CERVICAL CYTOLOGY EQA SCHEME

Principles and Protocols

January 2013
Aims and Objectives
The Cervical Cytology EQA Scheme aims to:
- Contribute towards the establishment and upholding of minimum national standards in the cervical cytology
- Promote consistency in reporting across the country
- Facilitate continuing education and professional development within laboratories by providing regular access to interesting and relevant cytological material.
- Enhance the experience and confidence of cervical cytopathology staff in their reporting practice
- Assist laboratories in meeting accreditation standards relating to EQA.

Introduction and background
Since the mid-1980’s, cytology laboratories have acknowledged the importance of external quality assurance in ensuring consistency and standards of reporting in cervical cytology. Key events in the development of the current scheme are listed in appendix 1.

The scheme was improved and developed in line with national guidance and standards with the development of interpretive assessment, educational and technical QA components. These were brought together into a single unified scheme in 2001 with the introduction of a single quality management system in 2005. During this time the scheme has followed a similar format with minor developments as required.

However, changes in the organisation and delivery of cervical cytology in Scotland over the last several years and into the future made it increasingly
difficult for the scheme components to be delivered effectively in their existing form and necessitated modification and streamlining of the scheme. The main drivers include the introduction of imager technology in many laboratories, review of the cervical cytology QA structure in Scotland, laboratory amalgamation and staff changes. Thus the scheme has been updated in line with these recent developments in Cervical Cytology structure and service provision. It conforms to the requirements for EQA of the National Services Division (NSD), National Quality Assurance Assessment Programme (NQAAP), the Royal College of Pathologists (RCPa) and is comparable to the NHS Cervical Screening Programme (CSP) proficiency testing schemes in England.

**Organisation and accountability**

NSD funds the EQA scheme with contribution from the DHSSPS in Northern Ireland. Appendix 2 shows the organisational relationships of the scheme. The scheme is accountable to NSD with respect to service delivery and, from a quality perspective, reports to the Quality Assurance Reference Centre (QARC) for cervical screening in Scotland via the chair of the Laboratory Quality Assurance (Lab QA) group.

**Key Features**

Interpretative assessment measures performance in cervical cytology reporting by regular testing. It is recognised as one method of demonstrating competence in cervical screening although the testing, scoring and assessment methods require sensitive interpretation. Every laboratory is tested every six months with each test comprising ten assessment slides and two or three educational slides.

Key features are:
- It is an objective test using peer-reviewed non-controversial liquid based cytology (LBC) (Thin-Prep™) slides representing the range of diagnostic categories in cervical cytology
- Participation is mandatory for all laboratories providing the cervical cytopathology component of the Scottish Cervical Screening Programme
(SCSP) and all individuals giving an opinion on a cytology sample that may be acted upon.

- The results of an individual’s performance are confidential to that laboratory except if a participant has persistent sub standard performance and then only identified by the identity code.
- It provides external confirmation of good practice and standards of reporting of individuals and laboratories.

The educational slides included provide regular access to challenging and interesting cytology slides for laboratory discussion and teaching. It is a mechanism for sharing material identified by laboratories as being of educational value. Two or three educational slides are included with the interpretive assessment slides twice a year. The emphasis is on a non-threatening means by which reporters can assess their screening skills and learn from material circulated. Slides are screened within the normal working environment and reporting conditions.

**Terms and Conditions of Participation**

Participation is mandatory for all laboratories providing cervical cytology services to NHS Scotland. Laboratories undertaking cervical cytology for the Department of Health, Social Services and Public Safety (DHSSPS) in Northern Ireland also participate. The scheme is open to any region wishing to adopt this format of EQA and to any laboratories wishing to participate. Every member of staff, in participating laboratories, responsible for reporting cervical smears must participate. The consultant in charge of cytopathology is responsible for ensuring participation by all staff who at any time issue a cervical cytology result on their own. Members of staff undergoing training in cervical cytology are eligible to participate and should participate regularly although their performance is not formally scored. While a locum is in post, he/she is required to participate in this scheme.

**Certificate of Participation**

Annually, laboratories are issued with a certificate confirming participation in the components of the scheme for the current year.
Roles and Responsibilities

Details of individual roles and responsibilities are listed in appendix 3.

The Laboratory Quality Assurance (Lab QA) group, which represents all laboratories in Scotland, oversees the operation of the scheme, discusses its development and direction in line with national developments in cervical cytology and monitors the (anonymised) performance of participants. The scheme reports to QARC through the Lab QA chairperson. The medical lead is invited to sit on the laboratory Lab QA group.

The medical lead has overall organisational responsibility and reports to the Lab QA group, the National Services Division (NSD) of National Services Scotland and the National Quality Assurance Advisory Panel (NQAAP). He/she ensures action on poor performance and assists the organiser with quality control of the scheme data. While in office, the medical lead is the scheme coordinator and has responsibility for the scope and direction of the scheme.

The scheme organiser, responsible to the medical lead is responsible for the day to day running of the scheme, organising tests, analysing and delivering results and monitoring participation and performance. The organiser is the main link with the laboratories and is responsible for maintaining participant confidentiality.

For each laboratory, there is a named lead consultant responsible for identifying all staff required to participate. The lead consultant receives the results of all participants in confidence and, in the event of substandard performance, ensures appropriate action. A fellow consultant is nominated to receive a copy of the lead consultant’s results should the latter have persistent substandard performance. Additionally, all laboratories have a nominated member of staff, the laboratory coordinator, to assist the organiser with the administration of the interpretive assessment at local level. The lead consultant nominated colleague and laboratory coordinator must be participants in the EQA scheme.
Confidentiality

Patient Confidentiality
While details of age and relevant history are retained, patient anonymity is ensured by relabeling all slides with coded scheme identities.

Confidentiality of feedback
For interpretative assessment all participating laboratories and individuals will receive personal and comparative results. These results are confidential at a personal level. Individual anonymity will be preserved when results are presented in reports, at local or national meetings or used in any other way.

Packaging
Scheme personnel have a duty of care over submitted material. With this in mind, the scheme uses high quality packaging, designed to be re-used by the participant in order to protect the material, to satisfy Post Office and Health and Safety regulations, to be environmentally friendly and to speed handling. All slides are stored in a locked cupboard prior to assessment and before they are returned to laboratories.

Remedial action
Integral to the scheme is the initiation of remedial action in the event of individual sub standard performance as defined for the scheme. This is confidential, supportive and constructive and involves cooperation between the consultant in charge of the laboratory and the medical lead. An agreed action plan is documented and the outcome reviewed. The laboratory clinical director is informed of persistent poor performance; likewise, instances of persistent poor performance are reported to QARC.

Complaints procedure
All complaints from individuals or laboratories regarding the administration or marking of the scheme must be addressed in writing either to the organiser of
the scheme concerned or directly to the medical lead. The medical lead and
organiser will consider the complaint and an acknowledgement and initial
written response will be issued within fourteen days. The LabQA group will
consider each complaint formally at the next Lab QA group meeting and a
final response will be given thereafter. A record of all complaints together with
the subsequent actions will be maintained by the medical lead.

Scheme evaluation
The scheme strives to meet the needs of its participants. Regular surveys are
undertaken to assess user satisfaction. In addition, participants are given the
opportunity to comment on the scheme via their representative on the
Laboratory QA group.

Accreditation of organisers
The laboratories with budgetary and organisational responsibility for the
components of the scheme must hold accreditation with Clinical Pathology
Accreditation (CPA) (UK) Ltd

Annual reports
Annual and mid-year reports are submitted to NSD. The reports outline
service developments, performance indicators, activity analysis and financial
outturn. Annual reports are publically available. An annual report is submitted
to the Royal College of Pathologists (RCPath)/NQAAP joint committee for
EQA schemes. Annual feedback on each component of the scheme is also
produced for laboratories and individuals participating.

Continuing Professional Development
The RCPath, Institute of Biomedical Scientists and British Association of
Cytology continuing professional development (CPD) schemes approve
participation in the scheme. Credits are awarded for participation in
interpretive assessment and reviewing educational slides
Participation arrangements
Every member of staff responsible for reporting cervical smears must participate in interpretive assessment. The consultant in charge of cytopathology is responsible for identifying to the organiser the names of all staff that at any time issue the result for a cervical smear test on their own and ensuring that all staff sits the test. If a member of staff misses a test due to holiday or minor illness the organiser will arrange for the slides to be returned to the laboratory at the end of the circulation. If a test is carried out while a locum is in post, he/she should take part unless he/she has already undertaken the current test.

Trainee staff
Trainee BMS, trainee cytoscreeners and junior pathologists are encouraged to participate in the test but should be identified to the organiser in advance. Their results will be sent to them individually and are included in the list of individual results provided to the consultant in charge.

Staff returning after prolonged absence
A member of staff in this situation who is having all reporting supervised may be considered a trainee for the current test. If the individual is reporting smears unsupervised he/she must sit the test.

Slide Donation
Interpretive assessment is dependent on acquiring high quality slides. Laboratories must have confidence in the quality of the slides included in the interpretive assessment. Each laboratory is required to contribute slides to the slide bank when requested to do so by the organiser. The organiser will review regularly the bank of slides currently held to determine the number and combination of slides to be donated by each laboratory. No inadequate or borderline smears should be requested or selected. Slides donated should be unequivocal good examples suitable for primary screeners, checkers and pathologists. Some slides may also include an “additional feature” (e.g. infection, postnatal changes, phase of menstrual cycle).
**Donation of Educational slides**

Each laboratory is requested to submit slides annually. Educational slides should illustrate an unusual feature or a diagnostic difficulty and demonstrate a learning point. A form is completed to accompany each submitted slide giving relevant clinical details, cytology and histology reports and teaching points.

The LabQA group may periodically review the range of educational material submitted and recommend particular diagnostic categories.

**Slide Selection**

Each donated slide is screened “blind” to the result by at least four participating members of the scheme independently. Only slides for which there is complete agreement are accepted. Slides that fail to pass this stage are returned to the originating laboratory. The remaining slides will be retained for at least two years with all slides returned to the originating laboratory, normally within three years.

Slides passing the first selection stage are then viewed by at least three members of the Lab QA around a multi-headed microscope. Slides that have complete agreement at this second stage will be added to the slide bank from which test sets for each cycle of interpretive assessment are drawn. The reference answers for marking are agreed at this stage. The reference answer must indicate clearly the category of result to be accepted (i.e. negative or neoplastic) and the grade of dyskaryosis or additional feature(s) present.

The Lab QA group monitors test sets and if appropriate, modifications are introduced. External review of the test slides may be sought.

Anonymity of the slides is assured by re-labelling with interpretive assessment coded identities between tests. Once allocated, the test sets should stay intact. Slides within a test set are only replaced if a slide is broken or has deteriorated beyond repair during the round and replacements should be documented. Slides are stored securely in a locked cupboard and a full audit trail is in place.

Educational slides are selected by the medical lead from those submitted for inclusion with the circulated test sets.
Arranging the test

Participants receive a set of 10 interpretive assessment slides plus 2-3 educational slides every six months. The organiser draws up a timetable for circulation of the sets and emails all laboratories prior to commencing testing to inform them when the slides will be available in the laboratory for review. The list of participants is confirmed with each named laboratory coordinator.

Each participant receives history and response sheets, explanatory details and an extra envelope for a photocopy of the participant’s response sheet. The first laboratory in the testing round also receives the slide set, keeps them for the specified dates and then forwards them to the next laboratory.

Test procedure

Interpretive Assessment

At all times confidentiality must be maintained. Each participating individual is issued with a unique code known only to the organiser and the participant. The code is used on the answer sheet and in all correspondence.

Once the laboratory has received the slides the laboratory coordinator informs the staff that the slides are available and arranges, if required, a rota for staff to review the slides. The conditions under which the EQA slides are examined should resemble as closely as possible those of normal working practice, the only difference being that the participants must not discuss the slides in any way before everyone has viewed them and recorded and returned their results. Participants should return their responses in the sealable envelopes that have been supplied by the organiser. Sealed envelopes are given to the laboratory coordinator who will return all responses to the organiser together. All participants are instructed to photocopy their response sheets, place them in a sealed envelope and hand to the laboratory coordinator for safe keeping. These copies are kept in case answer sheets are lost or there is dispute as to the responses submitted. Once the interim results have been issued the sealed envelopes may be returned to the participants to destroy; alternatively, the coordinator should dispose of them in the confidential waste.

Educational slides
Participants can view the educational slides at any time during the period that the test set and accompanying educational slides are in the laboratory. The response forms for the educational slides are returned to the organiser to ensure that participants who reviewed the educational slides receive CPD points. Participants may wish to photocopy their educational response sheets and hand them to the coordinator along with their interpretive assessment response sheets.

**Notification of Results**

**Confidentiality**
Results are confidential at personal level and anonymised for comparative purposes. Results are copied to the nominated consultant in charge of cytopathology. Thus, the test results for any individual will initially be confidential between the organiser, the individual and the consultant in charge of cytopathology.

**Interim results**
Written interim feedback is given to each participant as soon as possible after his/her response sheet is received. This report compares and scores the participant’s opinions against the diagnosis submitted and agreed by peer review. It is for educational feedback only. Final results will be issued once all participating laboratories have completed the round of testing.

**Final Results**
When all the results of an assessment have been submitted and analysed, only those slides reaching at least 80% consensus of opinion are accepted for marking. Slides that do not achieve an 80% consensus of opinion are discounted. All participants answer sheets are marked and each candidate is given a numerical score. Each individual participant is sent a written final report which contains the result of this test and also results of the participant’s performance in the previous two tests. Final results are issued as soon as possible after all laboratories in the group have reviewed the slides. Final marks are calculated according to the scoring system outlined in appendix 4.

**Procedure for Management of Substandard performance**

**Definition of Substandard Performance**
Substandard performance in an interpretive assessment is defined as an occurrence of one or more of the following:

- Scoring below the 2.5 centile point (determined by placing the scores for each round into rank order).
- Missing dyskaryosis.
- Failure to participate in an assessment except for legitimate long term absence would constitute a substandard performance for that assessment

* These terms apply to this assessment situation only; the assessment is a simulated and not a real screening or clinical situation.

**Action points**

Formal action is not instigated on the basis of a single assessment (even if a participant misses dyskaryosis on two or more occasions in a single set of slides) *Persistent* substandard performance however will trigger the following action points:

**First Action Point**

The first action point occurs when a participant is identified as having persistent substandard performance, namely substandard performance (as defined above) in two out of three consecutive assessments.

**Second Action Point**

The second action point is reached when a participant's performance continues to be substandard. i.e. his or her score falls below the 2.5 centile or he or she misses dyskaryosis in two out of three successive assessments after triggering the first action point.

The three consecutive assessments should be counted on a “rolling” basis, with calculation of performance based on the most recent three assessments. A participant whose performance in both of the last two assessments resulted in the first action point being reached will **not** reach the second action point if his or her performance in the current assessment is satisfactory. However, a further substandard performance in the current or subsequent test will trigger the second action point.
**Action in event of persistent substandard performance**

Any action taken as a result of an Interpretive assessment score out with the expected norms must take into account day-to-day performance in the laboratory and any other relevant factors.

**First Action Point**

The individual and the consultant in charge will be informed that the individual has reached the first action point. The consultant in charge will be asked to discuss the result with the participant and to take any remedial action required. Where the individual is the consultant in charge, the nominated consultant pathologist will be sent a copy of the result letter. All discussions, the action plan agreed, and the outcome are documented.

If internal quality control (IQC) results of the individual are satisfactory and the individual is participating in continuing education, it is probably sufficient to discuss the situation with the individual to confirm that there are no problems requiring remedial action. Further training, either in-house or off-site, may be considered appropriate. The laboratory lead consultant will confirm this in writing to the scheme organiser.

Where IQC results are not satisfactory, further training, and/or supervision is indicated. Communication regarding the management of substandard performance is limited to the laboratory lead consultant and the medical lead; individuals will be identified by candidate number only to ensure confidentiality.

The laboratory QA group will review the anonymised candidate’s results, along with the IQC results and the action undertaken and decide if further action is to be recommended.

**Second Action Point**

The individual and the consultant in charge will be informed that the individual has reached the second action point. The medical lead will inform the chairman of NQAAP. The individual and the NQAAP Chairman will be provided with details of the results which have resulted in this referral. This will
be done anonymously through the scheme organiser. The laboratory’s management will also be informed and may be involved if appropriate. Where the individual concerned is the consultant in charge of cytology, the nominated consultant pathologist must undertake the role of consultant in charge. A plan of appropriate action must be instigated and this together with the outcome and discussions must be documented. The outcome of the agreed action plan is reviewed by the laboratory lead consultant or nominated consulted where the participant is the laboratory lead consultant.

**Review on Completion of Round**
Results of the most recent Interpretive Assessment will be presented regularly at the Scottish Association for Clinical Cytology scientific meeting which is open to and attended by cytology medical and technical staff in Scotland.
Appendices

Appendix 1

Key Dates
1985  Slide Circulation Scheme established, funded by Clinical Resources Audit Group (CRAG).
1988  UK DoH “Protocol for a Proficiency Testing Scheme in Gynaecological Cytopathology”
1992  All laboratories in Scotland reporting cervical smears participating
1992  First round of Scottish Proficiency Testing Scheme (CRAG funded initially later Scottish Cervical Screening Programme, central coordinating unit)
1998  All Northern Ireland laboratories participating
1999  Introduction of Technical EQA scheme for Cytology
2001  Single management framework was established to co-ordinate three scheme components.
2005  Quality management system introduced. A copy of the Quality Manual is available to participants on request.
2006  Cervical Cytology EQA Scheme User Manual published
Appendix 2
Accountability

*Organiser – employed by NHS Tayside
Medical lead – employed by NHS Grampian
Appendix 3

Roles and responsibilites

**Laboratory QA Group**
The role of the Lab QA group is to:
- ensure that all laboratories in Scotland and Northern Ireland reporting cervical cytopathology are included in the scheme
- represent the interests of participating laboratories.
- monitor the quality and performance of individual slides
- monitor the overall results profiles for interpretive assessment
- audit the scheme with respect to participation, format and results
- develop the scheme in accordance with advances in cervical cytology

**Medical Lead**
The medical lead is responsible for:
- the overall organisation and scope of the scheme
- scheme compliance with the service level agreement and annual reporting to NSD
- quality reporting to NQAAP and the RCPath
- ensuring scheme and protocol development
- discussing and agreeing remedial action plans for anonymised individuals with substandard performance
- checking accuracy of results compiled by the organiser
- vetting material submitted for education slide circulations
- monitoring the performance of slides

**Scheme Organiser**
A part-time organiser, responsible to the committee, has the following responsibilities, to:
- oversee the compilation of test sets
- arrange interpretive assessment at each laboratory in turn
- ensure anonymity of material by labelling the slides and concealing any identifiable details
- facilitate the timely exchange of slides between laboratories and where necessary arranging for the slides to be returned due to sickness or annual leave.
- analyse participants’ report forms in accordance with the test reference answer sheets
- provide individual interim and final results
- feedback informally to the consultant in charge and individuals as requested and as appropriate
- compile the relevant sections of the annual report together with the medical lead

**Laboratory Lead consultant**
Each laboratory has a named consultant with overall responsibility for the participation of that laboratory in the scheme. This will usually be the consultant in charge of cervical cytology. Practical duties may be delegated to another responsible individual but the named consultant has specific responsibility for:
- indentifying all staff required to participate and ensuring their participation
- timely contribution of good quality slides for assessment and educational sets
- facilitating arrangements for interpretative assessment
- communicating individual results to staff as appropriate and providing the opportunity for staff to discuss them
- appropriate action in the event of individual poor performance and cooperation with the Medical lead and clinical director as required.

**Nominated Consultant**
All laboratory lead consultants are required to nominate a fellow consultant who will receive a copy of the lead consultant’s results in the event of two substandard performances out of three circulations. The nominated colleague must be a participant in the EQA scheme for cervical cytology.

**Named Laboratory Coordinator**
All laboratories will nominate a member of staff from the laboratory who will assist the organiser in administering the EQA Interpretive Assessment. Responsibilities include to:

- e-mail confirmation of slide receipt to Organiser.
- check that the slides are in order and inform the organiser of any breakages.
- inform the laboratory staff that the slides are available in the laboratory.
- as far is possible, ensure that the slides are seen by all participants within the given timescale. This may involve organising a rota.
- remind participants that there should be no discussion of slides until all participants have submitted their answer sheets to the laboratory coordinator
- inform the organiser of any members of staff who are unable to participate due to sick leave or prearranged annual leave. The organiser will make arrangements for these people either to view the slides in another laboratory or in their own laboratory at the end of the round.
- return answer sheets to the organiser, and slides to the next laboratory using the protocol as described below.
- retain in a secure place within the department, the sealed envelopes marked “Photocopy”. These contain a photocopy of the participants' answers
Appendix 4
Marking scheme

Marking scheme for final results:
Checkers and Screeners:
For the distinction between negative and abnormal: either 0 (zero) for a wrong answer or 2 (two) marks for a correct answer. Consensus results are based on responses from all participants in this group.
Medical staff / advanced practitioners:
An additional mark is given with respect to grading abnormalities. If the response lies within the 80% consensus at the same peer level, then a mark of 2 (two) is awarded. If the grading lies one grade away from the consensus answer than a mark of 1 (one) is allocated. If the grading lies more than one adjacent grade away then 0 (zero) marks are allocated. With regard to the marking of ? glandular neoplasia, 2 (two) marks are given for a correct response of glandular neoplasia if that is the 80% consensus. If the 80% consensus is ? glandular neoplasia then 1 (one) mark is given for severe dyskaryosis or ? invasive. No marks are given for other degrees of abnormality. Only medical staff/advanced practitioner responses are used to assess medical staff grading.
If a slide does not have 80% consensus for one diagnostic category but 80% of respondents have opted for one of two adjacent grades (eg. mild or moderate), both grades will be awarded 2 points and the grade one away (ie severe) will accrue 1 point.
Slides included with a negative diagnosis for which fewer than 80% of respondents agree that the slide is negative are excluded and not scored. Similarly an abnormal slide that does not achieve 80% agreement over two adjacent grades is excluded.