

Lord Carter's review of NHS Pathology Services

A submission from the Histopathology / Cytopathology Specialty Advisory Committee of the Royal College of Pathologists

Histopathology is unique amongst the disciplines of pathology in that its output is wholly qualitative rather than quantitative. **Histopathology reports are medical opinions, not measurements.** Histopathology reports contain interpretations, explanations, evaluations of probability and clinical judgements. They represent the outcome of a clinical consultation.

Consequently this submission will argue that, to provide a quality service, histopathologists must work side by side with clinical staff. A histopathology services is a clinical service which must be medically managed.

“Access, Convenience and Choice”

The tissue samples sent to histopathology laboratories are obtained by the doctors responsible for the patient's care. The results are returned to those same doctors. It is not currently possible for such samples to be taken in other settings (such as High Street pharmacies). Point of care testing is not a meaningful option for histopathology because of the nature of the specimens and their investigation.

Consequently, from the patient's perspective, 'access convenience and choice' are largely controlled by their doctor. The only significant route by which the histopathology laboratory can influence access convenience and choice is the speed with which the result is returned.

Speed is not the only consideration. **The Lay Advisory Committee of the Royal College of Pathologists has confirmed that patients are most concerned about getting treatment based on the correct result.** Within reason, speed of analysis is a secondary concern to result accuracy. Erroneous histopathology reports can also generate extremely costly litigation. Consequently, although changes to improve speed of analysis are obviously desirable, care must be taken not to compromise other aspects of quality. We are keen to develop and implement changes by which *reliable* results can be returned more swiftly.

The location of histopathologists in relation to patient care

In the pre-analytical phase, histopathologists guide clinicians as to the most appropriate methods for patient investigation. This improves patient care but also facilitates cost limitation, as exemplified by the RCPATH publication '*Histopathology of limited or no clinical value*' (www.rcpath.org), which seeks to eliminate unnecessary investigations. If laboratories have financial priorities which are independent from those of the organisations treating patients then the provision of such advice would be economically counter-productive. Waste would result and services would suffer.

In the post-analytical phase, the importance of close contact between histopathologists and those who receive histopathology reports has recently been emphasised by NICE requirements for histopathologists to attend multidisciplinary team (MDT) meetings in cancer care. More recent NICE guidance (e.g. skin cancer and brain cancer) goes further, insisting that initial reporting of cancer specimens should only be done by histopathologists having full and easy access to the patient, their records and attending clinical specialists.

MDT meetings have value not only in ensuring that histopathology reports are correctly translated into appropriate clinical care; the discussions and case review which they encourage are arguably the most effective quality control tool we have in histopathology. In isolation, histopathology reports have too often been regarded as an invariably correct 'gold standard'. This is naïve. Clinico-pathological discussion results

in review, especially of any reports which clinical staff find unclear or surprising. This has saved many patients from unnecessary or inappropriate treatment.

Data from the National Reporting and Learning System of the National Patient Safety Agency indicate that the single largest group of patient safety incidents in pathology is those associated with problems of identification and communication, at the interface between clinicians and the laboratory. Rapid, frequent and close clinico-pathological communication is essential to identifying, resolving and preventing such incidents.

Attempts to facilitate such communication at a distance, using techniques such as videoconferencing, are currently used in relation to rare conditions, but are very far from ideal. Wider application of such technology has been prevented by several factors including cost, reliability, technical complexity, the need for technical support, inflexibility and the need to schedule conferences in advance.

Frozen section analysis, an essential component of a wide variety of surgical interventions, presents an absolute requirement for a histopathologist to be located close to the patient. In this situation the sample is taken after the surgical patient is anaesthetised on the operating table. The result is needed for the appropriate completion of the operation. Every extra minute taken over the investigation is therefore an additional minute on the operating table for the patient, with consequent increases in risk to the patient and cost to the hospital. Experience demonstrates that the timing of, and sometime the need for, frozen section analysis cannot be predicted accurately, so protocols whereby a histopathologist and technician travel to a site where a frozen section may be needed are hugely inefficient and sometimes dangerous. Conversely, to transport frozen section samples to a pathologist located some distance away will introduce delays during an operative procedure.

Telepathology is used for frozen section analysis in some countries with small isolated hospitals, but this is invariably regarded as a solution to be employed only when geography precludes any other.

Fine needle aspiration cytology is widely used to provide almost immediate results, notably in breast cancer. The resultant 'one stop' clinics are highly valued by patients. This results in the same requirement for co-localisation of histopathologist and patient. Some histopathologists attend patients to take aspirates themselves, an approach which is known to produce the most reliable results (because the operator has immediate feedback on aspiration technique quality).

Post mortem services are best located on site, so that clinical staff can discuss the case with the pathologist and can attend the mortuary and personally view and discuss the effects of disease. Despite the recent decline in the number of post mortem examinations performed in the UK they remain a valuable tool for audit and education. A recent study from Birmingham, of patients who had died after close scrutiny on an intensive care unit, reported that in 39% of cases where a post-mortem was undertaken a major new diagnosis was found – most commonly undiagnosed myocardial infarction, cancer, or pulmonary embolus. (Crit Care 2003;7:R129-32) Consent for post-mortem examinations will not be requested and the benefits will not be achieved unless pathologists and clinical staff co-operate, as has been recently demanded by the Human Tissue Authority's new Codes of Practice. This can only be achieved if clinicians and pathologists are located on the same site.

Some services are so specialised that a centralised service is unavoidable. This provides us with concrete evidence of the problems which result for 'peripheral' sites. For example, **perinatal pathology** has to be organised on a network basis because of extreme shortages of skilled pathologists. Recurrent intractable day-to-day problems arise entirely as a result of the geographical separation of the pathologist and the referring clinician.

The location of histopathology laboratories in relation to histopathologists

If the above arguments are accepted it is evident that it is desirable for histopathologists to be located at the site of clinical care, and that some services make such co-location essential.

Providing immediate results (frozen section and rapid FNA clinics) also necessitates co-location of relevant technical staff and tissue processing. But some organisations have reduced costs by locating histopathologists with the patients, but centralising the bulk tissue processing services. Experience of this approach has shown that the increased financial efficiency has hidden costs:

1. Identification errors have already been mentioned as the single most important cause of patient safety incidents in pathology. Transport to another unit necessitates meticulous identification checks on every sample before dispatch and after receipt. This increases costs and introduces delays. Anecdotal evidence is available to support the logical expectation that it also introduces identification errors.
2. Transport (specimens to the processing laboratory, then microscope slides back to the clinical unit) generates 'batching' rather than linear flow and introduces delays which experience shows can accumulate to several days. This can be mitigated by increased expenditure on transport services; but this diminishes the cost efficiency gains. The temptation may arise later to cut the transport bill when new cost pressures arise and frequent transport services appear to be under-used.
3. Close interaction between histopathologists and biomedical scientists facilitates good laboratory quality control, as those who examine the laboratory output and those who produce it can discuss and resolve technical quality issues together. Failure to do this can result in small biopsies being destroyed without useful information being gained.

Experiments with large histopathology processing laboratories in 'greenfield sites' have also seen losses of staff morale and motivation, with high staff turnover, as workers feel divorced from the patients whom they joined the NHS to help. An evaluation of *all* the costs and benefits of local services versus centralised services is essential before making such complex judgements.

Can some parts of the workload be handled separately?

Most of the above arguments apply most convincingly to large and complex specimens. A few types of specimen, such as some cytological specimens, superficially appear to be reducible to a test with a short list of stereotyped possible results.

It may therefore be tempting to suggest that certain categories of 'simple' specimen could be identified for more efficient bulk processing in off-site 'production line' facilities.

This approach has several pitfalls.

1. It is difficult to identify any category of 'simple' specimen where there is no risk of occasionally encountering a 'complex' problem. For example, biopsies from polyps detected at colonoscopy might be a candidate category. But such polyps very occasionally have unusual causes, such as direct extension of a prostatic cancer – a condition which would demand completely different treatment. Identification of such unusual cases may require considerable skill and is greatly facilitated by the close clinico-pathological dialogue discussed above.
2. A report on a 'simple' specimen often results in the submission of a large surgical resection. Simultaneous examination of both is then necessary for reporting the second specimen and audit of the first. As a minimum this would require reliable and unified IT systems, which are currently some years away in the 'Connecting for Health' plan of development.
3. Removal of a segment of the workload would have an adverse impact on training and maintenance of skills. We support the comment in the main RCPATH submission that such fragmentation of services would cause problems with the quality training.
4. Depending on the financial agreements in place, 'creaming off' simple specimens to a separate unit could destabilise the unit handling the more complex specimens, by apparently inflating the unit cost of each complex specimen.

Balance and informed judgement are needed. There is considerable experience of centralisation of some 'bulk' services, notably cervical cytopathology. But even here there can be problems. The investigation into cervical cytopathology at Kent and Canterbury (the Wells report) specifically criticised the geographical separation of the cytopathology laboratory from the cytopathologists.

Histopathologists and training

We endorse the comments on training in the main RCPATH submission. Histopathologists have an important role in undergraduate and postgraduate education. However, the need for clinico-pathological interaction mentioned above makes it particularly important that trainee histopathologists regularly meet and discuss cases with clinical staff, in order to understand their needs. It seems unlikely that the private sector will voluntarily contribute to NHS staff training. In the context of the current severe national shortage of trained histopathologists care must be taken not to reduce training capacity.

Histopathologists and research

We endorse the comments in the main RCPATH submission. It will not be evident from national statistics, but histopathologists are enrolled to assist the research of other clinical staff even more often than they initiate their own research projects. It seems unlikely that the private sector will voluntarily contribute to NHS research and development. Co-localisation greatly facilitates such collaboration.

Handling results

Serious errors in patient management are likely to occur if the introduction of multiple service providers is allowed to fragment information storage. Lack of access to previous reports already causes problems for histopathologists when patients switch between private and NHS healthcare. We should not devise systems based on the availability of the electronic unified patient record until that service is actually working effectively.

Future developments

When planning changes to a service it is important to anticipate likely developments, to avoid implementing organisational changes which might inhibit desirable developments in the future. It is not possible to predict such developments with certainty. It is even less possible to predict how changes in organisation might impact on future developments without knowing what organisational changes might be proposed. Nevertheless we thought it appropriate to highlight some selected developments which we think are likely to occur.

1. **Changes in staff roles** will occur, with a continuation of the current process of non-medical biomedical scientists undertaking tasks traditionally only performed by medically qualified histopathologists. This is currently being developed by the RCPATH in several areas, in collaboration with the Institute of Biomedical Scientists (IBMS). The RCPATH welcomes such developments if it can be demonstrated that the quality of the service can thereby be maintained or enhanced. This will demand collaboration between pathologists and BMS staff, evaluation and central co-ordination.
2. **Virtual microscopy** will increasingly allow digital images of microscope slides to be viewed at a distance on high-resolution computer screens. This approach has some parallels to the use of digital images in diagnostic radiology. However, it is important to recognise that (unlike radiology) the ability of a microscope to display a glass slide at widely different magnification means that to digitise a slide at an adequate resolution produces remarkably large image files; one or two such files can fill a CD. With present technological standards this means that data transmission introduces a delay in refreshing the image on the computer screen, which currently makes this approach unsuitable for routine diagnostic work.

- 3. Introduction of new modes of investigation of tissue samples**, especially those based on nucleic acid analysis. This is currently being introduced gradually in relation to a few specialised tumours, but the process will accelerate and will lead to a growing requirement for histopathologists with better training in molecular biology, and molecular biologists with a better training in conventional histopathology.

New tests will impact not only diagnosis and prognosis but also choice of treatment, as recently exemplified by the need for HER2 testing to identify breast cancers which may be susceptible to treatment with Heceptin (Trastuzumab). Problems in relation to introducing HER2 testing have illustrated the importance of advance planning, authoritative evaluation and clear central guidance on when and how new tests should be introduced to the NHS. Central decisions will also need to be made on whether new modes of testing are implemented in a few referral laboratories or in local laboratories; the discussion in the first part of this document will be relevant to such complex judgements.

In the long term, it is likely that some specimens which are currently assessed by conventional histopathological techniques will be evaluated exclusively by molecular methods, such as gene expression profiling. This could eventually represent an opportunity to make assessments more quantitative and less subject to interpretive error, which we would welcome. However, in the foreseeable future we believe that for most types of specimen such molecular analyses will remain an extension of conventional histopathological assessment rather than a replacement.

Who should manage the histopathology service?

Histopathology is a clinical service, offering medical opinions and diagnoses, not measurements. This creates a requirement for close clinical co-operation, as explained above, and hence for a managerial system which understands these issues.

As a result, the concept of a histopathology service without medical management should seem as absurd as the idea of an NHS Trust without a Medical Director.

Conclusion

The Histopathology SAC believes that quality in histopathology cannot be evaluated simply on the basis of 'samples in, results out'. Rather, the assessment of quality should start with the right decision to take the right sample, handled in the right manner, and end with the timely implementation of the right treatment for the right patient based on the right interpretation of the right result.

We endorse the need to modernise and improve pathology services. We hope that our arguments have illustrated that this is a complex task, because 'quality' in histopathology has many components. Interventions to improve the quality of one part of the process can have unexpected adverse consequences in other parts of the chain.

The Histopathology / Cytopathology SAC will do all it can to promote the further development of a modern, efficient and high quality diagnostic service in the NHS. We recognise that this is a difficult task and we will therefore welcome any opportunity to advise and assist the process.