Programme Specific Operating Model for Quality Assurance of Cervical Screening Programmes

Public Health England leads the NHS Screening Programmes
About Public Health England

Public Health England (PHE) exists to protect and improve the nation’s health and wellbeing, and reduce health inequalities. We do this through world-class 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 are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

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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.

www.gov.uk/topic/population-screening-programmes
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1. Introduction

1.1 This document sets out the programme specific operating model (PSOM) for quality assurance (QA) of the NHS cervical screening programmes and should be read in conjunction with the ‘Operating Model for PHE Screening Quality Assurance Service: 2015/16 to 2017/18’ and the relevant screening quality assurance service (SQAS) generic standard operating procedures documents.

Background

1.2 The QA of NHS screening programmes consists of 2 elements:

- an assurance process - measuring the quality of screening services against a set of agreed standards
- quality improvement activities - to support screening programmes to increase the quality of their services

1.3 SQAS undertake a number of activities to assure and improve the quality of screening services. These include but are not limited to:

- peer review (QA) visits carried out every 3 to 5 years
- production of data reports (monthly/quarterly/annually)
- incident advice and support for investigations
- expert advice and support through regular attendance at screening programme board meetings
- network and educational meetings
- targeted support to providers

1.4 This PSOM has been developed by a working group led by the national portfolio leads for cervical screening and consisting of members from the SQAS teams and external stakeholders. It sets out how SQAS will work with, support and quality assure local cervical screening services.

1.5 All associated processes and documentation have been approved by the SQAS Quality Assurance Executive Group and the Screening Division Strategy Management Group.

Programme description

1.6 Cervical screening QA begins with the identification of eligible women and includes sample taking, cytology, colposcopy and histopathology. It ends with the
diagnosis of cancer, completion of the screening programme at 65 years of age, or the ending of a surveillance period, whichever is later.

Purpose and scope

1.7 The purpose of this operating model is to outline the agreed QA process for cervical screening programmes which should be adhered to by all SQAS staff and any professional and clinical advisors (PCAs) supporting the SQAS team. This will ensure consistency of approach across all screening providers.

The quality assurance process

1.8 The quality assurance process for the SQAS is provided in Appendix A and details:

- the relevant section of the screening pathway to be addressed
- specific activities to be conducted by SQAS staff and PCAs
- the evidence used to inform the QA process
- data and information sources that will be used for quality assurance
- the required frequency at which the QA activities should be carried out
- mapping of the QA activity to standards, key performance indicators (KPIs) or service specifications that detail the requirement
2. Quality assurance activities

Service engagement

2.1 A senior quality assurance advisor (SQAA) / quality assurance advisor (QAA) or deputy will attend programme steering or oversight boards to:

- identify new issues
- monitor progress against recommendations
- monitor other known issues
- support service improvement

Systematic and routine collection and analysis of data

2.2 SQAS will collect and/or review statistics and data on a monthly, quarterly or annual basis. This is described in chapter 3.

2.3 Services will be benchmarked using national data sets.

2.4 SQAS and PCAs (where appropriate) will perform an annual review of data and intelligence at a regional or sub regional level. This data set will also be used to complete the prioritisation matrix for SQAS activities.

2.5 Further information and intelligence may be collected via forms, submission of an annual questionnaire or attendance at programme steering/oversight boards. This will be supplemented by intelligence gained by SQAS staff in the course of their routine activities and interactions with services and national screening programmes.

Visits and reviews

QA visits

2.6 The frequency of QA visits starting in April 2017 will be based on findings from the prioritisation exercise. In most cases it will lie between 3 and 5 years. The maximum interval for a full visit for all services will be 5 years. This approach of targeting QA resources and visits to services which require support will be kept under review.

2.7 Visit schedules and other QA activities will be decided by assessment against an agreed set of criteria each year. This new approach is designed to align SQAS
resource according to services’ needs. SQAS will evaluate this approach and consider the impact on the average visit interval, findings at QA visits and SQAS capacity.

2.8 SQAS may undertake a focussed visit or assessment of any individual discipline or group of disciplines of the screening programme that require more detailed investigation or intervention outside the routine QA visit process. The level of intervention and most appropriate approach will be informed by the prioritisation assessment. A set of principles will be devised linked to a set of QA interventions, to support consistency of this approach. A review of the number, rationale and outcome of non-routine visit interventions will be undertaken as part of the evaluation of QA visit activities.

2.9 SQAS will share learning internally and with other relevant local services and commissioners where risks in service delivery are identified that are applicable to more than one service. This is to ensure that information can reach the front line in a rapid manner.

2.10 The QA visit process will include all providers delivering the full or part of the screening pathway. This includes private providers commissioned to deliver NHS screening programmes.

2.11 The QA visit and review of screening services will cover:

- programme management and governance
- the screening pathway
- referral to relevant diagnostic or treatment services
- relevant diagnostic or treatment services

2.12 QA of public health system leadership and commissioning has been developed and will be rolled out across all programmes from July 2017.

2.13 The visit and review process will be informed by:

- identified datasets by programme
- core evidence submitted and the completed evidence summary
- ad hoc data identified as required
- specified job descriptions
- specified protocols
- walkthrough of the patient journey where applicable
- Information shared in the professional meetings

QA visit reports
2.14 All reports will be addressed to the provider and commissioner(s). The provider may be an NHS trust or private sector organisation.

2.15 The hospital-based programme coordinator is the point of contact for liaising with the provider with respect to the factual accuracy check of the QA reports. They will be responsible for circulating the report to other service leads.

2.16 Recommendations for subcontracted services will be included in the reports for the lead provider.

**Executive summary publication on GOV.UK**

2.17 The chief executive of each organisation involved and the NHS England Director of Commissioning Operations (DCO) or their representative will be asked for their consent to publish the executive summary on GOV.UK. If SQAS do not receive a response, it will be assumed that consent is granted.

2.18 Executive summaries will be published online in accordance with national guidance.

**Reviews**

2.19 Any QA interventions due to ad hoc events such as incidents, identification of quality concerns, and so on, may be managed with recommendations or an action plan, similar to those for a QA visit.

**Follow-up against recommendations**

2.20 Recommendations designed to improve the quality of the service will be made at QA visits.

2.21 The wording of the recommendations will give the context to enable all reviewers, provider management and commissioners to understand the rationale for the recommendation.

2.22 The recommendations will have an associated timescale.

2.23 The provider is responsible for developing an action plan in collaboration with the commissioners to address the recommendations made within the available timeframe.
2.24 The commissioners require assurance that timely action is being taken to address the issues raised. Progress against the action plan should be an agenda item at the Programme Steering or Oversight Board meetings.

2.25 SQAS makes recommendations and states what evidence is required to close the recommendation. The Screening and Immunisation Lead (SIL) is responsible for ensuring that action is taken. It is the responsibility of the provider to send the evidence to the SIL and SQAS to review. SQAS will advise the provider and SIL if the evidence submitted provides assurance that the recommendation has been met.

2.26 SQAS will work with commissioners to monitor activity and progress in response to recommendations. This is for a period of 12 months following the issuing of the final report. This will allow adequate time for at least one response to all recommendations. A letter will then be sent to the provider chief executive and commissioners summarising the progress made and asking for their direct intervention to address any remaining issues.

2.27 Escalation to chief executives and commissioners will occur earlier if serious concerns are identified.

Support with screening safety incidents and serious incidents

2.28 The activity of the SQAS is outlined in PHE’s guidance ‘Managing safety incidents in NHS screening programmes (October 2015)’ and is detailed in PHE Screening Division’s ‘Managing safety incidents in NHS screening programmes standard operating procedure (March 2016)’.

2.29 The national and regional portfolio leads will work together to develop greater consistency in the handling of suspected or confirmed safety incidents and serious incidents.

2.30 SQAS regional teams track and record their advice from the reporting of each incident through to closure. SQAS records of active incidents will be reviewed regularly by each regional portfolio lead.

2.31 The national portfolio leads will contribute to producing quarterly detailed thematic reports. They will agree lessons to be shared and national actions with the programme managers. Lessons to be shared will be done in a timely manner appropriate to the incident.

Networking and support
2.32 There are a wide variety of approaches to professional networking support across SQAS. These have received good feedback, showing evidence of value to both SQAS and service representatives.

2.33 Professional meetings are an important forum for SQAS to share information relating to new standards, guidance and programme developments with the relevant professionals. They provide an opportunity to share data, discuss support needs, and enable feedback on products and plans. They help identify quality issues or potential risks which could inform future QA activity.

2.34 The forums are also important to the professionals working within local screening services. They can share issues, identify possible solutions, develop networks that foster resilience and share out tasks such as development of protocols.

2.35 The meetings can also be educational events with input from external speakers or the sharing of local audit information. SQAS will work in conjunction with the national screening programme where applicable to develop joint agenda for these meetings.

2.36 The frequency of these meetings will vary by professional group. There is expected to be no more than 2 per year per professional area. These will cover staff groups depending on prioritisation and current issues. This is likely to include some or all of the following professional areas:

- hospital-based programme co-ordination
- laboratory
- colposcopy

National cervical QA teams

2.37 Two QA teams have been established to undertake cervical QA work that is more effectively run on a single national basis.

2.38 The SQAS national call and recall team is based in Bristol and undertakes the QA of all cervical screening call and recall services. This includes QA visits, QA audits, QA advice to call and recall incidents and facilitative support to the provider and commissioner of call and recall activities.

2.39 SQAS national external quality assessment (EQA) scheme team is based in Birmingham. The team runs the operational aspects of the 2 published PHE screening cervical EQA schemes.
2.40 The gynaecological cytopathology EQA scheme is mandatory for all cytology laboratory staff reporting cervical screening tests. This scheme is accredited by the UK Accreditation Service to ISO/IEC: 17043 standards.

2.41 The technical EQA scheme is mandatory for all laboratories running a cervical screening service for the NHS. This scheme assesses the quality of laboratory staining of cervical cytology specimens. This scheme aims to apply for ISO/IEC: 17043 accreditation in due course.

2.42 Both schemes need to obtain feedback from participants and maximise the educational benefits. This is achieved through various means, including running an annual EQA workshop.
3. Data and intelligence for quality assurance

3.1 This chapter describes the specific data requirements for the cervical screening programme. General information on the data requirements of the Programme Specific Operating Models can be found in the ‘Programme Specific Operating Model Data & Intelligence Overview’.

Data sources

National Health Application and Infrastructure Services

3.2 National Health Application and Infrastructure Services (NHAIS) is a population database with details of all eligible women registered with GPs in England. The system is used to:

- invite eligible women at correct intervals
- notify test results to women and GP practices
- record screening histories and ensure these follow women when they move area
- provide a failsafe to ensure appropriate follow up and recall
- record human papilloma virus (HPV) vaccination status
- provide web-based controlled access to aggregated (KC53 and VSA15) and patient level data held on NHAIS (Open Exeter)

3.3 KC53 is run on a quarterly and annual basis by NHS Digital staff approximately 6 weeks after the end of each quarter. The geography level is upper tier local authority (ULA). Measures include number of women screened, invitations and screening test results. This data is sent to SQAS for analysis and distribution.

3.4 VSA15 is run monthly as an automatic report on the Open Exeter system by SQAS staff on a regional basis. The geography level is clinical commissioning group (CCG). Reports time from the date of screening test to the receipt of result by a woman. This supports the monitoring of the 14 day turnaround time standard. The national QA data and intelligence team produces the monthly VSA15 report for CCGs 3 days after the end of the month. It distributes this to regional SQAS teams in a standardised format for onward dissemination.

Laboratory information systems
3.5 Cytology screening samples reported by pathology laboratories are recorded on trust data systems. There are multiple laboratory information systems (LIMs) in use across England. All should be able to report the mandatory KC61 return in addition to the quarterly and annual laboratory data requirements for SQAS.

3.6 KC61 is run annually by pathology laboratories. The return is collected at SQAS regional level. Each regional SQAS is responsible for the validation of these local data according to standard validation criteria. The data are used for internal performance monitoring as part of the annual data review once validated. KC61 data are submitted to NHS Digital via a secure online portal for inclusion in the annual national Statistical Bulletin.

3.7 SQAS quarterly laboratory and annual laboratory data returns will be requested at SQAS regional level according to a national defined timetable. Each regional SQAS is responsible for the validation of these local data according to standard validation criteria. The data requested will include KPIs as defined in service specification No. 25 and national guidance. The data collected on a quarterly basis will be requested at service level only. The annual laboratory data will request more detailed individual level data such as workload and individual staff performance. Quarterly laboratory data will be circulated back to laboratory services so they can assess their performance in relation to other laboratory services.

**Colposcopy data systems**

3.8 Women with an abnormal screening test result or with a clinically suspicious cervix are seen in colposcopy clinics. Details of referrals, appointments and procedures are recorded on specialist data systems at trusts. There are multiple colposcopy data systems in use across England. All systems should be able to produce the mandatory KC65 return and annual or QA visit data requirements.

3.9 KC65 are run on a quarterly and annual basis by each colposcopy department. These data will be requested at SQAS regional level according to a national defined timetable. Collation of the data occurs at SQAS regional level. Each regional SQAS remains responsible for the validation of these local data according to standard validation criteria. The data are used for internal monitoring once validated. They are also circulated back to colposcopy services so they can assess their performance in relation to other colposcopy services. Annual KC65 data are forwarded to NHS Digital via a secure online portal for inclusion in the national annual Statistical Bulletin.

3.10 The SQAS annual colposcopy data return will be requested at the end of the financial year. Each regional SQAS is responsible for the validation of these local
data according to standard validation criteria. The data requested will include KPIs as defined in Service Specification No.25 and national guidance. The data collected on a quarterly basis will be requested at service level only. The annual colposcopy data submission will request more detailed individual level data such as workload and staff performance data.

3.11 Laboratory and colposcopy quarterly and annual data sets will be used to form the QA visit data pack. It may be necessary to ask services to run a more up to date annual laboratory or colposcopy return depending on the timing of the QA visit compared with the most up to date annual data available to SQAS.

Data analysis

3.12 The cervical SQAS will comply with the national SQAS methodologies.

3.13 SQAS undertakes validation on the data received by SQAS staff through production of SQAS standard operating procedures and/or automated validation processes.

Data reporting

3.14 Reporting and analysis will be done once, nationally where possible. Dissemination of data to local services will be done by the local SQAS team.

3.15 The current list of outline reports is given in the table below.

Key performance indicators

3.16 KPIs for cervical screening are a subset of screening standards and are identified as part of the section 7a service specification. They focus on areas where important improvements in quality can be made. Once a KPI consistently reaches the achievable level, the KPI is either withdrawn as a KPI and remains as a standard, allowing entry of another KPI or the KPI thresholds are reviewed to promote continuous improvement.

3.17 KPIs are collated and reported quarterly. If numbers are small, aggregate data is reported annually. The information on surveillance patients and the aggregated figures for each KPI are sent by the PHE national team to the local screening services for sign off in line with the published submission guidance. KPIs are published on GOV.UK.

Screening pathway reporting
The current list of outline reports is given in the table below.

<table>
<thead>
<tr>
<th>Report title</th>
<th>Geography</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>VSA15</td>
<td>CCG/ULA</td>
<td>Monthly</td>
</tr>
<tr>
<td>KC53</td>
<td>Call/recall</td>
<td>Quarterly/annual</td>
</tr>
<tr>
<td>KC61</td>
<td>Cytology lab</td>
<td>Annual</td>
</tr>
<tr>
<td>KC65</td>
<td>Colposcopy</td>
<td>Quarterly/annual</td>
</tr>
<tr>
<td>Cyto_Qtr</td>
<td>Cytology lab / staff level</td>
<td>Annual</td>
</tr>
<tr>
<td>Cyto_Annual</td>
<td>Cytology lab</td>
<td>Annual</td>
</tr>
<tr>
<td>Colp_Annual</td>
<td>Colposcopy / colposcopist</td>
<td>Annual</td>
</tr>
<tr>
<td>Visit Pack</td>
<td>Local screening service</td>
<td>At QA visit</td>
</tr>
</tbody>
</table>

Data sharing

Routine data sharing activities between PHE Screening and Chief Knowledge Officer directorates are covered by a data sharing agreement, ODR_2014_220b.

Routine data sharing between PHE Screening and NHS England for all 11 screening programmes is underpinned by the Memorandum of Understanding (MoU) signed by both organisations. This MoU extends to any onward sharing to any third party, for example, PHE Centre Directors, providers of screening services, local authority, CCGs, voluntary organisations and other health professionals using screening data to improve and monitor services. This is for the purpose of improving quality of screening services. The set of data items covered by the MoU is shared prior to publication and for management purposes only. Data flows, schedules and the list of data items shared are managed by the national data and information team.

Annual KC61 and KC65 data are shared with NHS Digital.

Routine data sharing includes the invasive cervical cancer audit. Data is cross exchanged between the National Cancer Registration and Analysis Service (NCRAS) and SQAS for the purposes of case ascertainment and notification of screening flags to NCRAS.

Non routine data requests from commissioners and service providers should be discussed with regional SQAS who will consider requests in line with data release principles including, but not limited to, the following questions:

- has the data already been shared via the MoU or available in the public domain?
- is the data likely to support population health improvement?
- is the data likely to improve the quality of screening services?
• what is the level of anonymisation required (open government licence to potentially identifiable and identifiable information)?
• what are the resources and costs required to extract, collate, quality assure and release the data set?

3.24 Regional SQAS will, if necessary, involve programme managers and the national data and information team in the initial discussion of non-routine data requests and seek advice from research committees where appropriate. All requests for personal confidential information will be discussed with the PHE Office for Data Release.

3.25 All data requests and releases will be centrally logged and tracked.
4. The QA visit

Objectives

4.1 The objectives of the QA visit are to:

- examine the performance of the local screening service
- verify achievement of national standards, identify variance from these standards and support professionals working in the local screening service to maintain and improve standards
- gain knowledge and expertise of areas for shared learning and disseminate this to all screening services
- share experiences and understanding of current problems or concerns in NHS cervical screening services and contribute to national development

Requirements

Frequency of visits

4.2 The frequency of QA visits starting in April 2017 will be based on findings from the prioritisation exercise and in most cases will lie between 3 and 5 years. The maximum interval for a full visit for all services will be 5 years. This approach of targeting QA resources and visits to services which require support will be kept under review.

4.3 Visit schedules and other QA activities will be decided each year by an assessment against an agreed set of criteria. This new approach is designed to align SQAS resource according to services’ need. SQAS will evaluate this approach and consider impact on the average visit interval, findings at QA visits and SQAS capacity.

4.4 PHE, NHS England and provider organisations will be informed of the proposed schedule of visits.

Membership of visiting team

4.5 The visiting team will be selected by the SQAS.

4.6 The visiting team will be led by the visit chair.

4.7 Members of the team may include the following PCAs:
cytopathology\textsuperscript{a}
biomedical science (cytology)\textsuperscript{b}
HPV virology (depending on local arrangements)\textsuperscript{b}
colposcopy (clinical)
colposcopy nursing
histopathology\textsuperscript{a}
commissioning

\textsuperscript{a}Roles can be done by the same PCA
\textsuperscript{b}Roles can be done by the same PCA

4.8 Members of SQAS:

- senior quality assurance advisor
  and/or
- quality assurance advisor / quality assurance facilitator (QAF)

4.9 Visiting team members will be asked to declare conflicts of interest before the visit. If this raises concerns about the use of a PCA for a visit, SQAS will take advice within PHE.

4.10 A maximum of 2 observers may also be present at a QA visit, for training and education purposes. The observers will only act in an observational capacity: they will not be involved with providing feedback nor will they have any input into the interviews or decision making processes.

Role of the QA visit chair and QA advisor in QA visits

4.11 The visit chair will normally lead all QA visits with the support of a SQAA or QAA.

4.12 For cervical screening, the visit chair will either be the regional head of quality assurance (RHQA) or head of quality assurance (HQA) who holds the cervical screening portfolio or a PCA who has undergone additional training in order to undertake this role. Where the visit chair is a PCA, this will be their sole role during the visit. They will not be acting in the capacity of a PCA, except in exceptional circumstances agreed in advance.

4.13 The visit chair is responsible for:

- chairing and directing the conduct of the QA visit
- providing considered, consistent feedback on the visit findings
- managing sensitively and appropriately any serious issues or concerns raised prior to or on the day of the QA visit
- facilitating the exchange of knowledge and ideas and encouraging productive networking in order to foster developments in quality

4.14 The SQAA/QAA supporting the visit chair is responsible for:

- ensuring that the local screening services are fully aware of what is required in preparation for the visit
- acting as a point of contact for any queries regarding organising and coordinating the visit
- assembling and managing the visiting QA review team who will be accountable to the visit chair during each visit (up to and including production of the final report)
- ensuring that all PCAs selected have undergone appropriate training
- ensuring collection of evidence to support the visit and that any required observational pre-visits have been completed
- ensuring that adequate preparatory work is undertaken
- supporting the visit chair to assemble feedback during the visit
- ensuring that an accurate, considered report of the visit is issued within an agreed timescale and disseminated to provider chief executives and NHS England / SILs
- ensuring that all agreed recommendations are followed up and monitored or escalated where necessary, within an agreed timescale
- arranging any preliminary meetings between the SQAS and the local screening service as necessary

Skills and experience of visiting QA team

4.15 Members of the visiting QA team will need to demonstrate the following generic skills and training:

- PCAs / QA training course
- report writing
- interview techniques
- public health aspects of screening
- have an understanding of incident identification and management
- analytical skills
- ideally will have observed a QA visit

4.16 Specialist skills required of the individual PCAs are documented in the cervical screening PCA person specification / job description.

Locations to be visited
4.17 The QA visit will be undertaken on an individual trust basis. Visits will be co-ordinated as far as possible so that all the trusts linked to a cervical cytology laboratory are visited together. This may be over a number of months depending on the local configuration.

4.18 It may not be possible to visit all screening sites on the same day if a trust has sites located away from the main provider unit. The SQAA/QAA will therefore liaise with the local screening service to arrange visits to the other sites before the day of the main QA visit.

Local screening service personnel attendance

4.19 The personnel from the local screening service who should attend during the visit, depending on service configuration, are:

- hospital-based programme co-ordinator (HBPC)
- lead pathologist (cytology)
- lead biomedical scientist
- lead HPV scientist (where this function is not undertaken within cytology)
- lead colposcopist
- lead colposcopy nurse
- lead pathologist (histology)

4.20 Staff attendance will be variable depending on the services provided by the trust being visited. The relevant PCAs would expect to meet the leads for each discipline as a minimum. Other staff involved in the service are strongly encouraged to attend in addition.

Sources of evidence considered as part of QA visits

4.21 The QA report will be built up from a number of sources of evidence. These will be:

- response of the local screening service to the pre-visit questionnaires, where applicable
- supporting evidence and documents submitted to the SQAS for review
- interviews undertaken during the QA visit
- observational visits, where applicable
- case reviews, where applicable
- analysis of annual report data and routine data for the preceding 12 month period
- analysis of audit reports
Preparation for a QA visit

4.22 The SQAS will liaise with the local screening service and commissioners to make arrangements for the visit at least 6 months prior to the visit date. A mutually convenient date within a set timeframe will be agreed and a named contact within the local service for visit preparation should be identified. This named contact will be responsible for ensuring that members of the local screening service team are invited and able to attend the visit. The date will not be changed once it is agreed, except in exceptional circumstances, and only with the agreement of both parties.

4.23 The chief executive of the host trust, stakeholding trusts, commissioners, providers of any associated services and treatment providers will be informed by the SQAS that a visit is taking place. They will be invited to attend or send a suitable representative to the summary of the visit feedback session and subsequent discussions as appropriate.

Preliminary meeting between Screening QA Service and the local screening service

4.24 A preliminary meeting between the SQAS and providers or commissioners may take place where applicable. This will vary by programme, for example, SQAS might request to attend the first scheduled local screening programme board meeting or operational group meeting after notification of the visit is made.

4.25 If a local screening programme board or other appropriate meeting has not been set between notification and the day of the visit, the SQAS might ask for one to be organised approximately 3 months before to the visit date.

4.26 A member of the SQAS will attend this meeting to inform the local screening service about arrangements for the visit. This will include arrangements for any observational visits, an outline of the agenda and answering any questions that the local screening service and its stakeholders may have. This will also give the local screening service an opportunity to comment on current progress.

Information to be provided by local screening service

4.27 Local screening services will be asked to provide the following information in preparation for a QA visit:

- action plans from previous QA recommendations (where not already available to SQAS)
- action plans from pre-visit questionnaire or desk top review (where applicable)
- completed pre-visit questionnaire (where applicable)
supporting documents and protocols as outlined in the pre-visit questionnaire or documentation

- performance reports as requested
- information on any incidents that have occurred in the last 12 to 24 months
- information on venue organisation – where the visit will be held and what rooms have been booked for interviews and feedback sessions
- other relevant information requested by the SQAS

4.28 This information should be provided to the SQAS at least 6 weeks prior to the visit date. There will be no flexibility on extending deadlines for evidence submission unless it enables a reduction in burden for the SQAS. Such cases will be agreed by the visit chair and SQAA/QAA responsible for the visit.

4.29 Evidence provided which is out of date, for example policies or guidelines, will not be assessed but will be used to inform decisions relating to local screening service governance.

4.30 Any request for clarification of evidence or for further evidence from providers should be coordinated by the SQAA/QAA responsible for the visit.

4.31 Any evidence transfer must conform to information governance rules. It must not contain patient identifiable or sensitive information and should be transferred to the SQAS following SQAS information governance protocols.

Observation of clinical practice and premises

4.32 In cases of trusts with multiple colposcopy clinics at different locations, a mutually convenient time will be agreed for the colposcopy nursing PCA to visit each clinic away from the main site. This visit will review the facilities and undertake a ‘patient journey’ walkthrough. It will take place before the main QA visit. The main site colposcopy clinic will be reviewed on the day of the full QA visit. A ‘specimen journey’ walkthrough will take place at each laboratory.

Observation of administration practices

4.33 If required based on the evidence review, the SQAA or other appropriate member of SQAS staff will arrange to visit the local screening service in advance of the visit to examine colposcopy administrative practice. This will take place before the QA visit and SQAS will liaise with the local screening service regarding when and where this visit will take place.

Review of evidence to inform the visit
4.34 The lead SQAA/QAA will review all the evidence submitted for the visit and complete a summary document to highlight areas for further discussion with PCAs at the QA visit.

The standing QA team

4.35 The regional SQAS works with a defined group of PCAs who provide expert advice to the SQAS for breast, bowel and cervical screening. These PCAs are known as the standing QA team. They support regional QA professional networking opportunities and form the visiting team at QA visits in addition to providing ongoing advice as required.

Information for the QA visit team

4.36 The SQAS will provide an information pack, usually in electronic format, for the visiting QA team which will include:

- contact details of visiting PCAs
- list of local screening service personnel
- agenda for the visit day (including details of venue and rooms booked)
- overview of the local screening service
- copy of last QA visit report (where applicable)
- all documents submitted by the local screening service, relevant to the PCAs professional area
- SQAS evidence review document
- outcome of the observation of clinical practice and premises (where applicable)
- outcome of the observation of administration practice (where applicable)
- data relating to performance of the local screening service
- results of annual prioritisation exercise

4.37 The information pack will be sent to the PCAs at least 3 weeks before the date of the visit.

Format of a QA visit

4.38 In some instances, a pre-visit may take place, for example where there are multiple laboratory or colposcopy sites.

4.39 The laboratory ‘specimen journey’ and ‘colposcopy clinic walkthrough’ at the main hospital site will take place on the day of the QA visit and will form part of the QA assessment of these areas. These will be arranged prior to the QA team meeting at the beginning of the day or during the professional discussion session as appropriate.
Components of the QA visit

Briefing for visit chair, PCAs and SQAA/QAAs

4.40 The visiting team will either meet before the day of the QA visit or just before the visit commences. The aims of the briefing meeting are to:

- introduce all members of the QA visit team
- enable the SQAS to provide PCAs with an accurate overview of the core elements of the local screening service prior to the QA visit
- initiate discussions and enable any potential areas of concern to be highlighted prior to the QA visit
- enable triangulation of initial findings from pre-visit evidence review generated by the PCAs and SQAS
- ensure that all members of the visiting QA team are aware of their roles and responsibilities for the QA visit

Introductions between the visiting team and the local screening service staff

4.41 Members of the visiting QA team and SQAS representatives will introduce themselves to the local screening service on the day of the visit.

A short presentation from the hospital-based screening co-ordinator about the local screening service’s achievements

4.42 The HBPC or designated representative will be asked to give a short 10 minute presentation giving a brief overview or description of the service including:

- changes since the last visit
- activity
- achievements
- any challenges or particular issues

Individual interviews between each PCA and the local screening service representative for that profession

4.43 Each PCA member of the visiting QA team will ideally meet their professional counterpart(s) in the local screening service. This will be a structured interview to assess service adherence to national minimum standards, professional performance and the relationship between the different components of the local screening service.
4.44 The PCA should summarise the discussion, feedback main issues and check for mutual understanding at the end of the interview.

Discussion by the visiting QA team of findings and preparation of feedback session

4.45 The visiting QA team will meet to discuss outcomes of individual interviews and amalgamate their findings. They will focus on areas of risk, recommendations and shared learning. Findings will be summarised and this may take the form of a presentation.

Feedback session

4.46 The feedback on the day will be given in 2 sessions.

4.47 The visit chair and SQAA/QAA will meet with the provider chief executives and NHS England DCO team representative, for example, SIL, to give a verbal summary of risks, high level findings and recommendations. This session may also be used to raise concerns regarding performance of an individual, or concerns for patient safety where it would not be appropriate to report these findings to a wide audience.

4.48 This session will usually, but not always, take place prior to the main feedback session and it is anticipated that this will last no longer than 15 minutes.

4.49 The main feedback session will consist of a short presentation by the visit chair of the main findings and recommendations to all local screening service staff and some stakeholders. All those interviewed should be invited to the main feedback session.

4.50 Senior management representatives of the provider trust, chief executives, CCG representatives (where applicable), NHS England DCO team representatives and other stakeholders identified by the local screening service will also be invited to attend this session. Directors of public health or their nominated representative can be invited to attend by the DCO team.

4.51 The feedback session will highlight:

- areas for shared learning
- risks
- recommendations
- intention to publish the report executive summary on an external facing website 8 weeks following the production of the final QA report
4.52 It is anticipated that this feedback session will take no longer than 30 minutes.

4.53 Where immediate concerns related to safety are raised, a letter from the RHQA or HQA outlining the main concerns and corresponding remedial actions will be sent to the chief executive of the provider organisation and the lead commissioner within 2 working days. The letter will be copied to the RHQA (where applicable) and to the National Lead, Screening QA Service. The national programme managers will be informed where applicable.

Feedback from local screening service provider on QA visit

4.54 Local screening services will be asked to complete a feedback questionnaire after the QA visit in order to evaluate the visit process and provide feedback for the SQAS as part of its ongoing review process.

Written report and follow-up

4.55 Each member of the visiting QA team will submit to the SQAA/QAA a summary of their findings. It is expected that these summaries will be available to the SQAA/QAA within one week of the visit (or earlier as agreed). It is the responsibility of the lead SQAA/QAA to produce a draft report for factual accuracy checking by the local screening service and commissioners within 20 working days of the visit. Day 1 is the first working day after the visit takes place.

4.56 The final report will be completed within 8 weeks of the visit.

4.57 The QA visit report will:

- be completed using the agreed report template and associated headings
- use plain, clear English in line with the PHE style guide
- include summary descriptions of local screening service organisation and leadership arrangements
- comment on the adequacy of resource, accommodation, and equipment to meet national standards
- identify areas of shared learning
- identify variance from national standards as a centre and within specialties
- identify strengths and weaknesses within the local screening service
- make structured recommendations to address issues identified

Circulation of the report

4.58 A copy of the report will be sent to:
- provider chief executive(s)
- NHS England DCO team representative, for example SIL and the Head of Public Health Commissioning (HOPHC)

4.59 The report will be sent via email and will be copied to the HBPC.

4.60 The chief executive and SIL will be asked to disseminate to relevant colleagues including those in the local health economy with a responsibility for screening services and relevant colleagues in public health centres. Details of where the executive summary will be published will be included in the correspondence.

4.61 The executive summary of the QA report will be published on the GOV.UK website 8 weeks after the final report is issued (16 weeks after the visits) with consent from the local screening service provider and NHS England commissioners. The provider may choose to submit an action plan with progress at this time and if so, details of where the action plan can be found will be provided.

4.62 Where consent is not given by the provider, the provider’s name and the date of the visit will be published instead with an acknowledgement that a visit took place and consent to publish the executive summary was declined. A similar note will be placed on the website if NHS England commissioners declined publication.

4.63 Provider and commissioning organisations should note that the full report can be requested by a member of the public using a Freedom of Information request and may be released by PHE if requested.

**Development of the action plan**

4.64 SQAS will support the providers and commissioner through the action planning process. Each provider and NHS England DCO team will have a named SQAA/QAA.

4.65 The QA process should identify whether providers have met the nationally agreed programme standards and any statutory guidance or guidelines and should state the evidence used to assess how the judgement about quality was made.

4.66 The SQAS will write recommendations from which action plans can be developed. The evidence required to show that an action has been completed will be stated as part of the recommendations.
4.67 A criteria for closure will be included detailing exactly what action or documentation is required to show that an action has been satisfactorily implemented.

4.68 Timescales for the recommendations should be specific, with dates for completion clearly stipulated.

4.69 It is the responsibility of the NHS England DCO team’s SIL (the commissioner) to ensure that the recommendations made in the QA visit report are implemented. This will be done in conjunction with the provider.

4.70 An action plan should be developed by the local screening service within 4 weeks of receiving the final report, which is agreed with the SIL or the HOPHC. It is good practice for this to be submitted to the next local screening programme board or equivalent governance structure within 3 months of the visit.

4.71 The SIL will ensure that progress against the action plan is maintained using relevant commissioner oversight mechanisms and levers, with SQAS kept informed via local programme / oversight boards and direct contact with the providers and commissioners.

4.72 SQAS will work with commissioners to monitor activity and progress in response to recommendations. This is for a period of 12 months following the issuing of the final report. This will allow adequate time for at least one response to all recommendations. A letter will then be sent to the provider chief executive and commissioners summarising the progress made and asking for their direct intervention to address any remaining issues.

**Escalation process**

4.73 Failure to undertake recommended actions will necessitate appropriate escalation by SQAS if progress is not being made. This will initially be through the local screening programme board or equivalent governance structure and NHS England DCO team.
5. Training and development

5.1 All staff taking part in QA activity should undertake training related to the role. The training requirements for professional and clinical advisors are set out in the relevant job descriptions / role outlines which are available from the SQAS team.

Continuous improvement

5.2 We are committed to improving our processes and measuring the impact of QA and as such we request feedback from local screening services and providers on all aspects of the QA process and visit. Any feedback received will be shared as appropriate in relevant forums, or individually where applicable, to improve the QA process.
Appendix A: The quality assurance process

Details of the process described below are in development and will be reviewed.

SQAS activity key:

- Black: provider function reviewed by SQAS
- Pink: public health system leadership and commissioning function (please refer to pre visit questionnaire for complete list of functions for peer review)
- Green: under development

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<td><strong>Identifying cohort</strong></td>
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<td>1. Review of annual NHS Digital/system audits by national call recall QA function</td>
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<td>4. National QA call and recall team/system audit reports</td>
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<td>5. Failsafe /e-FNRs</td>
<td>5. National QA call and recall team/system audit reports</td>
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<td>9. National QA call and recall team/system audit reports</td>
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<td>10. n/a</td>
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<td>11. QA of MoD call/recall functions</td>
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<td>Regional QA: QA of local MoD arrangements (see later sections)</td>
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<td>1. NTD</td>
<td>1. Check at QA visits</td>
<td>1. At visits/ ongoing</td>
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<td>2. Letters to women (invitations, reminders) and use of national leaflets</td>
<td>2. Check at QA visits</td>
<td>2. At visits</td>
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<td>3. Coverage data</td>
<td>3. Monitor quarterly and data provided to NHSE as part of KPI monitoring; discussed at programme boards</td>
<td>3. At visits</td>
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<tr>
<td>4. Out-sourced providers of letters, including information governance issues with data transfer and information handling</td>
<td>4. Check at visits including copies of sign up to the NHSCSP confidentiality policies</td>
<td>4. Quarterly</td>
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<tr>
<td>Regional SQAS Activities</td>
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<td>Primary Screening</td>
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<td>1. At QA visits</td>
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<td>Pathway Element</td>
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<td>2. Sample taker database and management, reporting to sample takers</td>
<td>SIT and laboratory</td>
<td>2. At QA visits</td>
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<td>3. Open Exeter access</td>
<td>2. Covered at QA visits</td>
<td>3. At QA visits</td>
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<tr>
<td>4. Checking of ID</td>
<td>3. National call and recall QA function visits</td>
<td>4. n/a</td>
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<td>5. Eligibility for screening</td>
<td>4. n/a</td>
<td>5. Annual</td>
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<tr>
<td>6. Recording of signs &amp; symptoms</td>
<td>5. Annual ceasing audit via call/recall; checked by national call/recall QA function</td>
<td>6. n/a</td>
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<td>7. Taking the sample</td>
<td>6. n/a</td>
<td>7. Rejection rates</td>
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<td>7. Laboratory rejection rates/sample acceptance policies</td>
<td>quarterly. Acceptance</td>
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<td>8. National call and recall QA function visits</td>
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<td>9. n/a</td>
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<td>10. n/a</td>
<td>10. n/a</td>
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<tr>
<td>12. Reducing health inequalities</td>
<td>11. Laboratory transport arrangements reviewed at visits/ Proportion of tests reaching the laboratory within 3 days of being taken</td>
<td>11. At QA visits/quartery</td>
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<td>a. Special needs</td>
<td>12. Linked to commissioning QA review arrangements; what is in place?</td>
<td>12. At visits/Quarterly</td>
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<tr>
<td>b. Information for women for whom English is not a first language</td>
<td>a)…. b)…. c) quarterly and annual coverage rates</td>
<td>and annual</td>
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<tr>
<td>c. Coverage rates and initiatives to improve attendance</td>
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<td>2. Sample taker database and management, reporting to sample takers</td>
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<td>3. Open Exeter access</td>
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<td>c. Coverage rates and initiatives to improve attendance</td>
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<td>Screening test reporting</td>
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<td>1. Leadership of cytology service</td>
<td>2. Are processes in place to ensure staff are appropriately trained</td>
<td>2. At visits/annual staff</td>
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<td>b. Locums</td>
<td>a) and b) Collection via KC61/Annual review/QA attendance at PBs  c) check non-conformance re UKAS/CPA assessment</td>
<td>data</td>
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<td>3. Accommodation and equipment</td>
<td>Annual KC61 Staffing appropriate for workload</td>
<td>Annual</td>
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<tr>
<td>a. Use of approved LBC technologies</td>
<td>Review relevant SOPS as part of QA visits</td>
<td>At QA visits</td>
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<td>b. Use of approved HPV testing technologies</td>
<td>Review relevant SOPs as part of QA visits/rejected sample rates</td>
<td>At QA visits</td>
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<td>c. UKAS/CPA accreditation compliance</td>
<td>Annual individual data reports</td>
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<td>4. Minimum laboratory workload (35,000)</td>
<td>National EQA Team runs EQA scheme for gynae cytology (individuals) and laboratory technical EQA (TEQA); participation of all schemes including HPV EQA checked annually and at visits</td>
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<td>5. Specimen management in line with national guidelines</td>
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<td>7. Minimum individual staff workloads (3,000 screeners, 750 checker, 750 pathologist/CBMS)</td>
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<tr>
<td><strong>Issuing results</strong></td>
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<tr>
<td>1. Result letters to women and use of national leaflets</td>
<td>1. National text and leaflets used; check at visits by national call/recall QA function</td>
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<td>1. Job description review at visit</td>
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<td>2. a) direct referral processes, b) c) referral acceptance processes</td>
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<td>a. Review processes in place for decreasing DNAs and improving access?</td>
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<td></td>
<td>16. At visits/ Annual review</td>
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<tr>
<td>10. Clinic IT systems and data quality</td>
<td></td>
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<tr>
<td>11. Effective colposcopy practice</td>
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<td>12. Prompt treatment where required</td>
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<tr>
<td>13. Provision of timely results</td>
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<tr>
<td>a. Patient information and letters</td>
<td></td>
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<tr>
<td>b. Discharge information to call/recall</td>
<td></td>
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<tr>
<td>14. Right result assessment</td>
<td></td>
<td></td>
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<tr>
<td>15. MDT case discussion and criteria</td>
<td></td>
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<tr>
<td>16. Patient experience</td>
<td></td>
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<tr>
<td></td>
<td>11. Will be collecting data on activity and performance against national standards of individual colposcopists. Needs further guidance on maintaining competence. Compliance with HPV triage protocol assessed via audit</td>
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<td></td>
<td>12. Monitoring via annual data review</td>
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<td></td>
<td>13. Monitoring via KC65</td>
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<tr>
<td></td>
<td>a. At QA visits</td>
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<tr>
<td></td>
<td>14. Right results review process to be developed based on existing tools available</td>
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<td></td>
<td>15. Check at visits</td>
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<td></td>
<td>16. Patient journey and review of patient survey findings at QA visits;</td>
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<tr>
<td>MDT</td>
<td>1. QA Visit; SOPs</td>
<td>1. At visit</td>
</tr>
<tr>
<td>1. Referral criteria and case selection by cytology, histology, colposcopy</td>
<td>2. MDT attendance sheets</td>
<td>2. At visit/annual</td>
</tr>
<tr>
<td>2. Cytologist/histologist/colposcopists present</td>
<td>3. QA visit</td>
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<tr>
<td>3. Appropriate equipment including monitors and video conferencing</td>
<td>4. QA visits; MDT notes</td>
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<td></td>
<td>5. QA visits; MDT notes</td>
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</tr>
<tr>
<td>Pathway Element</td>
<td>SQAS Activities</td>
<td>Frequency</td>
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<td>-----------------</td>
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<tr>
<td>4. Frequency meets national guidance</td>
<td>6. QA Visit</td>
<td></td>
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<tr>
<td>5. Appropriate record keeping of attendance</td>
<td>7. Local MDT audit on risk assessed basis</td>
<td></td>
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<tr>
<td>6. MDT discussion</td>
<td></td>
<td></td>
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<tr>
<td>a. Mismatch cases</td>
<td></td>
<td></td>
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<tr>
<td>b. Glandular/CGIN</td>
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<tr>
<td>c. Outside protocol HPV testing use</td>
<td></td>
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<tr>
<td>d. Other cases as defined by national guidance</td>
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<tr>
<td>7. Outcomes in line with national guidance principles and reported to the appropriate clinician</td>
<td></td>
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<tr>
<td><strong>Histopathology</strong></td>
<td><strong>SQAS Activities – to be updated in light of working group findings</strong></td>
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<tr>
<td>1. Leadership of cervical histology service</td>
<td>Will encompass the following:</td>
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<tr>
<td>2. Workload</td>
<td>a) Routine data collection (under development)</td>
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<tr>
<td>3. Safe transfer of biopsy specimens</td>
<td>b) Review of specific CPD activities at QA visits (under development)</td>
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<tr>
<td>4. SOPs for use of additional testing</td>
<td>c) Review of policies and procedures at QA visit</td>
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<tr>
<td>5. Evidence of standard use of appropriate minimum data set items</td>
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<td>6. Routine use of levels</td>
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<tr>
<td>a. Biopsy</td>
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<td>b. LLETZ</td>
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<td>7. Clear communication of results, supplementary reports and changed reports</td>
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<td>8. Clear process for getting second opinion/discussion of difficult cases</td>
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<td>9. Accurate final histology</td>
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<tr>
<td>Pathway Element</td>
<td>SQAS Activities</td>
<td>Frequency</td>
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<tr>
<td>10. Turnaround times</td>
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<tr>
<td>a. Biopsy</td>
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<td>b. Loops</td>
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<tr>
<td>11. Participation in a national EQA scheme encompassing gynae specimens</td>
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<tr>
<td>12. Participation in colposcopy MDT</td>
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<tr>
<td>Programme Management</td>
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<tr>
<td>1. Identified Hospital-based Co-ordinator with time and JD to cover the role;</td>
<td>1. QA visit</td>
<td>1. At QA visit</td>
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<tr>
<td>appropriate SLAs in place if not provided by local Trust</td>
<td>2. QA visit</td>
<td>2. At QA visit</td>
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<tr>
<td>2. Lines of accountability to Trust Board</td>
<td>3. QA visit</td>
<td>3. At QA visit</td>
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<tr>
<td>3. Organisational chart for the programme</td>
<td>4. QA visit</td>
<td>4. At QA visit</td>
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<tr>
<td>4. Risk assessment and management</td>
<td>5. QA visit</td>
<td>5. At QA visit</td>
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<tr>
<td>a. Business continuity and succession plans</td>
<td>6. QA visit</td>
<td>6. At QA visit</td>
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<tr>
<td>5. Clinical Governance, escalation processes and integration into Trust systems</td>
<td>7. QA visit a) and b) ongoing data monitoring/annual review</td>
<td>7. At QA visit/</td>
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<tr>
<td>6. Multi-disciplinary management meeting arrangements</td>
<td>8. n/a</td>
<td>annual/ongoing</td>
</tr>
<tr>
<td>a. Terms of reference and frequency</td>
<td>9. n/a</td>
<td></td>
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<tr>
<td>b. Appropriate representation</td>
<td>10. n/a</td>
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<tr>
<td>c. Recording and follow up of actions</td>
<td>11. Annual review/QA visit</td>
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<td>7. Invasive cervical cancer audit</td>
<td>12. n/a</td>
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<tr>
<td>a. Case ascertainment/prompt notification</td>
<td>13. n/a</td>
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<tr>
<td>b. Level of completeness</td>
<td>14. Ad hoc reporting &amp; QA visit</td>
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<td>c. Policy and process for audit and disclosure of</td>
<td>15. Ad hoc reporting &amp; QA visit</td>
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<td></td>
<td>16. QA visit</td>
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<tr>
<td>Pathway Element</td>
<td>SQAS Activities</td>
<td>Frequency</td>
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<tr>
<td>results</td>
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<td>d. Agreed assignment of responsibility shared with other providers (e.g. regional cancer centre)</td>
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<td>8. Information Governance</td>
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<td>9. Staffing current and projected</td>
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<td>10. Population current and projected changes</td>
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<tr>
<td>a. Approach to service capacity</td>
<td></td>
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<tr>
<td>11. Annual report to commissioners</td>
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<tr>
<td>a. Presentation to Trust(s) boards</td>
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<td>12. Equipment replacement programmes</td>
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<td>13. Maintenance contracts</td>
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<tr>
<td>14. Serious Incidents</td>
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<td>15. Patient Safety Incidents</td>
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<td>16. Complaints and compliments received</td>
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<tr>
<td>17. Relationship with SQAS office</td>
<td>17. Ongoing</td>
<td>QA visit</td>
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<td>15. Ongoing/</td>
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<td>QA visit</td>
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<td>16. At QA visit</td>
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<td>17. Ongoing</td>
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