

Guidance on inter-departmental dispatch of cellular pathology material for referral and clinical trials

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Comments	<p>This document replaces the 2014 College document, <i>Guidelines on inter-departmental dispatch of histopathology material for referral and clinical trials</i>.</p> <p>In accordance with the College's pre-publications policy, this document was on the College website for consultation from 4 July to 1 August 2016. Thirty-two items of feedback were received and the dataset was amended as necessary. Please email publications@rcpath.org if you wish to see the responses.</p> <p>Dr Lorna Williamson Director of Publishing and Engagement</p>

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Introduction

This document relates to the referral of cellular pathological specimens (including cytopathological and post-mortem specimens) for specialist opinions for the benefit of the patient, for clinical trials and for some research work in the context of the UK National Health Service.

Cellular pathological diagnosis is not an exact science and it is normal practice for cellular pathologists to refer cases to colleagues for a second opinion.

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 cellular pathologist 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.

In instances where material is reported as part of private practice, the principles presented in this document should apply. Arrangements for cost recovery in such circumstances would be a matter for the provider to resolve with other organisations and is not within the remit of this document.

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 as specified in network procedures (cancer units to centres).
4. Formally where a second 'primary' diagnostic opinion is required.
5. Subspecialty tertiary referrals linked to patient pathways.
6. Referral to a centre for review of material as part of a clinical trial or other research project.

The development of cancer centres and clinical networks has led to an increasing requirement for cellular pathology 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 hospitals at the request of clinicians. There are other clinical areas outside cancer treatment where it is required to refer or send material to another centre for review.

The reasons for requests to review 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.

College recommendations

The College recommends that pathologists:

- should facilitate the process of review and ensure that there is no obstruction to the process of dispatching cellular pathological and other diagnostic material between centres and the clinical teams caring for a particular patient
- recognise that 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 (normally whichever materials are requested by the referral department, typically paraffin blocks and/or appropriate original or unstained slides) and a copy of the original report to allow full review of the cellular pathology and the performance of appropriate immunocytochemical and/or molecular studies. Consideration should be given to sending original slides and blocks under separate cover
- permit the referral department to keep the referred materials while the patient’s care remains under the referral institution
- maintain full records and an audit trail of all dispatched samples
- reasonable precautions should be taken to ensure that the material is free of infection with category 3 or 4 agents. If this is not the case, special transport arrangements should be made in accordance with postal regulations.

Central referral centres

The College recommends that central referral centres should:

- be prepared to provide costings to organisations seeking to refer material
- maintain full records, including an audit trail for all samples received and returned
- process the material promptly; if delays are anticipated, the sample should be returned for referral elsewhere
- return blocks and slides to the referring hospital promptly when no longer needed for patient care at the referral institution unless there is a specific agreement to the contrary
- inform the referring hospital promptly if the patient’s diagnostic material is dispatched to a tertiary hospital and maintain an audit trail for the tertiary referral

- 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; where possible this should be to the treating clinician, if known, in addition to the referring pathologist
- ensure mechanisms are in place to enable rapid contact with the sender if there is diagnostic disagreement or discrepancy that will significantly alter the management of that individual patient.

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. Those making such arrangements should ensure that information is transferred according to procedures specified in their organisation to comply with requirements for data protection and confidentiality.

NHS.net email addresses are commonly used for transfer of confidential information between various NHS organisations. This mode of transfer can be used for transfer of digital images.

Referral of material in relation to 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 who are enrolled in trials in which central review of the specimen is mandated in the trial protocol should be dispatched without delay, on request. If this is not done, this would 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.

The dispatch of materials for use in clinical trials involves a cost to the primary hospital in terms of:

- clerical time for logging out, packaging, posting, and logging back in
- medical time for reviewing and choosing appropriate blocks
- materials for packaging safely.

Organisers of clinical trials should factor in these costs and be prepared to reimburse the centres providing the material.

Enrolment of patients in multiple clinical trials or research projects

Patients may sometimes be enrolled in more than one study that requires review of slides or further work on the preserved tissue.

The College recommends that:

- slides and/or blocks from patients co-enrolled in more than one project should be reviewed promptly by the first study and made available to other trials or studies for which the patient has given consent
- the centres should communicate with one another to ensure that the same translational work is not performed twice by two different groups
- the hospital department generating the original report should release extra material if it is available and requested by a second study or trial for which the patient has given consent.
- all centres should maintain full records, including an audit trail for all samples received and returned.

Funding of referrals outside a network

For referrals linked to cancer networks, in the first instance the referral should 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.

For referrals where a cellular pathologist 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 cellular pathologists 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. When a laboratory refers a case to another laboratory or pathologist for expert opinion, unless a prior agreement is in place to take such cases, the referrer should first establish that the intended recipient of the referral is willing and able to accept the case.

In the case of referrals that are requested by clinicians or patients, rather than those initiated by the pathologist, the pathologist should advise the clinician or patient that the referral is likely to accrue charges, and to ensure that the service or person who requests the referral accepts liability for the charges and delivery costs.

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 (e.g. courier services, transport of frozen material, etc.), 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.

It is recommended that pathologists audit discrepancy rates in referral work such that this can inform professional development. Pathologists may find it helpful to share such feedback with others in the department.

Commissioning groups need to be aware that cellular pathology referral is good practice and that this should be accounted for in budget allocations.