborn hearing screening for St Mary's hospital is provided by the Kensington, Westminster and Hounslow hearing service based within Chelsea and Westminster Hospital NHS

Foundation Trust. The newborn hearing screening service at Queen Charlotte's and Chelsea hospital is run in-house by Imperial.

Findings of this first antenatal and newborn Screening QA visit to Imperial College Healthcare NHS Trust

Immediate concerns

The QA visit team identified 2 immediate concerns. A letter was sent to the chief executive on 13 November 2017 asking that the following items were addressed within 7 days:

- the haematology and infectious diseases (IDS) laboratories identified incidents of the 'wrong individual's blood in tube' which potentially included antenatal screening samples. We were informed that the trust has investigated these incidents but it was not clear at the time of the visit whether antenatal screening samples were involved
- the recent change of provider for the antenatal sickle cell and thalassaemia (SCT) counselling service for the St Mary's site has resulted in a lack of clarity over delivery of key service elements such as prenatal diagnosis

A response was received and as antenatal screening samples were affected, the 'wrong blood in tube' incident has now been formally reported to the London screening quality assurance service (SQAS) and to commissioners at NHS England London and is being investigated.

The Trust has provided assurances that the SCT referral pathways are in place and that all women have been referred by the screening coordinators for counselling and prenatal diagnosis as required.

High priority

The QA visit team identified 15 high priority findings as summarised below:

- manage all screening patient safety incidents and serious incidents in accordance with 'Managing Safety Incidents in NHS Screening Programmes'
- update relevant Trust and local policies to include reference to managing screening incidents in accordance with 'Managing Safety Incidents in NHS Screening Programmes'
- undertake a screening programme staffing capacity review
- 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

- re-instate the direct notification to the screening teams for women identified at referral as known positive or carrier for infectious diseases or SCT
- develop an SCT guideline that meets national SCT programme guidance and standards
- complete a risk assessment to review the pathway/staffing structures and resilience in the SCT counselling service
- make sure laboratory turnaround times for reporting all haemoglobin variants meet national programme requirements
- implement a weekly failsafe list of all positive antenatal SCT results and father results to be sent from the laboratories to the screening teams and counsellors
- implement a weekly failsafe list of all positive antenatal IDS results to be sent from the laboratories to the screening teams and infectious diseases midwife
- implement and monitor a plan to submit KPI FA2 data
- make sure access to interpreting services is available within the antenatal sonography department
- document the roles and responsibilities for follow up of women that do not attend for scan appointments
- identify a newborn infant physical examination (NIPE) lead to oversee and monitor the programme
- make sure adequate numbers of staff in the neonatal units have access to the newborn bloodspot (NBS) Northgate database to make sure there is cover each day

Shared learning

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

- the recruitment of a matron to lead on screening and fetal medicine and a failsafe officer to further support screening pathways across the Trust
- the development of a newborn bloodspot competency document to assist with training and learning needs for clinical staff
- there are identified lead nurses for newborn bloodspot in both neonatal units
- changing default date settings on the NBS Northgate database to identify all eligible babies as early as possible

Recommendations

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

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1	NHS England London (NHSEL) to clarify the monitoring process for action plans	1-7	6 months	Standard	Process reported to the Trust Screening Steering Group (TSSG)
2	Amend the terms of reference of the TSSG to make sure there is a senior chair and the membership includes all relevant parts of each programme pathway	1-7	3 months	Standard	Amended terms of reference approved by the TSSG
3	Combine all open action plans into a single screening quality improvement plan and update as new actions arise	1-7	6 months	Standard	Integrated screening quality improvement plan with clearly assigned responsibility for actions
4	The commissioner should agree with the provider a schedule of audits for inclusion in the NHS standard contract	1-7	12 months	Standard	Copy of audit schedule presented to TSSG
5	Manage all screening patient safety incidents and serious incidents in accordance with ‘Managing Safety Incidents in NHS Screening Programmes’	8, 9	6 months	High	a. All staff trained in incident reporting b. Incident reports presented to TSSG

No.	Recommendation	Reference	Timescale	Priority	Evidence required
6	Update relevant Trust and local policies to include reference to managing screening incidents in accordance with 'Managing Safety Incidents in NHS Screening Programmes'	8, 9	6 months	High	Policy approved at TSSG and ratified
7	Undertake a screening programme staffing capacity review	1-7	3 months	High	a) Present the draft staffing capacity review and action plan to the TSSG for comments b) Final report and action plan presented to TSSG
8	The SCT laboratories should include a specific vertical audit of an antenatal sample in the audit schedule	12, 13	12 months	Standard	Confirmation to TSSG that antenatal sample vertical audit has been added to the audit schedule for: a) SMH SCT lab b) QCCH SCT lab
9	Complete a user survey to gather views about the antenatal and newborn screening pathways	1-7	12 months	Standard	Action plan of survey is discussed at TSSG

Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
10	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	1-4	3 months	High	b) Screen shot of tracking (failsafe) system b) Standard operating procedure for managing the tracking process with roles and responsibilities clearly outlined c) Submission of KPI data – ID1, ST1, ST2, ST3, FA1, FA2
11	Implement a tracking process to make sure that all samples sent to external laboratories are confirmed as received	1, 2, 4	6 months	Standard	Confirmation to TSSG that a documented tracking process has been implemented for samples being sent to: a) Birmingham (trisomy screening) b) Central Middlesex (SCT) c) Colindale (infectious diseases)

Identification of cohort – antenatal

No.	Recommendation	Reference	Timescale	Priority	Evidence required
12	Submit a screening incident assessment form to SQAS and NHS England London regarding the 'wrong blood in tube' incidents	8	7 days	Immediate	Screening Incident Assessment Form received by SQAS
13	Make sure antenatal laboratory request forms provide consent and decline options for each infectious diseases (IDS) condition	1, 13	6 months	Standard	Laboratory request forms updated

Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority	Evidence required
14	Implement the national NIPE SMART system	7	12 months	Standard	Confirmation to TSSG of NIPE SMART implementation
15	Document a 'data entry/NHS number error correction' work instruction for staff	5,6,7	6 months	Standard	Approval of document at TSSG
16	Update the bereavement checklist to include the need to update Northgate systems	5,6,7	3 months	Standard	Confirmation to TSSG that the checklist has been updated

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority	Evidence required
17	Re-instate the direct notification to the screening teams for women identified at referral as known positive/carrier for IDS or SCT	1, 4, 11, 12	3 months	High	a. Process for direct notification documented b. Confirmation to TSSG that notifications are being received
18	Review the location of the Screening Tests for You and Your Baby booklet link on the Trust's website to make it easier to find	1-7	12 months	Standard	Confirmation to TSSG that the link has been relocated

Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	See recommendation 8				
	See recommendation 10				
	See recommendation 11				
	See recommendation 12				
19	Review the SCT counselling processes at SMH to make sure counselling and referral pathways are in place	4, 11, 12	7 days	Immediate	Confirmation from Trust that pathway has been reviewed and counselling and pathways are in place
20	Develop an SCT guideline for the Trust with adequate local pathway detail that meets national SCT programme guidance and standards	4, 11, 12	3 months	High	a) Draft guideline presented to TSSG b) Guideline ratified

No.	Recommendation	Reference	Timescale	Priority	Evidence required
21	Make sure ST3 KPI data is accurate and the national KPI definition is used	10	6 months	Standard	Confirmation to TSSG that the data has been validated and only FOQs received with the specimen are included in the numerator
22	Complete a risk assessment to review the pathway/staffing structures and resilience in the SCT counselling service across the Trust	4, 11, 12	3 months	High	Action plan of the risk assessment to be presented to the TSSG
23	Implement a process for all women, who have had a termination or miscarriage to receive their SCT result	4	6 months	Standard	Documented processes included in the SCT and antenatal guidelines
24	Make sure laboratory turn-around times (TAT) for reporting all haemoglobin variants meet national programme requirements	12	3 months	High	Haemoglobin variant TAT audit presented to the TSSG
25	Implement a weekly failsafe list of all positive antenatal results and father results to be sent from the laboratories to the screening teams and counsellors	4, 12	3 months	High	Confirmation to the TSSG that a documented process is in place

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	See recommendation 10				
	See recommendation 11				
	See recommendation 12				
	See recommendation 13				
26	Review the resilience of the infectious diseases midwife role	1	6 months	Standard	a) Documented processes for all functions to be confirmed with the TSSG b) Arrangements for leave cover documented
27	Update the antenatal screening guideline IDS section to comply with national standards and guidance and reflect local practices	1, 14	6 months	Standard	Antenatal screening guideline updated and presented to TSSG
28	Audit the reasons for women not attending antenatal hepatology appointments to make sure the acceptable threshold for KPI ID2 can be achieved	1, 14	12 months	Standard	Audit findings and action plan presented to TSSG
29	Implement the NHSE London hepatitis B template letter for GP notification of women with a positive result	1, 14	6 months	Standard	Confirmation to TSSG that the NHSE London template is in use
30	Implement and monitor a process for notifying the Child Health Information Service (CHIS) of all babies who require hepatitis B vaccine scheduling and follow up serology	1, 14	6 months	Standard	a) Standard operating procedure for notification b) Annual audit of notifications

No.	Recommendation	Reference	Timescale	Priority	Evidence required
31	Implement a weekly failsafe list of all positive antenatal results to be sent from the laboratories to the screening teams and infectious diseases midwife	1, 13, 14	3 months	High	Confirmation to the TSSG that a documented process is in place

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	See recommendation 10				
	See recommendation 11				
32	Implement and monitor a plan to submit KPI FA2 data	3, 10, 19	3 months	High	KPI FA2 data submitted to national programme
33	Review the location of the phlebotomy in relation to sonography services on the SMH site to make sure it is as efficient and easy for women to attend phlebotomy as the estate constraints permit Risk assess the provision of phlebotomy services at SMH in relation to trisomy screening	2, 17, 19	12 months	Standard	Confirmation to TSSG that service location review has been completed and locations changed or risks mitigated
34	Make sure access to interpreting services is available within the sonography department	2, 3	3 months	High	Confirmation to TSSG that sonographers have access to interpreting services as per Trust guidance

No.	Recommendation	Reference	Timescale	Priority	Evidence required
35	Document the roles and responsibilities for follow up of women that do not attend for scan appointments	2, 3	3 months	High	Documented process approved by TSSG
36	Address sonography room issues at SMH to make sure the quality of the Trust's FASP is not compromised	2, 3, 16, 17	6 months	Standard	Sonography manager to provide updates to the TSSG on how the risk register issues are being progressed
37	Reinstate sonography departmental image review process	17	3 months	Standard	Confirmation to TSSG that image review has been reinstated

Newborn hearing screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
38	Action plans should be put in place to monitor and improve performance of KPI NH2	10, 22	6 months	Standard	Action plans and progress presented to TSSG
39	Implement and monitor a plan to improve performance of NH1 at SMH	10, 22	12 months	Standard	Action plan and progress presented to TSSG

Newborn and infant physical examination

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	See recommendation 14				
40	Update the NIPE guideline to comply with national guidance and include referral timeframes and pathways	20	6 months	Standard	Updated NIPE guideline approved by TSSG and ratified
41	Identify a NIPE lead to oversee and monitor the programme	7	3 months	High	Confirmation to TSSG of NIPE lead

No.	Recommendation	Reference	Timescale	Priority	Evidence required
42	Implement the agreed transfer of NIPE data to NWL CHIS hub	7	12 months	Standard	Confirmation to TSSG that data transfer process is in place

Newborn blood spot screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
43	Update the current action plan to make sure it addresses the avoidable repeat rate: KPI NB2	10, 23, 24	6 months	Standard	a) Updated action plan to be presented at the TSSG
44	Clarify the target audience for the NBS competency assessment document and include the process for using this document in the NBS guideline	5, 24	12 months	Standard	Updated NBS guideline to include the use of the competency training document
45	Document roles and responsibilities for how individual training needs are addressed for recurring avoidable repeats in maternity and neonatal unit	5, 10, 23, 24	12 months	Standard	Updated NBS guideline to include individual training needs pathway
46	Make sure adequate numbers of staff in the neonatal units have access to the NBS Northgate database to make sure there is cover each day	5, 23	3 months	High	Confirmation to TSSG that a sufficient number of staff in each NNU have access to Northgate
47	Streamline NBS database work to avoid duplication across national and local databases	5	12 months	Standard	Confirmation to TSSG that any duplication of work across databases has been eliminated

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.