



The Royal College of Pathologists

Pathology: the science behind the cure

Quality assurance in histopathology and cytopathology reporting practice

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Background

This paper has been written at the request of the Specialty Advisory Committee on Histopathology to provide guidance to pathologists and to commissioners of cellular pathology services on quality assurance of diagnostic histopathology and cytopathology reporting practice. It also considers the issue of 'double reporting', which may be used to describe different activities by different departments and in different diagnostic contexts.

It is important to recognise that the interpretative reports provided in histopathology and cytopathology are a reflection of the opinion of the reporting pathologist. There is therefore a subjective element in the content of any report. This is relevant when more than one pathologist reviews diagnostic material, as legitimate variations in opinion may, in some clinical contexts, be expected. The degree of uncertainty may also reflect the adequacy of the material provided for assessment and the nature of the disease process. Appropriate training and continuing experience should provide the pathologist with the skills required to manage this uncertainty and to ensure that patient safety is not compromised. It should also be recognised that it is not always possible to make a definite diagnosis on one biopsy specimen – repeated biopsies and observation of the progression of a disease over a period of time will often clarify an initially uncertain diagnosis or differential diagnosis.

A diagnostic pathology service requires appropriate laboratory staffing, space, equipment and consumable funding so that pathologists have sufficient time and technical support to provide a good quality of report for patient care. Aspects of this are considered as part of laboratory accreditation. The resource implications (pathologists' time and other laboratory resource) will vary considerably according to how quality assurance procedures are implemented and should normally be commissioned by local agreements with Primary Care Trusts. Tertiary referral work is currently largely unfunded and may be the subject of cross-charging between Trusts. Specialist commissioning may provide an alternative method of funding the review and referral of cases between Trusts in one Network, or across Networks, that is essential to achieve optimal patient care.

Detailed consideration of these issues is included in a separate 2009 College document, *Guidelines on inter-departmental dispatch and funding of histopathology referrals* (see www.rcpath.org/resources/pdf/G083_InterdeptDispatch_Feb09.pdf)

A discussion of specialist pathology practice is provided in another 2006 College document, *The recognition and roles of specialist cellular pathologists* (see www.rcpath.org/resources/pdf/G004-SpecialistCellularPathologists_Jun06.pdf).

Components of quality assurance in cellular pathology

1. Quality assurance of the interpretative elements of diagnostic histopathology and cytopathology is achieved by a number of measures that together constitute good medical pathology practice. These measures include factors specific to the individual pathologist and factors that are broadly related to their working environment.
2. Factors specific to the individual pathologist are those that would usually be considered by Advisory Appointments Committees for consultants, and are monitored during clinical appraisal. These factors include:
 - a. training and experience
 - b. continuing professional development (CPD)
 - c. audit of reporting practice

- d. participation in External Quality Assessment (EQA) schemes of a generalist or specialist nature, appropriate to the pathologist's practice. It is expected that pathologists acting as 'local leads' and those receiving referral cases would participate in a relevant specialist EQA scheme or, if an EQA does not exist, in a professional slide circulation and discussion scheme.
3. Factors determined by local practices and protocols.
 - a. Informal case discussions with colleagues within a department. This is often useful to confirm or explore difficult differential diagnoses. Departments should encourage individuals to have a low threshold for engagement in this practice to ensure constructive dialogue and to avoid the exposure of any difference of opinion at later stages in the diagnostic pathway.
 - b. Formal review by a second pathologist of cases of a particular diagnostic type, e.g. first diagnoses of malignancy, or a subset of cases as part of audit. It should be noted that this is *not* mandated by The National Institute for Health and Clinical Excellence (NICE) or College guidance for the generality of specimen types or diagnoses. Exceptions, where double reporting is recommended (if resources allow), are:
 - gastrointestinal dysplasia (high grade dysplasia in Barrett's oesophagus and in ulcerative colitis)
 - dysplastic naevi/malignant melanoma.¹
 - c. Formal review for the multidisciplinary team (MDT) by the pathologist who will present and discuss the case at the local MDT meeting.
 - d. Formal review for a specialist MDT as part of a Network referral pathway for specialist MDTs. NICE's Improving Outcomes Guidance (IOG) indicates that review by a specialist pathologist is required for a few relatively uncommon cancer types (thyroid, sarcoma, lymphoma) in order to facilitate consistency of diagnosis and/or where highly specialised investigations may be required to ensure optimal treatment.^{2,3,4}
 - e. Tertiary referral of diagnostically difficult or rare cases to pathologists with local or national expertise in a specific clinical area.
 4. The concept of 'double reporting' could refer to any of the quality assurance aspects in paragraph 3, and may range from a rapid review of slides to validate the accuracy of the diagnostic category to a full review of all the slides from a case in their clinical context (including review of imaging reports). The level of documentation involved is also potentially variable, as is the extent to which the reviewing pathologist is aware of the first pathologist's diagnosis. It is important to clarify the requirements in any service level agreement. Clearly, a case that is originally diagnosed by a specialist pathologist will not need to be reported by a second pathologist before the specialist MDT meeting in order to comply with IOG guidance. However specialist pathologists must be mindful of the need for appropriate EQA participation, discussion of difficult cases with a colleague and clinicopathological audit of their diagnostic work
 5. It is not possible to specify for all situations the types of case or the proportion of cases that should be subject to review. The relative contributions of each aspect of quality assurance will be influenced by the experience of the individual pathologist in the specific diagnostic area so that, for example, a recently appointed consultant is likely to discuss more cases with colleagues than a pathologist with many years of experience and a specialist interest in the relevant area.
 6. Consequently, it is recommended that agreed local protocols for quality assurance of the interpretative aspects of diagnostic histopathology reporting are developed within the framework outlined in paragraphs 2 and 3. With regard to 'double reporting,' a simplistic

approach such as 'All new diagnoses of malignancy' may not be warranted as some cancer diagnoses may have a very low error detection rate. Conversely, in some contexts, it might be more important to review specific biopsy categories that are *negative* for malignancy. Local audit and clinicopathological correlation will determine areas of potential benefit.

7. The existence of such protocols should never inhibit a pathologist from seeking a second opinion in some other category if there is any doubt about the correct diagnosis. All pathologists should be aware of the limits of their expertise and should be encouraged (and not inhibited) by local, Network and national policies to ensure that their diagnostic reports are as complete and accurate as possible, guiding patient care in an optimal fashion.
8. Pathologists should be encouraged to record the involvement of colleagues (with their agreement) in the production of a diagnostic report. Local protocols should determine whether this is noted in the text of the report or is achieved by some other method. Recording such data facilitates audit of good practice, especially if it is done in a way that permits electronic retrieval of those cases that have been assessed by more than one pathologist.
9. At all stages, it must be absolutely clear who is taking responsibility for the content and accuracy of the report and for communicating the report to clinicians. This is indicated by the report signatory in whose name the report is electronically authorised. If a range of opinions is expressed in the report, either a clear conclusion should be offered or the process whereby a conclusion could be reached should be described. Refinement or alteration of a diagnosis based on MDT meeting discussion should be formally notified to the attendant clinician by an authorised supplementary report.
10. It is important to remember the need to use resources efficiently when implementing quality assurance procedures. In most situations, there is unlikely to be sufficient evidence for a formal cost-benefit analysis. Consequently it is important to audit areas where 'double reporting' or other quality measures are implemented or being considered, to identify the detection rate of discrepant diagnoses and their potential clinical consequences. The results of such audits should be published to help shape future guidelines and to facilitate decision-making by others.

Summary and recommendations

1. Assurance of the quality of the interpretative element of diagnostic histopathology reports is achieved by a range of activities including audit, CPD and participation in appropriate EQA schemes. Participation in these elements should be monitored during a consultant's annual appraisal.
2. Pathologists are encouraged to be aware of their own limitations and to seek support whenever necessary to assure appropriate patient care.
3. While 'double reporting' and review of histopathological slides are regarded as best practice in some diagnostic situations, they are not mandated in NICE or College documents for most diagnoses. Local protocols should describe the range of situations in which specialist review and 'double reporting' are required to support colleagues and/or to meet the demands of agreed patient care pathways.
4. Pathologists should work with service provider organisations, Cancer Networks and service commissioners to ensure that the agreed quality assurance processes are appropriately resourced as part of clinical care pathways.

References

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