



Public Health
England

Screening Quality Assurance visit report

NHS Antenatal and Newborn Screening Programmes

Royal Devon and Exeter NHS Foundation Trust

Public Health England leads the NHS Screening Programmes

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](https://twitter.com/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 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.

www.gov.uk/phe/screening Twitter: [@PHE_Screening](https://twitter.com/PHE_Screening) Blog: phescreening.blog.gov.uk
Prepared by: Screening QA Service (South).
For queries relating to this document, please contact: phe.screeninghelpdesk@nhs.net



© Crown copyright 2018

You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence v3.0. To view this licence, visit [OGL](http://www.nhs.uk/ogp). Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

Published: September 2018
PHE publications
gateway number: 2018442

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 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 Royal Devon and Exeter NHS Foundation Trust screening service held on 27 February 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 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 shared with the south west regional SQAS as part of the visit process

Local screening service

The Royal Devon and Exeter NHS Foundation Trust provides services for a core population of over 460,000 people. The population is characterised as 97.6% white British with 2.4% non-white ethnic groups.

Local screening services are commissioned by Northern, Eastern and Western Devon Clinical Commissioning Group on behalf of NHS England south west.

The scope of this review includes services provided at Royal Devon and Exeter NHS Foundation Trust:

- the maternity service
- the sonography service for trisomy screening and the 18 to 20+6 week fetal anomaly scan

- laboratory services for sickle cell and thalassaemia and infectious disease screening

It also includes a review of the child health information service provided by Virgin Care on behalf of Devon Integrated Children's Services.

Delivery of this screening service involves interdependencies with other providers for parts of the pathway. Interfaces between the Royal Devon and Exeter NHS Foundation Trust and these services were included as part of this review.

Findings

This is the first QA visit to this service. Screening services are delivered by a team who are motivated and work well across all disciplines. With staffing challenges the service has already reviewed ways of working and is receptive to making further improvements.

Immediate concerns

The QA visit team identified no immediate concerns.

High priority

The QA visit team identified 3 high priority findings as summarised below:

- the majority of women accepting screening for sickle cell and thalassaemia are not screened by 10 weeks gestation
- audit of images for first trimester trisomy screening is not performed as recommended by the fetal anomaly screening programme
- the required training has not been completed by sonographers performing scans for first trimester trisomy screening

Shared learning

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

- education and training for staff working within the screening programmes is innovative and engaging
- there is a standard operating procedure for many of the functions of the screening team which supports resilience within the service at the Royal Devon and Exeter Hospital
- comprehensive audits of screening samples have been undertaken by the screening laboratories

- clear processes are documented within standard operating procedures for the child health information service
- competency assessment and continuing professional development for midwives who perform newborn infant physical examinations are monitored by the trust as part of the annual personal development review process
- the referral rate for quadruple testing for trisomy screening is less than 3%

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 that the Royal Devon and Exeter NHS Foundation Trust has signed contracts or service level agreements in place with the external laboratory for confirmatory testing for sickle cell disease	Service specifications 18	12 months	Standard	Confirmation at programme board that contracts are in place
2	Ensure that there is appropriate clinical oversight of the newborn infant physical examination programme and infectious diseases screening service	Service specifications 15 and 21	6 months	Standard	Named consultant clinical lead identified for the screening programmes and function included in job plan
3	Review terms of reference for the trust operational group and ensure all key stakeholders, including the commissioners are represented at each meeting	Service specifications 15 to 21	6 months	Standard	Terms of reference

No.	Recommendation	Reference	Timescale	Priority	Evidence required
4	Produce terms of reference for fetal medicine group meeting	Service specifications 16 to 18, 21	12 months	Standard	Terms of reference to formalise the purpose of the meeting, membership and shared learning
5	Manage all screening safety incidents in accordance with timeframes recommended within 'Managing safety incidents in NHS screening programmes' guidance	Managing Safety Incidents in NHS Screening Programmes	6 months	Standard	Incident investigation reports are completed and shared with relevant stakeholder with timeframes as defined in the guidance
6	Revise screening guidelines and pathways to ensure that local practice is reflected in current documents	Service specifications 15 to 21	12 months	Standard	Revised guidelines which have been benchmarked against NHS screening programme service specifications
7	Document a schedule of audits of the antenatal and newborn screening programmes	Service specifications 15 to 21	12 months	Standard	Agreed audit schedule presented at the programme board

Infrastructure

No.	Recommendation	Reference	Timescale	Priority	Evidence required
8	Undertake a screening service staffing capacity review	Service specifications 15 to 19, 21	12 months	Standard	Documented work force plan
9	Ensure counselling of women and couples at risk of sickle cell and thalassaemia is performed by appropriately trained staff	Service specification 18	12 months	Standard	All staff counselling women and couples at risk of sickle cell and thalassaemia must have completed the NHS screening programme accredited genetic risk assessment and counselling module or equivalent
10	Ensure the role and functions of the screening support sonographer are supported	Service specifications 16 and 17	6 months	Standard	Job description Evidence of protected time within the work rota
11	Ensure all staff involved in undertaking first trimester screening within the sonography department complete the e-learning modules in line with the fetal anomaly screening programme recommendations	Service specifications 16 and 17	6 months	High	Training records for staff

No.	Recommendation	Reference	Timescale	Priority	Evidence required
12	Formally record and monitor the risk within the process for generating NHS numbers for babies with the current maternity IT system	Service specifications 19 to 21	6 months	Standard	Trust risk register

Identification of cohort – newborn

No.	Recommendation	Reference	Timescale	Priority	Evidence required
13	Document the process for the generation of an NHS number in the case of the failure of the maternity IT system	Service specifications 19 to 21	6 months	Standard	Standard operating procedure
14	Document a process for notifying key stakeholders about deceased babies (including updating the baby's status as deceased on the screening IT systems)	Service specifications 19 to 21	6 months	Standard	Standard operating procedure

Invitation, access and uptake

No.	Recommendation	Reference	Timescale	Priority	Evidence required
15	Update the trust website to include the latest information on the antenatal and newborn screening programmes	Service specifications 15 to 21	6 months	Standard	Website updated

No.	Recommendation	Reference	Timescale	Priority	Evidence required
16	Implement and monitor a plan to meet the acceptable level for the key performance indicator for ST2 – women having antenatal sickle cell and thalassaemia screening with a screening result available by 10 weeks gestation	Service specification 18	12 months	High	Submission of KPI data for ST2 which meets the acceptable level
17	Revise the screening request form to meet minimum requirements specified by the infectious diseases screening programme	Service specifications 15	12 months	Standard	Revised request form
18	Ensure that women who have a miscarriage or termination receive screening results from the maternity service	Service specifications 16	6 months	Standard	Revised guideline

Sickle cell and thalassaemia screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
19	Implement a process for direct referral for couples or women known to be at risk of sickle cell or thalassaemia for pre-natal diagnosis	Service specification 18	6 months	Standard	Standard operating procedure

Infectious diseases in pregnancy screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
20	Revise the process for alerting the maternity service of rejected or untested samples for the infectious diseases screening programme and monitor receipt of follow up samples	Service specification 15	6 months	Standard	Standard operating procedure

Fetal anomaly screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
21	Perform quarterly departmental review of images for first trimester screening scans	Service specification 16 FASP: Handbook for ultrasound practitioners	6 months	High	Standard operating procedure Evidence presented at the antenatal and newborn screening programme board

Newborn blood spot screening

No.	Recommendation	Reference	Timescale	Priority	Evidence required
22	Implement and monitor a plan to meet NBS standard 5 – timely receipt of a sample in the newborn screening laboratory	NBS standard 5	12 months	Standard	Action plan that is agreed and monitored by the antenatal and newborn programme board
23	Implement and monitor a plan to meet the acceptable level for the key performance indicator NB4 – babies eligible for newborn blood spot screening who have a conclusive result recorded on the child health information system at ≤ 21 calendar days of notifying the CHRd of movement in	Service specification 19	6 months	Standard	Action plan that is agreed and monitored at the programme board meeting Submission of key performance data for NB4

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.