

Occasional articles

External quality assessment in histopathology: an overview

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In no other medical speciality is the maintenance of high standards of diagnostic accuracy of more fundamental importance than it is in histopathology. Pathology sees itself as the rock on which the very foundations of medicine are set down; and it is true to say that many of the reports issued by histopathologists include the primary diagnosis on which most other aspects of patient care depend. Pathology reports also claim to occupy a central role in medical audit procedures. As Professor Underwood and his colleagues from Sheffield pointed out in a letter to the *Lancet* earlier this year, "the low necropsy rate in the UK invalidates any form of clinical audit where death is a possible outcome".¹ It is all the more important, therefore, that the whole question of quality assurance should be taken very seriously indeed by histopathologists.

Perhaps it should be made clear at the onset what the term quality assurance actually implies. Quality assurance has been defined as the whole spectrum of quality improving activities which ensure the usefulness of laboratory investigation.² These activities can be divided into two broad groups—namely, *internal quality control* by which is meant the continuous day by day review of diagnostic and technical procedures, supplemented by such activities as case checking and case conferences; and *external quality assessment* (EQA) which involves the objective evaluation of standards by an external agency and is very much concerned with comparisons among laboratories and the assessment of competence within a national or even global context. Many pathologists will no doubt take the view that the quality of the service they provide is basically assured by the rigorous training schedules and examinations which have to be undertaken before becoming a consultant: but they also readily accept the importance of internal quality control procedures. In the past, however, they have

tended to give low priority to EQA even though they recognise the need to minimise interlaboratory variations. Most are also aware that EQA may have other benefits. For example, EQA is undoubtedly concerned with a general improvement in the standards of laboratory investigations and in the minimising of costly diagnostic errors. EQA can also have an educative function through the dissemination of information regarding diagnostic, technical, and managerial procedures. Such laudable objectives have long been accepted by the Royal College of Pathologists³ and represent the philosophy underlying the protocol which was formulated by the histopathology EQA forum and subsequently sent out to United Kingdom regional health authorities for implementation in 1986.⁴

The establishment of the EQA forum in February 1985 signalled the introduction of a more formal element into the whole question of EQA in histopathology. Instituted under the auspices of the Department of Health (DHSS) and the Scottish Home and Health Department (SHHD) the forum also had representatives from the College and the Association of Clinical Pathology (ACP) and was initially chaired and nurtured by Professor JR Tighe. This development was no doubt stimulated by the legitimate public concern which had been expressed about the performance of some of our laboratories in previous years. The need for an EQA forum has, of course, been reinforced by the recent proposals for reorganising the NHS. Central to these proposals is the necessity to improve medical audit procedures.⁵ It is also somewhat ironical that the relationship between the NHS and the private sector may also have precipitated further action in this area. It is not by chance that EQA schemes have been much more assiduously developed in countries such as Australia and the USA in which a large amount of laboratory work is carried out in the

private sector. It is clearly advantageous for private laboratories to be able to claim that their services are subject to quality assurance procedures. Whether we like it or not this would also apply to NHS laboratories, which in future may well have to pursue contracts not just in the private sector but in the new self-governing NHS hospitals.

The prospect of participating in EQA schemes of any kind has not met with universal enthusiasm among histopathologists as the initial response to the EQA forum initiatives can testify. There are several reasons for this. For one thing EQA presents organisational difficulties. Histopathology EQA schemes as currently envisaged have to be essentially regional in scope, and it is plainly a great advantage if some kind of local mechanism exists whereby the scheme can become established and through which information can be disseminated. The presence of a local enthusiast may have an even more catalytic effect. EQA has met with some success in Scotland because it consists of closely knit communities usually centred around a large teaching hospital. There is also a national histopathology (and cytology) subcommittee which, as part of a larger organisation called the Scientific Services Advisory Group, provides a useful mechanism for coordinating activities such as EQA. In Northern Ireland, which participates in the West of Scotland EQA scheme, the histopathological services also have this closely knit organisational structure. The main reason for the apparent lack of enthusiasm among pathologists for EQA in histopathology, however, is that it is concerned more with the *interpretative* rather than the technical aspects of the specialty. It is, of course, quite true that histopathology is not unique in this regard. There is certainly an interpretative component in haematology EQA and to some extent in microbiology as well. Even so, in histopathology it is the central feature of EQA. Many pathologists would actually welcome more in the way of *technical* EQA schemes judging by the success of the immunohistochemistry scheme which has been operating (from Mt Vernon Hospital) for the past four years. Such schemes have obvious benefits because laboratories which encounter difficulties with immunohistochemistry procedures would obviously like to know why this happens and how improvements can be made. This model could be applied with advantage to other technical procedures.

The position with regard to the interpretative component is a different story. Here it is consultant performance which is being tested. Not surprisingly, consultants have in the past been reluctant to participate in EQA schemes unless they can receive assurances about certain basic conditions. These are: first, that participation should be voluntary; second, that the results (whether a scoring system is introduced or not) should remain entirely confidential; third, that the procedure should be an entirely professional matter; and lastly, that the tests should be sensibly

designed. Although laboratories are not specifically mentioned in the recently issued working paper on medical audit,⁶ it is none the less plain that it is going to be increasingly difficult for any of these privileges to be preserved without qualification. It seems, for example, highly unlikely that participation will remain voluntary. Participation in medical audit procedures will almost certainly become a contractual obligation. It is true that assurances are given in the White Paper that the results must remain confidential in any individual case but, "the general results need to be made available to local management so that they can satisfy themselves that appropriate remedial action is taken where audit results reveal problems".⁶ Under these circumstances it is hard to see how confidentiality can be sustained completely. Someone will have to know the detailed results if such remedial action as seems required is deemed it to be "appropriate". This has serious implications for histopathologists. After all, the performance of a histopathology laboratory is very much a function of consultant competence. If something goes wrong it is seldom possible to blame machines or something in the environment, as may well be the case with other laboratory disciplines. Assurances are given that any system will be medically led; even so, it is made plain in the White Paper that, "the form of the audit should be agreed locally between the profession and management".⁶

One must not be too cynical and suppose that this type of arrangement might mean that the tests would become less sensible; no one could ever give a guarantee that such tests would be sensible anyway. Just the same, the protocol issued by the EQA forum presents guidelines for test procedures which are generally acceptable.⁴ There is, of course, considerable controversy regarding the kind of cases that are most suitable for such purposes. It is obvious that as in the final part of the MRCPath the cases must be diagnosable by haematoxylin and eosin with at most one additional special stain, and that the diagnosis must be beyond reasonable doubt. This is not an easy ideal to attain. If followed too rigorously the slide sets would be far too easy. On the other hand, there is little point in circulating rarities. The plain truth is that most errors that arise in practice involve what might be regarded as relatively mundane material. It may be argued that even in such circumstances the diagnosis will always remain subjective to some extent. There are now several studies showing quite serious inconsistencies among consultants in the diagnosis of such lesions as cervical intraepithelial neoplasia,⁷ breast pathology,⁸ urothelial dysplasia, endometrial hyperplasia and even less surprisingly, Hodgkin's disease.⁹ One must not be misled, however, into exaggerating these inconsistencies. What they reveal is that some of the minor nuances of histopathological diagnosis simply do not stand up to rigorous field testing and that there is clearly the need in many areas to establish far more robust criteria, even at the risk of being too dogmatic.

For example, in the study carried out (under the auspices of the SHHD) in Ninewells Hospital in Dundee it became apparent that most consultant pathologists had little difficulty in identifying non-neoplastic states such as immature metaplasia at one extreme and CINIII at the other,⁷ in both of which the value for the κ statistic in all studies undertaken was above the acceptable level of 0.4, and in some reached the excellent agreement level of 0.76. The real difficulties arose in distinguishing between CINI and CINII, in which the κ value was usually much less than 0.4 (mean about 0.25), and between CINI and simple reactive changes due to virus infection, for example. It would seem that if CINI and II were subsumed into a single category called, say, "low grade CIN" as opposed to the "high grade" category represented by CINIII, that the " κ " rating could be substantially improved all round. This designation may also incidentally have clinical value as "high grade" CIN undoubtedly has malignant potential, being usually associated with HPV types 16–18, whereas low grade CIN may well be a benign condition (associated with HPV types 6, 10).¹⁰ Some pathologists, however, have also pointed out that the kind of tests that are generally used are not suitable for pathologists in specialised areas. This may not matter very much. Most pathologists (however specialised) still wish to sustain a general interest in diagnostic pathology, and it may be that in future it will be increasingly difficult for pathologists to restrict their activities to specialised areas. I suspect that in most academic departments even specialised pathologists have to do the routine work like everybody else.

EQA in cytology also has peculiar problems not least of which is control of an interpretative exercise, which by any standard is massive. Whereas diagnostic cytology is carried out by medical staff in much the same way as histopathology, the cervical screening programme involves staff with widely differing qualifications, experience, and degrees of responsibility. Cytology EQA schemes have to take these differences into account. Another problem is that obviously it is not possible to duplicate material, and this implies that the same material must be circulated to all the participants in a particular scheme. This is scarcely possible on a national basis and has led to the development of the "cluster" concept, in which cytology smears are circulated within a limited group of laboratories, and forms the basis of the current EQA Forum protocol. Whether this concept represents, in strict terms, a form of EQA is somewhat debatable. In some aspects it more closely resembles the kind of consistency exercise mentioned earlier with regard to histopathology.⁷ Another way of resolving these various difficulties is the New York Proficiency Testing Scheme at present under trial (in modified form) with the Department of Health Advisory Committee on assessment of laboratory standards.¹¹ Briefly, the main features of this concept is that a

designated person (known as the facilitator) travels around laboratories with sets of slides which have been selected by a regional or national committee and invites all the staff members in a cytology department involved in screening (including consultants) to participate in the test most appropriate to the individual concerned. A series of questionnaires is also provided to acquire data about staffing and workload statistics. The results are then discussed locally and are also referred back to the central organising committees. The aim is, of course, to identify those who perhaps require further training or experience. Needless to say, this project has aroused a great deal of controversy. It cannot be denied, however, that schemes of this kind could be useful if they had clearly defined objectives. It would, for example, be very useful to know if a screener were unable to identify the changes associated with, say, viral infection of the cervix.

To summarise, many pathologists still feel that EQA schemes which predominantly involve the interpretative component of histopathology are both unnecessary and impractical. On the other hand, in the intensely competitive atmosphere in which laboratories may have to operate in future, pathologists must be prepared to face the reality that should voluntary participation prove to be inadequate for administrative purposes much more draconian measures may well be imposed on them whether they like it or not. It is for this reason that pathologists would perhaps be better employed in devoting their energies towards creating useful and educative EQA systems rather than in opposing the concept altogether.

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