OCCASIONAL ARTICLES

Royal College of Pathologists' United Kingdom pilot study of laboratory accreditation

The College Accreditation Steering Committee

Abstract

The Royal College of Pathologists recently commissioned a pilot study to assess the feasibility, desirability, and cost of establishing a national scheme for laboratory accreditation in the United Kingdom. Using a format similar to that designed by the College of American Pathologists, eight inspectors visited 24 laboratories comprising the major disciplines of two district hospitals, two teaching hospitals, a specialised (paediatric) hospital and a private hospital. Nine were considered accreditable without reservation, but 15 had deficiencies identified of differing importance which needed to be corrected before accreditation could be awarded. Problems identified were variable, but none related to technical performance and many did not require extra resources to correct. The exercise was conducted without organisational difficulty at an approximate direct cost of £300 per laboratory.

The study shows that the format used could form the basis of a cost effective nationwide strategy. The type of problems identified suggest that such a strategy is more likely to succeed if it is organised from within the pathology professions.

In many parts of the world the standard of diagnostic pathology is extremely variable. The worst laboratories are frequently guilty of dangerous practice and profiteering, but in that respect Britain is fortunate. There must be very few such institutions in the United Kingdom, though as the Health Service shifts towards a philosophy of market economics it is important to make sure that none is encouraged to appear. It is also arrogant to assume that average standards of British pathology are incapable of improvement, particularly at a time when there is a crescendo of interest in the introduction of clinical audit. The combination of these two incentives has made many pathologists agree that the time is right to follow the example of Canada, the United States, and Australasia in the introduction of a national scheme for laboratory accreditation in the United Kingdom.

Sensitive to this, and as part of its commitment to improving professional standards, the Royal College of Pathologists took an initiative in setting up an Accreditation Steering Committee which commissioned a pilot study. As a result, eight inspectors appointed by the College, and all senior heads of departments, exhaustively examined the facilities and practice of 24 clinical laboratories in one region during the exceptional heat of July 1989.

The departments in question were the four major disciplines of two district general hospitals, two university teaching hospitals, a small specialised (paediatric) hospital and a private hospital. All involved had volunteered for the exercise, the aim of which was simply to assess the feasibility, value, and cost of establishing a "profession-led" accreditation scheme for British pathology laboratories. This report outlines the main findings and conclusions of the exercise.

Methods

The format of the study was loosely based on the system used by the College of American Pathologists. An anglicised and much less detailed protocol was prepared which was prescribed by three basic documents. The first, *Guidelines for Laboratory Accreditation*, contained the general requirements for a laboratory to be accredited together with the codes of practice for the four major disciplines as already prepared by the United Kingdom College specialty committees. The document thus laid out the standards to be attained. The second, *Application for Accreditation*, was designed to be filled in by the candidate laboratories and to provide data on type of laboratory, staffing, workload, repertoire, equipment and quality assurance measures. The third, the *Inspection Checklist*, one specific to each discipline, was designed to be filled in by an outside inspector during an on-site visit and contained detailed yes/no questions about adequacy of facilities, organisation, management, technical performance, quality assurance and safety.

Each inspector also received an *Inspector's Manual* describing intended protocol for the site visit and including an unstructured form for a report. The contents laid great emphasis on the need for inspectors to meet privately with hospital managers and (separately) elected clinical users for a brief appraisal of their opinions of the laboratories to be inspected. Following their visits, in addition to the

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completed checklists, each Inspector submitted a detailed report to the College steering committee about the departments they had visited. This report was eventually transmitted verbatim to the heads of the departments concerned.

There were two teams of inspectors—four in each team. The first group visited the two district general hospitals, spending a day at each, and the second assessed the two teaching units plus the specialist and private hospitals, taking three days in the process. Each team was constructed to "match" as far as possible the laboratories being inspected (professors for the teaching hospitals, for example), and care was taken to ensure that each inspector came from outside the region of the study.

Results

The exercise was completed without organisational difficulty after full and careful briefing of both inspectors and inspected before the event. The general standard of all laboratories was thought to be high, though only nine were considered accreditable without reservation. The remainder had deficiencies identified of a minor or not so minor nature which, in the opinion of the inspectors, required correction before full accreditation could be granted.

The deficiencies noted were wide ranging but few related simply to technical performance or methodology. Few also related directly to safety as the pilot study carefully avoided areas more properly the province of the United Kingdom Health and Safety Executive. Problems identified included, for example: tardiness of report despatch for no obvious reason, poor liaison between clinicians and pathologists, poor relations among pathologists of different disciplines, lack of an isolated blood bank telephone for use during major accidents, excessive cytology and necropsy workload for a single-handed histopathologist, unnecessarily sophisticated repertoire, cramped office accommodation, specimens not dated/timed on receipt, reports not dated/timed on despatch, request forms not containing adequate patient identification data, inadequate microscopes, lack of manual for laboratory users, lack of capital equipment replacement plan, lack of investment in electronic data processing, and lack of a safety cabinet to work on hazardous specimens. This list is indicative rather than exhaustive, and it should be emphasised again that these deficiencies were noted against a background standard of practice that was considered to be uniformly high.

As far as the documents were concerned, inspected departments felt that the application forms could have been simpler. There was a general feeling, shared by the inspectors, that the "Guidelines" document would benefit from careful revision, particularly to achieve homogeniety of style and detail in the various discipline specific codes of practice. There was also a unanimous view that the "checklists" were too long, too detailed, and too time consuming, though everyone appreciated the need for a well defined framework to make the inspection process as consistent as possible. Most inspectors felt that a full day was barely adequate to inspect a large department.

Protocol for teams visiting very large institutions had to differ from that for district or small specialist/private hospitals but it was felt that this was satisfactorily arranged on an ad hoc basis. It was thought useful that there had been a "team leader" for each group of inspectors who had acted as spokesman, coordinated the others, and liaised with the chairman of pathology of the unit concerned. It was also thought important that there had been a local facilitator (the pilot study co-ordinator on this occasion) whose role had been to explain to applicant laboratories what was expected of them and to make practical arrangements for the visiting inspectors.

All inspectors indicated that the visits had been instructive and constructive, a feeling reciprocated without exception by those heads of the visited departments who filled in "feedback" forms immediately after they had been inspected.

After a debriefing meeting of all the inspectors and after their reports had been considered by the accreditation steering committee, a return was sent back to the heads of inspected departments comprising: (a) the unabridged confidential report of the inspector concerned: (b) a "laboratory profile" outlining any deficiencies identified; and (c) a letter from the steering committee indicating that the department had or had not reached the standard required for accreditation. No laboratory was considered to be of such a standard that accreditation should be refused outright. Those departments only provisionally accredited would, if the study were to be adopted as a national scheme, be expected to rectify deficiencies within 12 months or be subject to a further full inspection before accreditation could be reconsidered.

Discussion

Whether laboratory accreditation as attempted in this pilot study is worthwhile could best be assessed by the beneficial effects it seemed to bestow on the inspected laboratories. All had tidied themselves up in preparation for the event; most had improved their written protocols for laboratory use and inhouse methods: many had smartened up their internal organisation and quality assurance programmes, and one had extracted a promise of new equipment from the hospital manager.

Many of the deficiencies laboratories were charged to correct involved relatively little in the way of new resources that were not already planned or anticipated, though in some cases the problems identified suggested the need for considerable organisational review. There were some equipment and staffing deficiencies noted, and it is likely that heads of the departments affected would have found the inspectors' reports helpful in support of bids for improvements.

The usefulness of the scheme for managers based on a small pilot study is much harder to

assess, especially as no report was sent directly to anyone other than the heads of the inspected departments on this occasion. (The decision not to send managers any resumé report was taken because of the voluntary nature of the pilot study, though any national scheme derived from it would almost certainly do so). Despite this, considerable managerial interest in the study was evident, and United Kingdom health authorities and private hospitals would probably pay a modest amount to ensure that their laboratories are of the recommended standard. If they did so it is reasonable to assume that there would be an automatic benefit to clinicians and patients provided the exercise did not shift resources from direct patient care to any important degree.

As far as cost is concerned, it is perhaps rash to attempt to extrapolate from a pilot study to a full scale national scheme, but the main areas of direct expenditure can be identified. These are three. First, administration and clerical time; secondly, the expenses of the inspectors' meetings and visits; and thirdly, office overheads—printing, stationery, postage and telephone. Adding all costs together and dividing by the number of laboratories in the study gives a rough figure of £250–300 per department. Using these figures as a guide, for a national scheme based on a quinquennial renewal of accreditation, a global figure of £500 per department every five years might be enough to cover costs—at 1989 prices. This, of course, only relates to direct marginal costs and assumes that inspectors would work voluntarily and only receive expenses. It does not take into account any charge the inspectors' employing authorities might make for their time.

So, provided enough inspectors can be found, provided the institutions seeking recognition are prepared to pay, and provided the "hump" of initial applications for accreditation from large numbers of first-time laboratories can be overcome, then, based on this pilot study, there is no practical reason why an economical and effective British profession-led laboratory accreditation scheme should not be established.

Whether to proceed with such a scheme on a national basis has yet to be decided. There can be no doubt that the standard of practice in most National Health Service laboratories is already high. It should be noted that accreditation will define minimum standards but will not necessarily provide an effective means of checking profligacy or other unnecessary expenditure (unless performance is impaired) and so will not provide managers with value-for-money audit. For less than adequate laboratories, the tangible benefits of accreditation will be more obvious as they may also be for the private sector where recognised laboratories are likely to be more attractive in their market place, but the main beneficiaries of this type of scheme should be patients who will be reassured that approved laboratories are of an adequate standard.

The problems identified by the pilot study were of particular interest because hardly any related to technical performance (so would not be detected by any EQA scheme), and few, by design, related to safety. Most would not have been picked up by the College or CPSM inspection schemes for professional training, so it seems that accreditation reaches parts of the laboratory service that other schemes cannot reach (with apologies).

It is perhaps helpful to remember that quality control is simply concerned with getting the right result. Quality assurance, which is what accreditation should be assessing, is concerned with much more. It is not just about getting the right result, but getting it from the right test done for the right reason on the right patient. Not only that, but the test should be done in the right way in the right environment by the right staff, then sent to the right clinician at the right time with the right interpretation. It is difficult to see how other than a senior head of a similar department could decide whether all these things were being carried out satisfactorily in any given laboratory.

There is an added incentive to start a profession-led scheme if recognition for training in the pathology professions could be linked with accreditation and so avoid the need for separate training inspection visits. Enthusiasm for this is apparent.

Conclusion

The College accreditation steering committee is convinced that the time is right for a national accreditation scheme and that a profession-led initiative is to be preferred. It feels the pilot study had indicated such to be acceptable, affordable, feasible and potentially effective.

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The steering committee is most grateful to the staff of the departments who willingly offered themselves as guinea pigs for this study, and to the inspectors whose hard work was a major factor in its successful completion.