

Telepathology: Guidance from The Royal College of Pathologists

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Contents

1	Introduction.....	3
2	A comparison between telepathology and teleradiology.....	3
3	Potential benefits of telepathology.....	4
3.1	Rapid provision of expert opinion	4
3.2	Provision of an urgent (intra-operative) diagnostic service in the absence of a local pathologist	5
3.3	Provision of an on-call service	5
3.4	Distant provision of a diagnostic service for the routine workload.....	5
3.5	Local provision of a diagnostic service for the routine workload ('telemicroscopy').....	5
3.6	Image analysis and quantitation.....	5
3.7	Education and training	6
3.8	External quality assurance.....	6
3.9	Assessments and examinations.....	6
4	Real and potential problems	7
4.1	Introduction.....	7
4.2	Legal issues	7
4.3	Quality issues	8
4.4	Communication and teamworking issues.....	10
4.5	Familiarity issues	11
5	Summary	11

1 Introduction

- 1.1 Telepathology is the electronic transmission of pathological images, usually derived from microscopes, from one location to another, for the purpose of interpretation and diagnosis.
- 1.2 Within this definition, there is considerable variation in the method used to transmit the images and in the application to which telepathology is put.
- 1.3 **Transmission of images** may be of still images or video (either recorded or sent as a live feed from a video camera attached to a microscope). More commonly, digital scans of a whole slide at a range of magnifications produce a 'virtual slide' for remote viewing, in which case the distant viewer can control all functions of a 'virtual' microscope.
- 1.4 **The applications of telepathology** include case referral for expert opinion, provision of an emergency service in the absence of a resident pathologist, case conferences including multidisciplinary meetings, quality assurance, education (undergraduate, postgraduate and continuing professional development [CPD]) and assessment of competence. There is increasing demand to use 'virtual slides' for certain core diagnostic services in the absence of a local pathologist. This is likely to increase in the future.
- 1.5 This diversity of applications of telepathology makes the provision of guidance complex. If telepathology is used to facilitate a discussion between two competent pathologists, with follow-up by exchange of microscope slides in the post, little guidance is needed beyond applying the familiar requirements of professional standards and clinical governance.
- However, if pathological preparations produced in one location are being routinely reported at a distant site via a telepathology link without input from a local pathologist, several new and difficult problems are raised.
- 1.6 Different issues arise in quality assurance and assessment of competence, where major concerns are the provision of a 'level playing field'. It is important to ensure that there is equivalence between telepathology and the pathologist's usual method of practice, or that the differences are recognised and acknowledged.
- 1.7 This paper is intended to provide guidance on the issues that might arise when telepathology is used to support clinical practice. As technology in this field is advancing rapidly, we anticipate that it will need to be updated regularly.
- 1.8 We are very grateful to our colleagues at The Royal College of Radiologists for their permission to draw heavily on their published guidelines, *Teleradiology – A Guidance Document for Clinical Radiologists*.

2 A comparison between telepathology and teleradiology

- 2.1 Pathology and radiology are both specialties that rely heavily on the use of images to make a diagnosis. At present, teleradiology systems are in more widespread use than telepathology systems, and The Royal College of Radiologists has produced guidance on the use of teleradiology. However, there are important and subtle differences between telepathology and teleradiology that need to be highlighted to prevent established standards and procedures for teleradiology from being uncritically assumed to be directly applicable to telepathology.
- 2.2 In radiology, the diagnostic investigation itself very commonly produces images that are already in a digital form. There is then no need to convert the image data to digital form (for example by scanning or photographing an X-ray film) before it can be sent electronically from one place to another. It is therefore possible to transfer **all** the original

diagnostic information contained in the image from one place to another and thus to ensure that, when referring the case to another radiologist, none of the original diagnostic information has been lost or degraded. In histopathology, the original specimen is usually a glass slide. The image must be digitised before transmission, with consequent possible loss of quality.

- 2.3 Well-established international standards in radiology for image acquisition, storage and transfer (DICOM) have been adopted by manufacturers, ensuring some conformity between disparate systems. These are also being developed for histopathology.
- 2.4 In radiology, images are viewed at a relatively limited range of magnifications, whereas in histopathology selected areas may be viewed at a very wide range of magnifications, up to the limit of resolution of the light microscope. To digitise all the material on a microscope slide at a resolution equivalent to x 1000 magnification results in data files several orders of magnitude larger than digital radiology images. In the absence of established image standards or technical specifications for image capture, storage and transmission in diagnostic histopathology, there is no minimum requirement placed upon system suppliers and there is no guarantee of image quality.
- 2.5 It is not uncommon for a pathologist to request several supplementary investigations, such as immunohistochemical stains. A comparable procedure for further investigation does not exist in radiology without recalling the patient, which demands renewed local clinical input.
- 2.6 The fact that radiological images are often captured in digital form means that, for many years, radiologists have been trained to understand the underlying principles of digital imaging and factors that influence digital image quality.

There is as yet no comparable requirement for training and assessment in digital imaging techniques in histopathology, so pathologists are less likely to recognise and correct problems with image quality.

3 Potential benefits of telepathology

3.1 Rapid provision of expert opinion

- 3.1.1 All pathologists from time to time are faced with a case where an expert or second opinion is of value. Telepathology has the potential to allow a pathologist rapidly to seek the opinion of a second pathologist. This is likely to be of particular value in smaller departments although, with increasing specialisation, even in departments where there are many pathologists, telepathology would allow case discussions with other specialists. There is no need for irreplaceable blocks or slides to leave the local department.
- 3.1.2 A 'live' telepathology consultation allows the local pathologist and expert to consider the case at the same time. This significantly improves the educational potential over that of a conventional consultation, because the local pathologist can observe at first hand the diagnostic approach taken by the expert. Digitised images have the potential for pathologists to develop more effective ways of working. Navigation of large slides, or multiple sections on one slide, is much easier than when using conventional microscopy. This might prevent errors through not viewing all tissue fragments, and may make comparison of multiple sections/stains/IHC much easier.
- 3.1.3 If telepathology makes the process of consultation easier and faster, there is the likelihood that it will be used more frequently, improving diagnostic accuracy and speed, and hence patient care.
- 3.1.4 There is a long history of using telepathology for provision of expert opinion, with a variety of modes of image transmission; from static images selected by the referring pathologist, through video links, to 'virtual slide' technology.

3.2 Provision of an urgent (intra-operative) diagnostic service in the absence of a local pathologist

3.2.1 Telepathology has been used for many years to provide an intra-operative frozen section service for small hospitals in sparsely populated areas, notably northern Scandinavia, where the hospital does not have a resident histopathologist. The distant pathologist is usually provided with remote control of a local microscope, with the sections and maintenance of equipment being provided by local technical staff. More recently, the development of virtual slide technology has provided an alternative way to deliver the same type of service.

3.2.2 Remote diagnosis using this model has been used in a small number of sites in the UK.

3.3 Provision of an on-call service

3.3.1 With increasing specialisation, pathologists working in areas where an on-call service is needed (such as transplant pathology) have difficulty in finding a sufficient number of local colleagues who are able to share an on-call rota. The use of telepathology potentially allows a larger number of pathologists, well beyond the catchment area of a single provider, to contribute to an out-of-hours service. With improved network connections in the community, pathologists may be able to provide expert opinions from home without needing to travel to the laboratory.

3.4 Distant provision of a diagnostic service for the routine workload

3.4.1 With increasing service demands, staff shortages and pressure on costs, new technologies such as 'virtual slides' create the possibility of the complete diagnostic service being provided by pathologists based far from the patient's local hospital. There is no technological reason why the pathologist should be in the same country as the patient. Attempts to use this approach are as yet very limited, but are likely to grow. If this use of telepathology is to be cost-effective, the implication is that there is no 'conventional' review of the microscope slides at a later date. There are also issues of communication if there is no local pathologist who can interact directly with laboratory staff and clinical staff.

This mode of telepathology therefore raises numerous problems, which are discussed in more detail below. When information is transferred, there are issues with consent and confidentiality and also those linked to data protection legislation.

3.5 Local provision of a diagnostic service for the routine workload ('telemicroscopy')

3.5.1 Recent advances in virtual slide technology have led some manufacturers to suggest that, in the future, slides produced in a local laboratory will be digitised and supplied to local pathologists for examination on computer monitors, rather than using a microscope. This is sometimes described as 'telemicroscopy', to distinguish it from telepathology. In this application, issues relating to image quality, reliability, etc. are important but problems of communication and legal issues (as discussed below) are unlikely to be relevant.

3.6 Image analysis and quantitation

3.6.1 There are many aspects of routine pathology where semi-quantitative assessments are required, such as tumour grade, degree of dysplasia, severity of inflammation or fibrosis. These assessments are subjective and poorly reproducible. Some pathologists have attempted to improve reproducibility by applying various techniques of image analysis to digital images. These approaches have not been widely adopted, at least in part because of the resource implications of producing the digital images and the measurements. If digital images are routinely produced for diagnosis, the implementation of quantitative techniques becomes more practical and may increase reliability of assessment of prognostic and therapeutic biomarkers.

- 3.6.2 The introduction of such measurements raises issues of clinical relevance, reproducibility, quality control and external quality assessment. These are common to the introduction of any new diagnostic method or assay and therefore will not be discussed further here.

3.7 Education and training

- 3.7.1 Telepathology is already quite widely used to support education and training. There are many excellent online resources that have cases or images of very high quality and the breadth of material available provides a valuable adjunct to more traditional journals and books. Streamed video from meetings and case conferences supported by video conferencing are becoming part of routine training. Virtual slide technology has the potential to allow many pathologists to view rare, educational cases as if at their own microscope. Viewing images and cases online significantly reduces the time and cost of travel, can be undertaken at a time that suits the learner and is a recognised CPD activity. External quality assurance (EQA) schemes are increasingly using a component of virtual slide technology.
- 3.7.2 The techniques of telemicroscopy can also be of value in the undergraduate curriculum, with the potential to introduce students to the value of microscopy in a structured way, without the need to maintain large numbers of optical microscopes.

3.8 External quality assurance

- 3.8.1 Online methods to support EQA have also been developed and are used quite widely in some schemes in the UK. Telepathology is a particularly useful way of distributing material from biopsies that are too small to allow sufficient replicate sections to be cut. It can also be used to distribute the answers from a scheme that is based around a slide circulation, as it allows all participants to see and discuss the same images and maintains a record that can be used in the future as a learning resource.
- 3.8.2 Using telepathology to provide the images for an EQA exercise has the benefit that all participants see exactly the same material and can access them simultaneously if necessary. To that extent, it produces a more 'level playing field' for participants. However, it is important to be certain that this advantage is not being undermined by participants having different quality of equipment and software to view the images. Participants will also differ in the level of skill with which they manipulate digital images. There is evidence that the expertise required for diagnosis using a microscope is not the same as that required for diagnosis using a computer screen. Consequently, while pathologists still use conventional microscopes for routine diagnostic work, EQA schemes that use telepathology to distribute material should be introduced in such a way that equivalence with conventional microscopy has been reviewed and found to be fair for the participants.
- 3.8.3 In using telemicroscopy systems for EQA, consideration should be given to creating a list of minimum system requirements for participation, e.g. monitor and computer specifications and operating systems. Organisers of such schemes should provide other methods for the distribution of digital images such as DVDs for those participants whose internet connections are slow. There should be an open and uncensored means for participants to provide feedback to scheme organisers and other participants on their experiences with such a component to an EQA scheme.

3.9 Assessments and examinations

- 3.9.1 As with EQA, qualifying professional examinations in pathology might see telepathology methods (especially 'virtual slides') as a method of producing a 'level playing field' for all candidates. It should not be assumed that the skills required for telepathology are the same as those needed for routine diagnosis using microscopes. The potential uses of virtual microscopy in examinations need to be scrutinised to ensure that relevant skills are being assessed, and that these skills are comparable for glass and digital formats.

4 Real and potential problems

4.1 Introduction

4.1.1 Problems with the introduction of telepathology vary with the application under consideration. Problems in relation to EQA and examinations relate to clinical relevance, the equivalence to conventional microscopy and the 'level playing field', as discussed above. The introduction of quantitative techniques raises issues of clinical relevance, precision, accuracy and quality control, which are familiar from other areas of pathology practice. This section will therefore concentrate on problems in relation to using telepathology for diagnostic work.

4.1.2 Even within the area of diagnostic work the problems vary, largely depending on whether or not there is a local pathologist who is able to accept responsibility for the final report that leaves the laboratory. Using telepathology to check a specific point of interpretation with a colleague is a far simpler issue than using telepathology to provide the entire diagnosis of a case.

4.1.3 **The following discussion of problems therefore relates mainly to the most problematic application, that of distant diagnosis in the absence of a local pathologist who is able to take overall responsibility for the diagnostic process.**

4.2 Legal issues

Since telepathology could be used to send images anywhere in the world for diagnosis, there are several legal issues that arise when a telepathology service is used from outside national boundaries. Some of these issues are provided for by European Union (EU)-wide directives. However, where a non-EU country is involved, EU directives are not applicable.

4.2.1 Registration and revalidation

- The registration of the reporting pathologist must be recognised by the regulatory body of the EU member state where a hospital, health authority or other organisation purchases a telepathology service. This is an essential requirement in order to maintain proper standards of reporting. Reporting pathologists must demonstrate that they undergo appropriate continuing medical education and that they are properly trained for the tasks to be undertaken.
- In the UK, the General Medical Council requires that doctors demonstrate their continued fitness to practise by the process of revalidation. It is essential that this process of assurance is also applied to those clinical pathologists providing telepathology services from outside the UK.

4.2.2 Liability

- Principles of duty of care are similar throughout the EU, and it is likely that in law any clinical pathologist who reviews images has this responsibility, whether the images are viewed using a microscope or a computer screen. In the National Health Service (NHS), it is the Trust that bears responsibility for patient care. In Scotland, this responsibility is borne by the Health Boards. Where harm to the patient occurs due to the negligence of a clinician employed or contracted by the Trust, then it is the Trust that bears vicarious responsibility for the acts or omissions of the clinician. However, it is important that in contracts between Trusts and suppliers of telepathology, liability of the supplier of the service and the reporting pathologist are clearly defined.
- If the production of digital images is undertaken by a third party (e.g. a commercial imaging company), then the contractual agreement with that third party should make explicit the liability arising from the responsibility of the third party to produce digital images of (clearly defined) acceptable quality.
- If duty of candour is enshrined in law, telepathology providers would have to inform patients when they became aware of a possible negligent act or omission.

4.2.3 Jurisdiction

- Reporting that is carried out outside the UK does not affect the Trust's responsibility or potential liability to the patient. Moreover, a British patient who alleges that they have been harmed as a result of negligent reporting by a reporting pathologist practising within Europe, and who wishes to proceed against him or her directly, may issue proceedings either in the country in which the report was generated (known as the 'Primary Jurisdiction') or in the UK (the 'Alternative Jurisdiction').

4.2.4 Patient confidentiality

- The telepathology service must ensure patient confidentiality. The technical specification must be sufficiently robust to ensure compliance with data protection and other privacy legislation. This is a complex area and expert advice on data protection compliance may be needed if patient-identifiable or **potentially** identifiable information is being transmitted.

4.2.5 Working Time Directive

- The providers of the service must abide by EU health and safety legislation, including the Working Time Directive. If a distant pathologist is working in isolation, especially if remuneration is on the basis of a fee per specimen reported, there may be no way to ensure that excessive hours are not being worked, with consequent risk to reporting standards and patient safety.

4.3 Quality issues

4.3.1 Image quality

- At present, there are no defined minimum technical standards in telepathology for image capture, storage, transmission or viewing. Such standards might include:
 - the image resolution
 - the colour depth that should be captured
 - the speed with which images should be transferred from one site to another
 - the necessary qualities of any viewing station to ensure that the captured information is not degraded at the remote site.
- Defining such standards will be difficult, because they will change with technological developments and with the different uses of telepathology. For example, in a 'real time' consultation between two pathologists, problems of relatively low image resolution may be mitigated by expert selection of relevant fields by the local pathologist, and the use of higher power objective lenses. Conventional video resolution (640 x 480) may therefore be sufficient. When transmitting pre-selected still images, the experience of the AFIP indicates that images of higher resolution produce more accurate diagnoses. When using 'virtual slide' technology, the available resolution is limited by the resolution at which the slide is scanned. A resolution that is sufficient for most purposes (e.g. x 200) may be inadequate for some diagnostic problems (such as assessing nuclear chromatin pattern or glomerular pathology).
- The speed of transmission is unimportant where selected still images are transferred, but becomes crucial when viewing distant virtual slides. When assessing this aspect of telepathology systems, it should be remembered that the response time of the human eye is of the order of 0.1 second; hence this is the response time for data (images) offered to the eye through a conventional microscope. A telepathology system that refreshes an image in 1 second is currently technically impressive, but is much slower than a conventional microscope. Consequently, one should expect diagnosis using such a system either to take longer than using a conventional microscope, or to be less accurate. Most published work has considered only diagnostic accuracy, not speed.

- The provision of laboratory accreditation standards that address these issues should be a priority. Nevertheless, even if formal technical specifications were available, it would still be necessary for an assessment to be made by the reporting pathologist, who has a duty of care to the patient. That assessment should include:
 - is the image that is presented to a remote pathologist sufficient to make an accurate, unequivocal diagnosis?
 - is the image fit for the purpose?
 - has sufficient image information been transmitted from the original section to allow other diagnoses to be excluded?
 - is the supporting clinical and macroscopic information appropriate and sufficient to make a safe and unequivocal diagnosis?
- The general principles of validation and verification of laboratory equipment and analyses apply here (see CPA website: www.cpa-uk.co.uk/support/files/MP-CPA-Position_on_Validation_and_Verification_Policy.pdf).

4.3.2 Training in telepathology skills

- It must be recognised that skill at diagnosis using a microscope does not immediately and automatically translate into skill at using a telepathology system. Investment in training will be needed. As telepathology systems become more widespread, assessment and revalidation procedures will increasingly have to incorporate the evaluation of knowledge and skills specific to telepathology. Until such procedures are implemented, pathologists should carefully consider, on a case-by-case basis, whether or not they are competent to offer a diagnosis on the basis of viewing digital images (see section 4.2.2 – Liability).

4.3.3 Deskilling

- Telepathology has great potential as a tool for training and education, as noted above. However, if in one laboratory a particular category of specimen is routinely allocated to reporting by a distant pathologist, the long-term result could be a damaging loss of relevant local expertise. This could be a particularly important problem in relation to the training of new pathologists, who must see all relevant specimen types.
- Routine distant reporting of one specimen type could also lead to processes that must take place locally, such as gross dissection and sampling, taking place without adequately skilled staff being available to provide supervision.

4.3.4 Discrepancy reporting and audit

- When a telepathology system is being introduced, it is essential that a representative proportion of cases are 'double reported' by conventional and telepathology systems to ensure congruence; it is not sufficient to rely on low rates of discrepant diagnoses as reported in the published literature, as these will be influenced by the skill and experience of practitioners, quality of equipment and case mix. The proportion of cases subjected to such double reporting may be reduced as experience is gained, but ongoing audit remains essential to detect subsequent changes in the quality of the service. A system of discrepancy reporting must be in place. There must be a 'no blame' approach to identify and rectify errors, to analyse the underlying causes and to improve systems to prevent recurrence.

4.3.5 Reliability

- Laboratories must have procedures to maintain activity in the event of equipment failure. If reporting comes to rely on single, expensive pieces of equipment (such as a slide scanner, a large computer server and high bandwidth network links), there must be procedures in place to ensure sufficiently rapid repair or replacement of such

equipment, or the laboratory must remain prepared to revert to 'conventional' diagnostic methods.

4.4 Communication and teamworking issues

4.4.1 Between the distant pathologist and clinical staff

- The provision of a diagnostic service includes pre-and post-analytical phases in addition to the interpretation of images. In the pre-analytical phase, advice for clinical staff must be available to ensure appropriate sampling and fixation of the material. Even more important is the dialogue between the clinician and pathologist in the formulation of diagnosis, prognosis and treatment strategies, and ensuring that the pathologist fully understands what information is important to the clinical team in each case. The importance of this in histopathology has been emphasised by the development of multidisciplinary team meetings. It is essential that a pathologist be available to take part in such meetings, even if attendance is by videoconference link rather than in person.
- There must be a route by which urgent consultations can be arranged between the pathologist and clinician, to facilitate the transfer to the pathologist of clinical information that is relevant to the pathological diagnosis, and to permit the rapid transmission to the clinician of urgent and unexpected laboratory results.

4.4.2 Between the distant pathologist and local laboratory staff

- When pathologists work on site as a team with local laboratory staff, they are readily available to identify and help to solve technical problems, and to collaborate on the implementation of new technical developments. The importance of this interaction for team morale has sometimes been underestimated.
- Dissection and sampling of gross pathological specimens by laboratory staff is increasingly accepted, but remains problematic for large and complex specimens. For such specimens, if the distant pathologist is not involved with the macroscopic dissection and sampling, gross photographs should be made available as part of the telepathology service. There must also be meticulous protocol-driven description, dissection and sampling of the specimen to avoid misunderstanding about the nature and site of origin of the tissue blocks. It is arguable that telepathology is not appropriate for the analysis of large, complex or unusual resection specimens unless it is done by close collaboration between local and distant pathologists.
- This interaction between distant pathologist and local laboratory staff must facilitate the rapid and efficient provision of any further samples, sections or special investigations that may be required.
- The distant pathologist must have rapid access to laboratory archives of relevant previous reports and samples, for comparative purposes.
- Where a pathologist develops a large referral practice, it is at present possible for that pathologist to schedule the examination of referred microscope slides at his or her convenience. The development of 'live' distant consultation produces the possibility of sudden unexpected demands for the pathologist's instant attention, which could be extremely disruptive. There may be a need to schedule such telepathology consultations. This form of work will have to be recognised in consultant job plans.

4.4.3 Linguistic problems

- If telepathology is used to connect pathologists, clinicians, laboratory staff and clerical staff who do not share a common language, linguistic problems can be expected and minimum standards of communication in one common language (usually English) must be assured. However, even where all participants use English as their first language, local idioms and dialects can generate misunderstanding, especially if abbreviations are used. Misunderstandings of this type are particularly likely – and

particularly difficult to detect – where subjective quantitative assessments are involved (such as the severity of a process). There may be scope to alleviate this by the inclusion of digital photographic evidence in reports.

4.4.4 Staff morale

- It will be important to ensure that distortion of local skills and reporting patterns does not lead to a loss of staff morale and problems with recruitment.

4.5 Familiarity issues

4.5.1 Where the distant pathologist has trained and worked in a country with a widely different framework of common diseases, the index of suspicion for unfamiliar diagnoses may be too low for accurate practice. One would not expect a competent UK pathologist to be proficient in the diagnosis of tropical diseases without a period of supplementary training, and the reverse also applies. Comparable issues may arise in relation to unfamiliar work practices in laboratories or clinical medicine. For example, a method of sampling or a laboratory stain may carry the same name in two distant locations, but may nevertheless differ considerably in performance and results.

5 Summary

5.1 The methods of telepathology have potential to improve several aspects of pathology practice, for the benefit of patient care.

5.2 There is an urgent need to agree accreditation standards for the use of telepathology, in relation to its mode of use, image quality, training and communications. These standards may need to be specific to each of the various applications of telepathology.

5.3 The training and assessment of pathologists needs to incorporate the acquisition, manipulation and use of digital images. Established pathologists also need digital imaging to be incorporated into continuing professional development.

5.4 Proficiency at diagnosis using a conventional microscope does not necessarily indicate proficiency at diagnosis using telepathology. This will vary between pathologists and for different diagnostic problems. Pathologists should ensure that they have verified that they have the abilities and equipment required to make accurate diagnoses either by convention or digital microscopy.

5.5 The introduction of telepathology must be accompanied by an adequate audit and quality control programme.

5.6 If telepathology is to be used to provide a diagnostic service that does not involve a responsible local pathologist, numerous legal issues and communication issues arise. This use of telepathology has many parallels with the provision of a diagnostic service by transfer of microscope slides to a distant pathologist when a laboratory is unable to recruit pathologists. This issue has been considered by The Royal College of Pathologists in its August 2003 guidelines, *Code of practice for pathologists participating in remote reporting of histopathology or cytopathology*. The conclusions of that report are relevant, whether the remote reporting is achieved by transfer of microscope slides or by telepathology.

5.7 The best pathology services are delivered in a context of clinical governance, laboratory accreditation and well-functioning laboratory and clinical teams with good communications.

5.8 Remote reporting may provide a short-term solution for coping with a workforce shortage, but careful attention must be paid to the issues outlined above. Local reporting by trained pathologists who work closely with the relevant clinical teams must be regarded as the preferred approach in most situations.