Public Health England

Protecting and improving the nation's health

Screening Quality Assurance visit report

NHS Cervical Screening Programme
The Royal Wolverhampton NHS Trust

23 April 2018

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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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Executive summary

The NHS Cervical Screening Programme invites women between the ages of 25 and 64 for regular cervical screening. This aims to detect abnormalities within the cervix that could, if undetected and untreated, develop into cervical cancer.

The findings in this report relate to the quality assurance visit of the Royal Wolverhampton NHS Trust screening service held on 23 April 2018.

Quality assurance purpose and approach

Quality assurance (QA) aims to maintain national standards and promote continuous improvement in cervical 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 pre-review visits to the Royal Wolverhampton NHS Trust on 18 April 2018
- information shared with the Midlands and East regional SQAS as part of the visit process

Local screening service

Since 2013 commissioning of cervical screening for the Wolverhampton population has been undertaken by the Midlands and East (West Midlands) Screening and Immunisation Team (SIT). The Royal Wolverhampton NHS Trust cervical screening programme (the programme) provides screening services provides screening services for women served by the Wolverhampton clinical commissioning group (CCG). Royal Wolverhampton NHS Trust is situated in Wolverhampton. It serves a population of over 253,000 people. The eligible population for cervical screening covered by the Wolverhampton CCG is approximately 69,000 women.

The cervical cytology laboratory for the programme is based at the New Cross Hospital, Wolverhampton. Human papilloma virus (HPV) testing for the programme is undertaken by microbiology department and is based in the same building as the cytology service.

The cervical histology service is in the laboratory based New Cross Hospital. There is one colposcopy service based at New Cross Hospital.

Findings

At the time of the last visit in 2013, there had just been a major reconfiguration of the cervical cytology service across the Birmingham and the Black Country resulting in work transferring from 3 laboratories to the new hub cytology service laboratory at New Cross Hospital. There is evidence of well-established links with the other Trusts involved in the reconfiguration. This visit confirms how well the service managed the complex transfer of this work. The excellent turnaround times for cytology samples is evidence of a stable service, even during times of peak workload and uncertainty about the future with the implementation of HPV testing in 2019. Despite national issues with recruiting and retaining consultant pathologists, the histology service is also maintaining excellent turnaround times for reporting cervical histology samples. The colposcopy team is also meeting waiting time standards despite having had some staffing issues.

Since the last visit, there has been some changes in leadership roles. There is a need to document and clarify the roles and responsibilities and ensure sufficient time is available for them. Documentation across the cervical screening service needs to be updated to reflect working practices and national guidance. Patient feedback on colposcopy needs to be gathered and acted upon routinely.

A number of recommendations from the last visit have been made again. Ensuring that changes in practice are embedded into routine activity is essential. Improved governance is required to achieve this. Processes to monitor, audit and assess performance against national standards, issues and risks in sufficient depth to identify necessary actions and then address them promptly is also essential. Incident management awareness across the whole of the programme needs to be in place. This will ensure transparency and appropriate reporting across the service.

The high priority issues identified are summarised below as well as a number of areas of shared learning. For a complete list of recommendations, please refer to the table of all recommendations or to the related section within the full report.

Immediate concerns

The QA visit team identified 1 immediate concern. A letter was sent to the chief executive on 24 April 2018, asking that the following items were addressed within 7 days:

- demonstrate British Society of Colposcopy and Cervical Pathology (BSCCP) accreditation for all colposcopists

Responses were received on 30 April and 10 May 2018. Evidence of BSCCP accreditation has now been received and this recommendation is considered complete.

High priority

The QA visit team identified 9 high priority findings.

- there is no evidence that all staff across the programme are aware of how to recognise and manage all screening patient safety incidents and serious incidents in accordance with national guidance
- there is no evidence that the Trust incident policy includes reference to the national guidance on managing screening incidents
- there is no documented risk management process covering all areas of the screening programme
- there is no forum for discussion of colposcopy operational issues
- not all colposcopists are meeting the annual requirements for minimum workload
- individual colposcopist performance against a number of key performance indicators is not in line with national standards
- not all colposcopists are following the national HPV triage and test of cure protocol and discharging patients to primary care for follow up when required
- there is no evidence of an annual user survey of colposcopy services
- not all colposcopists are meeting the minimum of attending 50% of the multi-disciplinary meetings

Shared learning

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

- a clearly documented incident tracker and comprehensive escalation process in relation to incident management within the SIT
- the SIT is prioritising work on increasing screening attendance through commissioning sample taking in community and sexual health clinics and running local sample taker workshops
- Microsoft Excel spreadsheet developed to match the label on the cytology form and the bar code on the specimen vial before any further action is taken in the cytology laboratory
- sustained achievement of cytology and histology sample turnaround times, including letters sent to sample takers in relation to samples not received within 3 days and prioritisation of samples

- all 4 pathologists participate in the national specialist gynaecological histology external quality assessment scheme
- World Health Organisation checklist in place within colposcopy to reduce risk

Recommendations

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

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
1	Implement the new national guidance on the cervical screening provider lead role	1	3 months	Standard	Updated role description. Gap analysis against the guidance with evidence of action taken to address any gaps
2	Develop and implement a whole Trust audit schedule for cervical screening services	1,2	3 months	Standard	Evidence of the audit schedule and the minutes of the meeting where it was approved
3	Update, ratify and implement the Trust policy on invasive cervical cancer audit and disclosure (and define roles and responsibilities)	3	3 months	Standard	Evidence of the updated and ratified policy and the minutes of the meeting where it was approved
4	Complete an audit to demonstrate offer of disclosure of invasive cervical cancer audit	3	6 months	Standard	A copy of the report from the annual disclosure audit undertaken, the findings and any action(s) taken as a result
5	Recognise and manage all screening patient safety incidents and serious incidents in accordance with ‘Managing Safety Incidents in NHS	2,4	3 months	High	Evidence of process in place and confirmation that all staff have been made aware

No.	Recommendation	Reference	Timescale	Priority	Evidence required
	Screening Programmes' and ensure staff awareness				
6	Provide the Trust policy to include reference to managing screening incidents in accordance with 'Managing Safety Incidents in NHS Screening Programmes'	2,4	3 months	High	Copy of policy
7	Put in place a consistent system for recording and reporting issues and errors occurring in cytology and histology	2	6 months	Standard	Details and documentation of system established
8	Put in place a risk management process	2	3 months	High	Confirmation of process in place
9	Appoint a lead histopathologist for cervical screening with responsibility for ensuring good practice, compliance with protocols and that NHS Cervical Screening Programme (CSP) standards are met	2	3 months	Standard	Job description, job plan with dedicated professional activity allocation
10	Document the arrangements for the microbiology input into Human Papilloma Virus (HPV) testing, including escalation arrangements within microbiology	5	3 months	Standard	Document of arrangements in place
11	Demonstrate evidence of time allocation and accountability for lead colposcopist role	2,6	3 months	Standard	Job plan with dedicated professional activity allocation, accountability within the job description
12	Document the appointment and roles and responsibilities of the lead colposcopy nurse	2,6	3 months	Standard	Job description, job plan with dedicated professional activity allocation

No.	Recommendation	Reference	Timescale	Priority	Evidence required
13	Put in place Trust-wide 3 monthly colposcopy operational meetings	6	3 months	High	Terms of reference and minutes of the meetings that have occurred since the visit

Cytology

No.	Recommendation	Reference	Timescale	Priority	Evidence required
14	Audit and validate the document archiving and scanning system to ensure it works as expected	7	6 months	Standard	Provide audit findings and any actions required
15	Put in place trained cover for the use of the 'COGNOS' cytology data reporting system	7	3 months	Standard	Confirmation of trained staff
16	Update service level agreements (SLAs) for cytology sample transport and specimen collection	2,7	3 months	Standard	Updated and signed SLAs
17	Implement a system to track and ensure cervical cytology and histology specimens sent out of the Trust are returned	2,7	3 months	Standard	Details of system in place
18	Update the laboratory standard operating procedure (SOP) for sample acceptance to reflect the national policy	8	3 months	Standard	Updated and approved SOP
19	Update the triage and test of cure SOP to reflect national guidance for the HPV testing in the follow up of untreated cervical intraepithelial neoplasia (CIN) grade 1	9	3 months	High	Updated and approved SOP
20	Update the failsafe SOP to reflect national guidance	7	6 months	Standard	Updated and approved SOP

21	Ensure that comprehensive individual performance data are provided to pathologists/consultant biomedical scientists	7	3 months	Standard	Details of arrangements in place and evidence of regular provision of performance monitoring data to staff

HPV testing

No.	Recommendation	Reference	Timescale	Priority	Evidence required
22	Demonstrate evidence of including internal quality control (IQC) material in each sample batch tested	5	3 months	Standard	Evidence of inclusion of IQC material in each sample batch

Sample taker register

No.	Recommendation	Reference	Timescale	Priority	Evidence required
23	Update the screening and immunisation team document detailing the arrangements for the sample taker register and feedback to sample takers	2, 8	3 months	Standard	Updated protocol

Diagnosis – histology

No.	Recommendation	Reference	Timescale	Priority	Evidence required
24	Update SOPs for cervical cancer and large loop excision of the transformation zone dissection and demonstrate inclusion within the laboratory quality management system	10	6 months	Standard	Updated and approved SOP

No.	Recommendation	Reference	Timescale	Priority	Evidence required
25	Document the criteria for what constitutes an inadequate biopsy	10	3 months	Standard	Updated and approved SOP
26	Undertake an audit of inadequate biopsy reporting by individual clinician	10	6 months	Standard	Copy of the audit report and details of the actions taken as a result
27	Ensure that comprehensive individual performance data are provided to pathologists	11	3 months	Standard	Details of arrangements in place and evidence of regular provision of performance monitoring data to staff

Intervention and outcome – colposcopy

No.	Recommendation	Reference	Timescale	Priority	Evidence required
28	Demonstrate British Society of Colposcopy and Cervical Pathology (BSCCP) accreditation for all colposcopists	6	7 days	Immediate	Provide proof of BSCCP accreditation
29	Put in place a system to ensure all colposcopists meet the requirements for BSCCP accreditation	6	6 months	Standard	Document detailing system in place
30	Demonstrate that there are 2 nurses available in the colposcopy clinics at all times	6	3 months	Standard	Documented evidence that 2 nurses are in each clinic
31	Ensure information technology back-up processes for the colposcopy database are in place and formally documented	6	3 months	Standard	Copy of the SOP
32	Update the colposcopy guidelines to include conservative management of CIN grade 2	6	3 months	Standard	Ratified guidelines with evidence of implementation

No.	Recommendation	Reference	Timescale	Priority	Evidence required
33	Update and compile into a single document all administrative arrangements for the colposcopy service	6	6 months	Standard	Updated document, including the inclusion of a clinical review of the colposcopy discharge information prior to sending
34	Update colposcopy clinic guidelines to encompass all operational arrangements for the running of the service including details of the process in place for the presence of a friend or relative for the woman about to undergo colposcopy	6	6 months	Standard	Updated and ratified guidelines detailing operational arrangements for colposcopy and minutes of meetings where these were discussed and signed off
35	Establish arrangements for access to screening history information and pre-populated request forms for samples taken within the Trust but outside colposcopy	12	3 months	Standard	SOP for samples taken outside of colposcopy and confirmation of access to ‘Open Exeter’
36	Ensure all colposcopists meet the annual throughput requirements for 50 new NHS CSP referrals a year	6	6 months	High	Data submission showing number of new NHS CSP referrals for each colposcopist in the period 1 April 2017 to 31 March 2018
37	Audit large loop excisions of the transformation zone (including depth and number of pieces), ablative treatments, biopsy of high grade abnormal referral cytology, positive predictive value and treatments undertaken under local anaesthetic	6	3 months	High	Audit results and details of any resulting actions taken

No.	Recommendation	Reference	Timescale	Priority	Evidence required
38	Implement a rolling colposcopy audit programme to link with the Trust-wide audit schedule	6	3 months	Standard	Details of the audit programme
39	Ensure all colposcopists are following the national HPV triage and test of cure protocol including discharge to primary care for follow-up	9	3 months	Standard	Copy of audit report and any actions required
40	Update invitation and result letters to reflect national guidance	13	3 months	Standard	Updated example of letters
41	Complete an annual service user survey	6	6 months	High	Outcome of survey and any actions required
42	Undertake an equality impact assessment on access to clinic	6	3 months	Standard	Results of assessment and actions taken

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 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.