



Guidelines on inter-departmental dispatch and funding of histopathology referrals

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Produced by	Professor Mike Wells, on behalf of the Specialty Advisory Committee on Histopathology
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Comments	<p>In accordance with the College's pre-publications policy, this document was on the College website for consultation from 29 October to 26 November 2008. Fourteen pieces of feedback were received. Professor Wells considered the feedback and amended the document accordingly. Please email publications@rcpath.org if you wish to see his responses to the feedback received.</p> <p>This document replaces two earlier College documents:</p> <ul style="list-style-type: none">– <i>Guidelines on inter-departmental dispatch of samples from patients sent to another hospital or centre for assessment and/or treatment (2nd edition, 2006)</i>– <i>Guidance on histopathology referral practice (2007).</i>

The Royal College of Pathologists
2 Carlton House Terrace
London, SW1Y 5AF
Tel: 020 7451 6700
Fax: 020 7451 6701
Web: www.rcpath.org

Registered charity in England and Wales, no. 261035

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Introduction

This document relates to the referral of histopathological specimens (including cytopathological and post-mortem specimens) for specialist opinions for the benefit of the patient, in the context of the UK National Health Service.

Histopathological diagnosis is not an exact science and it is normal practice for histopathologists to refer cases for second opinion to their colleagues (see also *Quality Assurance in Histopathology*, www.rcpath.org/resources/pdf/q082_gahistoreporting_feb09.pdf).

The College, through *Good Pathology Practice*, recommends that all pathologists should actively participate in some form of referral practice as this is in the best interests of patients, good continuing professional development (CPD) and good practice. A histopathologist who never seeks other views is a potential cause for concern. It is important that pathologists are not discouraged from this practice because of cost implications.

Examples of referral categories

1. Internally within a department, e.g. difficult cases discussed.
2. Informally between colleagues in adjacent hospitals, e.g. a generalist pathologist seeking advice from a pathologist in sub-specialist practice.
3. Routinely within cancer networks (cancer units to centres).
4. Formally where a second 'primary' diagnostic opinion is required.
5. Subspecialty tertiary referrals linked to patient pathways.

The development of cancer centres and clinical networks has led to an increasing requirement for histopathology and haematology departments to forward material to centres where patients have been sent for further treatment and management. This usually relates to cancer patients sent to specialist centres for definitive chemo- or radiotherapy, following initial biopsies or resections in another hospital. Increasingly, material is referred between district general hospitals at the request of clinicians.

The reasons for requests for review of diagnostic material in patients treated at cancer centres are multiple:

- to confirm the diagnosis before potentially harmful therapy is given
- to ensure a complete archive of patient-related information at the cancer centre and that previous biopsy material is available for comparison with subsequent biopsies. This includes frozen sections at subsequent operations and biopsies to assess response to therapy or relapse
- to ensure uniformity of reporting of cases within the cancer centre. This is essential for patients in trials. It also allows for the collection of data that may be missing from the referring pathologist's report, but which is considered vital for patient management at the cancer centre
- to provide material for the assessment of molecular markers of predictive and prognostic value. Examples would be testing for HER2 expression by immunohistochemistry and fluorescent *in-situ* hybridisation (FISH) or cytogenetic investigations for soft tissue tumour classification, as well as samples for DNA/RNA analysis.

If the request for tissue is for the benefit of a relative rather than for the patient, then the consent requirements of the Human Tissue Act need to be satisfied. An assertion by the clinician requesting the tissue that consent is in place will suffice, because the Act requires only a “reasonable belief” that consent is in place, and there is also a specific offence of falsely claiming that consent is in place. However, this is an ethically complex area and specialist advice may be needed.

The College recommends that pathologists:

- should facilitate the process of review and ensure there is no obstruction to the process of dispatching histopathological and other diagnostic material between centres and the clinical teams caring for a particular patient
- recognise there are no legal or ethical obstacles, nor issues of consent, since the purpose of the exercise is diagnosis in the patient’s best interest; although in some contexts it is best practice that the patient be informed, and different issues can arise in review as part of a clinical trial (discussed below)
- when requested, promptly send sufficient and appropriate material (e.g. all necessary blocks, appropriate original or unstained slides) and a copy of the original report if appropriate to allow full review of the histopathology and the performance of appropriate immunocytochemical and/or molecular studies. Consideration should be given to sending original slides and blocks under separate cover
- reasonable precautions should be taken to ensure that the material is free of infection with category 3 or 4 agents such as hepatitis B and HIV. If this is not the case, special transport arrangements should be made in accordance with postal regulations
- maintain full records and an audit trail of all dispatched samples.

Central referral centres should:

- maintain full records, including an audit trail for all samples received
- process the material promptly
- return blocks and slides to the referring hospital promptly
- return slides generated in the referring laboratory to that laboratory, unless there is a specific agreement to the contrary
- obtain original stained slides when the deeper sections fail to show the diagnostic features or when indicated for other reasons. Where new slides are made, these will normally be retained at the referral centre; the referring centre should be informed
- feed back findings to the referring centre by issuing a copy of the report
- ensure mechanisms are in place to enable rapid contact with the sender if there is diagnostic disagreement or discrepancy, irrespective and independent of the situation, to allow an opportunity for learning.

Transfer of digital images

Digital images are capable of precise electronic replication. Where some or all of the material transferred is in the form of digital images, a copy should normally be retained in the referring centre. A decision on storage in the referral centre will need to be made; this decision is likely to be influenced by whether the patient's care is being transferred to the referral centre, but the referring centre should be made aware of that storage decision.

The ready reproducibility of digital images raises the level of concern about confidentiality. Particular care should therefore be taken. Transfer of identifiable material over the open internet should not occur unless an adequately secure encryption method is used. This requires software written for the purpose; merely using password protection in 'routine' computer programs is unlikely to be sufficiently secure. Alternatively, coded identifiers and encrypted identifying clinical information could be sent in separate transactions.

Referral of material for multi-centre clinical trials or any Multicentre/Local Research Ethics Committee-approved trial funding of referrals outside a network

Research is outside the scope of this document, but there are occasions where material originally taken and examined for diagnostic and therapeutic reasons is requested at another site for research purposes.

The centre requesting the material should explicitly confirm that appropriate consent and ethical approval are in place for this work, but sight of the patient's signature on a consent form is not essential.

Diagnostic material from patients in trials in which central review of the specimen is mandated in the trial protocol should be dispatched on request. If this is not done, the referring hospital will be acting against the wishes of the patient who will have given informed consent at entry into the trial, including consent for the stipulated handling of their specimens.

Funding of referrals outside a network

For referrals linked to cancer networks, the referral should, in the first instance, be from cancer unit to cancer centre within a single cancer network. Such referrals should be routine, and systems for charging, if necessary, should be agreed through the network. Only in difficult cases should it go to tertiary or national centres, thereby becoming a supra-network referral.

The Department of Health has made it clear that no central funding for referrals will be provided other than through existing networks such as the National Specialist Commissioning Advisory Group for ophthalmic services and bone tumour services.

For referrals where a histopathologist wishes to obtain a second diagnostic opinion from outside their own organisation, there is a historic culture of expectation that a service will be provided *gratis* by expert histopathologists on complex cases. However, in the context of pathology modernisation, payment by results and tighter commissioning, models of funded referral practice need to be established.

The College recommends that referring trusts outside an individual organisation or network should be recharged and such trusts employing the referring pathologist should expect a charge to be made for the service. All pathologists should ensure that there is a local expectation that when material is sent away for a specialist opinion a charge will be made for the service, and that

arrangements are in place to ensure that the charge will be paid. This charge should include a fee for both technical service and professional clinical opinion.

Any managerial requests to avoid referral to minimise costs should be countered on the basis of good clinical governance. A pathologist who believes that good patient care demands an expert referral, but is not allowed to make that referral on the grounds of cost, has a duty to make this problem known to management and to the clinician responsible for the patient in question. Where individuals have referral practices, whether inside or outside cancer networks, the College recommends that this be recognised in their job plans.

This document deliberately does not provide guidance on what is an appropriate fee, but the expectation is that the fee should cover the costs of professional, technical and secretarial time.

This document also does not cover overseas referrals. It is specifically noted that some UK pathologists provide a referral service to assist medical provision in underdeveloped countries and it is hoped that such work can continue without charge.

Cost of transportation

As a basic principle, the organisation that makes the request should be willing to cover the cost of appropriate packaging and transportation. However, if the specimen is small and non-perishable and the cost is no more than basic postage, an invoicing process may cost more than the amount recovered; so sensible flexibility is needed. If the organisation complying with a request intends to use more expensive methods of transportation (courier services, transport of frozen material, etc.) then agreement to refund the costs should be obtained first, unless the clinical need is too urgent. A prior agreement is desirable if requests are frequent.

Audit

The College recommends that pathologists audit their patterns and frequency of referrals so that they can demonstrate the number of cases being referred over a period of time and costs can be built into pathology business plans. To that end, we advise that a record of additional consultations – including the name and location of the colleague consulted – should, where practicable, be made in the relevant pathology report.

Primary care trusts and other commissioning groups need to be aware that histopathology referral is good practice and that this should be accounted for in budget allocations.

Professor Mike Wells

Specialty Advisory Committee on Histopathology

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