Public Health England

NHS

Screening Quality Assurance visit report

Basildon and Thurrock Hospitals NHS Foundation Trust Cervical Screening Programme

27 June 2017

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 to advise and support government, local authorities and the NHS in a professionally independent manner.

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

Published: April 2018
PHE publications
gateway number: 2018032

PHE supports the UN
Sustainable Development Goals

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 (QA) visit of the Basildon and Thurrock University Hospitals NHS Foundation Trust cervical screening service held on 27 June 2017.

QA purpose and approach

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 shared with the Midlands and East regional SQAS as part of the visit process

Local screening service

Since April 2013, commissioning of cervical screening for the Basildon and Thurrock population has been undertaken by the Midlands and East (East) Screening and Immunisation Team (SIT).

The Basildon and Thurrock University Hospitals NHS Foundation Trust cervical screening programme (the programme) provides screening services for women served by 2 clinical commissioning groups (CCGs), Basildon and Brentwood, and Thurrock. The eligible cervical screening population (25 to 64 year old women) for Basildon and Thurrock is approximately 120,000.

The programme is delivered by 2 providers. The colposcopy service for the programme is provided by Basildon and Thurrock University Hospitals NHS Foundation Trust (BTUH). The cytology and histology services are provided through a joint venture arrangement between the 2 cytology services formerly based at BTUH and Southend

University Hospital NHS Foundation Trust (SUHT). Along with the private company Integrated Pathology Partnerships (iPP) forming Pathology First, a Limited Liability Partnership (LLP). The laboratory screening staff are employed by iPP and the consultant staff are employed by the respective NHS Trusts. The cytology service for both Trusts is delivered from a new purpose built site in Basildon. The histology services are delivered on each individual Trust site by Pathology First. The human papilloma virus (HPV) testing is also provided by Pathology First at the new cytology site in Basildon.

The laboratory receives approximately 40,000 cytology samples per year and makes direct referrals to the colposcopy services at Basildon and Southend, depending on the postcode of the woman's GP practice.

The BTUH colposcopy service receives approximately 1,000 screening referrals per year in total. The annual cervical histology workload for Basildon comprises approximately 500 histology specimens.

Findings

The team felt unable to quality assure all aspects of the cervical screening service provided by the Trust because of a lack of evidence and documentation provided. Some evidence that was provided raised potential issues about the quality of the service. 3 immediate recommendations were made requesting further data and information in order for SQAS to make a more detailed assessment.

The evidence submitted for the visit and further information collected on the day showed an absence of leadership and governance in each department, together with a lack of strategic direction, poor engagement and lack of communication across the service as a whole. A number of working practices, particularly within the laboratory, compromise service quality and potentially patient safety. There is evidence that some staff in leadership roles are not fulfilling their designated responsibilities.

The working arrangements for consultant pathologists reporting cervical screening tests at the new laboratory do not meet national guidance, which requires integrated working with laboratory staff. Clinical oversight of the cytology service has become separated from laboratory management, in part due to the physical relocation of the laboratory service to an off-site facility.

There is no evidence of systematic service or individual performance monitoring or audit and many of the recommendations from the previous QA visit in April 2015 have not been acted upon. A number of the recommendations from the Pathology First QA visit in May 2016 are also outstanding.

There is a need to formalise the internal governance arrangements including lead roles, incident reporting, cervical screening business meetings, escalation and reporting, along with Trust representation at commissioner meetings. The service should ensure that comprehensive guidelines, covering all aspects of the cervical screening programme, including failsafe across the pathway, are agreed and documented.

Immediate concerns

The QA visit team identified 3 immediate concerns. A letter was sent to the chief executive on 4 July 2017 asking that the following items were addressed within 7 days:

- provide detailed performance data covering cytology, colposcopy and histology to determine performance against national standards for the service and individuals
- perform a detailed multi-disciplinary team (MDT) case review against national guidance for all the cases discussed at the following MDT meetings; November 2016, January 2017 and February 2017

To provide an action plan to address the following issues within 3 months of the QA visit:

- leadership, governance and escalation arrangements to Trust Board, including meeting structures and identification of director level screening lead
- establish comprehensive written performance review procedures for all areas of the programme
- lone working by pathologists in cytopathology
- failsafe arrangements across the pathway

A response was received which provided information on all immediate recommendations and on the Trust plans to address the issues raised and mitigate the identified risks. The performance data and MDT case review information provided raised further queries and so additional information was sought by SQAS. The Trust provided this promptly. SQAS and its professional and clinical advisors have undertaken a detailed assessment of all the information provided.

As a result, 3 further immediate recommendations were issued to the Trust on 6 September 2017:

- engage expert external cytology laboratory management support, that is supported by the Screening QA Service, to undertake a detailed assessment of the day to day practice within the cytology laboratory and make recommendations to the Trust on improvements necessary to be assured of the quality of the service

- undertake targeted training of all cytology staff on how to manage the uncertainty between negative, inadequate and borderline/low grade abnormalities and the associated checking processes
- undertake targeted training of cytology laboratory management on the identification, management and governance of potential poor performance in cytology

The Trust provided confirmation within the timescale given that satisfactory initial arrangements have been made for all 3 additional recommendations. Evidence that these recommendations have been completed has been requested by 6 October 2017. Evidence was received on 13 October 2017, which showed that actions were either complete or underway against all 3 recommendations and that they would be complete by the end of December 2017.

The detailed SQAS assessment identified significant issues with parts of the service and the required quality could not be assured in cytology. More extensive follow up will take place outside the QA visit process. This will involve a further visit to assess progress in the next 6 to 12 months.

High priority

The QA visit team identified 30 high priority findings. These have been summarised below:

- there is a lack of documentation detailing the requirements of the Hospital Based Programme Co-ordinator (HBPC) role, time allocation, accountability and allocation of administrative support
- there are no quarterly multi-disciplinary cervical screening business meetings in place
- there are a lack of governance reporting, clear accountability and escalation arrangements within departments, and across the cervical screening programme
- there is a lack of departmental audit and no overall cervical screening programme audit schedule
- the invasive cancer audit has a significant backlog, and an invasive cancer audit and disclosure policy has not been established so women are not being offered their audit results
- not all staff involved in cervical screening activities have undertaken the mandatory NHS Information and Governance training
- not all cervical screening staff are aware of how to identify incidents or potential incidents and that they need to bring them to the attention of the HBPC
- there is a lack of risk management processes to ensure cervical screening risks are placed on the relevant risk registers
- there is a lack of failsafe audit throughout the programme

- there is no documented system to establish that all locum cytology staff have the appropriate qualifications and are appropriately inducted
- not all pathology, screening or colposcopy staff meet minimum standard for annual screening workload
- performance monitoring and management arrangements are not in place throughout the cervical screening pathway and supporting documentation requires updating
- some specific aspects of sample reporting in cytology and histology are not in line with national guidance or accepted practice
- multi-disciplinary team (MDT) arrangements, documentation and attendance do not meet the national standards

Shared learning

The QA visit team did not identify any areas of practice for sharing.

Recommendations

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

Governance and leadership

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R1	Cervical screening programme leads should attend the cervical screening programme board meetings	1	3 months	Standard	Minutes of the meetings showing attendance
R2	Provide an action plan to address leadership/governance, performance reviews for all areas of the programme, lone working by pathologists and failsafe arrangements across the pathway	1	7 days	Immediate	Copy of the action plan
R3	Provide detailed cytology, colposcopy and histology performance data to determine performance against national standards for the service and individuals	1	7 days	Immediate	Data demonstrating performance against standards for the service and individuals
R4	Ensure the Hospital Based Programme Co-ordinator (HBPC) has an agreed job description that includes accountability through to the Chief Executive Officer, dedicated time and administrative support	1	3 months	High	Copy of the approved job description encompassing time allocation, clear accountability and administrative support

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R5	Establish quarterly cervical business meetings chaired by the HBPC with representation from all cervical screening service leads	1	3 months	High	Copy of the terms of reference along with the minutes of the meetings occurring since the QA visit and dates of meetings for the next 12 months
R6	Establish annual and 6 monthly reporting to a senior Trust governance committee	1	3 months	High	Documents detailing the arrangement agreed, a copy of the first report given and minutes of the meeting where it was presented
R7	Develop and implement a whole Trust annual audit schedule for cervical screening services	1	3 months	High	Annual audit schedule covering cytology, HPV testing, colposcopy and histopathology
R8	Ensure that the national invasive cancer audit data collection is up to date	2	6 months	High	Completion of all outstanding cases
R9	Implement a ratified policy for the offer of disclosure of invasive cervical cancer audit	2	3 months	High	A copy of the policy
R10	Complete an audit to demonstrate offer of disclosure of invasive cervical cancer audit	2	12 months	High	A copy of the report from the first annual disclosure audit undertaken, the findings and any actions taken as a result

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R11	Confirm all staff are up to date with information governance requirements	1	3 months	High	Confirmation of training received
R12	Document a reference to national screening incident guidance in the Trust policy on managing serious incidents	1	6 months	Standard	Copy of the Trust policy on managing serious incidents
R13	Establish a mechanism for identifying incidents or potential incidents related to cervical screening activities and bringing them to the attention of the HBPC	1	3 months	High	Documentation such as standard operating procedures (SOPs), demonstrating the agreed process and meeting minutes at which staff have been made aware
R14	Establish a risk management process for ensuring that all risks are recorded on Trust risk registers and discussed at relevant meetings	1	3 months	High	Documents detailing the process agreed
R15	Provide a lead cytopathologist job description approved by the Trust, including a designated time allocation	1	3 months	Standard	Copy of the approved job description
R16	Nominate a designated deputy for the lead cytopathologist	1	3 months	Standard	Details of nominated deputy
R17	Provide a lead histopathologist job description approved by the Trust, including a designated time allocation	1	3 months	Standard	Copy of the approved job description
R18	Nominate a designated deputy for the lead histopathologist	1	3 months	Standard	Details of nominated deputy

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R19	Develop an organisational accountability structure for cytology and histology services including detail of escalation routes for governance and performance issues in Pathology First and how this links to the associated Trusts	1	6 months	High	Copy of the structure and escalation routes
R20	Revise the job description for the consultant BMS/laboratory lead to demonstrate appropriate allocated time to carry out all expected duties	1	3 months	Standard	Copy of the approved job description
R21	Establish quarterly laboratory governance meetings with clear terms of reference and reporting lines within Pathology First and the associated Trusts	1	6 months	High	A copy of the terms of reference along with the minutes of the meetings and dates of meetings for the next 12 months
R22	Nominate a designated deputy for the lead colposcopist	1	3 months	Standard	Details of nominated deputy
R23	Establish colposcopy operational meetings with clear terms of reference and reporting line within the Trust	1	6 months	High	A copy of the terms of reference along with the minutes of the meetings occurring since the QA visit and dates of meetings for the next 12 months
R24	Develop an organisational accountability structure for the colposcopy service including detail of escalation routes for governance and performance issues	1	6 months	High	Copy of the structure and escalation routes

R25	Establish a colposcopy protocol for the review of invasive cancer audit cases	2	6 months	Standard	Copy of the protocol

Cytology

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R26	Establish pathologist reporting practice that meets national guidance on lone working	3	3 months	High	Job plans, sessional rota and arrangements in place
R27	Carry out a data validation check between 'Cyres' software system and the laboratory computer system performance data for the period in 2016/17 when Cyres was not working to ensure that the data on the laboratory system and Cyres match fully	1	3 months	Standard	Copy of data validation report
R28	Validate the quarterly cytology turnaround data for quarter 4 of 2016/17 and the monthly data supplied to SQAS for the same period to ensure the process for data collection is accurate and reports are the same	1	3 months	Standard	Copy of data validation report and actions
R29	Complete an audit to show that archived (scanned) screening data are fully captured, filed and retrievable	1	6 months	Standard	Copy of the audit and details of the action taken as a result
R30	Update sample acceptance SOP to include human papilloma virus (HPV) vial date checks	4	3 months	Standard	Copy of updated SOP for sample acceptance
R31	Update HPV triage and test of cure SOP to include all relevant cases	5	3 months	Standard	Copy of updated SOP

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R32	Use read/delivery receipts to ensure that result files have arrived safely at call/recall	1	3 months	Standard	Confirmation that use of read/delivery receipts is in place
R33	Update direct referral SOP	6	3 months	Standard	Copy of updated SOP to include standard practice for referral of potentially invasive or glandular cases, use of secure email addresses and up to date document references
R34	Carry out a retrospective audit of direct referrals made but not confirmed as received by colposcopy to ensure that all referrals have been successful	6	3 months	Standard	Copy of the audit report and details of the action taken as a result
R35	Update performance monitoring SOP	3 & 7	3 months	High	Copy of updated SOP including staff inadequate rates, checks on locum staff, contingency for IT failure and recording of staff discussions
R36	Check all locum staff meet national standards for employment of locum staff	3	3 months	High	Copy of the actions taken in relation to existing locum staff
R37	Undertake targeted training of all cytology staff on how to manage the uncertainty between negative, inadequate and borderline/low grade abnormalities and the associated checking processes	1 & 3	1 month	Immediate	Confirmation of arrangements made (within 2 weeks) Completion of training (within 1 month)

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R38	Undertake targeted training of cytology laboratory management on the identification, management and governance of potential poor performance in cytology	1 & 3	1 month	Immediate	Confirmation of arrangements made (within 2 weeks) Completion of training (within 1 month)
R39	Update cytology reporting SOP to include management for ?glandular neoplasia (non-cervical) cases and the recording of individual staff opinions on samples	3	3 months	High	Copy of updated SOP
R40	Update practice for transporting cervical screening slides to include receipt confirmation	3	6 months	Standard	Copy of updated SOP
R41	Carry out an audit of failsafe for the period when the software used for failsafe activities was not available	6	3 months	High	Copy of the audit report and details of the action taken as a result
R42	Engage expert external cytology laboratory management support, approved by the SQAS, to undertake a detailed assessment of the day to day practice within the cytology laboratory and make recommendations to the Trust on improvements necessary to be assured of the quality of the service	1	1 month	Immediate	Confirmation of arrangements made (within 2 weeks) Completion of training (within 1 month)
R43	Ensure that all cytopathologists report or review minimum of 750 cases per annum	3	6 months	High	Data showing that all pathologists meet the minimum workload standard

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R44	Implement a plan to achieve cervical screening sample turnaround times that support the standard for women to receive results within 14 days of their test	1	6 months	Standard	Recovery plan supported by data submission and evidence of achievement
R45	Establish monitoring of individual staff inadequate sample rates and update documentation	3	3 months	High	Copy of SOP and confirmation that monitoring is in place
R46	Establish regular performance monitoring for senior staff including provision of regular performance data	3	3 months	High	Evidence of SOP, performance monitoring reports and actions taken
R47	Improve the chain of custody arrangements for sample identification to reduce the likelihood of sample mix up	3	3 months	High	Copy of SOP and confirmation of bar code scanner implementation
R48	Improve storage arrangements for processed sample vials so that they are available for additional testing if required	1	6 months	Standard	Copy of SOP

HPV testing

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R49	Assess internal procedures against the Hologic HPV system operations manual and take action to ensure that manufacturer's advice is followed	8	3 months	High	Copy of SOP

R50	Audit the service against the most recent national HPV laboratory quality control and assurance guidelines and update SOPs accordingly	9	6 months	Standard	Copy of audit report, details of the actions taken and copy of SOP(s)

Sample taker register

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R51	Provide performance feedback to general practices and commissioners in line with NHS Cervical Screening Programme (CSP) guidance	1	6 months	Standard	Documents showing that appropriate sample taker feedback is provided

Diagnosis - histology

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R52	Include the Royal College of Pathologists data set in all reports	10	6 months	Standard	Audit of results and action taken
R53	Audit the usefulness of 3 levels on loop excisions as it is in excess of the national guidance	11	6 months	Standard	The audit report and details of the action taken as a result
R54	Develop and implement procedures for the management of performance issues in cervical histopathology	12	6 months	Standard	Copy of SOP

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R55	Implement and monitor a plan to achieve recommended turnaround times for histopathology	11	6 months	Standard	Data showing that cervical histology specimens are being reported in line with national standards
R56	Establish a process to ensure the regular feedback of individual performance data to all pathologists and document in a SOP	12	6 months	Standard	Copy of SOP
R57	Implement an annual audit schedule for cervical screening histology as part of the Trust cervical screening audit schedule	1	3 months	High	Annual audit plan and actions taken to date
R58	Assess individual reporting of cervical glandular histology and ensure that all pathologists report in line with national guidance	12	3 months	High	Report of assessment, action taken and evidence of involvement of all pathologists

Intervention and outcome - colposcopy

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R59	Make sure there are enough colposcopy nursing and administrative staff to meet the requirements of the NHS CSP	13	6 months	Standard	Colposcopy staffing structure, defined responsibilities and absence cover arrangements protocols

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R60	Update the local Trust colposcopy clinical guidelines to reflect NHS CSP guidance	13	6 months	Standard	Copy of revised ratified colposcopy guidelines and evidence of dissemination to all relevant staff
R61	Document nursing procedures for the colposcopy clinic	13	6 months	Standard	Copy of SOPs
R62	Document SOPs for colposcopy administrative processes	13	6 months	Standard	Copy of SOPs
R63	Complete an audit of failsafe processes in the colposcopy service	13	3 months	High	Failsafe audit and actions taken
R64	Document electrosurgery guidelines within the colposcopy setting	13	6 months	Standard	Copy of the guidelines
R65	Ensure all colposcopists meet the annual throughput requirements for 50 new NHSCSP referrals a year	13	6 months	High	Data showing that all colposcopists will meet the NHS CSP annual workload criteria
R66	Meet and maintain the standard that 90% of results are sent to women within 4 weeks and 100% within 8 weeks of their colposcopy appointment	13	6 months	Standard	Data demonstrating sustained achievement of the standards for issuing colposcopy results
R67	Implement and monitor a plan to reduce colposcopy ‘did not attend’ (DNA) follow up rates	13	6 months	Standard	Copy of the action plan and audit data showing national standards are met

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R68	Audit and monitor positive predictive value (PPV) of colposcopists	13	6 months	Standard	Copy of audit report and details of the action taken as a result
R69	Meet the national colposcopy standards	13	6 months	Standard	Audit reports and details of the actions taken as a result for standards related to biopsies taken in women with persistent low grade cytology over 2 years, the proportion of women biopsied who have treatment within 4 and 8 weeks and treated women with no dyskaryosis at 12 months
R70	Establish an annual rolling colposcopy audit programme to incorporate audit of service-wide and individual colposcopist performance	1	6 months	High	Colposcopy audit plan, minutes of the meeting at which it was agreed and audit reports
R71	Update Trust patient information leaflets and examples of result letters sent to patients to meet national requirements	14 & 15	6 months	Standard	Updated patient information leaflet. Anonymised examples of result letters
R72	Establish an annual patient survey	13	6 months	Standard	Copy of survey, report and actions taken

Multidisciplinary team

No.	Recommendation	Reference	Timescale	Priority	Evidence required
R73	Ensure all colposcopists attend a minimum of 50% of multi-disciplinary team meetings (MDT)	13	6 months	High	Copy of attendance register
R74	Perform a detailed MDT case review against national guidance for all the cases discussed at the MDT meetings for November 2016, January 2017 and February 2017	13	7 days	Immediate	Copies of the anonymised MDT case reviews and any relevant comments from the team about each case
R75	Provide a comprehensive SOP that will cover all aspects of the MDT (to include case selection, full details of the cases, review outcomes and management plan)	13	3 months	High	Copy of the SOP

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 outline any further action(s) needed.