

This publication was archived on 15 February 2016

EXTERNAL QUALITY ASSESSMENT
SCHEME FOR GYNAECOLOGICAL
CYTOPATHOLOGY: PROTOCOL
AND STANDARD OPERATING
PROCEDURES

This publication was archived on 15
February 2016

NHSCSP PUBLICATION No 15

Fifth edition

31 January 2013

Authors

Janet Rimmer
NHS Cancer Screening Programmes

Editor

Kiera Chapman
NHS Cancer Screening Programmes

Typesetting and Design

Mary Greatorex
NHS Cancer Screening Programmes

Published by

NHS Cancer Screening Programmes
Fulwood House
Old Fulwood Road
Sheffield
S10 3TH

Tel: 0114 271 1060
Fax: 0114 271 1089

Email: info@cancerscreening.nhs.uk
Website: www.cancerscreening.nhs.uk

© NHS Cancer Screening Programmes 2013

The contents of this document may be copied for use by staff working in the public sector but may not be copied for any other purpose without prior permission from the NHS Cancer Screening Programmes.

ISBN: 978-1-84463-095-0

Document Information	
Title	External EQA scheme for gynaecological cytopathology: protocol and SOPs
Policy/document type	EQA guidance
Electronic publication date (date of issue)	31 January 2013
Version	5 th edition
Superseded publications	Versions 1-4
Review date	January 2014
Author/s	Janet Rimmer
Owner	Comments may be sent to janet.rimmer@cancerscreening.nhs.uk in readiness for review
Document objective (clinical/healthcare/social questions covered)	Produced on behalf of the NHSCSP to provide the protocol and Standard Operating Procedures for the external EQA scheme
Population affected	Cytology practitioners, laboratories, QARC staff
Target audience	Cytology practitioners, QARC staff
Circulation list	EQA Facilitators, National Coordinating Group for Laboratory Quality Assurance, EQA subcommittee.
Archived	Current document

CONTENTS

ACKNOWLEDGEMENTS	v
EXECUTIVE SUMMARY	1
SECTION ONE: PROTOCOL	2
1. INTRODUCTION	3
2. GENERAL DESCRIPTION OF THE EQA SCHEME	3
3. SCOPE OF THE SCHEME	3
4. OBJECTIVES OF THE SCHEME	4
5. JOINT WORKING GROUP FOR QUALITY ASSURANCE	4
6. EQA SCHEME ORGANISATION	5
6.1 NHS Cervical Screening Programme (Scheme Provider)	6
6.2 National Organiser of the scheme	6
6.3 National Coordinating Group for Laboratory Quality Assurance	6
6.4 Scheme Secretary	6
6.5 National Quality Manager	6
6.6 Operation of the scheme	6
6.7 Regional Organiser	7
6.8 Regional Coordinating Group for Laboratory QA	7
6.9 Regional EQA Facilitator	7
6.10 Regional Quality Manager	8
6.11 Relationships within the scheme	8
7. PARTICIPATION	10
8. CIRCULATION OF CASES	10
9. SELECTION OF CASES	10
10. OPERATION OF THE SCHEME	12
10.1 Conditions for examining EQA slides	12
10.2 Routine practice and marking of slides	12
10.2.1 Non-medical staff	13
10.2.2 ABMSPs in cervical cytology	13
10.2.3 Medical staff	13
10.2.4 Trainee staff	14
11. SCORING OF RESPONSES	14
11.1 Individual responses	14
11.2 Consensus opinion	15
11.2.1 Levels of consensus	15
11.2.2 Identifying missed dyskaryosis	15
11.2.3 Grading consensus	15
11.3 Assessment of performance	16
11.3.1 Primary screeners and checkers	16
11.3.2 Pathologists/ABMSPs	16
11.4 Marking scheme	16
11.4.1 All staff	16
11.4.2 Non-medical staff	16
11.4.3 Medical staff	16
11.5 Identification of substandard and persistent substandard performance	17
12. FINANCIAL ASPECTS	18

SECTION TWO: STANDARD OPERATING PROCEDURES	19
STANDARD OPERATING PROCEDURE 1	21
STANDARD OPERATING PROCEDURE 2	22
STANDARD OPERATING PROCEDURE 3	23
STANDARD OPERATING PROCEDURE 4	24
STANDARD OPERATING PROCEDURE 5	25
STANDARD OPERATING PROCEDURE 6	26
STANDARD OPERATING PROCEDURE 7	27
STANDARD OPERATING PROCEDURE 8	28
STANDARD OPERATING PROCEDURE 9	29
STANDARD OPERATING PROCEDURE 10	30
STANDARD OPERATING PROCEDURE 11	33
STANDARD OPERATING PROCEDURE 12	34
STANDARD OPERATING PROCEDURE 13	35
STANDARD OPERATING PROCEDURE 14	36
STANDARD OPERATING PROCEDURE 15	37
STANDARD OPERATING PROCEDURE 16	38
REFERENCES	39
APPENDIX 1: REFERRAL OF ABNORMAL SLIDES FOR REPORTING FORM	40
APPENDIX 2: NHS CERVICAL SCREENING PROGRAMME EXTERNAL QUALITY ASSESSMENT SCHEME RESPONSE SHEET	41
APPENDIX 3: SCORING MATRIX FOR SCREENERS/CHECKERS	42
APPENDIX 4: SCORING MATRIX FOR PATHOLOGISTS/ ABMSPS	43
APPENDIX 5: TABLE OF PERFORMANCE EXAMPLES WITH ACTION POINTS	44

ACKNOWLEDGEMENTS

This updated and amended version of the *Protocol and Standard Operating Procedures* reflects the evolution of the External Quality Assessment Scheme for Gynaecological Cytopathology since its introduction in to the NHS Cervical Screening Programme (NHSCSP) in 2004. It has also been developed in response to the many comments and issues raised during its operation. The editor is especially grateful to the National Laboratory Quality Assurance (QA) Group, members of the EQA subcommittee of the National Laboratory QA Group, and Regional EQA Facilitators for their contribution to the success of the scheme.

ARCHIVED

EXECUTIVE SUMMARY

This version of the Protocol and Standing Operating Procedures for the external EQA scheme updates the terminology that the scheme employs to bring it into line with the publication of the third edition of *Achievable Standards, Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology*.¹ The document also makes provision for the use of online systems to facilitate the EQA scheme.

ARCHIVED

SECTION ONE:
PROTOCOL

ARCHIVED

1. INTRODUCTION

External Quality Assessment (EQA) is one of several tools used by cytopathology laboratories to improve standards in the NHS Cervical Screening Programme (NHSCSP). The aim of EQA is to maintain and improve the quality of patient care by promoting a high standard of performance and by facilitating personal education. To achieve these goals, the NHS Cervical Screening Programme (NHSCSP) uses an external agency to check laboratory results. This system delivers an acceptable degree of reliability and consistency between labs by educating, advising, and supporting all participants. EQA complements other Quality Assurance (QA) systems, such as the collection of laboratory statistics and QA site visits.

EQA, or 'proficiency testing' as it has been termed, was introduced to the NHSCSP in 1988, when the Department of Health Advisory Committee on the Assurance of Laboratory Standards published the *Protocol for a Proficiency Test Scheme in Gynaecological Cytopathology*.² This led to the development of regional schemes, each of which developed its own interpretation of the *Protocol*, resulting in a number of different methodologies.

A new scheme to create a greater degree of national uniformity was therefore designed and introduced in 2004. It was based on published recommendations from the Royal College of Pathologists' Working Group on Histopathology External Quality Assessment Scheme Accreditation³ but also drew on the successful implementation of an EQA scheme for breast screening pathology in the NHS Breast Screening Programme. However, the *External Quality Assessment Scheme for Gynaecological Cytopathology*⁴ (as it is known) is still implemented on a regional basis, due to the large number of participants and to the fact that cervical cytology does not currently allow the production of multiple identical specimens, which would allow a nationally administered scheme.

This document outlines the protocol and Standard Operating Procedures (SOP) for the scheme, reflecting amendments made in the light of feedback from both regional Quality Assurance Reference Centres (QARCs) and participants.

It should be noted that some QARCs are now using an online EQA reporting system. References to 'written' documents in this publication therefore include electronic communications sent to the participant via email. Where online EQA reporting is used, participants should provide a secure personal email address to the EQA Facilitator.

2. GENERAL DESCRIPTION OF THE EQA SCHEME

The name of the scheme is the NHS Cervical Screening Programme External Quality Assessment Scheme for Gynaecological Cytopathology.

3. SCOPE OF THE SCHEME

The SOPs set out here apply to the NHS Cervical Screening Programme in England.

4. OBJECTIVES OF THE SCHEME

The objectives of the scheme reflect the needs of the participants. They are to:

- provide an external assessment of the quality of participants' reporting of cervical cytology samples.
- maintain and improve quality by promoting consistent good practice.
- promote education and training through formal feedback.
- identify substandard performance and its causes, enabling remedial action to be taken.
- respond to participant satisfaction and complaints.
- achieve recognition through the appropriate accreditation bodies.

5. JOINT WORKING GROUP FOR QUALITY ASSURANCE

The Joint Working Group for Quality Assurance in Pathology (JWG) is a committee of the Royal College of Pathologists, reporting to the Professional Performance Panel. The JWG's is responsible for the oversight of all pathology EQA in the UK, including the approval and registering of schemes, and the setting of policy and maintenance of appropriate professional standards. As part of this remit, the JWG monitors the EQA performance of clinical laboratories in the UK. This is achieved through the use of discipline-specific panels, known as National Quality Assurance Advisory Panels (NQAAP), which report those laboratories that have failed to rectify quality problems to the JWG. For more information on NQAAP, see:

<http://www.rcpath.org/committees/intercollegiate-and-joint-committees/joint-working-group-for-quality-assurance-in-pathology/joint-working-group-for-quality-assurance-in-pathology>

The JWG subsequently works with failing laboratories to improve standards. However, the JWG has the responsibility to report persistent poor performance to the Care Quality Commission (see Figure 1).

The JWG consists of:

- representatives from the pathology professions.
- representatives from professional societies.
- Chairpersons of the NQAAPs.
- observers from national government offices.
- observers from Clinical Pathology Accreditation (UK) Ltd (CPA), a wholly-owned subsidiary of the United Kingdom Accreditation Service (UKAS).

The JWG is also responsible for the recognition of NQAAPs and steering committees, and for most scheme-related professional matters.

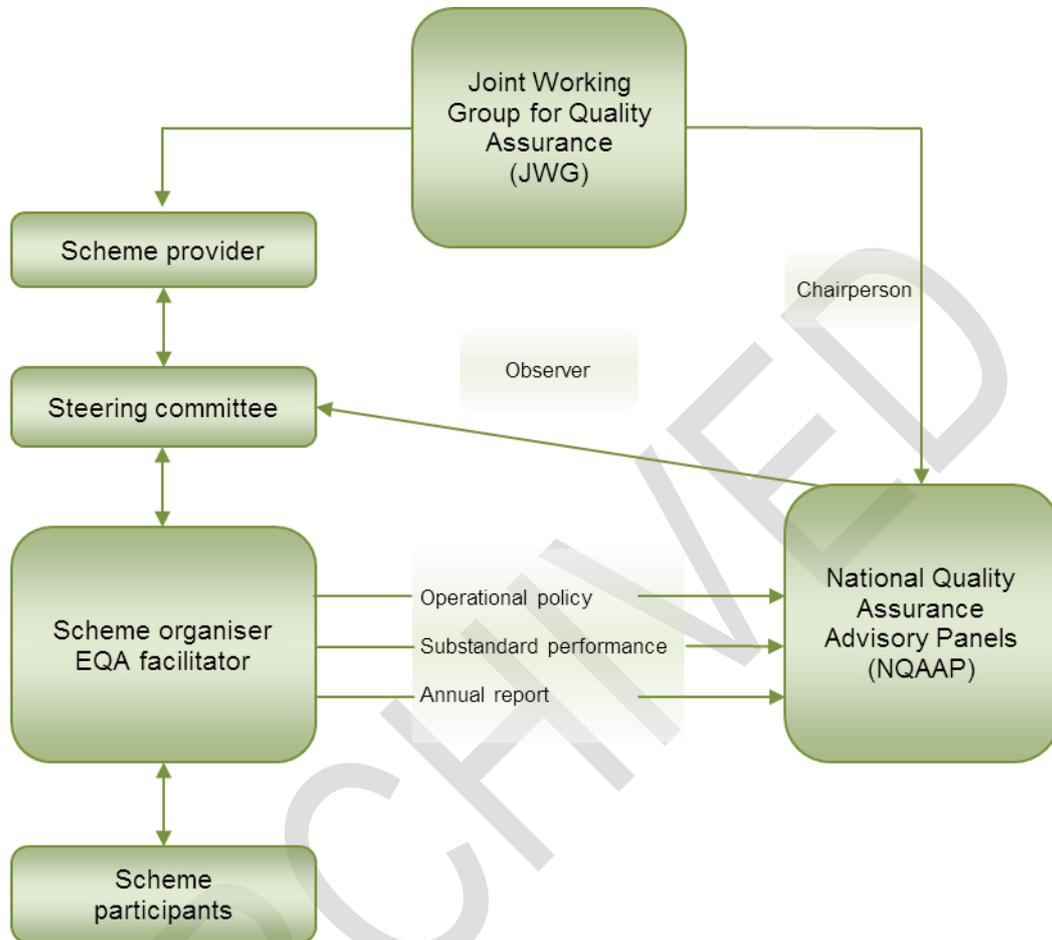


Figure 1 Pathology EQA in the UK

6. EQA SCHEME ORGANISATION

6.1 NHS Cervical Screening Programme (Scheme Provider)

The NHSCSP forms part of NHS Cancer Screening Programmes. Contact details for their national office are as follows:

NHS Cancer Screening Programmes
Fulwood House
Old Fulwood Road
Sheffield
S10 3TH

Tel: (0114) 271 1060
Fax: (0114) 271 1089

www.cancerscreening.nhs.uk.

6.2 National Organiser of the Scheme

The National Organiser of the scheme is the Chair of the English National Coordinating Group for Laboratory Quality Assurance. This individual also participates in the scheme.

6.3 National Coordinating Group for Laboratory Quality Assurance

The steering committee for the scheme is the National Coordinating Group for Laboratory Quality Assurance (National Laboratory QA Group). The steering committee is responsible for setting, reviewing, and revising the objectives of the scheme, which are based on the needs of the participants.

The Group includes the Chairs of the regional EQA scheme organising committees (see section 6.8). A subgroup of the steering committee (the EQA subcommittee) assists and supports the wider group in managing general scheme activity and coordinating the annual review.

6.4 Scheme Secretary

The Scheme Secretary is provided by the national office of the NHSCSP.

6.5 National Quality Manager

A national Quality Manager, provided by the national office of the NHSCSP, is responsible for ensuring that the scheme's quality management system functions correctly. The national Quality Manager is responsible to the National Organiser, and these two roles cannot be fulfilled by the same individual.

6.6 Operation of the scheme

Due to the large number of participants, and to the fact that cervical cytology currently does not currently allow the production of multiple identical specimens, the national scheme is implemented on a regional basis (see section 1). The scheme is organised through the regional QA framework of the NHSCSP (Figure 2). A *Handbook for Facilitators*⁴ has been developed to ensure consistency of delivery across the nation.

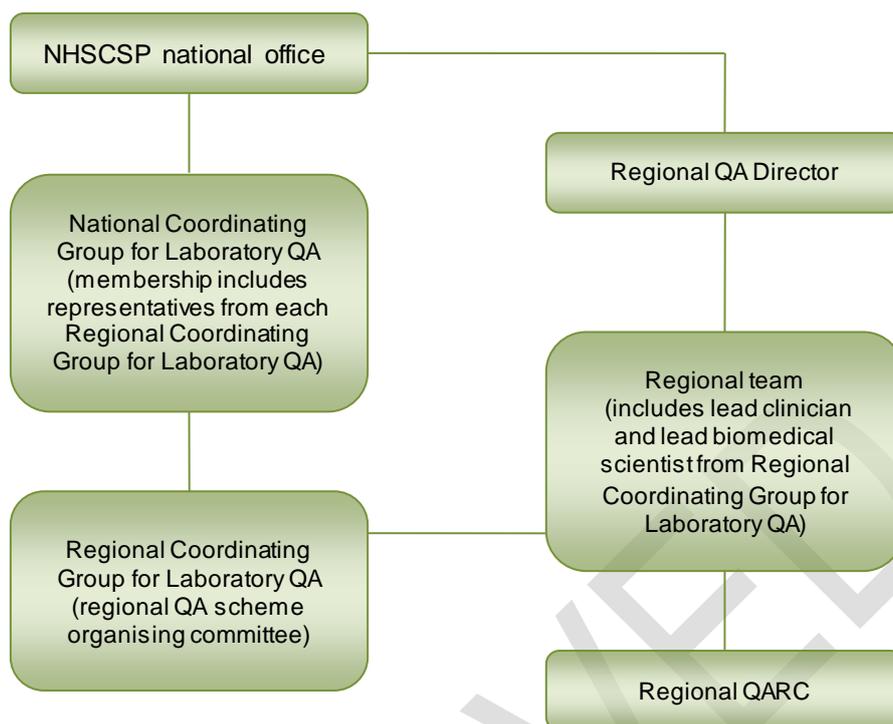


Figure 2 QA relationships for pathology in the NHSCSP

6.7 Regional Organiser

At a regional level, overall professional responsibility for the EQA scheme lies with the Regional Organiser, who also participates in the scheme. It is recommended that this individual should also be the Chair of the Regional Coordinating Group for Laboratory QA.

6.8 Regional Coordinating Group for Laboratory QA

The Regional Coordinating Group for Laboratory QA acts as the regional organising committee for the EQA scheme.

6.9 Regional EQA Facilitator

A Regional EQA Facilitator undertakes the day-to-day running of the scheme at a local level. Based at the regional QARC, he or she acts as the regional EQA scheme secretary and is responsible for ensuring that the scheme operates efficiently.

Key duties include

- identification of participants.
- organisation of slide sets.
- collection of slides.
 - arranging the review of submitted slides.
 - assembly of slide sets.
 - delivery and collection of slide sets.
- analysis and interpretation of results.

- feedback to participants.
- dealing with instances of substandard performance.
- record keeping.

An essential element of the EQA Facilitator's role is to maintain the confidentiality of participants in the scheme, while allowing anonymous communication between those individuals who are involved in managing cases of persistent substandard performance. Only the EQA Facilitator (who should not be a participant in the local scheme) should therefore know the identities and scores of local participants. He or she must not divulge these except under the terms of this protocol.

The EQA Facilitator is responsible to the Regional Organiser for the efficient running of the scheme. For other functions, the EQA Facilitator is responsible to the Regional QA Director who employs him or her. All Regional EQA Facilitators in England meet at least annually to discuss the scheme.

6.10 Regional Quality Manager

The Regional Quality Manager ensures that the quality management system is effective at a local level. He or she is responsible to the Regional Organiser, and these two roles must not be fulfilled by the same individual.

6.11 Relationships within the scheme

Relationships within the EQA scheme are shown in Figure 3.

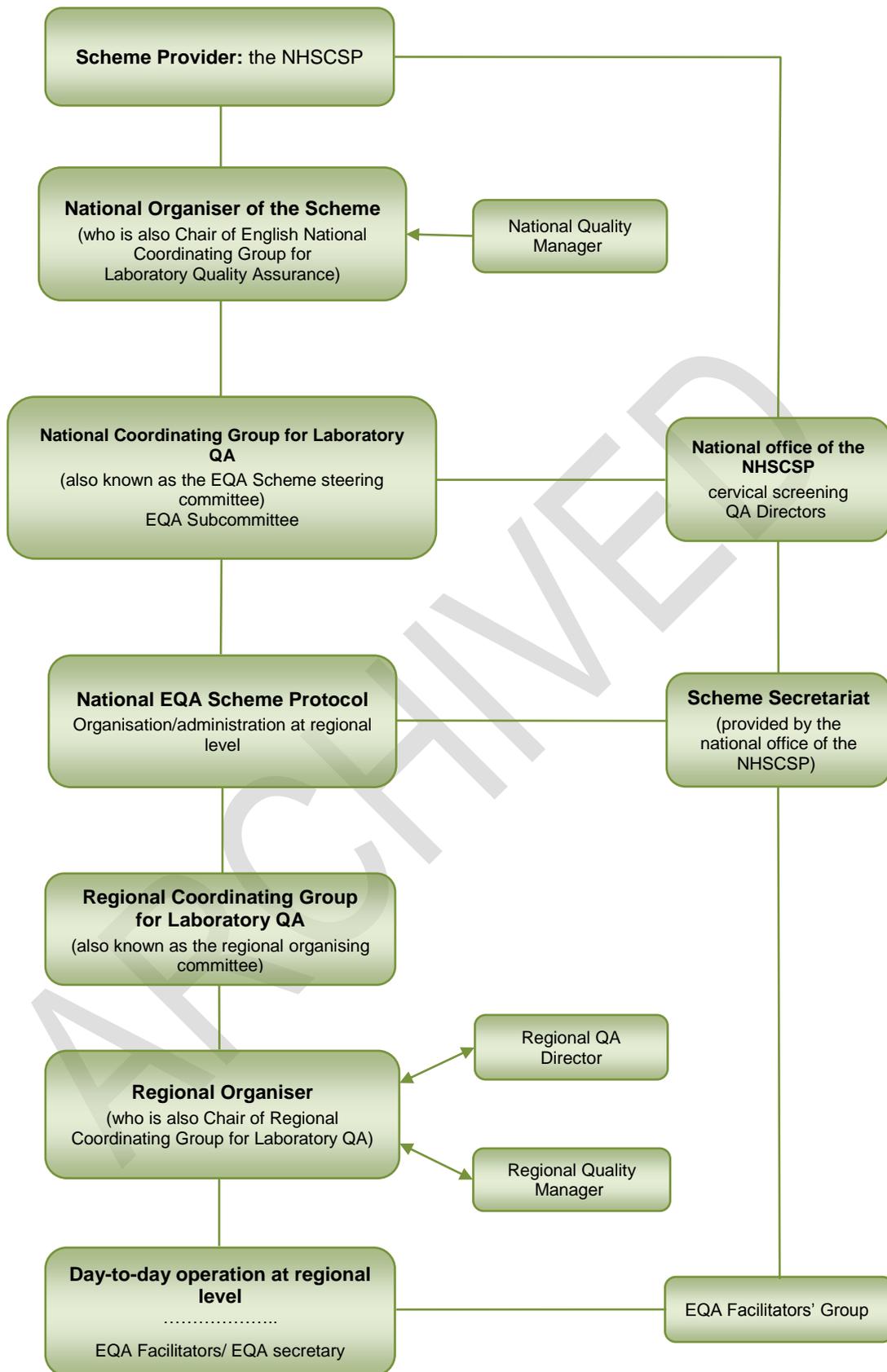


Figure 3 Relationships within the EQA scheme

7. PARTICIPATION

Guidance for the NHS published in EL(98)2, *Oversight of Provision of External Quality Assessment Schemes in Histopathology, Cytopathology, Cytogenetics and Molecular Genetics for Pathology Laboratories*⁵ makes participation in EQA schemes mandatory for all staff delivering the NHS Breast and Cervical Screening Programmes.

This guidance also requires all cervical screening laboratories participating in the NHSCSP to apply for accreditation by Clinical Pathology Accreditation (UK) Ltd (CPA). Participation in relevant EQA schemes is a prerequisite for CPA accreditation.⁶

Participation is mandatory for all individuals (including staff working as locums) who report gynaecological cytology for the NHSCSP. Names, addresses, participant code numbers, and email addresses (where electronic reporting and communication is used) are recorded by the Regional EQA Facilitator in participant files, which are held securely at the regional QARC.

8. CIRCULATION OF CASES

The EQA scheme is based on the assessment of slide sets by all staff who report cervical cytology on behalf of the NHSCSP. Individual reporting is compared to consensus reporting to determine whether an individual's performance falls within an acceptable range.

The basic structure of the EQA scheme is as follows:

- There are two rounds (i.e. two circulations of slide sets) in each EQA year. An EQA year runs from April 1st of a given year to March 31st of the subsequent year.
- There are 10 slides in each slide set per circulation, though additional slides may be included for special educational interest.
- Slides will be circulated to all laboratories participating in the NHSCSP. A list of these laboratories is available from the national office. Each QARC also holds a list of those laboratories for which it is responsible.

9. SELECTION OF CASES

The slides may range across the classifications recognised by the British Association for Cytopathology, and must show good (but not necessarily easy) examples. The following classifications are covered; for further explanation see the latest edition of *Achievable Standards, Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology*¹:

- inadequate.
- negative.
- borderline change in squamous cells.
- borderline change in endocervical cells.
- low-grade dyskaryosis.
- high-grade dyskaryosis (moderate).
- high-grade dyskaryosis (severe).
- ?invasive squamous carcinoma.
- ?glandular neoplasia of endocervical type.
- ?glandular neoplasia (non-cervical).

Participants are expected to assess slides showing borderline changes in squamous cells, borderline change in endocervical cells, low-grade dyskaryosis, or negative cytology independently of the results of any associated HR-HPV tests. HR-HPV test results will not accompany EQA slides during circulation, since this would give an indication as to the cytological classification of the slide.

Cases involving infections may be included in EQA. The final composition of slide sets for circulation will be decided by the Regional EQA Facilitator in line with guidance published in the *EQA Scheme for Gynaecological Cytopathology Handbook for Facilitators*.⁴ The cases circulated must be typical of routine practice, and must not be rarities, although slide sets will need to include a higher proportion of abnormal cases than is routinely seen.

- a) Adequate clinical information must be provided by the laboratory with each submitted slide. This should be derived from the standard request form, HMR101, or its electronic equivalent.
- b) All NHSCSP laboratories that are currently performing satisfactorily according to the *External Quality Assessment Scheme for the Evaluation of Papanicolaou Staining in Cervical Cytology*⁷ (i.e. all those that are not at a national action point) will be required to submit slides to the QARC. Each slide must be accompanied by a consensus opinion from at least one primary screener, one checker, and one cytopathologist/advanced biomedical scientist practitioner (ABMSP). Laboratories acting as 'spoke' laboratories for liquid-based cytology (LBC) processing arrangements will also be eligible to submit slides, provided that their 'hub' laboratory meets the above requirement. Duplicate slides produced from a single LBC sample may be submitted by a laboratory, but these must be considered as entirely separate cases for EQA purposes (it cannot be assumed that each will give rise to identical consensus).

Histology is routinely obtained only for samples showing a high-grade abnormality, i.e. high-grade dyskaryosis (moderate) or worse. Histological confirmation of the classification is therefore required for any high-grade abnormality that is to be included. However, cytology samples showing low-grade dyskaryosis or borderline change in squamous or endocervical cells may not have had further follow-up, since the woman may have been returned to routine recall after HPV triage. In such cases, it may not be possible to obtain histological confirmation, and slides falling into these reporting categories therefore do not need to be supported by further slides and/or histology. Negative or inadequate slides therefore do not require a second slide confirming the classification to be included in the EQA scheme.

- c) A Review Panel of three participants (including a pathologist/ABMSP, a checker, and a screener) will ensure that the submitted slides are technically adequate by reviewing each one individually. Slides will be assessed for their technical quality, including stain quality, mounting, and any cracks.
- d) Before accepting a slide into the scheme, and without knowing the submitted classification of the slide, the Panel must agree a classification that is consistent with the patient history or histology. Occasionally, the Panel's opinion may differ from the submitted classification: for example, there may be disagreement on whether to report the slide as negative, inadequate, or abnormal; or, alternatively, the agreed Panel opinion may be that the slide should be reported as high-grade (moderate) or worse, whereas the laboratory may have reported the slide as borderline change in squamous or endocervical cells, or low-grade dyskaryosis. In such cases, the EQA Facilitator will inform the laboratory at which the slide

originated, and will return the slide immediately. It is the responsibility of the medical Head of the submitting laboratory to take any necessary follow-up action.

- e) The Panel members should be drawn from a single region, and must not participate in the scheme for which they are reviewing slides. If they participate in another region's EQA scheme, Panel members must consent to the sharing of their EQA performance data with the Regional EQA Facilitator in their area, who will manage any issues arising.

The names of the patient and the submitting laboratory should be obscured for the purposes of the EQA round. However, this information should not be effaced from the slide. Instead, the laboratory is responsible for concealing the patient's details on the slide before submission, while the EQA Facilitator will relabel the slides on receipt to ensure that details of the submitting laboratory are not visible during Panel review or the EQA round.

For medicolegal reasons, the positioning of any dots on the slide should be recorded by the submitting laboratory before the slide is submitted. Upon receipt of the slide, and before it is circulated to any participating laboratory, the EQA Facilitator should ensure that any dots are removed.

The EQA Facilitator is expected to know the whereabouts of every circulated slide at all times. This is to ensure that any patient's slide can be located if necessary. Once the slide is no longer needed for EQA purposes, it should be returned by the QARC to the submitting laboratory at the end of the round.

The educational value of the scheme may be enhanced if extra cases are included to add interest. These should be clearly identified as supplementary, and should not be used for personal performance analysis.

10. OPERATION OF THE SCHEME

10.1 Conditions for examining EQA slides

Participants will be asked to examine EQA slides under conditions similar to those used in their routine practice (i.e. they will not undertake the assessment in examination conditions). However, participants must not discuss EQA slides in the laboratory until all mandatory participants (excluding absentees) have seen the slides and recorded and submitted their results. Senior members of staff should reiterate this on each occasion that EQA slides are to be reported, emphasising that any evaluation of personal performance is meaningless if such discussion takes place, and explaining that it not only reduces the value of the EQA scheme, but may also propagate false responses, adversely affecting individual performance.

Talking about the slides is encouraged once all mandatory participants (excluding absentees) have submitted their responses, and before the slides leave the laboratory. However, inter-laboratory discussion of the slides or discussion with absentees prior to their participation is not permitted.

10.2 Routine practice and marking of slides

All participants should examine cases in a manner appropriate to their routine practice. Laboratories using different LBC systems will form separate assessment groups for the purposes of EQA. Staff whose laboratories routinely use more than one LBC system will be required to complete EQA for one system in one round, and for the alternate system in the subsequent round.

All participants will receive feedback on all aspects of their participation, and not solely those used for performance monitoring.

10.2.1 Non-medical staff

In NHSCSP laboratories there are two clearly identifiable tiers of activity undertaken by non-medical staff: primary screening and checking. At present, staff (other than ABMSPs) who are not medically qualified should not report abnormal slides; instead, they should sort slides into those that they will report as negative or inadequate, and those that will be passed to more senior colleagues for further review. Non-medical staff are therefore assessed on the basis of their ability to distinguish between negative, inadequate, and abnormal slides. However, many laboratories routinely encourage their non-medical staff to suggest a classification, and checkers often require this. The scoring scheme described in section 11.4.3 can therefore be extended to all staff, in order to enhance the educational benefit of the scheme.

Primary screening: Individuals (usually cytology screeners and biomedical scientists) who undertake primary screening decide whether a slide is negative, inadequate, or potentially abnormal. Abnormal slides are referred on for more detailed reporting. Individuals who routinely carry out primary screening should undertake EQA with unscreened and unmarked slides. Pathologists or ABMSPs may also wish to participate in this type of EQA in addition to their regular EQA. However, their responses will not be assessed or included in any consensus calculation or performance analysis for this slide set.

Checking: Experienced cytology screeners and biomedical scientists have varied duties. Checkers usually undertake some primary screening, and should participate in the EQA scheme as primary screeners. However, there may be some checkers who undertake no primary screening at all, and who instead receive marked slides. When participating in the EQA scheme, members of this group should have their slides marked by primary screeners who are themselves participating in the scheme.

10.2.2 ABMSPs in cervical cytology

ABMSPs sign out abnormal slides and provide management recommendations. They may, in addition, undertake checking duties and report unchecked slides, effectively acting as their own 'checker'. EQA for these staff should be based on slides that have been screened by primary screeners and other checkers, in line with routine practice in the laboratory. While ABMSPs act under the direction of the consultant pathologist, they are not under his or her direct supervision. From an EQA point of view, it is therefore appropriate that they be considered alongside medical practitioners. Any references in the SOPs to medical staff should therefore be taken to include ABMSPs in cervical cytology.

10.2.3 Medical staff

The two major activities undertaken by most pathologists who routinely report for the NHSCSP are:

- The reporting of slides referred from primary screeners and checkers as potentially abnormal.
- The review of slides that have previously been reported as negative or inadequate by primary screeners or checkers, and have later been identified as requiring medical review.

The EQA scheme for pathologists will therefore assess an individual's performance in providing an opinion on slides identified as potentially abnormal and in reviewing negative and inadequate slides that have been through primary screening. Primary screeners and checkers may wish to participate in this type of EQA in addition to their regular EQA, but their responses should not be used for performance assessment, and should not be included in the analysis of this slide set.

EQA for medical staff should be based on slides that have been screened by primary screeners and checkers in line with routine practice in the laboratory. Practice varies between laboratories, but primary screeners and checkers often mark slides. Where this is normal practice, it should be retained for EQA purposes. Pathologists and ABMSPs should know which slides have been referred by screeners and which by checkers, but not the conclusions reached by either group.

Appendix 1 contains a sample form for use by medical staff when identifying potentially abnormal slides for EQA purposes. This is in line with recommendations from the British Society for Clinical Cytology, in particular their *Code of Practice for Cytopathology Laboratories*,⁸ which states that the cytopathologist should see all abnormal material and a proportion of negative material to ensure that accuracy and quality are being maintained.

In addition, the pathologist should have experience of screening unmarked slides (and, in particular, of rescreening negative slides when abnormalities have subsequently been found), and of rescreening an entire slide when equivocal cell groups have been identified as requiring an opinion. It is therefore envisaged that cytopathologists who undertake the EQA assessment will examine the whole of every slide, including slides that have already been marked by primary screeners and checkers.

10.2.4 Trainee staff

Trainee cytology screeners, trainee biomedical scientists, and trainee medical staff who intend to work in the field of cervical cytology are encouraged to participate in EQA. However, the scheme is considered to be of purely educational value for these staff. Although they should be allocated a mark and given the same level of feedback as qualified staff within their peer group, their results should be excluded from any consensus calculation or performance analysis of the slide set.

11. SCORING OF RESPONSES

11.1 Individual responses

All participants in the EQA scheme will register their opinion concerning the cytological pattern and specific infections on an EQA slide in a format consistent with both standard British Association for Cytopathology reporting and the standard request form (HMR 101). An example response form is included at Appendix 2.

It is the participant's responsibility to ensure that his or her responses have been recorded correctly, as transcription errors will be penalised according to the guidance given in section 7.2 of the *EQA Scheme for Gynaecological Cytopathology Handbook for Facilitators*.⁴

The opinions that have been provided will be released once all mandatory participants within the laboratory (excluding absentees) have viewed the EQA slides and recorded and submitted their results. The response from each participant will be formally scored by the EQA Facilitator against the consensus classification for each

slide. Consensus results (calculated after the completion of the EQA round) are based on the valid responses of all eligible participants within a peer group, irrespective of whether or not they received pre-screened slides.

However, all individuals will also be given confidential provisional feedback (also known as interim feedback) soon after they have participated in the circulation. This will allow individuals to compare their own responses with the submitted opinions for the slides at an early point, prior to the release of consensus results. This written interim feedback will be provided as soon as possible after participation, and ideally within two weeks.

11.2 Consensus opinion

The 'correct' classification of a slide will be based on consensus opinion. Only slides that achieve 80% consensus from participants in the relevant regional peer group reporting the slides (screeners/checkers or ABMSPs/medical pathologists) will be used for personal performance monitoring. Although the calculation of consensus will result in a delay in the provision of final feedback to participants, the difficulties inherent in reaching an agreement on cytological classification mean that this approach is necessary.

If the consensus opinion differs significantly from that of the submitting laboratory (e.g. if there are conflicting reports on whether a slide is negative, inadequate, or abnormal; or if the consensus opinion on the degree of abnormality would result in a higher-grade management recommendation for the woman than that of the laboratory's initial report) the EQA Facilitator will inform the laboratory and return the slide immediately. In such cases it is the responsibility of the medical Head of the submitting laboratory to take any necessary follow-up action.

11.2.1 Levels of consensus

Consensus agreement on negative, inadequate, and abnormal slides will be based on all valid participant responses for the particular slide.

11.2.2 Identifying missed dyskaryosis

For the purpose of identifying missed dyskaryosis (see section 11.3), consensus agreement will be determined by assessing whether all valid responses of low-grade dyskaryosis or worse across the peer group form 80% of the total responses or greater.

11.2.3 Grading consensus

Consensus agreement on the grading of abnormal slides will be based on all valid opinions reported on the slide by each peer group. The amalgamation of 'adjacent' grades (e.g. low-grade dyskaryosis and high-grade dyskaryosis (moderate); or high-grade dyskaryosis (moderate) and high-grade dyskaryosis (severe)) will be permitted if this is necessary to achieve an 80% consensus classification. The classifications ?glandular neoplasia of endocervical type and ?glandular neoplasia (non-cervical) may also be combined with each other and/or with high-grade dyskaryosis (severe) or ?invasive squamous carcinoma if this is necessary to achieve 80% consensus. The grading consensus for screeners and checkers is provided for educational feedback.

Only the opinions of individuals who are responsible for issuing reports will be included in the consensus. Trainees will be encouraged to participate in the scheme, but their opinions will not contribute to the consensus classification (see section 10.2.4).

11.3 Assessment of Performance

At the end of the circulation, formal scores can be determined by comparing participant responses with the consensus opinion on the slide. The formal assessment of personal performance differs for the two peer groups of participants.

11.3.1 Primary screeners and checkers

For primary screeners and checkers, personal performance will be assessed on the individual's ability to distinguish between negative, inadequate, and abnormal slides. Any instance of missed dyskaryosis is also counted. Quantitative and qualitative feedback on the grading of abnormalities will be provided for personal educational purposes. Qualitative feedback on the identification of infections will also be provided.

11.3.2 Pathologists/ABMSPs

Personal performance will be assessed on an individual's ability to distinguish between negative, inadequate, and abnormal slides, the grading of cytological patterns for abnormal samples, and any instance of missed dyskaryosis. Qualitative feedback on the identification of infections will also be provided.

11.4 Marking scheme

The marking scheme is outlined below. Further detail is presented in Appendices 3 and 4.

11.4.1 All staff

Incorrect identification of a slide as negative, inadequate, or abnormal results in zero marks. Two marks are given for a correct answer. In both cases, an individual's response is compared with the consensus opinion, which is based on valid responses from all qualified participants on both the screener/checker set(s) and the pathologist/ABMSP set(s).

11.4.2 Non-medical staff

The responses of non-medical staff are used to assess non-medical staff alone. Primary screeners and checkers will receive feedback on their grading of abnormalities, but this will not be used to calculate their score.

11.4.3 Medical staff

An additional mark is given for the grading of abnormalities.

- If the individual response lies within the 80% consensus from the relevant peer group, then two marks are awarded.
- If the individual response is one adjacent grade from the consensus answer, then one mark is awarded.

- If the individual response lies more than one adjacent grade away, then no marks are allocated (i.e. the score is zero).
- If the 80% consensus is ?glandular neoplasia of endocervical type, then one mark is given for an individual report of ?glandular neoplasia (non-cervical), high-grade dyskaryosis (severe), or ?invasive squamous carcinoma. No marks are given for reports of any other degree of abnormality (i.e. the score is zero).
- If the 80% consensus is ?glandular neoplasia (non-cervical), then one mark is given for an individual report of ?glandular neoplasia of endocervical type, high-grade dyskaryosis (severe), or ?invasive squamous carcinoma. No marks are given for reports of any other degree of abnormality (i.e. the score is zero).
- If ?glandular neoplasia of endocervical type and ?glandular neoplasia (non-cervical) have been combined to achieve the 80% consensus, two marks are awarded for an individual response of ?glandular neoplasia of endocervical type or ?glandular neoplasia (non-cervical). One mark is given for a response of high-grade dyskaryosis (severe) or ?invasive squamous carcinoma.
- Only medical staff and ABMSP responses will be used to assess medical staff/ ABMSP grading.

11.5 Identification of substandard and persistent substandard performance

Substandard performance can be identified by placing the scores for each peer group in rank order for each circulation. The participant code numbers of those with scores below the 2.5 percentile point must be noted: these individuals will be classed as having substandard performance. In addition, one instance of missed dyskaryosis in a round will mean that the participant receives a result of substandard performance.

When a participant is identified as having persistent substandard performance, an action point is reached. Persistent substandard performance is defined as the occurrence of either of the following in two out of three consecutive EQA rounds:

- an individual score below the 2.5 percentile point.
- one instance of missed dyskaryosis.

A participant cannot be classified as showing persistent substandard performance on the basis of the results from a single round. For example, if a participant misses dyskaryosis on two or more occasions in one round, or misses dyskaryosis on one or more occasions and also falls below the 2.5 percentile point in the same round, his or her performance will be graded as substandard, but not as persistently substandard.

After this first action point has been reached, a second action point occurs when a participant's performance continues to be substandard in two out of three rounds. However, because persistent substandard performance is determined on a 'rolling' basis using the results of the last three consecutive rounds, performance in rounds undertaken prior to the first action point being reached will be used to calculate the second action point.

After the first action point is reached, failure to participate in a round (for reasons other than legitimate long-term absence) will be counted as substandard performance.

12. FINANCIAL ASPECTS

Funding of the EQA scheme is included in the budget for regional QA. NHS laboratories therefore pay no subscription for participating in the scheme.

ARCHIVED

SECTION TWO:
STANDARD OPERATING PROCEDURES

ARCHIVED

CONTENTS

SOP 1	Maintenance of protocols and standard operating procedures	21
SOP 2	Scheme membership	22
SOP 3	Enrolment of new participants	23
SOP 4	Obtaining case material	24
SOP 5	Initiating a circulation	25
SOP 6	Confidentiality	26
SOP 7	Receipt and analysis of EQA responses	27
SOP 8	Participants' meetings	28
SOP 9	Feedback to participants	29
SOP 10	Persistent substandard performance	30
SOP 11	Communications and complaints	33
SOP 12	Oversight	34
SOP 13	Managerial accountability	35
SOP 14	Finance	36
SOP 15	Staffing	37
SOP 16	Training	38

ARCHIVED

Standard Operating Procedure 1

Maintenance of protocols and standard operating procedures

The steering committee (the National Coordinating Group for Laboratory QA) will meet at least twice yearly and will conduct an annual management review of the quality management system and all its services. This review will identify any changes that are needed to meet the needs of the participants and any actions that are required to ensure the continuation of the service. Annual reports will be produced on the basis of the review, and copies of these will be submitted to NQAAP, EQA Facilitators, and participants. A copy of the executive summary of the annual management review report will also be forwarded to CPA/UKAS.

There will be formal arrangements and meetings between relevant QARC staff and the regional EQA organising committee (the Regional Coordinating Group for Laboratory QA). Within a region, the scheme should be discussed by the participants and an annual report should be produced by the Regional Organiser in collaboration with the regional QARC. The Regional Organiser will review each SOP annually before submitting an annual report to the regional EQA scheme organising committee.

In addition to the regional annual report, each region will submit data/information, in accordance with a national proforma, to the national office of the NHSCSP. This information will include a summary of participant satisfaction data and participant complaints recorded during the year. Each region's submission will be discussed at the national steering committee meeting and will be used to compile national reports.

Proposals to amend a SOP will be submitted to regional groups initially. If they gain regional support, they will then be submitted to the national office of the NHSCSP for consideration by the national EQA steering committee and subcommittee.

The SOPs will be kept in a loose-leaf folder in the office of each Regional EQA Facilitator. A master set will be held by the NHSCSP national office. These will be controlled documents, with all amendments to the SOPs signed and dated.

Signed(Regional Organiser)

Dated

Standard Operating Procedure 2

Scheme membership

The *Quality Assurance Guidelines for the Cervical Screening Programme*, published in 1996, recommended as a quality standard that all staff screening or reporting cervical cytology on behalf of the NHSCSP should participate in EQA (or 'proficiency testing', as it was then known) and should demonstrate an acceptable level of performance.⁹ Participation in EQA is therefore mandatory for all staff who report gynaecological cytopathology samples in the NHSCSP, whether they are employed on a temporary or a permanent basis. This includes cytology screeners, biomedical scientists, ABMSPs, and pathologists.⁵ Individuals who are not involved in screening and reporting, or individuals currently being trained in cervical cytology are not eligible to participate in the EQA scheme.

Locums must ensure that they participate regularly in a regional scheme and will be required to provide evidence of their participation in each round. Locum screeners must meet all NHSCSP standards before they are employed.

A participant who moves between regions or schemes, whether permanently or on a locum basis, must be willing to provide original certificates of participation and EQA results for their last two rounds. This will enable the Regional EQA Facilitator to manage any persistent substandard performance or non-participation. If these results are not provided, the EQA Facilitator will inform the medical/scientific Head of the employing laboratory, as appropriate. Students and trainees who intend to pursue a career that includes cervical cytology may participate, but their scores will be excluded from the performance analysis.

Staff working in private laboratories where screening is undertaken for the NHSCSP are required to participate in the scheme and must comply fully with its conditions and arrangements. Staff working in private laboratories where private screening alone is performed are not required to participate, but may choose to do so. Private laboratories are expected to pay a subscription for this service.

The primary purpose of EQA is to improve standards through education. However, one consequence of the scheme is that instances of persistent substandard performance by an individual may occasionally be revealed, necessitating investigative, and sometimes corrective, action. As stated in EL(98)2,⁵ EQA schemes are designed to complement other systems that are already in place for the early identification of problems that might affect patient care; therefore, the identification of persistent poor performance by an individual via the EQA scheme will probably be a rare occurrence. In such cases, it should be remembered that EQA does not fully replicate the routine clinical situation and has only limited value as a means of assessing clinical competence. Therefore, the results of the EQA scheme should not be interpreted or used in isolation but, like clinical audit, should be viewed as part of wider laboratory QA activities and local arrangements for clinical governance.¹⁰

Signed(Regional Organiser)

Dated

Standard Operating Procedure 3

Enrolling new participants

Prospective participants will be directed to the current online version of the scheme protocol and Standard Operating Procedures. A paper copy may also be requested.

Participants are asked to read these documents and to confirm, either in writing or electronically, that they agree to the EQA scheme's terms. Once this confirmation is received by the Regional EQA Facilitator, a participant code number will be issued to the individual. This code will not be known to the Regional Organiser; instead, the data will be held securely at the QARC, and treated as confidential.

The process for amendment of the protocol and SOPs is described at SOP12. Where changes are made that require NQAAP approval, all participants will need to agree in writing that they have read and understood any alteration. The procedure for obtaining this agreement should follow the process described above for enrolling new participants.

Signed(Regional Organiser)

Dated

ARCHIVED

Standard Operating Procedure 4

Obtaining case material

All laboratories that are currently performing satisfactorily (i.e. that are not at a national action point) in the *External Quality Assessment Scheme for the Evaluation of Papanicolaou Staining in Cervical Cytology*⁷ will be required to submit good examples of material for the EQA scheme to the appropriate QARC.

Slides submitted by the laboratory should have a classification that has been agreed by at least one primary screener, one checker, and one pathologist or ABMSP. All slides will be checked by the Review Panel to assess their technical adequacy before they are included in the EQA round. The Panel must agree on the classification of the slide, and their opinion must be consistent with that of the submitting laboratory, and with patient history or histology (where appropriate).

Signed(Regional Organiser)

Dated

ARCHIVED

Standard Operating Procedure 5

Initiating a circulation

Slide sets will be assembled by the Regional EQA Facilitator, using slides approved by the Review Panel, in line with the process outlined in the document *External Quality Assessment Scheme for Gynaecological Cytopathology: Handbook for Facilitators*.⁴

Explanatory details and response sheets for each participant will accompany the delivery of the slide sets, or will be made available online. An example of a referral sheet for medical staff that includes initial opinions from primary screeners and checkers is included at Appendix 1.

The Regional EQA Facilitator will liaise with laboratories over the delivery and return of the slide sets and a closing date will be given for receipt of responses. To ensure that each laboratory receives slides that have been processed using the same modality that they regularly employ, it may be necessary for some laboratories to participate in an EQA round provided by another region. If this is the case, the performance of each participant will be fed back to the Regional EQA Facilitator, who will manage any instances of persistent substandard performance or non-participation.

Participants who are unable to participate on agreed dates (e.g. because of prearranged annual leave or illness) may participate at another laboratory in the region. If this is not possible, then one further, mutually agreed date for participation will be offered within two weeks of the completion of the planned circulation. Written records will be kept detailing which slides have been used by which laboratory and on which dates.

Signed(Regional Organiser)

Dated

Standard Operating Procedure 6

Confidentiality

Responses from participants will be identified only by the participant code number. The code numbers are allocated to participants by the Regional EQA Facilitator, and must be held in a locked cabinet or a password-protected file accessible only to the EQA Facilitator. The Regional Organiser, National Organiser, and national Scheme Secretary will communicate with participants only by their code number through the EQA Facilitator, and will therefore remain unaware of the individual identity of each participant.

Any confidential material from the Regional Organiser should be passed to the EQA Facilitator with only the relevant code number exposed. It can then be placed in an appropriately addressed envelope by the EQA Facilitator without the EQA Facilitator examining the contents.

The link between participant names and code numbers may be divulged by the EQA Facilitator in only two circumstances:

1. When writing to a participant who requests a reminder of his or her code number (code numbers must not be divulged by telephone).
2. On a member of medical staff/ABMSP reaching the second action point, when circumstances dictate that the Chair of the JWG on Quality Assurance must be notified, as set out in SOP10.

Screeners and checkers are required to identify themselves to the scientific Head of their department when the first action point is reached, to enable an action plan to be implemented.

No EQA result may be divulged to any other authority (see Executive Letter EL(98)2)).⁵ All communications between the QARC and participants will be treated as confidential.

Signed(Regional Organiser)

Dated

Standard Operating Procedure 7

Receipt and analysis of EQA responses

A participant's responses to a slide set will be returned to the Regional EQA Facilitator in confidence, e.g. in a sealed envelope, or via secure online submission using an appropriate system. An example of a response form is given at Appendix 2.

Responses must be given using standard British Association for Cytopathology terminology. The Regional EQA Facilitator will analyse the individual results and, working with the Regional Organiser, will prepare the list of regional results. These will be reported to the regional QA scheme organising committee. The region will subsequently make a report to the national steering committee (National Coordinating Group for Laboratory QA).

Signed(Regional Organiser)

Dated

ARCHIVED

Standard Operating Procedure 8

Participants' meetings

A regional meeting of participants will be held at least annually. This will allow participants to comment on, and contribute to, the EQA scheme. A summary of the regional results may be presented at the meeting, comparing the consensus across the region with known or expected outcomes. Slides may also be available at the meeting for viewing and discussion.

Nationally, a comparison of each region's performance will be prepared by the EQA subcommittee.

Signed(Regional Organiser)

Dated

ARCHIVED

Standard Operating Procedure 9

Feedback to participants

The Regional EQA Facilitator will issue written interim feedback to individuals as soon as possible after participation, and ideally within two weeks. This feedback will compare individual performance against the initial submitted classification from the laboratory. The report will include the participant's code number. The envelope/email in which it is sent will be marked 'personal and confidential'.

Consensus results will be made available when all participants have reported the slides. At the end of the circulation, a final written report will be prepared for each participant by the EQA Facilitator. This will compare the participant's responses with the consensus opinion. Formal individual scores will be calculated, and the EQA Facilitator will check the database to determine whether any of the participants fulfil the criteria for persistent substandard performance. The reports, together with anonymous results for all participants and any general communication that the Regional Organiser considers necessary, are then posted/emailed to the appropriate participants or made available online via a secure system. The EQA Facilitator may also send a cumulative analysis of a participant's results to allow trends in performance to be recognised.

Individual and laboratory participation certificates are distributed with the analysis of results.

Signed(Regional Organiser)

Dated

Standard Operating Procedure 10

Persistent substandard performance and action points

Action points, and the remedial measures taken when action points are reached, are defined by the NQAAP (histopathology and cytopathology).

Persistent substandard performance is defined as the occurrence of either of the following in two out of three consecutive rounds of the EQA scheme:

- Scoring below the 2.5 percentile point.
After each circulation has been scored, scores are put into rank order. Participant code numbers are recorded for those individuals who fall below the 2.5th percentile.
- Missed dyskaryosis.
If a participant classifies a slide as negative or inadequate when the consensus opinion is that it should be reported as low-grade dyskaryosis or worse, this constitutes an instance of missed dyskaryosis.

First action point

This is reached when persistent substandard performance, as defined above, is identified.

A participant cannot be classified as showing persistent substandard performance on the basis of the results from a single round. For example, if a participant misses dyskaryosis on two or more occasions in one round, or misses dyskaryosis on one or more occasions and also falls below the 2.5 percentile point in the same round, his or her performance will be graded as substandard for that round, but not as persistently substandard.

Second action point

The second action point is reached when a participant's performance continues to be substandard in two out of three consecutive rounds after the first action point has been reached. However, because persistent substandard performance is determined on a 'rolling' basis, using the results of the last three consecutive rounds, performance in rounds undertaken prior to the first action point being reached will be used to calculate when the second action point has occurred.

A table of performance examples with action points is included in this document at Appendix 5.

Failure to participate in an EQA round after the first action point has been reached (for reasons other than legitimate long-term absence) will be counted as substandard performance.

Failure to participate in two out of three consecutive rounds (other than on the grounds of legitimate long-term absence) should result in an individual ceasing to report cervical cytology. Non-participation will consequently be reported by the EQA Facilitator to the Regional Organiser/Laboratory QA Lead and Regional QA Director. The Regional Organiser should also inform the Chair of NQAAP.

Medical staff/ABMSPs

A pathologist who reaches the first action point will receive a 'Dear Colleague' letter from the Regional Organiser. The letter will be sent from the Regional EQA Facilitator's office and will use the participant's confidential personal code number so that the Regional Organiser remains unaware of the identity of the addressee. Careful discussion between the Regional Organiser and the EQA Facilitator is necessary to maintain confidentiality through this process. If the prospective recipient is the Regional Organiser, however, the EQA Facilitator should act on his or her own initiative.

The recipient will be asked to reply to the Regional Organiser within four weeks, confirming that the letter has been received, offering an explanation for the substandard performance, and suggesting a remedy. The letter should be sent via the EQA Facilitator and the individual should identify himself or herself only by his or her personal code number.

When the first action point is reached, the EQA Facilitator will record the fact, and the subsequent actions taken, against the participant's code number. If an acknowledgement is not received from the participant within four weeks, the Regional Organiser will send a reminder; if a reply is not received within another three weeks, the Regional Organiser will inform the Chair of NQAAP of the position.

When the second action point is reached, the Regional Organiser will inform the QA Director and the Chair of NQAAP, who will convene an appropriate Investigation Panel. The Chair of NQAAP has the discretion to co-opt a respected local pathologist to assist, such as the regional Scheme Organiser or QA Director (if he or she is a pathologist). The Regional Organiser will provide the Chair of the Investigation Panel and the participant with details of the EQA responses that have resulted in this referral. The individual concerned will remain anonymous, and the details will be provided via the EQA Facilitator.

The task of the investigation panel is to determine whether the participant's low EQA scores relate to standards of routine practice that may compromise patient care. The investigation will therefore consider all possible explanations for the low scores, including a review of the EQA scheme, but will concentrate on the participant's routine practice, working conditions, and workload. The emphasis will be on identifying problems and implementing remedial measures, rather than on punitive action. The Chair of the Investigation Panel will need to correspond with the participant. This can initially be done anonymously, through the EQA Facilitator.

These steps should be completed within a maximum of four weeks. If the Chair of the Investigation Panel is not satisfied that there is a reasonable explanation for the poor performance, or if lack of cooperation from the participant appears to be slowing the investigation, the participant's name can be released. The Chair of the JWG on Quality Assurance will be informed, and will refer the matter to the Professional Performance Panel of The Royal College of Pathologists and to the Medical Director of the appropriate Trust. The Professional Performance Committee will convene a review panel consisting of three of the pathologist's peers, one of whom will have been selected by the pathologist under review.

Non-medical staff

When the first action point is reached, the Regional Organiser will write to the participant, copying the letter to the laboratory scientific Head for cervical cytology.

The letter will be sent from the Regional EQA Facilitator's office and the participant's personal code number will be used to keep the identity of the recipient from the Regional Organiser.

The participant will be required to identify him or herself to the scientific Head of the laboratory so that an action plan can be implemented. The laboratory's scientific Head must inform the lead consultant for the cytology service and the medical Head of department. If it is the scientific Head whose performance is in doubt, the copy letter should go to the consultant pathologist responsible for reporting cervical cytology.

The Regional Organiser will expect confirmation within four weeks that the participant has identified themselves, and that an appropriate action plan is in place. All correspondence should be routed via the Regional EQA Facilitator, and the participant should be identified only by his or her personal code number. A copy of the action plan, as agreed by the laboratory scientific Head or medical Head of department, should be included. If this is not received to the satisfaction of the Regional Organiser, a reminder is sent; if a satisfactory reply is not received within another three weeks the Regional Organiser informs the Chair of NQAAP of the position.

When the second action point is reached, the Regional Organiser must inform the Chair of NQAAP, who will liaise with the Regional QA Director about further action.

Signed(Regional Organiser)

Dated

ARCHIVED

Standard Operating Procedure 11

Communications and complaints

All written communication relating to EQA with the regional EQA Facilitator, the Regional Organiser, and the QA team or QARC will be stored in accordance with the retention times outlined by The Royal College of Pathologists and the Institute of Biomedical Science in *The Retention and Storage of Pathological Records and Specimens*.¹¹ If a telephone or verbal communication is made, the Regional Organiser or EQA Facilitator who receives it will make a note summarising its contents and date, and will store this note in the appropriate file.

EQA Facilitators will ensure that participants have the opportunity to complete a questionnaire on an annual basis to gather feedback and assess the needs and requirements of users. Complaints from individuals or laboratories about the organisation of the EQA scheme may be detailed in the questionnaire, but can also be made separately to the regional organising committee via the EQA Facilitator or the Regional Organiser.

Where a communication can be construed as a complaint, the action taken to remedy it will be recorded, dated, and added to the appropriate file. If the Regional Organiser judges the complaint to be justified and to warrant changes to the scheme's procedures, the preferred sequence for introducing such changes is as follows:

1. Consideration by the regional organising committee and recommendation to the national office of the NHSCSP.
2. Discussion at the EQA subcommittee meeting and possible referral for approval to the scheme's national steering committee.
3. Discussion and approval of the revision by the national steering committee.
4. Production of a draft revision to the relevant SOP.
5. Implementation of the revision pending approval by NQAAP (where required).
6. Notification of the revision to EQA Facilitators, participants, and NQAAP.

In the event of failure to resolve a complaint to the satisfaction of a participant, the individual in question can complain to the National Organiser of the Scheme. If satisfaction is still not obtained, the participant can then complain to the Chair of NQAAP.

Signed(Regional Organiser)

Dated

Standard Operating Procedure 12

Oversight

EQA scheme management will be responsible for setting, reviewing, and revising the scheme's objectives. The scheme will demonstrate its commitment to participants by establishing a quality policy and a quality management system and by performing annual management reviews. The managers of the regional QARCs must ensure that all of the resources that are necessary to the efficient operation of the scheme are available.

The annual management review must include:

- regional reports and data.
- an assessment of participant satisfaction and complaints.
- internal audits of the quality management system.
- internal audits of EQA scheme operation.
- status of preventative, corrective, and improvement actions.
- a description of any major changes in organisation and management, resource, or procedure.
- a follow-up to previous management reviews.

Comments on the way in which the scheme operates are invited at every participants' meeting. Changes proposed at these meetings will normally be reviewed by the regional organising committee, followed by the EQA subcommittee/national steering committee, and then NQAAP if necessary, as described in SOP11. Proposals made by a scheme member for a replacement Scheme Organiser (national or regional) should be discussed first at the participants' meeting. As far as possible, decisions taken at the participants' meeting should be made on a democratic basis by those present.

The annual management review report will be provided to NQAAP. It must include:

- a summary of the national results
- details of any changes to the operation of the scheme, the SOPs, the assessment procedure, or the procedures for managing substandard performance for the rounds since the last report, whether these are actual or planned.
- an outline of the number of participants who triggered action in response to substandard performance in the previous year.

A copy of the executive summary of the report will be forwarded to CPA (UK) Ltd / UK Accreditation Service.

Signed(Regional Organiser)

Dated

Standard Operating Procedure 13

Managerial accountability

The scheme operates from the regional QARCs. At least one QARC is located in each region. Every QARC is overseen by a regional QA Director, who is accountable to the Director of the NHSCSP.

The national scheme is overseen from the national office of the NHSCSP. The Director of the NHSCSP is accountable to the Department of Health.

Signed(Regional Organiser)

Dated

ARCHIVED

Standard Operating Procedure 14

Finance

The costs of overseeing the scheme at a national level are included in the budget of the NHSCSP national office.

The costs of operating the scheme and of supervising it at a regional level are included in the budget of the regional QARC.

The costs incurred by laboratories or individuals participating in the scheme must be borne by those laboratories or individuals (e.g. when locums travel to centres other than those employing them to participate in EQA).

Signed(Regional Organiser)

Dated

ARCHIVED

Standard Operating Procedure 15

Staffing

The role of National Organiser is a function of the post of Chair of the National Coordinating Group for Laboratory QA (the national steering committee). This position is held for a period of three years. The Scheme Secretary and the National Quality Manager are provided by the national office of the NHSCSP, which is also responsible for the administration of the scheme.

Each Regional Organiser must hold a senior post in a laboratory providing gynaecological cytopathology for the NHSCSP and must have appropriate training and experience for this role. The Regional Organiser should be a participant in the EQA scheme and should be appointed following consultation with regional scheme participants.

The EQA Facilitator will be appointed by the Regional QA Director.

Signed(Regional Organiser)

Dated

ARCHIVED

Standard Operating Procedure 16

Training

The Regional EQA Facilitator must be involved in a general training programme as a condition of their employment. The NHSCSP provides a regular meeting forum and support for all EQA Facilitators.

Signed(Regional Organiser)

Dated

ARCHIVED

REFERENCES

1. *Achievable Standards, Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology*, 3rd edition. NHS Cancer Screening Programmes, 2012 (NHSCSP Publication No 1).
2. *Protocol for a Proficiency Test Scheme in Gynaecological Cytopathology*. London, Department of Health Advisory Committee on the Assurance of Laboratory Standards, 1988.
3. *Recommendations for the Development of Histopathology/Cytopathology External Quality Assessment Schemes*. London, The Royal College of Pathologists Working Group on Histopathology External Assessment Scheme Accreditation, 1998.
4. *EQA Scheme for Gynaecological Cytopathology Handbook for Facilitators*, Version 6. NHS Cancer Screening Programmes, April 2013.
5. EL(98)2. *Oversight of Provision of External Quality Assessment Schemes in Histopathology, Cytopathology, Cytogenetics and Molecular Genetics for Pathology Laboratories*. London, Department of Health, 1998.
6. *Standards for the Medical Laboratory (H5)*. Clinical Pathology Accreditation (UK) Ltd, 2007.
7. *External Quality Assessment Scheme for the Evaluation of Papanicolaou Staining in Cervical Cytology* (NHSCSP Publication No 19). NHS Cancer Screening Programmes, 2004.
8. *Recommended Code of Practice for Laboratories Participating in the UK Cervical Screening Programmes*. London, British Society of Clinical Cytology, 2010
9. *Quality Assurance Guidelines for the Cervical Screening Programme* (NHSCSP Publication No 3). NHS Cervical Screening Programme, 1996.
10. *A First Class Service. Quality in the New NHS*. London, Department of Health, 1998.
11. *The Retention and Storage of Pathological Records and Specimens*, 4th edition. London, The Royal College of Pathologists and the Institute of Biomedical Science, 2009.

APPENDIX 1 Referral of abnormal slides for reporting form

Comment

Referral for reporting is on the basis that the slides indicated are, in your opinion, potentially or probably abnormal. You will not be marked on the basis of your responses on this form. Please treat the slides as you would in normal practice within your laboratory (for example, ringing, dotting or marking as appropriate).

Primary screener

If you are a primary screener, please indicate with an 'R' the slides you would refer to a checker or pathologist for reporting on the basis of your opinion. The pathologist will examine the slide according to his or her normal practice and form his or her own opinion.

Checker

If you are a checker, please indicate with an 'A' the slides you would refer to a pathologist for reporting on the basis of your opinion. Please look only at slides marked 'R' by the primary screener. The pathologist will examine the slide according to his or her normal practice and form his or her own opinion.

Hospital

Slide set identification

Please mark in the appropriate box

Slide number	1	2	3	4	5	6	7	8	9	10
Primary screener										
Checker										

APPENDIX 2 NHS Cervical Screening Programme EQA scheme response sheet

Personal identity code

Date of participation

Slide set identity

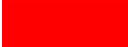
You **must** tick one box and **only one box** in the Result column of the Cytological Pattern section for each slide. Failure to tick a box or ticking more than one box in any column in this section will be penalised as an overall or undercall as appropriate. Please complete the Additional Features section as appropriate.

Cytological pattern	Result										
	Slide number										
HMR101 category	Result code	1	2	3	4	5	6	7	8	9	10
Inadequate	(1)										
Negative	(2)										
Borderline change in squamous cells	(8)										
Borderline change in endocervical cells	(9)										
Low-grade dyskaryosis	(3)										
High-grade dyskaryosis (moderate)	(7)										
High-grade dyskaryosis (severe)	(4)										
?invasive squamous carcinoma	(5)										
?Glandular neoplasia of endocervical type	(6)										
?Glandular neoplasia (non-cervical)	(0)										

Additional features	Result										
	Slide number										
	1	2	3	4	5	6	7	8	9	10	
No infection present											
<i>Trichomonas vaginalis</i>											
Candida											
Koilocytosis											
Herpes virus											
<i>Actinomyces</i> -like organisms											
Other											

APPENDIX 3 Scoring matrix for screeners/checkers

		Consensus			
		Negative	Inadequate	Abnormal	
Response	Negative	2	0	0	
	Inadequate	0	2	0	
	Abnormal	Borderline changes	0	0	2
		Low-grade dyskaryosis	0	0	2
		High-grade dyskaryosis (moderate)	0	0	2
		High-grade dyskaryosis (severe)	0	0	2
		?invasive squamous carcinoma	0	0	2
		?Glandular neoplasia of endocervical type	0	0	2
		?Glandular neoplasia (non cervical)	0	0	2

 Slide correctly interpreted
 Slide incorrectly interpreted

APPENDIX 4 Scoring matrix: pathologists/ABMSPs

		Response								
		Inadequate	Negative	Borderline	Low-grade	High-grade Moderate	High-grade Severe	?Invasive	?GN endocx	?GN non-cx
Consensus	Inadequate	2	0	0	0	0	0	0	0	0
	Negative	0	2	0	0	0	0	0	0	0
	Abnormal/no grade	0	0	2	2	2	2	2	2	2
	Borderline	0	0	4	3	2	2	2	2	2
	Bord/Low-grade	0	0	4	4	3	2	2	2	2
	Low-grade	0	0	3	4	3	2	2	2	2
	Low-grade/HG Mod	0	0	3	4	4	3	2	2	2
	High-grade Moderate	0	0	2	3	4	3	2	2	2
	HG Mod/HG Sev	0	0	2	3	4	4	3	3	3
	High-grade Severe	0	0	2	2	3	4	3	3	3
	HG Sev/?Inv	0	0	2	2	3	4	4	3	3
	HG Sev/?GN endocx	0	0	2	2	3	4	3	4	3
	HG Sev/?GN non-cx	0	0	2	2	3	4	3	3	4
	HG Sev/?GN	0	0	2	2	3	4	3	4	4
	?Invasive	0	0	2	2	2	3	4	3	3
	?Inv/?GN endocx	0	0	2	2	2	3	4	4	3
	?Inv/?GN non-cx	0	0	2	2	2	3	4	3	4
	Inv/?GN	0	0	2	2	2	3	4	4	4
	?GN endocx	0	0	2	2	2	3	3	4	3
	?GN non-cx	0	0	2	2	2	3	3	3	4
?GN (?GN endocx/?GN non-cx)	0	0	2	2	2	3	3	4	4	

	Slide correctly interpreted		Slide incorrectly interpreted
	One grade from consensus opinion		More than one grade from consensus opinion

APPENDIX 5 Table of performance examples with action points

	1 st Round	2 nd Round	3 rd Round	4 th Round	5 th Round	6 th Round	7 th Round	Rounds contributing to 1 st Action Point	Rounds contributing to 2 nd Action Point
Participant A	Substandard	Satisfactory	Substandard 1 st Action Point	Substandard 2 nd Action Point				1, 2 & 3	2, 3 & 4
Participant B	Substandard	Satisfactory	Substandard 1 st Action Point	Satisfactory	Substandard 2 nd Action Point			1, 2 & 3	3, 4 & 5
Participant C	Substandard	Non-valid non-participation	Satisfactory	Substandard 1 st Action Point	Satisfactory	Non-valid non-participation 2 nd Action Point		1, 3 & 4	4, 5 & 6
Participant D	Substandard	Substandard 1 st Action Point	Satisfactory	Satisfactory	Substandard	Satisfactory	Substandard 1 st Action Point	1 & 2 5, 6 & 7	-
Participant E	Substandard	Substandard 1 st Action Point	Substandard 2 nd Action Point					1 & 2	1, 2 & 3
Participant F	Substandard	Substandard 1 st Action Point	Satisfactory	Substandard 2 nd Action Point				1 & 2	2, 3 & 4
Participant G	Substandard	Substandard 1 st Action Point	Satisfactory	Satisfactory	Substandard	Substandard 1 st Action Point		1 & 2 4, 5 & 6	-
Participant H	Substandard	Satisfactory	Substandard 1 st Action Point	Non-valid non-participation 2 nd Action Point				1, 2 & 3	2, 3 & 4
Participant I	Substandard	Substandard 1 st Action Point	Satisfactory	Non-valid non-participation 2 nd Action Point				1 & 2	2, 3 & 4
Participant J	Substandard	Substandard 1 st Action Point	Satisfactory	Satisfactory	Non-valid non-participation	Satisfactory	Satisfactory	1 & 2	-
Participant K	Satisfactory	Non-valid non-participation	Satisfactory	Non-valid non-participation Cessation of screening				-	-