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Screening Quality Assurance visit report

NHS Cervical Screening Programme Manchester University NHS Foundation Trust

7,11 and 12 February 2020

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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 (NHS CSP) 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 Manchester University NHS Foundation Trust screening service held on 7, 11 and 12 February 2020 and commissioner interviews on 27 January and 17 March 2020.

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:

- 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 North regional SQAS as part of the visit process

Local screening service

Manchester Clinical Sciences at Manchester Royal Infirmary within Manchester University NHS Foundation Trust (MFT) provide human papillomavirus (HPV) and cytology screening for all the North West. This visit is limited to the screening population from Central and South Manchester and Trafford that access colposcopy services at the three colposcopy sites which are:

- Saint Mary's @ Oxford Road Campus Hospital
- Saint Mary's @ Trafford General Hospital
- Saint Mary's @ Wythenshawe Hospital

Cervical histopathology services for the 3 colposcopy units are provided by 2 histopathology laboratories within Manchester Clinical Sciences, one based at the Manchester Royal Infirmary and one at Wythenshawe Hospital.

Findings

Manchester University NHS Foundation Trust (MFT) was formed on 1 October 2017 following the merger of Central Manchester University Hospitals NHS Foundation Trust (CMFT) and University Hospital of South Manchester NHS Foundation Trust (UHSM). Since the 2017 merger, the lead roles for cervical screening provider lead, colposcopy and histopathology are maintained on the historic trust footprint which is:

- Central Manchester Foundation Trust (CMFT) – colposcopy at St Mary’s Oxford Road and Trafford Hospital sites, cervical cytology, HPV testing and histopathology at Manchester Royal Infirmary (MRI)
- University Hospital of South Manchester (UHSM) – colposcopy and histopathology at Wythenshawe Hospital

In preparation for the QA visit, the trust management has started to agree the alignment of the historic service configuration into a single unit model for the trust. Plans are at an early stage.

Following the last QA visit in October 2016, CMFT has implemented most of the recommendations. These include:

- formalising the cervical screening leadership roles with dedicated sessional commitment and administrative support
- implementing CMFT footprint Cervical Screening Provider Lead (CSPL) led meetings
- implementing a multi-disciplinary audit schedule
- alignment of policies, protocols, letters and leaflets between the two colposcopy units
- purchase of new colposcopy equipment

Following the last QA visit to UHSM in November 2016, 14 out of 27 recommendations have not been closed. The open recommendations relate to the hospital programme coordinator role (now cervical screening provider lead), lead roles, colposcopy meetings, audits, standard operating procedures, colposcopists seeing the required number of NHS CSP cases and colposcopy MDT attendance. Following the formation of MFT, some recommendations are no longer relevant. Staffing capacity has also had an impact on the service being able to address some of the recommendations.

Immediate concerns

The QA visit team identified no immediate concerns.

Urgent priority

The QA visit team identified one urgent finding. A letter was sent to the service leads on 13 February 2020 asking that an action plan be developed to address, within 3 months:

- the colposcopy database at the Saint Mary's @ Oxford Road unit showing patients that had not received treatment for more than 6 weeks following a result of CIN biopsy

A response with an action plan was received within 14 days, which assured the visit team that appropriate steps will be taken to address the urgent finding.

High priority

The QA visit team identified 21 high priority findings which were:

- colposcopy and histopathology services organised to the historical footprint and not managed as a single service within one trust, with no whole trust lead colposcopist, lead histopathologist and lead colposcopy nurse, and no alignment of standard operating procedures and processes
- insufficient colposcopy clinic capacity to sustainably meet key performance indicators
- different colposcopy service administration processes, IT and patient information leaflets at the three sites
- not all colposcopists see the minimum expected number of new cases for the NHS CSP and do not attend a minimum of 50% of multi-disciplinary team (MDT) meetings
- colposcopy database unable to reliably produce all the cervical screening data requirements with different failsafe processes in place
- nursing support outside of recommended levels in nurse led colposcopy clinics
- colposcopy clinical guidelines do not include detail about the management of colposcopic emergencies at the St Mary's Oxford Road and Trafford sites
- variation in see and treat completed for high-grade referrals at individual colposcopist level
- histopathology operating as two separate services within a single trust governance structure
- manual processes for histopathology data collection
- working environment causes problems with sample tracking (non-screening samples) at Wythenshawe
- delays in the completion of the histopathology element of the invasive cervical cancer audit at Wythenshawe

- no sustainable plan for laboratory equipment replacement and contingency planning for equipment breakdown
- no single process for the MDT meetings and no auditable documentation of confirmation of completion of actions

Shared learning

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

- Screening and Immunisation Team have undertaken proactive work to improve cervical screening coverage by the commissioner, including insight work, working with partners to target support to practices with populations who are most at risk, commissioning of community based approaches to raise awareness of cervical screening including the Answer Cancer campaign and brief interventions in pharmacies
- Screening and Immunisation Team have mapped cervical screening pathways for out-of-hours provision in GP hubs across Greater Manchester and this has been shared across North West region to encourage a standard approach
- Screening and Immunisation Team have planned work to improve availability and equity of access in sexual health services
- Screening and Immunisation Team have plans for the commissioning of a bespoke cervical screening service for transgender men
- Screening and Immunisation Team have plans to develop additional support for people with learning disability to access screening and immunisation services in partnership with learning disability nurses
- Screening and Immunisation Team supporting education sessions focusing on improving clinical skills including recognition of an abnormal cervix
- good example of a template for disclosure of invasive cervical cancer audit
- comprehensive clinical guidelines for managing colposcopy emergencies at Wythenshawe
- links into safeguarding team to support women with learning disability
- proactive staff development used to train advanced biomedical scientists in histology cut up procedures at Wythenshawe
- focus on histopathology training at Manchester Royal Infirmary with thorough peer review of cases supporting calibration of histology reports

Recommendations

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

Governance and leadership

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|---|--|-----------|----------|--|
| 01 | NHS England and NHS Improvement cervical screening commissioner to complete the planned work to formalise the arrangements with clinical commissioning groups (CCGs) for performance monitoring of colposcopy services, including documentation of a defined route for escalation of concerns | National service specification 25 | 6 months | Standard | Confirmation of CCG arrangements for performance management Documented escalation process |
| 02 | Appoint a trust wide cervical screening provider lead with agreed job description, accountability to the chief executive, dedicated time, and administrative support to oversee the whole NHS Cervical Screening Programme across all sites | NHS Cervical Screening Programme: the role of the cervical screening provider lead | 3 months | Standard | Confirmation of appointment, Job description, Job plan |
| 03 | Formally appoint a deputy for the cervical screening provider lead | NHS Cervical Screening Programme: the role of the cervical screening provider lead | 3 months | Standard | Confirmation of appointment |
| 04 | Document an organisational | National service | 3 months | High | Copy of the |

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|--|--|-----------|----------|--|
| | accountability structure that demonstrates leadership for all areas of the NHS Cervical Screening Programme delivered by the trust including escalation routes for governance and performance issues | Specification 25 | | | Structure and escalation routes |
| 05 | Ensure that the provider report to the Greater Manchester Cervical Screening Programme Board includes all services delivered by the trust | National service specification 25 | 3 months | Standard | Report |
| 06 | Establish whole trust quarterly cervical management meetings chaired by the cervical screening provider lead to update all cervical screening service leads | NHS Cervical Screening Programme: the role of the cervical screening provider lead | 3 months | Standard | Terms of reference, meeting schedule |
| 07 | Produce an annual performance report and a 6 monthly update to cover all NHS Cervical Screening Programme services to clinical governance committee | NHS Cervical Screening Programme: the role of the cervical screening provider lead | 12 months | Standard | Cervical screening provider lead report and 6-monthly report with circulation list |
| 08 | Implement an annual audit schedule that includes all elements of the NHS Cervical Screening Programme delivered by the trust and documents outcomes and actions | National service specification 25 | 12 months | Standard | Annual audit schedule covering colposcopy and histopathology with confirmatory evidence of actions taken |
| 09 | Establish a trust-wide protocol for the completion of the invasive | NHS CSP 28 | 6 months | Standard | Ratified protocol |

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|--|--|-----------|----------|---|
| | cervical cancer audit | | | | |
| 10 | Ensure that there is sufficient capacity for timely completion of histopathology element of invasive cervical cancer audit | Cervical Screening Programme: Histopathology Reporting Handbook, NHS CSP 28 | 3 months | High | Confirmation from lead histopathologist |
| 11 | Implement a trust-wide policy for the offer of disclosure of invasive cervical cancer audit results | NHS CSP 28 | 6 months | Standard | Ratified policy |
| 12 | Complete an audit to demonstrate offer of disclosure of invasive cervical cancer audit | NHS CSP 28 | 12 months | Standard | Audit findings and action taken |
| 13 | Document the process for results and referral for cervical samples taken in the trust outside of colposcopy | National service specification 25 | 6 months | Standard | Ratified protocol |
| 14 | Update the colposcopy failsafe procedures to ensure consistent processes at all sites | NHS Cervical Screening Programme: the role of the cervical screening provider lead | 6 months | Standard | Protocol |
| 15 | Ensure that the cervical screening provider lead is informed of all incidents for the NHS Cervical Screening Programme pathway | NHS Cervical Screening Programme: the role of the cervical screening provider lead | 3 months | Standard | Documented process |
| 16 | Risk assessment impact of laboratory environment on sample tracking processes for NHS Cervical Screening Programme samples | Cervical Screening Programme: Histopathology Reporting | 6 months | High | Risk assessment |

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|---|--|-----------|----------|---|
| | | Handbook | | | |
| 17 | Ensure that histopathologists are aware of and follow national screening incident guidance | Cervical Screening Programme: Histopathology Reporting Handbook | 3 months | Standard | Standard operating procedure |
| 18 | Ensure that there is a contingency plan in place for managing waiting times in colposcopy between the different the sites in times during staff absence | NHS CSP 20 | 6 months | Standard | Contingency plan |
| 19 | Appoint a lead histopathologist for whole trust with responsibility for ensuring good practice, compliance with protocols and that NHS Cervical Screening Programme standards are met | National Service specification 25, Cervical Screening Programme: Histopathology Reporting Handbook | 6 months | High | Job description, job plan with dedicated professional activity allocation |
| 20 | Nominate a deputy histopathologist for the NHS Cervical Screening Programme | Cervical Screening Programme: Histopathology Reporting Handbook | 6 months | High | Confirmation of appointment |
| 21 | Implement a single lead colposcopist with sufficient capacity to oversee the service across all trust sites with a job description, allocated time and administration support | National Service specification 25, NHS CSP 20 | 6 months | High | Job description, job plan with dedicated professional activity allocation |
| 22 | Formally appoint a deputy lead colposcopist | National Service specification 25, NHS CSP 20 | 6 months | Standard | Confirmation of appointment |

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|---|---|-----------|----------|---|
| 23 | Formalise the lead colposcopy nurse role and ensure that they dedicated time and appropriate administration support | National Service specification 25, NHS CSP 20 | 6 months | High | Job description, job plan with dedicated time |
| 24 | Ensure that there is senior leadership oversight and dedicated cross-cover for all colposcopy administrative duties to reduce the administrative burden on nurse colposcopists and prevent future incidents | National specification 25, NHS CSP 20 | 6 months | Standard | Confirmation of leadership oversight, administration cross cover arrangements |

Infrastructure

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|--|---|-----------|----------|---|
| 25 | Implement the new colposcopy database to ensure that the system can reliably produce the data required for the NHS Cervical Screening Programme and support failsafe processes | National Service specification 25, NHS CSP 20 | 12 months | High | Updates on progress and implementation date |

Diagnosis – histology

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|---|---|-----------|----------|-------------------|
| 26 | Review service configuration and develop a workforce plan to sustainably meet specimen turnaround times | Cervical Screening Programme: Histopathology Reporting Handbook | 12 months | High | Workforce plan |

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|---|---|-----------|----------|--|
| 27 | Document the procedure for the assessment and acceptance of locum staff prior to appointment | Cervical Screening Programme: Histopathology Reporting Handbook | 6 months | Standard | Standard operating procedure |
| 28 | Ensure there is a sustainable plan for laboratory equipment replacement and implement contingency planning for continuation of screening programme in case of equipment breakdown | Cervical Screening Programme: Histopathology Reporting Handbook | 3 months | High | Plan |
| 29 | Reduce manual data collection processes, and document procedure for data extraction for monitoring of NHS Cervical Screening Programme histopathology dataset | Cervical Screening Programme: Histopathology Reporting Handbook | 12 months | High | Data collection protocol |
| 30 | Implement standards outlined within the histopathology reporting handbook to include individual performance monitoring and reporting profiles | Cervical Screening Programme: Histopathology Reporting Handbook | 6 months | Standard | Audit of service model against guidance and action taken to address gaps |
| 31 | Align histology processes and standard operating procedures across both sites so that departments function as one service | Cervical Screening Programme: Histopathology Reporting Handbook | 12 months | High | Meetings, protocols, standard operating procedures |
| 32 | Improve the consistency of reporting of NHS Cervical Screening Programme specimens with standard form for reporting and include relevant dataset | Cervical Screening Programme: Histopathology Reporting Handbook | 6 months | Standard | Standard reporting form |

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|--|---|-----------|----------|---|
| 33 | Re-audit local protocol for routine examination of 8 levels for cervical punch biopsies to demonstrate additional benefit | Cervical Screening Programme: Histopathology Reporting Handbook | 12 months | Standard | Audit |
| 34 | Formalise process for identification, management and escalation of poor performance in NHS Cervical Screening Programme histopathology | Cervical Screening Programme: Histopathology Reporting Handbook | 6 months | Standard | Protocol |
| 35 | Implement annual histopathology audit schedule for NHS Cervical Screening Programme work | Cervical Screening Programme: Histopathology Reporting Handbook | 12 months | Standard | Annual audit schedule with confirmatory evidence of actions taken |

Intervention and outcome – colposcopy

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|--|---|-----------|----------|---|
| 36 | Ensure that there is sufficient colposcopy clinic capacity to sustainably meet key performance indicators across all sites | National Service Specification 25, NHS CSP 20 | 12 months | High | Review of clinics and documented outcomes |
| 37 | Ensure that there is consistent compliance against the minimum NHS Cervical Screening Programme requirements for nursing support in nurse-led colposcopy clinics | NHS CSP 20 | 3 months | High | Confirmation of nursing support |

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|---|------------|-----------|----------|---|
| 38 | Ensure that NHS Cervical Screening Programme individual colposcopy performance monitoring is included within annual appraisal process for all medical colposcopists | NHS CSP 20 | 12 months | Standard | Confirmation from lead colposcopist |
| 39 | Document the process for managing extended recovery at all sites | NHS CSP 20 | 3 months | Standard | Standard process with site specific flow charts |
| 40 | Review, align and update the clinical guidelines, including the management of colposcopic emergencies | NHS CSP 20 | 6 months | High | Ratified trust clinical guidelines |
| 41 | Ensure that the nurse colposcopists have allocated quiet office space for completion of NHS Cervical Screening Programme administration work | NHS CSP 20 | 6 months | Standard | Review of office space and actions |
| 42 | Ensure that there is direct access to the colposcopy database within theatre at Wythenshawe | NHS CSP 20 | 6 months | Standard | Confirmation of access |
| 43 | Ensure that colposcopy staff have access to Open Exeter | NHS CSP 20 | 3 months | Standard | Confirmation of access |
| 44 | Audit the patients identified in the colposcopy database failsafe system as not having had a treatment for more than 6 weeks following result of CIN biopsy | NHS CSP 20 | 3 months | Urgent | Audit outcomes and actions taken |
| 45 | Update and align colposcopy failsafe processes | NHS CSP 20 | 3 months | High | Failsafe protocol |
| 46 | Address the inequity in lack of ablative treatment availability at Wythenshawe | NHS CSP 20 | 6 months | Standard | Availability of ablative treatment |

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|--|---|-----------|----------|--|
| 47 | Standardise administration processes between colposcopy sites | NHS CSP 20 | 6 months | Standard | Standard operating procedure |
| 48 | Ensure a single process across all sites for the notification of next test due date on the colposcopy discharge template for NHS Cervical Screening Programme cases only | NHS CSP 20 | 6 months | Standard | Standard operating procedure |
| 49 | Make sure the colposcopy discharge template is validated by a clinician and submitted to the Cervical Screening Administration Service using the online portal | Cervical screening: cytology reporting failsafe (primary HPV) | 3 months | Standard | Standard operating procedure |
| 50 | Audit the clinic cancellation rate at the Wythenshawe site to demonstrate reduction | NHS CSP 20 | 6 months | Standard | Audit |
| 51 | Monitor and take action to reduce the 'patient did not attend' rates at Wythenshawe site | NHS CSP 20 | 6 months | Standard | KC65 quarterly data return |
| 52 | Undertake an audit on see and treat for high grade referrals, including standards for excisional biopsy by individual colposcopist and take action to meet the required standard | NHS CSP 20 | 12 months | High | Audit findings and action taken |
| 53 | Ensure that all colposcopists see the minimum number of new cases required for the NHS Cervical Screening Programme | NHS CSP 20 | 12 months | Standard | Data submission showing number of new NHS CSP referrals for each colposcopist in the period April 2020 to March 2021 |

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|--|--|-----------|----------|---------------------------------|
| 54 | Audit the low-grade biopsy rate to ensure that it meets the needs of the local population | NHS CSP 20 | 12 months | Standard | Audit findings and action taken |
| 55 | Develop clinical audits in colposcopy to drive quality improvement and performance | NHS CSP 20 | 6 months | Standard | Clinical audit schedule |
| 56 | Standardise all patient information leaflets used across all colposcopy sites | NHS CSP 20 | 6 months | Standard | Example leaflets |
| 57 | Increase the information about see and treat in the patient information leaflet | NHS CSP 20 | 6 months | Standard | Example leaflet |
| 58 | Make sure there is translated information about access to information in other languages within patient information leaflets | National Service Specification 25. NHS CSP 20 | 6 months | Standard | Example leaflets |
| 59 | Implement a standard process for patient result letters across all sites | NHS CSP 20 | 12 months | Standard | Standard result letters |
| 60 | Complete an annual patient user satisfaction survey for colposcopy | National service specification 25, NHS CSP 20 | 12 months | Standard | Survey |

Multidisciplinary team (MDT)

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|--|------------|-----------|----------|-------------------|
| 61 | Ensure that multidisciplinary team (MDT) meeting frequency meets the minimum standard of monthly intervals | NHS CSP 20 | 3 months | Standard | MDT schedule |

| No. | Recommendation | Reference | Timescale | Priority | Evidence required |
|-----|--|---|-----------|----------|---|
| 62 | Make sure all colposcopists attend a minimum of 50% of multidisciplinary team (MDT) meetings | NHS CSP 20 | 12 months | High | MDT meeting attendance audit April 2020 to March 2021 |
| 63 | Develop and implement a trust wide multidisciplinary team (MDT) meeting protocol with an aligned process at all sites | NHS CSP 20, National Service specification 25 | 3 months | High | Protocol |
| 64 | Ensure that there is administration support for the documentation of minutes for all multidisciplinary team meetings | NHS CSP 20 | 3 months | Standard | Confirmation of administration support, Minutes |
| 65 | Ensure that there is a documented monitoring process for completion of actions agreed at the multidisciplinary team meetings | NHS CSP 20 | 3 months | Standard | Agreed MDT documentation |

Next steps

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