The Royal College of Pathologists

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Recommendations for the development of histopathology/cytopathology external quality assessment schemes

April 1998

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RECOMMENDATIONS FOR THE DEVELOPMENT OF HISTOPATHOLOGY/CYTOPATHOLOGY EXTERNAL QUALITY ASSESSMENT SCHEMES 1998

Preface

Diagnostic standards in pathology laborat ories are maintained and improved by:

- external quality assessment (EQA) schemes
- clinical audit
- laboratory accreditation
- continuing medical education
- clinicopathological case review meetings.

These processes are inter-relate d: for example, feedback from EQA provides opportunities for continuing medical education, and participatio n in relevant EQA schemes enables compliance with accreditation standard F1 (Clinic al Pathology Accreditation (UK) Ltd).

For EQA, many general and specialist schemes have been developed during the last few decades. Participation has been voluntary, ex cept for schemes associated with breast and cervical screening, and the emphasis has been on education. In 1996, the Department of Health indicated that it wished to devolve oversight of EQA schemes in histopathology and cytopathology to Clinical Pathology Accreditat ion (CPA). This would involve CPA approving EQA schemes by a process independent of laboratory accreditation (CPA(EQA)).

Another significant development is a strength ening of the General Medical Council's role, empowered by the Medical (Professional Performance) Act 1995, in respect of clinical performance that might be a danger to patients. The relevance to EQA is, first, that a record of satisfactory performance could provide evidence leading to the exoneration of a pathologist suspected of being a risk to patients, and, second, that a record of substandard performance could be evidence that a participant's routine practice is a risk to patients.

To consider these issues, and to make recommendations for the future of EQA in histopathology and cytopathology, the Departme nt of Health established a Working Group on Histopathology EQA Accreditation. The College and the Associati on of Clinical Pathologists were represented on this Working Group which wa s chaired by Dr Peter Furness, with the following membership: Dr BW Codling, Dr DJ Goldie (CPA observer), Dr AM Lessels, Prof AJ Malcolm, Prof JP Sloane, Prof JCE Underwood. The Working Group's draft report was then subjected to widespread consultation by the De partment of Health. In the light of comments received, the Working Group produced the fina l report, which has been endorsed by the College and is reproduced in full in this booklet.

Acting on the Working Group's recommendations, the College has established the Steering Committee for EQA in Histopathology to be chaired by Dr PF Roberts (Consultant Histopathologist, Norfolk & Norwich Hospital), with the following membership: Dr S Beck, Dr CM Boyd, Dr P Furness, Dr C Gray, Dr M Lesna, Dr AM Lessels, Dr AD Ramsay, Prof JP Sloane, Prof JCE Underwood. The remit of th e Steering Committee is summarised in the Working Group's report.

Some aspects of these developments merit emphasis. CPA(EQA) will be responsible for accrediting EQA schemes; compliance with CPA's EQA standards is likely to strengthen the educational benefit of participating in accredit ed schemes. The College will be responsible for setting performance standards and for inve stigating any substandard performance. Performance standards will be a matter for the Steering Committee and the investigation of substandard performance will be initiated by the National Quality Assurance Advisory Committee for Histopathology and Cytopathology. It is recognised that EQA schemes cannot mimic fully the routine clinical situation and there are limitations in using EQA as a surrogate for assessment of clinical competence. Therefore, the principal function of EQA is to continue to maintain and improve standards through *education* rather than by performance surveillance. The emphasis on education is throug h confidential feedback of performance to individual participants prompting, if necessa ry, their own action for improvement, and by discussions and relevant literature dissemi nated through local and national schemes.

The emphasis on education is reinforced in the NHS Executive Letter EL(98)2 which states:

> *"...in common with EQ A schemes in other pathology specialties their principal function is educational rather than as a means of performance assessment. They should complement the other systems in place for the early identification of potential problems which might affect patient care, and the identification of individual poor performance through an EQA scheme will be exceptional."*

We recognise that the workload of consultant histopathologists and cyto pathologists has risen significantly in recent years, in both volume a nd complexity. In addition, the time and effort required to sustain the improvement in diagnos tic standards undoubtedly adds to this burden.

The College must however, with its Members and Fellows, continue to show its commitment to leading developments in quality standards in clinical practice, and we therefore strongly commend and support the Working Group's reco mmendations. These recommendations also enable histopathologists and cytopathologists to have a major role in implementing the concept of clinical governance enunciated in the White Paper on *The new NHS*.

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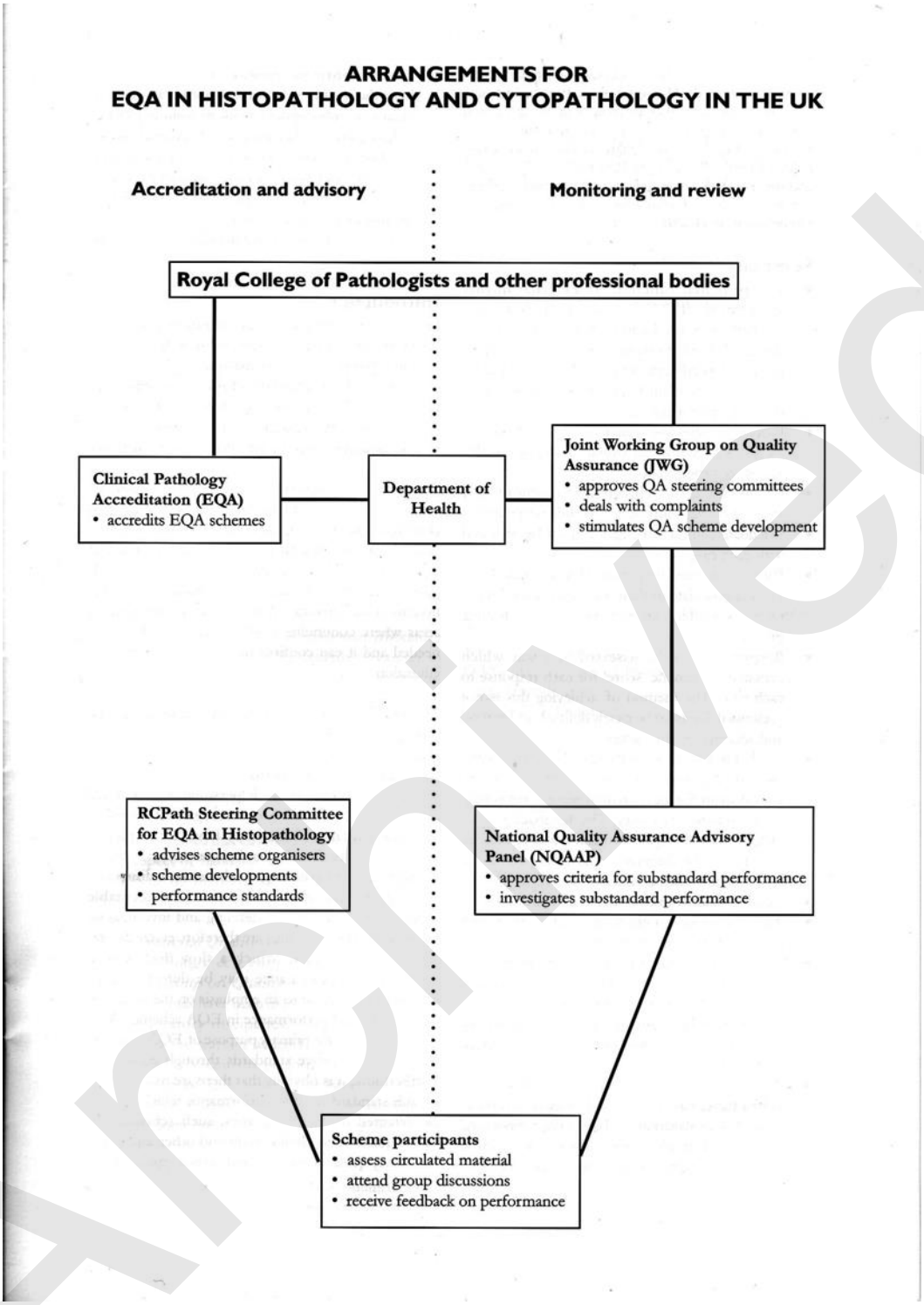
April 1998



These recommendations were developed by the Working Group on Histopathology External Quality Assessment Scheme Accreditation, from the discussion document "Standard operating procedures for Histopathology External Qual ity Assessment Schemes" published in the *Bulletin of the Royal College of Pathologists* [1], and subsequently ame nded after consultations carried out by the Royal College of Pathol ogists and the Department of Health.

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Summary

- The principal function of external qualit y assessment (EQA) in histopathology and cytopathology is education. Educational valu e is derived not only from the content, but also from personal feedback which allows individual participants to identify and correct problems in their own performance.
- External quality assessment, like clinical au dit, is an essential part of an overall laboratory quality assurance programme.
- Circulated cases must be typical of routine practice and not rarities more suited to slide seminars.
- Adequate clinical information must be provided with each case.
- Participants must be permitted to examin e EQA cases appropriate to their routine practice, and to omit cases which are not part of their routine practice.
- Responses must be assessed in a way which generates a numeric `score' for each response to each case. The method of achieving this is not prescribed, but must be clearly defined, understood and accepted by the participants.
- Feedback to participants should relate to the individual pathologists who normally accept responsibility for the content of reports , rather than to the whole laboratory. The feedback should include, if necessary, in formation and references to support the diagnosis. The emphasis of the feedback must be on education.
- Confidentiality must be strictly assured.
- There must be a defined procedure by which complaints by participants are handled.
- Schemes should have written operating proc edures, which are made available to all participants, covering all aspects of sche me organisation, opera tion and performance assessment. Regional schemes should seek to operate to common agreed standards.
- A confidential mechanism to evaluate sub-st andard performance has been devised which concentrates on finding explanations and providing support and solutions, but which can assist in protecting standards of pa tient care if this is necessary.
- Sub-standard performance in an EQA scheme can have many causes, so it must not be assumed to equate to sub-standard work in routine practice unless there is other evidence. Conversely, good EQA performan ce cannot guarantee good routine work, so other audit measures are also necessary.
- These developments require that EQA schemes are more closely regulated; oversight mechanisms in line with those in place in other disciplines are described.

Introduction

Diagnostic histopathology external quality asse ssment (EQA) schemes involve the circulation of `test' material to participants, usually consisting of histological sections and appropriate clinical information. Diagnoses and comments are returned to the person who organises the scheme, and reports rela ting to individual performance are returned to the participants.

EQA is an important educational tool in Hist opathology. The educational component has two elements. First, viewing the material circulated will be educational. Second, *Quality Assessment* requires that *quantitative* feedback must be provided for each participant. This feedback has educational value, because it can provide unambiguous information on areas where continuing medical education (CME) is n eeded and it can confirm the effectiveness of that education.

The use of quantitative feedback inevitably mean s that some pathologists will perform better in EQA schemes than others. Experience shows that a small number of individuals persistently perform at a low level in such schemes. The causes of such `persistent sub-standard

performance' have never been investigated, for reasons of confidentiality. Some may have a completely acceptable cause, but it must be assumed that others will represent histopathologists whose *routine* diagnostic performance has also fallen below an acceptable standard. Mechanisms for defining and investigating sub-standard performance are therefore essential, and will form one way in which a slow decline in a pathologist's performance may be detected. This consideration has led to an emphasis on the detection of sub-standard performance in EQA schemes. This should not mask the primary purpose of EQA schemes, which is to improve standards through education. Furthermore, it is obvious that there are many causes of sub-standard routine performance which will *not* be detected by EQA schemes; such schemes are complementary to clinical audit and other aspects of laboratory quality assurance, and do not replace them. These aspects of interpretative EQA are clearly recognised in a recent Executive Letter on the subject (EL(98)2) which states that "*...their principal function is educational rather than as a means of performance assessment"* and "*...the identification of individual poor performance through an EQA scheme will be exceptional*." (Para. 6)

The possibility that sub-standard performance in a diagnostic histopathology EQA scheme could lead to investigation of the competence of an individual histopathologist makes it vital that schemes are well-run and properly regulated. This document represents an outline of how schemes should be run, how sub-standard performance may be defined, and what remedial measures may be taken to ensure that standards of patient care are maintained.

Oversight of EQA schemes

In parallel with EQA schemes in other disciplines, there will be three types of oversight.

1) CPA(EQA)
Laboratory accreditation by CPA requires that laboratories participate in relevant EQA schemes (Standard F1). Clinical Pathology Accreditation Ltd (CPA) has already set up a new wing, CPA(EQA), to accredit EQA schemes which are of a sufficient standard to be accepted in consideration of laboratory accreditation. This requires the scheme Organiser to affirm compliance with a number of defined Standards, followed by an inspection before EQA accreditation is confirmed; the system parallels laboratory accreditation. This mechanism has already been accepted in other laboratory disciplines; its extension to Histopathology required some minor adjustments to the Standards, which have been agreed by CPA(EQA).

It must be stressed that CPA(EQA) will not be involved in any aspect of handling sub-standard performance, nor will it be involved in day-to-day running of schemes.

2) The National Quality Assurance Advisory Panel (Histopathology & Cytopathology) of the Joint Working Group on Quality Assurance
Advisory Panels have been in existence for some years in all laboratory disciplines. Their duties include scrutinising the ways in which EQA schemes detect and handle sub-standard performance and also the investigation of individual cases of sub-standard performance as they arise. The Histopathology / Cytopathology Panel (currently chaired by Professor James Underwood) has hitherto only had to deal with aspects of technical quality, but its role also encompasses interpretative schemes, as outlined below.

3) Steering Committee
It is part of the CPA(EQA) Standards that the Organiser of an EQA scheme should not run the scheme in isolation, but should receive the advice of a suitable Steering Committee on practical aspects of scheme management. Its remit is to advise the Organiser on the scope, organisation

and development of schemes and on performance criteria, data an alysis and data presentation. It should audit overall scheme activities. It should provide a route by which participants in the EQA scheme should be able to lodge complaints about the running of the scheme, if a problem arises which is not resolved by discussion with the Organiser. The Steering Committee should review each scheme's activities at least yearly, and should be cons ulted before any major changes to a scheme are implemented.

Many histopathology EQA schemes serve a limited geographical area, as it would be impractical to run a satisfactory scheme for general histopathology on a national basis. Consequently, to facilitate harmonisation of EQ A schemes across the country all schemes will be required to use a single Steering Committee, which will be set up under the auspices of the Royal College of Pathologists. It will liase closely with the existing Histopathology technical EQA steering committee (SAG). It will include representatives with experience in local general histopathology EQA, national specialist EQA a nd cytopathology. Its membership will be drawn predominantly from district general hos pitals rather than teaching hospitals.

Financial support for these bodi es is discussed below.

Types of scheme

Diagnostic histopathology EQA schemes exist on a local basis and a national basis. Local histopathology EQA schemes cater for the need s of general histopat hologists. These should cover any material which a general histopat hologist should be capable of reporting.

Some types of material are routinely reported onl y by histopathologists with a special interest in a single organ system. In recognition of the need for these pathologis ts to participate in EQA relevant to their special expertise a limited number of national schemes have been set up. Currently these include Neuropathology, Rena l pathology, Oral pathology, Ophthalmic pathology and Orthopaedic pathology. The existence of these schemes does *not* mean that straightforward specimens from these organ systems are not appr opriate for general diagnostic histopathology EQA, nor does it mean that st raightforward cases from these systems must always be referred to a pat hologist who participates in th e relevant National scheme. More recently, national specialist schemes have been se t up relating to organ systems which are, for most histopathologists, covered adequately by the activities of general EQA schemes; for example, gynaecological and urological pathology.

The choice of which scheme(s) an individual s hould join must initially be made by that individual, but its appropriateness will be revi ewed by CPA in the process of laboratory accreditation.

Cytology EQA
An EQA scheme in cervical cytology is currently under developmen t, and it is anticipated that it will follow the guidelines in this document and will seek CPA(EQA) accreditation in due course. Schemes in non-gynaecological cytopathology are less well developed or non-existent, largely due to problems with replicating diagnos tic material. The development of such schemes is to be encouraged; it is anticipated that in due course they too will follow these guidelines, as far as the special considerations of their subjects permit.

Scheme organisation

The general running of the scheme should be the responsibility of one individual, referred to as the Organiser. The Organiser will normally also be a participant in the scheme.

Schemes may choose to have an `organising committee' with a rotating membership drawn from the participants; the Chairman of such a committee may then be considered to have the function of the Scheme Organiser. This approach is likely to be practical only in schemes which are limited to a small geographic area.

The scheme must have written documentation of its procedures , describing how the scheme runs, how cases are selected, how the assessment mechanism operates, how the criteria of sub-standard performance are defined, what steps are taken when sub-standard performance is identified and what pathways are open to partic ipants who seek to improve their performance. This documentation must comply with the Standards and Guidelines of CPA(EQA).

The scheme must have a clear definition of who is eligible to participate.

There must be a defined mechanism by which participants can pursue complaints about the way in which the scheme is run. If satisfaction is not obtained by discussion with the Scheme Organiser, or if such discussion would break confidentiality, the route will usually be to the Steering Committee.

It is important to hold meetings of participants , at least annually, at wh ich all aspects of the running of the scheme may be discussed. This discussion may include the identity of the Organiser; the meeting may institute a change of Organiser if that is considered appropriate. The wishes of such meetings should be followed, subject to adherence to nationally agreed guidelines. For example, if a majority agree that a case was, for whatever reason, unsuitable for EQA purposes then that case should not be used further in any personal performance analysis.

It is a responsibility of the scheme Organiser to make all relevant written information about the scheme available to participants when th ey join the scheme and whenever changes are made.

Funding

Running an EQA scheme requires financial suppor t to pay a part-time secretary, to provide computing, printing and photocopying facilities and postage. There are other costs which may be `hidden', including the organiser's time, specimen preparation and the costs of buildings, heating *etc.* At present, schemes are funded from a variety of sources. In the future, it is anticipated that schemes will be funded on a non-profit making basis by subscriptions from participants. The cost to laboratories will be rela tively small compared to the cost of EQA in other laboratory disciplines, and will have to be passed on in contract prices to commissioners. The basis for this is explained in the Executive Letter EL(98)2, dated 23rd January 1998, which has been sent to all NHS Trust Chief Execu tives, Health Authority Chief Executives and SHA Chief Executives (Paragraphs 8-10).

Subscriptions will have to be set so that sc hemes can fund the activities of the Steering Committee and the Advisory Panel, and pay fo r CPA(EQA) accreditation. If a Scheme organiser elects or is asked to attend a meeting of the Steering Committee or Advisory Panel, the scheme will have to meet the Organiser's travelling expenses. CPA(EQA) has agreed with the Department of Health to set its accreditat ion fee at no more than 2 % of annual scheme turnover (subject to a minimum which has not yet been agreed). As the Steering Committee and the Advisory Panel are small and cover all EQ A schemes, these costs should also be small.

It is anticipated that oversight of the financ ial arrangements will be performed by the host institution, in much the same way as research contracts are managed. The Steering Committee will expect evidence that the host instituti on is not running the scheme at a profit.

Specimen selection

Cases should be contributed by all participants in rotation, following agreed guidelines. They must not be all selected by one person.

The material used in the EQA Scheme should be selected by a clearly defined method which is understood by the participants, such that the ma terial bears some resemblance to a routine workload. Extremely `simple' cases may be avoided, to an extent to be determined at meetings of the participants, but bizarre cases and ca se-report material ar e not appropriate. One suitable method would be to ask participants to contribute cases, in rotation, from those personally reported within a defined brief time peri od. The `difficulty' of the cases can then be adjusted by modifying the time within which the case must have been received.

Since the intention is to mimic cases which form part of the diagnostic workload, it is not acceptable to withhold relevant clinical info rmation which was available when the initial report was formulated. An EQA scheme is not a `slide club' and should not supplant such activities.

The availability of special stains *etc*. poses problems. If special stains which contributed to the formulation of the original report cannot be ci rculated, then a photogra ph may be circulated or the interpretation of the submitting pathologis t may be described. If the absence of a special stain has genuinely caused diagnostic difficulty, the meeting of participants may need to decide whether the case is suitable for personal analysis.

Schemes may wish to include a small proportion of `difficult' ca ses to add interest and to enhance the educational element, but these s hould be clearly identified as such to the participants and should not be used for s ubsequent personal perf ormance analysis.

The number of cases circulated must be sufficient to permit reasonable confidence that serious sub-standard performance will be identified wi thin a reasonably short time. The methods by which this may be achieved are discussed below.

Feedback and confidentiality

Schemes must have some form of confidential coding of participants, where the key linking codes to pathologists' names is he ld by one person, usually a secretary (referred to as `the EQA secretary'), whose role in the scheme is to put numbered letters and reports into correctly addressed envelopes. By this method Organisers can be kept in ignoran ce of the performance of all participants except for their own. This me thod can also be used if it is necessary for the Organiser to send letters to participants discussing their personal performance. The EQA secretary addressing the envelopes can be kept in ignorance of the contents.

Schemes must have a method of analysis of coded responses from participants which can provide confidential personal reports to indicate each participant's performance, and to allow the individual to draw comparisons with the relevant peer group. The requirements of such a system are discussed below.

The assessment mechanism
The provision of a personal score to each partic ipant is the most important way in which EQA schemes differ from slide clubs. Participants in schemes which undertake such scoring will attest to the fact that it introduces a furthe r dimension to the educational benefits of the schemes, and helps to pinpoint areas requi ring continuing medical education.

Appropriate cases
For a case to be appropriate for use in an EQA assessment system, it is necessary that, after the case has been circulated and the opinions of the participants collated:

i) one diagnosis has been agreed by a large proportion of the participants. If not, then either the case is so difficult that it should be in the `education and interest' category or there was something misleading about the material circulated;

ii) there is no good evidence that the most popular diagnosis is `wrong';

iii) any other diagnoses proffered differ significantly from the most popular diagnosis.

The participants' meeting
After the cases have been circulated and diagnoses have been received by the Organiser, they should be discussed at an open meeting of participants. Such meetings also have an educational component. Decisions on whether an i ndividual case fulfils these criteria should be made by the meeting of participants rather th an by the Organiser; if not, they should not be used for personal performance analysis. The Part icipants' Meeting should also be a forum for discussion of all aspects of scheme management, subject to adherence to national guidelines and the oversight mechanisms outlined above.

Methods of assessment
It is anticipated that schemes will adopt a method of assessment which results in each pathologist being given some form of confidential numeric `score'. Various methods of achieving this are already available, both computerised and manual. The Steering Committee is responsible for advising on appropriate mech anisms. However, the method of assessment must:

i) be understood and agreed by the participants;

ii) allow each participant to evaluate their performance objectively against the best, the worst and the mean of the group, and iden tify specific areas of weakness;

iii) allow no advantage or disadvantage to any participant in comparison with the whole group;

iv) be acceptable to the Steering Committee and the National Quality Assurance Advisory Panel.

The method of scoring must not rely on one indi vidual to define what is a `correct' diagnosis in every case; it would otherwise be open to idiosyncrasy or even abuse . An appropriate method is to use the consensus of the whole grou p, as expressed in their responses. Consensus may also be sought at the open meeting of participants, or from a smaller group drawn from the participants on a `rolling' basis. If outside `experts' are needed then the case is probably not appropriate for EQA purposes; the pa rticipants' meeting should decide.

Release of results
The communication of results between Organiser and participants must be confidential. By using a secretary to link partic ipation codes to addresses (as outlined above) it should be possible for the Organiser to remain unaware of individuals' results.

Failure to respond
Individuals may have good reasons occasionally to fail to participate, so an occasional failure to participate should be omitted from the asse ssment rather than being recorded as a low score. However, schemes must have a defined minimum rate of participation which justifies the issuing of a `certificate of participation'. Th e initial suggestion is that participation in two out of any three consecutive circulations is required.

Certificates of participation can be used to claim CME credits and can be shown to CPA laboratory inspectors as evidence of participation in relevant schemes. Such participation is a condition of CPA laboratory accreditation, so adequate EQA participation will become a requirement for laboratories wh ich seek accreditation.

Participation certificates will document only the fact of participation, not measures of performance.

Variations in individual practice
Mechanisms are needed to allow for variations in pathologists' practice. For example, many pathologists normally see cases fr om a limited range of organ systems. Participants must be allowed to inform the Organiser of areas wh ich are outside their normal practice, and thereafter be allowed to omit responses to cases in that area. The consequence of such a request would be that the excluded area would be identified on the certificate of participation which will be required for laboratory accreditation purposes.

Apart from such `excluded areas', responses with in one circulation must be on an `all or none' basis; failure to provide a diagnosis for a case should be considered to be a diagnostic error.

There is a trend in large depart ments for pathologists to become more specialised, to a small number of organ systems. Such pathologists may find their work best covered by the specialist national EQA schemes rather than a local general EQA scheme.

Consultation
Consultation with colleagues is an important pa rt of routine diagnostic practice. However, if pathologists correctly identify their areas of normal practice (as outlin ed above), and if the cases are correctly chosen as EQA material rather than rarities, the desire for consultation should be infrequent. Furthermore, if consultation is permitted in EQA schemes, it would be impractical to regulate or limit its extent. Extensive consultation woul d make any attempt to evaluate personal performance meaningless. The maximum educational benefit is obtained when EQA schemes provide feedback on the opinions of individual pathologists, rather than those of their colleagues. Consequently, consultation with colleagues is not acceptable in EQA schemes.

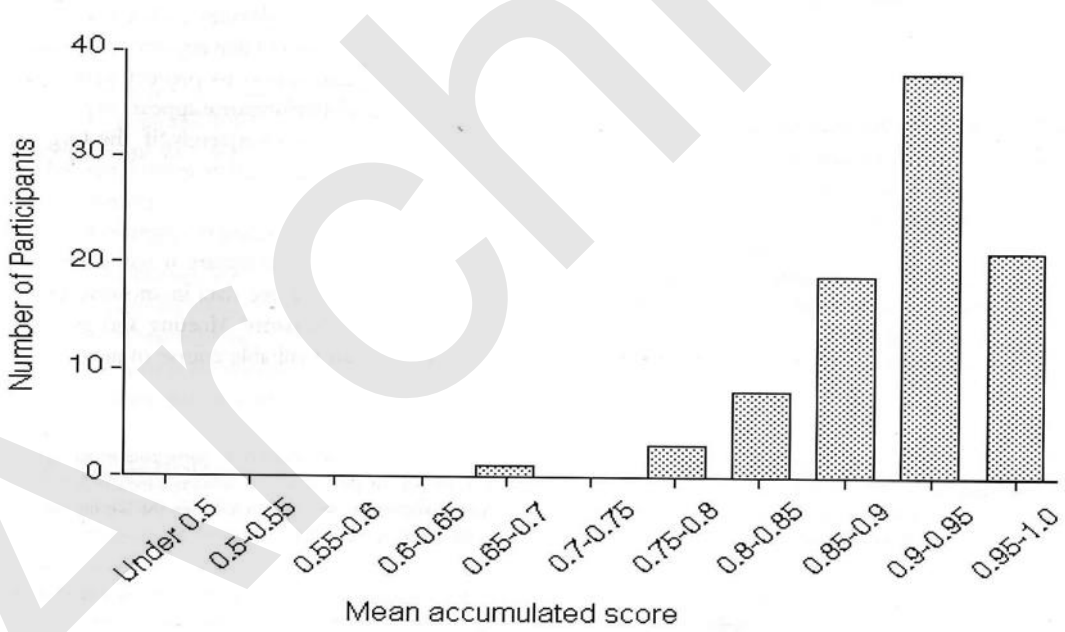
Development of a uniform national standard
It is important that criteria of sub-standard performance do not vary across the U.K. It is anticipated that in the course of time, mech anisms will be developed by which EQA schemes can exchange material, to allow compar ison of responses between schemes.

Defining 'action points'

The introduction of any scoring system inevitably means that some participants will gain higher scores than others. In the vast majority of cases low scores will facilitate self-directed continuing medical education and no further action will be needed; but there exists a possibility that a pathologist's responses in an EQA scheme could be of a standard which gives cause for concern.

Experience of EQA scoring systems has shown th at a group of pathologists typically produces a distribution of scores similar to that shown in Figure 1. It is *likely* that the `outlying' pathologist with a low score has an entirely i nnocuous explanation, such as having responded to cases in organ systems which are outside that pathologist's norma l area of practice. However, the presence of `outliers' with low scor es puts the Organiser in an invidious position, because there is a *possibility* that the participant's performan ce might have genuinely declined for some reason, to an extent which puts patien t care at risk. The Organiser therefore cannot ignore the situation; every doctor is obliged by the General Medical Council to take appropriate action if the performance of a colleague is suspected of being a danger to patients. In at least one case, members of an informal slide club which did not `score' responses were criticised for not acting when one member repeatedly produced erroneous diagnoses. The Organiser of a formal EQA scheme would, in a similar situation, be liable to much more severe criticism and possibly disciplinary action.

Figure 1. A typical (but fictitious) distributi on of pathologists' average scores, accu mulated over 5 circulations, in a diagnostic histopathology EQA scheme which scores responses on a scale of 0 (incorrect) to 1 (completely correct)



Although every other discipline in Pathology ha s EQA schemes which include scoring systems and clear definitions of what constitutes persis tent sub-standard performance, it is obvious that diagnostic histopathology EQA schemes are fundamentally diffe rent. Opinions, not measurements, are involved; the performance of individuals is being assessed rather than whole laboratories. However, if systems are designed carefully there is no reason why histopathology should remain an exception, and there are cogent reasons why our patients should expect this standard of care and responsibility from us.

Sub-standard performance in diagnostic histopathology EQA schemes does not necessarily equate with poor performance in routin e practice; rather it indicates there *may* be a problem, and therefore there is a need for peer review rather than immediate action to protect patients. If a definition of persistent sub-standard performa nce is properly drafted, occasions when it is detected should be infrequent. Furthermore, we anticipate that in most cases it should be possible for the participant to take appropriate remedial action without anyone else knowing who was involved. Only in exceptional cases will it be necessary to break confidentiality and invoke a peer review process.

The proposed form of such a peer review process is described below, but it is appropriate to emphasise that the need for action would be d ecided upon by `peers', not international experts in the field. The review process would first seek an explanation of the low scores in the design of the EQA scheme; it would then concentrate on the participant's routine work, including the conditions of work, rather than exclusively studying the erroneous EQA responses. In order to protect patients, the final sanction of suspension or compulsory re-training must be available, but this should be an extremely rare event.

Hence it is necessary to define `action points' at which the Organiser must take steps to investigate persistent sub-standard performance. Such action points must be clearly explained in the documentation of the scheme, and must be made known to participants. They must not require subjective interpretation by the Organi ser. They must be fair, and must not be activated unless a participant's EQA performance is clearly below standa rd; but they must be as sensitive and rapid as possible in order to en sure that any problem is identified as soon as possible.

It is impossible to identify a single minimum acceptable score, as there will be variations between schemes in the difficulty of the cases and in the method of scoring. Even within one scheme, the difficulty of the cases and the methods of analysis are likely to vary considerably over time.

The best available approach is to compare indi viduals' scores with those of their peers. In Figure 1 the distribution of scores in the group is not `normal', so non- parametric methods are the most appropriate tools for further analysis.

Definition of the first action point

Three definitions of an action point have been c onsidered, of which the first is essential as it minimises subjective interpretation.

1) After each circulation has been `scored', the Organiser should put the scores into rank order and note the participant code numbers of the bottom 2 1/2% of participants. Any pathologist can make occasional erroneous diagnoses, so the first action point should be defined as when a participant's code number has been noted in this way in two out of three successive circulations in which that individual participates.

(This approach has been tested in the Nati onal Breast Screening EQA Scheme and in the National Renal Pathology EQA scheme. It results in the identification of a very small number of participants. In the past, there has been no mechanism by which the causes of such performance could be investigated, but review of the individual responses confirms that this approach identifies only individuals whos e responses had already caused the scheme Organisers some subjective concern).

2) Schemes may also, in suitable circumstances, choose to have additional, more subjective, criteria for action. For example, the Participan ts' Review meeting may be asked to categorise some errors as `serious'. Experience suggests that consistent identification of *clinically* serious

errors is difficult and contentious. Furthermore, some errors of no clinical importance may be of such a bizarre nature as to raise obvious que stions of competence. Consequently, a `serious error' may be better defined by pathological than clinical criteria. In this context, a definition of sub-standard performance must be drafted not in absolute num bers of errors, but in relation to the number of such diagnoses made by the whole group; otherwise, the definition would vary with case difficulty and the criteria for defining `serious'.

3) Nothing in this document detracts from th e GMC requirement that any doctor should take appropriate action to protect patients if a colle ague's performance appear s to put patient care at risk. Consequently, if the Organiser becomes convinced that action is needed, there is an obligation not to delay. However, if doubt re mains in the Organiser's mind as to whether rapid action is necessary it will probably be prude nt to put the data in anonymous form to the Participants' Meeting and ask advice on the most suitable course of action.

These recommendations will be kept under review by the Advisory Panel in the light of the number and character of cases which are referred to the Panel. The definitions may also be modified for specific schemes (subject to advice by the scheme's Steering Committee) when approval of the scheme is sought from the Advisory Panel.

Remedial action

Reaching the first action point would result in a `Dear Colleague' letter being sent by the Organiser to the participant, pointing out the position, inviting an explanation offering assistance, and explaining the next steps. Th is letter should be sent using a confidential mechanism in the EQA scheme office, using the scheme's confidential codes and the services of the EQA secretary, so that the Organiser remains unaware of the identity of the recipient of the letter.

The recipient of such a letter will be asked to write to the Organiser, through the EQA secretary and thus identified only by code number, confirming that the letter has been received, and preferably offering an explanation and su ggesting a remedy. If such an acknowledgement is not received within a month the Organiser w ill write again. If an acknowledgement is not received within two months the Organiser will contact the Chairman of the Advisory Panel, as outlined below.

Definition of the second action point

After the first action point has been reached, the Organiser should record the event against that participant's code number.

The definition of the second action point may then be exactly the same as the first. However, at this stage failure to participate in a circulat ion will be recorded as a score within the bottom $2^1/2$ % of the ranked order, otherwise withdraw al from the scheme could cause a delay in further assessment.

This slightly closer surveillance should be continued for three circulations, after which the conditions of participation should return to t hose applied to all othe r pathologists in the scheme. The presence or absence of a plausible reason for the sub-standard performance should not affect this procedure.

Remedial action

The following procedures do not over-ride the GMC-imposed obligations on any doctor to take action to protect standards of patient care . Furthermore, although there is emphasis on

the maintenance of confidentiality, these proc edures do not preclude the development of local agreements to resolve problems. The participan t in question may choose voluntarily to break confidentiality; for example, the participant m ay wish to inform appropriate managerial staff if it can be demonstrated that poor EQA performance is a consequence of poor local conditions of work.

When the second action point is reached, th e Organiser will inform the Chairman of the Histopathology National Quality Assurance Adviso ry Panel, who will initiate an appropriate investigation. The Organiser will provide to the Panel Chairman and to the participant details of the EQA responses which have resulted in this referral. This can again be done anonymously through the EQA secretary who holds the key to the participant's confidential code.

The task of the investigation is to determine whether the low EQA scores relate to standards of routine practice which may put patient care at risk. The investigation will therefore seek all possible explanations of the low scores, including a review of the nature of the EQA scheme, but concentrating on the participant's routine practice, including conditions of work. The emphasis will be on tracing problems and implem enting remedial measures rather than punitive action.

The Chairman of the Panel will correspond with th e participant. This can initially be carried out through the EQA secretary and need not requi re breaking of confidentiality. If that correspondence does not satisfy the Panel Chairman that there is an acceptable explanation and patient care is not being put at risk, the pa rticipant's name will be released to the Panel Chairman, enabling a direct conversation and possibly a site visit.

The Panel Chairman may choose to delegate this phase of investigation to a respected local pathologist, if the Chairman and the particip ant can jointly identify an individual who is acceptable to them both.

The Chairman of the Panel should discuss the problem with the other members of the Panel, but in such a way that will not reveal to the other members the identity of the pathologist under review.
These steps should be completed with reasonable speed; a few weeks at most. If the Chairman of the Advisory Panel has still not been satisfied of an innocuous explanation, or if any lack of co-operation appears to be slowing the evaluati on, the Chairman of the Joint Working Group on Quality Assurance will be informed, and will pass the matter to th e appropriate body. In the case of histopathologists, that body w ill be the Royal College of Pathologists.

The matter will be passed to the Professional Performance Committee, which has been set up by the Royal College of Pathologists to ha ndle any questions of professional competence, however such questions arise. This will organ ise a review by a panel of three of the pathologist's peers, one of whom will have be en selected by the pathologist under review, preferably identified on joining the EQA scheme rather than when problems arise. If the problem cannot be resolved or if it is considered that patients are at risk, it would then be necessary to ensure that the Medical Director of the hospital concerned had been informed.

The effects of these proposals will be kept und er close scrutiny and will be amended if an inappropriate number of pathologists are being referred to the Advisory Panel Chairman.

These procedures should be activated only in exceptional circumstances, and should cause no more concern to EQA participants than the current possibility of being reported for incompetence by a colleague. The main purpose of Histopathology EQA schemes should

remain educational, as it has remained in other disciplines. We anticipate that EQA schemes will continue to be valued by pathologists for this reason.

In recommending accreditation of histopa thology and cytopathology EQA schemes by CPA(EQA) Ltd. it must be emphasised that CPA will not be involved in any way in the investigation of substandard performance. CPA's onl y interest in this regard is to be satisfied that accredited EQA Schemes have explicit and validated criteria for substandard performance, and a confidential mechanism for its investig ation. There are conse quently considerable advantages to histopathologists and cytopat hologists to participating in EQA schemes conforming to CPA(EQA) standards.

Implementation

The possibility of implementing these proposals in a `pilot' phase was considered. However, it is evident that although some schemes will be able to implement these proposals quite quickly, others have major changes to make and will take l onger. It is therefore proposed that the effect of these proposals will be monitored by the Advisory Panel as schemes voluntarily seek CPA(EQA) accreditation over the next two years.
It is anticipated that all schemes will have sought accreditation by the end of 1999, by which time participation in appropriate accredited EQA schemes will be an essential part of CPA laboratory accreditation.

Reference

1. Furness PN. Standard operating proce dures for Histopathology External Quality Assessment Schemes. *Bulletin of the Royal College of Pathologists* 1995; **92**:22-25.

Action to be taken by EQA Scheme Organisers who wish to obtain accreditation by CPA(EQA) for their schemes

- Review the current practices of your scheme in the light of the requirements of the Standards and Guidelines of CPA(EQA), and the recommendations in this document.
- Consider what changes in the running of th e scheme are necessary and how these might best be achieved.
- Write the results down in the form of a set of Standard Operating Procedures.
- Circulate the SOPs to your participants, a nd seek their approval. Amend the SOPs as necessary.
- Submit your SOPs to the Steering Committee for discussion; if any changes are required, consult your participants.
- Submit your methods for participant scoring and definitions of sub-standard performance to the National Qu ality Assurance Advisory Panel (Histopathology) of the Joint Working Group on Quality Assurance.
- Implement the agreed procedures in at least one EQA circulation. If problems arise, design modifications and seek the approval of participants / Steering Committee / Advisory Panel as necessary.
- Apply to CPA(EQA) for accreditation.

Membership of the Working Group

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Dr AM Lessels
Professor AJ Malcolm
Professor JP Sloane
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Chairman of the Diagnostic Histopathology / Cytopathology EQA Steering Committee
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