



Cancer Screening Programmes

QA VISIT REPORT

Unilabs

Tuesday 19th January 2010

**East of England Screening Quality Assurance Reference Centre
Compass House, Vision Park, Chivers Way, Histon CB24 9AD**

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Acknowledgements

The East of England Quality Assurance Team would like to record their thanks to Dr Glen Dixon and all staff working in the Cytology Laboratory for welcoming the visiting team.

The East of England QA Reference Centre has taken the utmost care to ensure that the statements of fact included in this Report are true and accurate and that, where an opinion of the QA peer review team who conducted the quality assurance visit is expressed, such opinion is honestly held by the team, based on true and accurate information and has been arrived at in good faith and without malice.

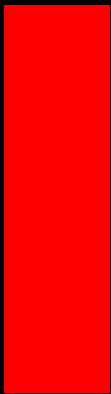

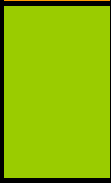
Notes on QA report and table of recommendations

Each professional lead has provided a report and made a number of recommendations based upon data submitted in advance of the QA visit and their observations on the day.

All the QA recommendations made in the body of the report are presented in a table at the beginning and have been colour coded to give an assessment of the risk of the current process or practice at the Unit and consequences of the Service failing to mitigate this risk.

In making this assessment of risk, the QA Team have exercised a judgement based upon the input from the expert QA advisors and the wider experience across the NHSCSP.

Colour Key

	<p>A recommendation has been coded red if, either, unaddressed it could lead to significant risk of harm to women seen by the service, or where due to an absence of data or evidence the quality of the Unit cannot be assessed because the QA process cannot be conducted satisfactorily.</p> <p>We acknowledge that there are occasions when a recommendation may be allocated a high risk grading even though the probability that an adverse event will occur is small. This is because even though the occurrence may be rare, the event would have a significant impact on the patient.</p>
	<p>A recommendation has been coded amber when a process or practice does not meet the expected standard or the recommended practice of the NHSCSP but does not lead to direct clinical risk to individual women. Many of the NHSCSP standards are designed to ensure the acceptability of the screening programme, the maintenance of the value of screening by adhering to professionally-agreed performance standards and quality measures to reduce the anxiety of users.</p> <p>Units should be aware that there is significant political, social and reputational damage to the Unit and the NHSCSP of failure to meet the required standards of the Programme.</p>
	<p>A recommendation has been coded green when it carries no risk to the women seen by the service but which, if implemented could enhance the performance of the Unit and/or the experience of the women screened.</p>

List of Visitors

Jem Rashbass	QA Director
Xenia Tyler	QA Pathologist
Sarah Flower	QA Cervical Manager
Mary Hirschfeld	QA Biomedical Scientist
Jill Buckland	QA Facilitator
Simon Wrathall	QA IT and Data Manager

1. Introduction & Summary

A request for a formal Quality Assurance visit to the Unilabs Laboratory, a private pathology service based in London, was received by the East of England QA Reference Centre for the NHS Cervical Screening Programme from the senior management at Unilabs. The laboratory is keen to provide services to the NHS and wished to ensure that they met the requirements of the NHS Cervical Screening Programme. Initial discussions with the laboratory revealed that there were potential conflicts of commercial interests with the London QA team, and in order to avoid this, the East of England QA service had been approached. The East of England QARC has provided a copy of the register of interests of the QA team members to Unilabs. No conflicts of interest were felt to exist.

The laboratory was provided with the standard data questionnaire that would be used for a QA visit to an NHS service and asked to complete this in advance of a formal visit.

A formal visit by the QA team took place on Tuesday, 19 January 2010 to the Unilabs offices and laboratories in New Cavendish Street, London W1. The QA visit followed the same protocol as that used for any NHS service provider (see Appendix 1).

This is a well-organised and highly focused commercial service providing an excellent quality of diagnostic cytopathology to a wide range of clients. The facilities are secure and comparable to those found in the NHS; the Policies and Procedures are equivalent to those that would be seen in the NHS Cervical Screening Programme.

Staff are trained in both Surepath and ThinPrep (Cytyc) liquid based cytology technologies. Appropriate external and internal quality assurance methods and monitoring are in place to ensure that staff work to a high level of competence in both methodologies. Data on staff screening performance, inadequate and abnormality detection rates are entirely consistent with the range of performance in the NHS Cervical Screening Programme.

The current internal computer systems are fit for purpose and negotiations are at an advanced stage to establish a link to the NHS network, N3. There are also plans to appoint their own Caldicott Guardian to oversee information governance arrangements at this Service.

At present the Service does not provide significant diagnostic support to the NHS; there are no systems in place for direct data entry into the NHS computer systems and no links with Call Recall. These issues have not been addressed as part of this QA visit and any potential NHS partner wishing to use this Service would need to ensure that the data transfer to and from this laboratory meet with their own information governance requirements.

2. Summary Table of Recommendations

Recommendation No	Details	Owner	Priority	Date for resolution
1	The medical Cytopathologists, who also practice in the NHS, should provide their performance data in their own NHS laboratories to the lead cytopathologist at this Service.	Cytopathologists/Lead Cytopathologist		Within 6 months

3. Cytology Reporting

In the year December 2008 to November 2009 the laboratory screened around 31,000 samples, 10,600 of which were for the NHS from three different trusts; two using Surepath (9,500 samples) and one using ThinPrep (Cytyc) (1000 samples). The screeners are qualified to look at both ThinPrep (Cytyc) and Surepath specimens. They take part in External QA for both methods. Work is arranged so that an individual is screening either one or the other preparations for any given session.

The cytology department is well staffed with seven staff of varying grades performing primary screening, review and checking. All staff have the NHSCSP certificate in cervical cytology screening. Six members of staff screened in excess of 2700 samples (both private and NHS work; both ThinPrep (Cytyc) and Surepath), while one screener looked at <2000 samples in the previous twelve months. This screener works less than seven hours a week on primary screening, which probably explains the low number of samples screened. They also had a particularly low screening sensitivity of 77% for all abnormalities and 82% for moderate dyskaryosis and above. There is a departmental standard operating procedure that describes the method of handling this discrepancy in performance and it is being followed with regard to this individual. It was understood that this screener was only performing primary screening, not checking, and was planning to retire in the coming months. Two of the other screeners also had slightly low sensitivities of 81% and 84% for all abnormalities, but high sensitivities for moderate dyskaryosis and above of 96% and 100%.

Comparison of the data for this Service with an average from a range of NHS laboratories shows that the distribution of abnormalities and negative smears for the screening staff is entirely within the parameters that would be expected across the NHS Cervical Screening Programme.

Four medical staff report gynaecological cytology in this Service, virtually all of which is for the private sector (although they report NHS work as part of other contractual commitments elsewhere). One of the four only joined the team in the past two months and so no workload figures were available. The Medical Director of Cytopathology reports the majority of the work, with cover provided by one of the other four. The reporting profile for one of the pathologists is very different to the other two; including a negative rate of 84% (compared to around 47% for the other two) and a PPV of 100%. A PPV of 100% is somewhat surprising and anomalous and warrants further investigation by the lead cytopathologist in the Service. It may be explained by the type of work being looked at. It is possible that the normal ranges provided by the NHSCSP are not appropriate for a population of women who have a sample taken annually, or are outside the screening age range.

The QA team noted that the information on workload and reporting profiles for the medical cytopathologists that was provided for this visit is based only on the data available from the practice in the private sector. It is suggested that figures for the work carried out at any NHS hospital should be included separately with this data, in order to demonstrate the pathologists' overall performance for all work undertaken for both NHS and private sectors.

The laboratory provides processing and diagnostic services in both cytopathology and histopathology and routine testing for HPV and Chlamydia. This QA visit focused only on the cervical cytopathology service.

QA Opinion

QA would recommend that for the medical Cytopathologists who also practice in the NHS, their performance data from their own NHS laboratories should be provided to the Lead Cytopathologist at this Service. This would allow the private service to ensure that there are no significant differences between the practice in the two services and also let the performance of individuals be assessed on their entire annual workload rather than just the proportion conducted in the Unilabs' service.

Staining Technologies

In contrast to NHS laboratories that work with a single type of LBC preparation, this service can take diagnostic work for both Surepath and ThinPrep (Cytyc). It is recognized that the two staining techniques produce different appearances of the cells on the slide and that staff must be appropriately trained in each technology if they are to screen both. Since this situation never arises in the NHS the visiting QA team explored the internal quality assurance processes in some depth to satisfy themselves that the practice and controls were robust and safe.

The Service and staff recognise that there are significant differences in the appearance when using these two staining technologies. Cytoscreening staff do not switch randomly from one technology to another but if there are differently stained slides to report will do one type on one day another on a different day. Furthermore, if there has been an extended period of time (more than 3 months) since they last read one or other technology they will sit an EQA test provided by the Birmingham Cytology Training School to ensure that they remain competent in the appropriate staining technology. The full-time medical cytopathologist is trained in both staining technologies and this ensures that the laboratory can provide a medical opinion on all the material they receive. The other Cytopathologists who work part-time on a sessional basis at the laboratory only read ThinPrep (Cytyc) stained slides and this is the same technology that they report at their non-Unilabs laboratories.

QA Opinion

The staff in this service are trained to read both Surepath and ThinPrep (Cytyc) stained slides. The Service recognises that this creates a challenge that does not occur in the NHS. The visiting QA team are of the view that the practices, internal and external quality assurances processes in place in this Service are sufficient to ensure that this practice is safe.

4. Environment & Physical Aspects of Laboratory Services Provision

The Unilabs pathology service is based in central London, a short distance from University College Hospital and almost adjacent to the old Middlesex Hospital site. The processing laboratory and the offices and reporting facilities used by cytoscreeners and pathologists are on separate sites, separated by about 300 metres but requiring a short walk down New Cavendish Street.

Planning regulations from Westminster City Council require that the laboratory services are located below ground. Both facilities are physically secure with controlled door entry systems at street level and into the main offices. Where appropriate there are bars covering windows to prevent forced access. No clinical data would be viewable through windows to either passers-by or from adjacent offices in other buildings.

The laboratory has the facilities to process ThinPrep (Cytyc) specimens and has both a T3000 and T2000 processing machine. The machines are covered by maintenance contracts and the service support ensures that there is either same day or immediate next day repair should this be required.

The specimen processing room is in a basement room 300 meters along the road from the screening rooms and offices, but there is a secure system in place for transporting slides and forms by foot. The room was extremely tidy and organised, with adequate space. The smell of xylene seemed strong, but we were assured that regular measurements taken are within acceptable levels. All NHS work undertaken currently is processed by the sending lab and only the slides are received by Unilabs.

The screening room was light and pleasant and suitable for the purpose although there is no means of varying the temperature of the room without opening the window. Each screener had their own designated space with a PC and ergonomic microscope, although the desks and chairs were not ergonomic.

Transport of specimens

The laboratory and the reporting facilities are separate and therefore clinical material must be transferred between the two sites. The processes to handle this are well developed. There is a dedicated internal transfer service; material is appropriately packaged when it is moved between the two sites and all material when moved from one site to the other is signed-in and signed-out and accounted for at both ends of the transfer process.

Specimens received from other hospitals are sent in appropriately secured packages and use courier services that are also used to handle patient information in the NHS.

QA opinion

The specimen receipt and internal transfer of material through the laboratory meets the current standards required by the Information Governance polices of the NHS.

5. Turnaround time for smears

In the previous year the service reported around 31,000 specimens and the majority of the work is received from the private sector. Occasional small contracts are taken from the NHS from individual Trusts on an *ad hoc* basis to cover backlog work. In general the NHS work is only for primary screening although infrequently an NHS Trust will send specimens for a medical cytopathology opinion. The private sector users of the laboratory send a mixture of specimens, those for ThinPrep (Cytyc) can be processed within the laboratory, those for Surepath are received ready stained from other services.

The data provided did not separate private from NHS work. The laboratory turnaround time (TAT) is 95% in 7 days, 99.7% in 14 days.

The work from NHSCSP sites is from a backlog at individual sites. There is a contractual commitment to report NHS work (primary screen and check) within 5-7 days and we were told that this turnaround time is always achieved, although we did not see any documentary proof of this. Private specimen turnaround is extremely rapid and depending upon the contractual arrangements with their clients is usually within 24 to 48 hours. The laboratory is confident that they can apply the same working practices to material received from the NHS if required.

6. Staffing and Recruitment

The cytoscreening staff adhere to the policies of the NHS Cervical Screening Programme; specifically they do not screen for more than 20 hours in any one week and for no more than five hours in any one day. The number of staff is appropriate for the workload and they all attend regular update courses.

A cytoscreener post has been vacant for 18 months but this is due to a recruitment freeze. This position is likely to be filled by the current locum BMS.

7. Training

All staff participate in regular training courses and each member of staff has a training log, competency log and CPD record. All training covers both Surepath and ThinPrep (Cytoc) screening techniques.

8. Internal Quality Control Procedures

All samples are primary screened and most are given a full secondary screen. All staff participate in both ThinPrep (Cytoc) and Surepath EQA schemes, participating in at least two per year, either both ThinPrep (Cytoc) or one of each technology. All staff performance figures are regularly collated and monitored and there is regular documented discussion between the Laboratory manager and the Lead Consultant.

The Lead BMS is aware of screening performance figures and had already taken remedial action over a poorly performing screener.

9. Protocols

Appropriate protocols appear to be in place and are readily available.

10. Computerisation

The laboratory uses a Swedish computer system to manage its pathology services and this appears entirely fit for purpose. Crystal Reports is used to extract data on lab activity, screener performance, revenue etc. A member of the IT team has now been trained in Crystal

Reports so that queries can be written in-house. A wide variety of reports are available to the laboratory manager to allow monitoring of screener performance.

The current computer system appeared to be fit for purpose. There is no access to Open Exeter, so that cases are reported in isolation with no regard to the patient history, unless it is provided on the HMR101 form or accompanying paperwork. Unilabs are presently working with third parties to fulfil the requirements of the NHS Information Governance toolkit and the Information Governance Statement of Compliance which will allow them access to the NHS N3 network. This will allow them to look up screening histories for NHS patients. It is planned for this work to complete in Quarter 4 of 2010. As part of the toolkit, Unilabs are working to identify a suitable candidate to act as Caldicott Guardian for the laboratory.

Access to the system is available to all staff in the Cavendish Street office and the laboratory. Pathologists are able to log-in remotely to authorise reports etc using a token which generates a time-limited code.

All staff are signed-up to confidentiality agreements as part of their contract of employment.

QA Opinion

At present the service does not provide significant diagnostic support to the NHS and there are no systems in place for direct data entry into the NHS computer systems, including Call/Recall. The issues of failsafe, data transfer and links with Call/Recall have not been addressed as part of this QA visit. Any potential NHS partner wishing to use this Service would need to ensure that the data transfer to and from this laboratory meet with their own information governance requirements.

11. Communication

The lab is only providing screening and checking services for NHS work and, therefore, no communication with clinicians and Call/Recall is required. There is no requirement to be represented on a local Cervical Cytology Steering Group.

12. Failsafe

There is no requirement for the lab to be involved in failsafe activities for the NHSCSP.

13. Management Arrangements

The screening staff appeared to be well managed by the Lead BMS. The work was organised and seemed to flow through the screening room into the office. The lab was able to cope with the pressures of reporting a proportion of the work within one day and prioritising the work to achieve this.

Appendix 1: Visit protocol

**GUIDELINES FOR QUALITY ASSURANCE VISITS
IN THE CERVICAL SCREENING PROGRAMME**

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PREFACE

These guidelines describe the principles for the organisation of quality assurance visits in the NHS Cervical Screening Programme. They are based on the experience of regional QA teams in organising QA visits and on discussions which took place at a workshop in Birmingham in 2005 and at a series of working groups. A toolkit of proformas for QA reference centres to use as previsit questionnaires and as templates to record discussions at the QA visit has also been developed and is available on the NHSCSP web site (www.csp.nhs.uk).

ACKNOWLEDGEMENTS

The national office would like to thank QA directors and coordinators who have contributed to and commented on successive drafts of this guidance. Particular thanks go to Linda Garvican for drafting the principles of QA visits and to Philippa Pearmain for contributing the organisational diagram of the NHSCSP.

1. PRINCIPLES OF QUALITY ASSURANCE VISITS

1.1 Purpose of the quality assurance visit

The purpose of the quality assurance (QA) visit is to assure the quality of the cervical screening programme by:

- assessing compliance with minimum standards for each discipline and interrelationships within the whole programme
- identifying and promoting good practice
- identifying areas for improvement and making recommendations to achieve this.

Each element of the programme is subject to QA. The QA visit is only one part of the ongoing QA process of monitoring performance and sharing good practice in order to maintain and improve the quality of the cervical screening programme. QA visits are based on both an assessment of performance against numerical standards and published guidance and a qualitative judgement and assessment of risk.

1.2 What constitutes a local programme to be visited?

Local screening programmes often comprise a complex interrelationship of screening offices with one or more laboratories and several colposcopy clinics. The organisational links are shown in Figure 1. The simplest programme model is one primary care call/recall agency (the screening office), one laboratory and one colposcopy clinic commissioned by one primary care trust (PCT). However, in practice, a laboratory may provide a service for more than one programme or part of several PCTs. Some screening offices cover whole counties and may relate to several laboratories.

The QA reference centre (QARC) needs to define the boundaries and agree in advance what constitutes a programme to be visited, bearing in mind that the links between the different elements of a programme are a common source of problems. There needs to be local flexibility to reflect the complexity and geographical spread of programmes. The aim is to be inclusive of all the following elements of a programme which serve an identified population of women:

- overall programme coordination and links to public health and commissioning
- call and recall
- cytology sample taking (mainly in primary care)
- laboratory services
- colposcopy clinics.

In most places, visits are designed around the host organisation which provides laboratory services. The visit includes all associated colposcopy clinics (whether or not in the same host organisation) and all PCTs for which the laboratory provides cytology reporting. In some areas, visits are designed around all elements of a screening programme which is

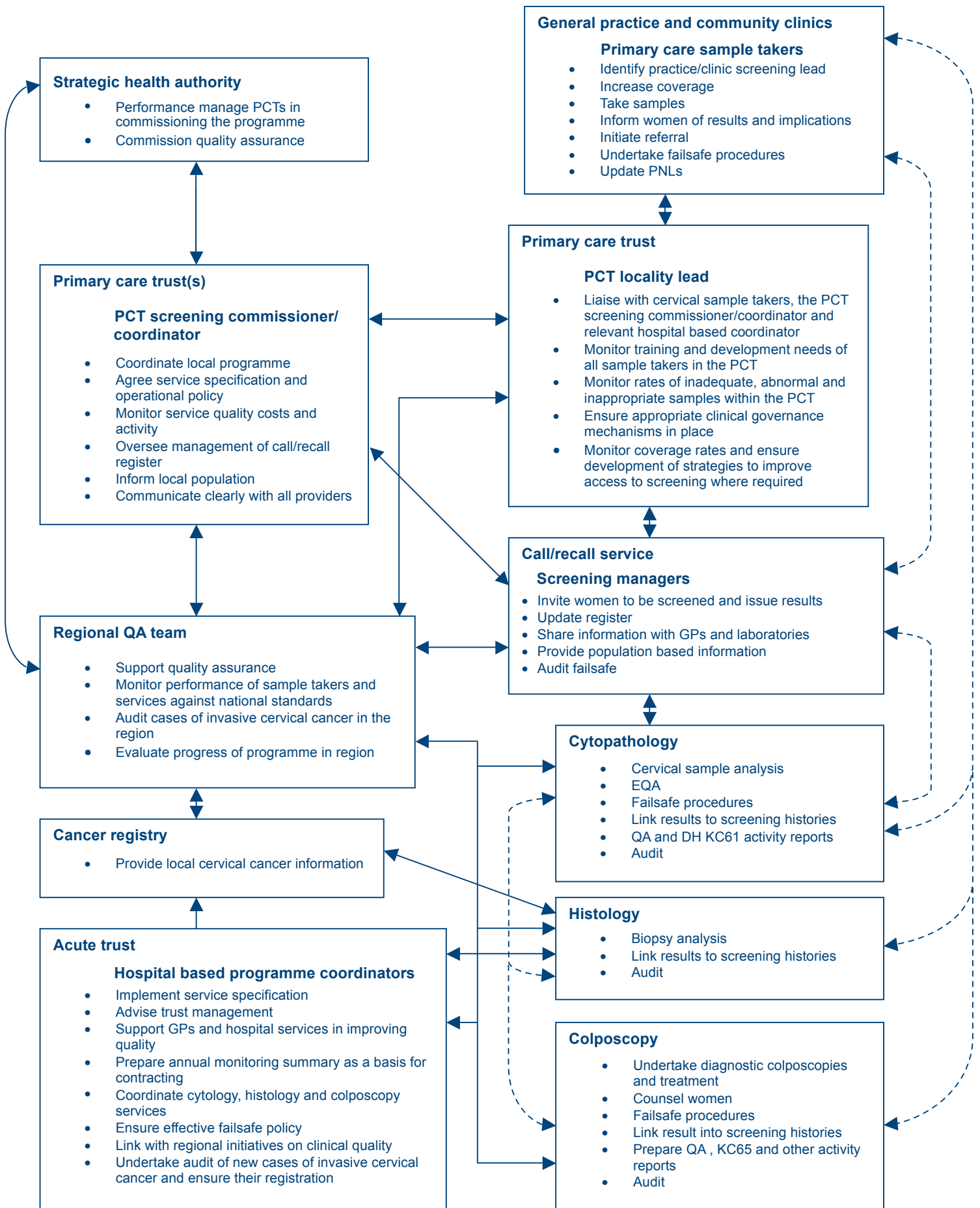


Figure 1 Organisational links in the Cervical Screening Programme. - - - - = patient pathway; ——— = programme links.

commissioned by a PCT or PCTs, including all laboratories and colposcopy clinics (which may be in several host organisations). In either case it is the responsibility of the QARC to ensure that all elements of a screening programme are covered in a round of visits, including the interrelationships between different providers.

It is not necessary to visit a service repeatedly if performance is satisfactory. For instance, a single visit (in each round of QA visits) to a screening office which relates to several laboratories should suffice. However, for each programme review it is essential that the bilateral relationships should be assessed each time by means of a previsit questionnaire or attendance of the appropriate people, such as the screening manager, at the QA visit.

1.3 Key questions

The use of key questions may facilitate the qualitative judgement and assessment of risk. Many of the key questions are common to several elements of the programme, and comparison of answers may enable a judgement to be made about the overall quality of the programme. The key questions can also be used to give a common structure to the QA visit report.

Obtaining key information prior to the visit allows the QA team to have time to fully assess important documentation and get a good understanding of the service. More attention can therefore be given at the QA visit to areas where there may be issues or concerns.

A list of key questions is given in Appendix 1. Detailed questions and documentary evidence to support the answers should be sought through previsit questionnaires. These should be sent out for completion in advance of the visit and used as a checklist to identify areas for particular focus during the visit. Examples of the questionnaires are given in the Toolkit for QARCs, which is available on the NHSCSP web site (www.csp.nhs.uk).

1.4 The Concordat

The Concordat is a voluntary agreement between organisations that regulate, audit, inspect or review elements of health and health care in England. It enables such organisations to coordinate and streamline activities such as audits, reviews and inspections. A summary of Concordat objectives relevant to the NHSCSP is at Appendix 2. QARCs are encouraged to register QA visits on the Concordat web site (www.concordat.org.uk).

2. VISITING QUALITY ASSURANCE TEAM

2.1 Team structure

The visiting QA team is a multidisciplinary team, led by the QA director or nominated representative. The QA coordinator is responsible for organising the visit on behalf of the QA director. The visiting team usually includes the following QA professional leads (or an agreed deputy):

1. QA director
2. QA coordinator and audit staff from the QARC
3. PCT screening commissioner/programme coordinator and/or PCT locality lead
4. call and recall manager (screening manager)
5. pathologist(s) – both cytology and histopathology should be represented
6. scientific laboratory lead
7. medical colposcopist
8. colposcopy nurse
9. primary care nurse
10. general practitioner.

Optional team members include:

11. hospital based programme coordinator (if not already represented by one of the QA or professional leads listed above)
12. patient representative
13. others (eg cancer/laboratory network representative)
14. observers, from the same or other regions
15. trainee QA team members.

The QA visit provides a learning environment, so it should be possible to facilitate this by inclusion of trainees or other observers wherever possible, and providers should be willing to accommodate this.

2.2 Deputy team members

There must be formal arrangements in place for nominating deputies. It may be desirable to incorporate deputies into the QA team to reduce the commitment of time for a single lead professional.

2.3 Training for team members

Training must be provided for new team members in how to interpret standards so as to achieve consistent assessment of programmes. Observation of a visit in members' own and/or another region is a key part of the induction process for team members, as is a process of handover from the outgoing lead professional. The QA director must ensure that all team members have skills in interviewing and report writing. Training should be offered if needed.

Some members of the QA team may have been trained as peer reviewers for the cancer network peer review process. This training is helpful, but QA team members need to appreciate the different approaches of the two assessment systems.

3. ORGANISATION OF QUALITY ASSURANCE VISITS

3.1 Cycle of visits

A visit to each programme should be undertaken at least every four years (core specification for QA services, 2005), but preferably every three years if funding and staffing resource permits. The cycle of visits should be drawn up by the QARC. The QARC may also initiate a visit in response to a request, a failure to meet CPA standards or following the identification of a failure to meet minimum programme standards.

3.2 Notification and duration of visits

It is the responsibility of the QARC to notify the relevant people of a QA visit. Arrangements will vary with the organisation of the programme. The QARC should give a minimum of three months' notice of an intended visit. The choice of dates will depend on the availability of visiting team members and those being visited. The QA visit process should complement other processes such as peer review and CPA accreditation and, where reasonably possible, there should be at least a three month gap between QA visits and peer review visits. QARCs are encouraged to register planned visits on the Concordat web site (www.concordat.org.uk).

3.2.1 *Trust based programme visit*

The QARC will notify the Regional Director of Public Health (RDPH) and screening lead at the strategic health authority (SHA), PCT chief executive(s), PCT screening commissioner/coordinator, trust chief executive and hospital based programme coordinator (HBPC) about the QA visit.

The HBPC is responsible for coordinating the visit and notifying the service leads and relevant managers in the provider trust. The PCT screening commissioner/coordinator is responsible for notifying the PCT locality lead(s) and screening manager(s).

If the programme is located on a single site it may be possible to complete the visit in a day. Outlying clinics may require previsits in the preceding two weeks.

3.2.2 *PCT based programme visit*

The QARC will notify the RDPH and screening lead, PCT chief executive(s), PCT screening commissioner/coordinator, provider trust chief executives and the relevant HBPCs about the QA visit.

The PCT screening commissioner/coordinator is responsible for coordinating the visit and for notifying PCT locality leads, and the screening manager. The HBPCs are responsible for notifying the service leads and relevant managers in their trusts.

The duration of a visit will depend on the complexity of the local programme and on geography. It may be possible for the complete assessment to take place on a single day or it may need to be spread over a longer period (up to six weeks) to allow previsits to satellite clinics and visits to the main provider trusts.

- 3.3 Previsit planning** The HBPC or PCT screening commissioner/coordinator should assist with practical arrangements for a visit (or nominate a lead contact for this purpose). The trust or PCT will need to provide suitable accommodation, including a room for the main feedback session that is large enough to seat all who might wish to attend and a range of smaller rooms that can be available prior to this for separate professional interviews and review of previsit questionnaires. The trust or PCT will also need to provide refreshments for the visiting team and to provide details of the location of the rooms to be used and car parking arrangements for the services/trusts to be visited.
- 3.4 Programme overview and data set** The QARC must provide an overview for the visiting team of the elements of a local screening programme (call and recall, sample taking, laboratories and colposcopy clinics) before the visit, together with the agreed data set for each element. Examples are given in the Toolkit for QARCs. This should be part of the programme information held and regularly updated by the QARC.
- A process map of the data collection pathway can highlight administrative, data quality, confidentiality or failsafe issues and data processing bottlenecks and may be useful to include prior to the visit so that the visiting team is aware of any issues identified in advance. This could be carried out by QARC staff or an appropriate member of the QA team.
- 3.5 Previsit questionnaires** Nationally agreed previsit questionnaires are available as part of the Toolkit for QARCs. These should be issued by the QARC for completion before the visit in order to help to identify issues for further examination during the visit. QARCs may make amendments to the questionnaires or include additional questions depending on local circumstances.
- The questionnaires include a list of supporting documents which the QARC may wish to see before the QA visit or to have available for inspection on the day of the visit. Examples include copies of relevant policies and protocols and information materials such as letters and leaflets which are provided to patients.
- Previsit questionnaires should be adapted to the structure of the local screening service. It is important that the people in post (or acting in post) and responsible for the points under discussion are the individuals completing the questionnaire, and it should be clear on the submitted material who has completed the questionnaire.
- Previsit questionnaires must be sent out by the QARC to the providers being visited, preferably in electronic format, six to eight weeks before the visit date and returned to the QARC no less than two weeks before the visit date.
- 3.6 Information for the visiting team** The QARC must send copies of the programme overview and data set and completed previsit questionnaires to each visiting team member two weeks before the visit. The QARC must also provide the visiting team with a copy of the report from the previous QA visit and the response from the service so that progress can be assessed.

4. CONDUCT OF QUALITY ASSURANCE VISITS

4.1 Quality assurance team previsit discussion

The purpose of the previsit meeting is to review the programme data and completed previsit questionnaires. Identifying pertinent issues helps ensure that these can be discussed at the visit by all relevant members of the QA team.

In a large region the visiting team may need to travel the previous day and meet the night before the visit to finalise the arrangements and plans, and agree important issues for discussion the next day. Sometimes it may be possible to have the previsit discussion first thing on the day of the visit.

4.2 During the visit

During the visit the different professional members in the QA team will meet separately with their professional colleagues and peers from the laboratory, colposcopy clinics, call/recall and the PCT(s). Each lead professional being visited should be given the opportunity of a meeting with the relevant QA professional lead on a one-to-one basis. It may also be useful for the QA lead to have meetings with other members of staff on a one-to-one basis or in small groups. Asking similar questions of staff of different professional backgrounds is helpful in identifying different perspectives on particular issues.

The purpose of the professional meetings is to validate and further explore information already provided in the previsit questionnaire and to view the facilities provided. Audit and performance data may be discussed and staff may be asked to 'walk through' local procedures.

Each QA lead is responsible for ensuring that his or her discussions are documented. The QA lead may either take notes in person or arrange for a member of the QARC staff to take notes. The content of the previsit questionnaires may be amended or added to during a visit, and the questionnaires may be a useful template for recording the professional meetings. Once the visit is complete the questionnaires may be amended only to include additional information provided by a person who was not able to be present at the meeting or to correct factual inaccuracies.

The QA director and QA coordinator must attend sufficient professional meetings to get an overview of the whole programme. They are responsible for ensuring the consistency and quality of the visit and reporting process, particularly where the membership of the visiting teams varies.

4.3 Call and recall

Visits should be onsite and not just be a paper exercise. All members of the screening team should be involved and interviews should not just be with the screening manager. Documented protocols and database settings should be reviewed against national standards, and working practices assessed for compliance with the protocols. This will be carried out by discussion with the screening manager and by reviewing the NHAIS

(National Health Applications and Infrastructure Services) database and system printouts and reports, and by discussion with individual members of the screening team. The QA visit process should complement rather than repeat other processes such as the NHAIS audit.

4.4 Pathology

Visits to laboratories must follow the pathway of a screening sample. Histology should be included in the visit, including possibly a review of some slides and their associated reports. Cytology slide review is not required as this is covered by external quality assessment (EQA) schemes. The QA visit process should complement other processes such as peer review and CPA accreditation. The CPA status of a laboratory should be ascertained as part of the QA visit process. Non-compliance with CPA requirements within cytology must be followed up.

As a minimum, the visiting team must include the QA lead pathologist and QA lead biomedical scientist (BMS). The host team should include as a minimum the medical head of cytology and the scientific head of cytology. It is recommended that, at least initially, interviews are carried out separately with each member of the host team. Other staff members, including the training officer, failsafe officer, lead BMS in charge of liquid-based cytology (LBC) processing ('hub' laboratories only) and representatives of administrative and clerical staff, should be available on request. There should be opportunities to meet with other staff of all grades during the laboratory visit or individually as appropriate. If the laboratory operates as an LBC processing 'hub', then senior representatives of the 'spoke' laboratories may also attend if required.

4.5 Colposcopy

Visits to colposcopy clinics must follow the patient journey. A review of a sample of colposcopy case notes may form part of the assessment.

As a minimum, the visiting team should include the QA lead medical colposcopist and QA lead colposcopy nurse. The host team should include as a minimum the lead colposcopist and the lead colposcopy nurse. It is recommended that, at least initially, interviews are carried out separately with each member of the host team. An interview with the colposcopy data coordinator may also be considered. If appropriate, a joint meeting of all colposcopy staff may also be held.

4.6 Feedback

Verbal feedback should be provided at the end of the completed visit. When the professional meetings are complete, the QA team will meet in private with the QA director to consider their recommendations and prepare the verbal feedback. Any members of the team not able to be present at the time/on the day, for instance because they visited a remote site at a previsit, must ensure that their comments are available in writing to the QA director in time for this session so that comprehensive feedback can be provided.

Everyone who has been visited must be invited to attend the feedback session. The PCT chief executive(s), trust chief executive(s) and other senior managers as appropriate must also be invited. The session should be chaired by the QA director. Ideally, it should be attended by the whole visiting team so that they can answer questions from their peers and

management colleagues. However, this may not be practical in a complex visit if their contribution was at a preliminary visit or single site visit only. In this case, local key issues can be fed back at the preliminary visit, on the understanding that these comments are provisional and subject to completion of the visit process.

Areas of good practice identified during the visit should be acknowledged and recommendations for service improvements should be given. Any areas of particular concern should be indicated so that urgent action can be taken. Unless there is an exceptional situation, no recommendation or issue should be included in the visit report that was not addressed at the visit feedback session.

Criticism of individuals should not be given in the session, but individuals should be given warning if the visiting team have concerns about their competence or other issues. If the concerns are serious and the individual is at a senior level, the QA director should raise the concerns by letter to the relevant PCT chief executive(s) or the trust chief executive immediately after the visit and should also notify the national office.

4.7 Patient/public involvement

If there is no patient representative on the visiting team, the trust Patient and Public Involvement Forum (PPIF) may invite a patient to attend the whole visit or the feedback session. Any appropriate patient involvement initiatives should be highlighted as good practice by the visiting QA team.

5. QUALITY ASSURANCE VISIT REPORTS

5.1 Writing the report

The QA director is responsible for the content of the report and overall conclusions, including any summary. The appropriate QA lead professional is responsible for the relevant content of the report. If agreed before the visit, QARC staff may take notes and submit comments on elements of the visit attended by them, but each lead professional must endorse the content and recommendations relating to their own discipline.

Team members need to set aside enough time to complete/agree their sections of the report so the whole report is not delayed. It is a condition of appointment that QA leads produce their reports on time as agreed with the QA director.

The report is a snapshot in time based on the facts available on the day and the information provided for the visit. No changes to the conclusions of the report should be made after the report is drafted, unless these were based on factual inaccuracies.

5.2 Content of the report

All the key questions from previsit questionnaires (see Appendix 1) should be commented on. The visit report may also include comment on other issues which have been identified during the visit. The QA director is responsible for commenting on management issues and issues which cover more than one professional area. Comments should focus on compliance of the service with key minimum standards.

Comments about named individuals should not be included, but any concerns about the professional competence of individuals must be raised in confidence by the QA director in writing to the relevant PCT chief executive(s) or trust chief executive as soon as possible after the visit.

The report should include clear recommendations for action. All recommendations should be prioritised by risk to the service and should have clear timetables for responses from the service visited. Recommendations which require urgent action should be highlighted.

A summary of the main findings, areas of good practice and recommendations should be published as part of the report to make the information readily accessible for other organisations, such as the Healthcare Commission, which assess the performance of health care organisations. The summary should be structured using the key questions (see Appendix 1).

5.3 Timescales for visit reports

The QARC should send the visit report in draft to the services which have been visited within four weeks of the end of the visit. The report should be sent electronically as a PDF file and clearly marked as a draft. The purpose of sending the draft report is to give the services visited

the opportunity to comment on factual accuracy. If the services do not respond within two weeks then the QARC should assume that there are no errors of fact.

The final report should normally be available within eight weeks of the completion of the visit.

5.4 Sharing the visit report

The final visit report should be sent to the chief executives of all of the constituent organisations involved in the programme. A copy should be sent to the PCT screening commissioner/coordinator and the HBPC, who are responsible for further distribution in their own organisations.

A copy of the report, or a shorter summary (containing as a minimum an executive summary and recommendations), should be sent for information to:

- the RDPH and the screening lead at the SHA
- the head of the relevant Cancer Networks
- the head of the Cancer Peer Review zonal team
- the QA director for the cross-boundary QA team if appropriate
- the director of the NHS Cancer Screening Programmes.

5.5 Response to recommendations

The PCT screening commissioner/coordinator should work closely with the HPBC(s) and lead professionals in the trust(s) to agree a response to the recommendations of the QA visit report.

Some recommendations may require major investment, and an extended timescale, whilst others require only minor reorganisations of aspects of the service without additional funding and can be completed quickly. Some improvements may require the cooperation of third parties or be dependent on completion of previous work or organisational changes. The trust(s) should clearly indicate how it proposes to address each recommendation, and the likely timescale for completion. As it may not be possible for some recommendations to be implemented mid-financial year without additional funding, the PCT commissioner should work jointly with the provider trust to implement improvements.

The QARC should monitor progress on meeting recommendations. The QA director should refer non-compliance with important recommendations to the commissioning PCT and the SHA, and the national office should also be notified.

5.6 Availability of summary report and service response

The summary report and response from the service must be available from the QARC six months after the date of the visit.

Other inspecting bodies will need to know what the QA visit process is, have access to the summaries of QA visits and know what further information is available. They are likely to rely on QA teams for an in-depth knowledge of the quality of cervical screening programmes.

The QARC should alert the Cancer Peer Review zonal team if serious concerns are found at the QA visit about cervical cancer services at a trust. The trust should be informed that this is being done.

5.7 Document keeping

Reports of QA visits and QA visit questionnaires must be kept for at least eight years to provide evidence if a problem with a cervical screening service comes to light in the future.

APPENDIX 1: KEY QUESTIONS FOR QUALITY ASSURANCE VISITS

	Key questions	Programme element
KQ1 INFORMATION FOR WOMEN	Are there effective arrangements for sending information, invitations and test results to women eligible for screening or referred for colposcopy?	PCT programme coordination Call and recall Colposcopy
KQ2 PROGRAMME COMMUNICATIONS	Are there effective communications with other parts of the local cervical screening programme?	PCT programme coordination PCT locality lead Call and recall HBPC Pathology Colposcopy
KQ3 IMPLEMENTING NATIONAL POLICIES	Are there effective arrangements for implementing national and local policies?	PCT programme coordination PCT screening leads Call and recall HBPC Pathology Colposcopy
KQ4 MONITORING PERFORMANCE AGAINST NATIONAL STANDARDS	Are there effective arrangements for monitoring and reviewing performance against national standards?	PCT programme coordination PCT locality lead Call and recall HBPC Pathology Colposcopy
KQ5 STAFF TRAINING AND DEVELOPMENT	Are there effective arrangements for training, education and workforce planning?	PCT locality lead Call and recall Pathology Colposcopy
KQ6 DATA QUALITY	Are there effective arrangements for auditing data quality?	PCT programme coordination PCT locality lead Call and recall Pathology Colposcopy
KQ7 SHARING BEST PRACTICE	Are there effective arrangements for developing and sharing best practice across the local programme?	PCT programme coordination PCT locality lead Call and recall Pathology Colposcopy
KQ8 ACCOMMODATION AND FACILITIES	Are there suitable accommodation and facilities for cervical screening?	Pathology Colposcopy

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	Key questions	Programme element
KQ9 LABORATORY PROTOCOLS	Are there safe laboratory procedures and practices?	Pathology
KQ10 RECORDING TEST RESULTS	Are there accurate and reliable arrangements for inputting and transfer of test results?	Call and recall Pathology Colposcopy
KQ11 COLPOSCOPY PROTOCOLS	Are there safe colposcopy practices?	Colposcopy
KQ12 TREATMENT AND FOLLOW-UP	Are there effective arrangements for treatment and follow up of women referred for colposcopy?	PCT programme coordination PCT locality lead Pathology Colposcopy

APPENDIX 2: SUMMARY OF CONCORDAT OBJECTIVES

Objective one: inspections are coordinated with other reviews and collections of data

- define and explain the remit of QA visits
- use existing data sets whenever possible
- share information with other bodies
- share plans for QA visits with other relevant bodies
- use findings of other competent organisations to avoid replicating inspections in areas which have been inspected recently by others.

Objective three: inspections support improvements in quality and performance

- recognise improvement and good practice
- spread good practice and learn from experiences
- focus on improving care and outcomes for women who are screened
- contribute to the development and delivery of policy
- facilitate self assessment and continuous improvement of services.

Objective five: inspections are independent, consistent and fair

- consistent standards are applied to providers
- standards are consistent with those applied by other inspecting bodies
- standards and criteria are based on published research where this is available.

Objective seven: inspections are transparent and accountable

- standards and methodology for QA visits are published
- services visited are provided with draft findings in advance of publication and have the opportunity to comment on factual accuracy
- findings are published in ways that are timely and accessible.

Objective nine: inspectors are suitably qualified, trained and skilled

- QA visitors have suitable skills and the selection criteria are clearly stated and applied fairly
- QA visitors have appropriate training and qualifications and their continuing competence as a visitor is reviewed regularly.

Summarised from *Working in Partnership. Getting the Best from Inspection, Audit, Review and Regulation of Health and Social Care*. Commission for Healthcare Audit and Inspection, 2006. Available at www.concordat.org.uk