Cross Border Pathology

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The delivery of pathology services can now transcend national borders. Recent examples of cross-border pathology applications include the outsourcing of the entire cervical cytology workload in one country to a commercial laboratory based in another and the establishment of medical laboratories that invite the international transport of blood and other samples for analysis. Comparable processes have already been seen in radiology, where digital images can be transferred electronically for professional interpretation anywhere in the world.

These developments have highlighted problems previously considered to be merely theoretical risks. These include the absence of internationally agreed quality standards or accreditation schemes, lack of access to quality assurance and audit data and concerns over legal liability and the credentialing of pathologists in the telemedicine era. If errors in work carried out in a distant location cause damage or injury to patients, those patients should not be inhibited in their ability to seek legal redress. Local healthcare providers must not be allowed to transfer their responsibilities to distant jurisdictions.

Large-scale international transfer of laboratory services can also result in deskilling of local pathologists and laboratory services, with implications for the training of pathologists and for research. For example, cytopathology services for the whole of one country were briefly delivered entirely by laboratories in another continent. If this situation had not been reversed it would have resulted in cytopathology services throughout that country being irreversibly undermined, once staff previously involved with cytopathology were redeployed and deskilled. This arrangement also limited the ability to provide a complete the histopathology training program; local trainees were placed at a severe disadvantage in achieving any internationally recognized histopathology qualification.

These concerns prompted the International Liaison Committee of Presidents (ILCP) of societies of pathology to issue this position paper on good practice in cross border pathology.

Definitions

Pathology

The terms 'pathology' and 'pathology services' are used to include all medical laboratory services used to support the delivery of medical care. These include those services known in various countries as clinical pathology, histopathology, cytopathology, cellular pathology, hematology, microbiology, virology, immunology, clinical chemistry, biochemistry, embryology, toxicology and the laboratory-based aspects of genetics services. This is not an exclusive list of terms.

Local site

This refers to the location where the patient attends in person to obtain healthcare. It is synonymous with '*the jurisdiction in which the patient seeks medical advice or investigation*. It is recognized that patients may choose to travel, sometimes to countries distant to their normal home, to seek diagnosis and treatment. If such travel occurs at the request or instigation of the patient, we believe that the regulatory system in the location in which the patient obtains diagnosis or treatment is the appropriate regulatory system. However, if the patient travels to another location at the instigation or request of a healthcare provider, then we believe that that healthcare provider has responsibilities for the quality of care that is recommended, and therefore the regulatory environment at the point where healthcare is first sought is the relevant one.

Referral site

This refers to the location, organization or individual responsible for providing the cross-border pathology service, from a jurisdiction that is *not* the one in which the patient seeks medical advice or investigation.

Cross-border pathology

Cross-border pathology is defined as the delivery of pathology, in whole or in part, by staff and/or services located outside the area of regulation of healthcare in which the patient seeks medical advice or investigation. The 'border' in question may be a national / federal border or a state border, depending on how the delivery of healthcare is regulated in the location of the patient.

Cross-border pathology can be delivered by sending the patient's sample (e.g. tissue specimen, blood or other body fluid) into the area of another jurisdiction. This is facilitated by modern international transport systems and by internet-based delivery of results.

The international transport of such samples can be initiated by a patient sending material directly to a company in another jurisdiction (i.e. 'direct to consumer' testing) or by a local health service provider sending material to a referral site. This paper refers only to the latter situation, where the use of a distant referral site is not under the direct and exclusive control of the patient.

In some circumstances (notably where the report represents the result of professional interpretation, such as anatomical pathology), cross-border pathology can be delivered by telepathology.

Telepathology

Telepathology has been defined as the electronic transmission of pathological images, usually derived from microscopes, from one location to another, for the purpose of interpretation and diagnosis.

This document considers the implications of telepathology for the regulation of the delivery of pathology services. It is therefore important to distinguish the various ways in which telepathology can be used. These include:

- obtaining the primary diagnosis
- obtaining a second opinion from a specialist pathologist
- teaching
- quality assurance
- research

The first two of these uses impact directly on patient care. For these two uses there is therefore a need for a clearly defined regulatory environment to maintain quality, to ensure patient safety and to identify unequivocal lines of responsibility.

Obtaining the primary diagnosis

This document considers only the appropriate regulation of the situation where the report delivered to the clinician is generated without any local individual or organization that accepts such direct responsibility for producing the content of the report.

Obtaining a second opinion from a specialist pathologist

A pathologist who is licensed to take primary responsibility for issuing pathology reports at the local site, in the jurisdiction in which the patient resides, may sometimes seek a second opinion using telepathology. We believe that the responsibility for the timeliness and accuracy of the report remains with that local pathologist. In that circumstance, the fact that a specialist opinion has been sought should be declared, thereby indicating that the case is a difficult one. The clinician who needs to act on the report will thus be able to bear in mind the fact that this is a difficult case when interpreting the report.

Principles for the use of Cross-Border Pathology (including Telepathology)

The overarching principle is that any proposed cross-border pathology service must ensure that the quality of care and the accuracy of interpretation are not compromised. The quality of the service must be clearly defined and must not fall below the quality of provision expected at the local site.

Ensuring quality

Healthcare providers should not rely only on contractual arrangements between pathology companies and their employees, nor on indemnity provided by such companies, to guarantee the quality of patient care.

Quality assurance processes for any cross-border pathology service must be agreed by local and referral sites. This should include participation by the referral site in an appropriate, internationally recognized and independent clinical pathology laboratory accreditation scheme. All relevant reports from such a laboratory accreditation process should be made available to the person or organization seeking cross-border pathology services. The information provided should include the published scope of the accreditation scheme and any non-compliances or suggestions for improvement identified during the most recent accreditation process.

A designated lead pathologist at the local site (normally holding an appointment at a level that justifies independent reporting rights) should be responsible for the coordination of the service (including ensuring the validity of the quality assurance process, appropriate communication between clinicians, patients, the referral site laboratory service and the referral site pathologists). Full access to quality assurance and audit data must be available to the lead pathologist and to both the originating and referral sites

All details of the pathology practice should be documented in standard operating procedures which should be available for inspection by staff at both originating and referral sites, and by patients.

Policies and procedures for ongoing monitoring and evaluation of effective management, safety and proper performance of equipment at the referral site should be open to scrutiny by the lead local pathologist.

It is the responsibility of the local site contracting telepathology services to ensure that the reporting pathologist at the referral site is appropriately registered/licensed, credentialed, indemnified and possesses the required specialist qualifications and linguistic competence in the jurisdiction of the local site.

In some circumstances it may be difficult for the local institution to detect surrogate reporting (“ghosting”) at the referral site, where reporting is actually undertaken by an individual who is less well qualified than the referral site pathologist who appears to take responsibility for the report. In such circumstances, the use of cross-border pathology is not acceptable.

Communication

Whenever a cross-border pathology service is in operation, patients and local clinicians should be informed at the time the sample is taken of the location(s) where their pathology results may be generated.

The provision of a diagnostic service includes pre-and post-analytical phases.

In the pre-analytical phase, advice must be available for clinical staff at the local site to ensure appropriate sampling and fixation of the material. Staff at the referral site must be able freely to seek further information from the clinicians treating the patient, to ensure correct handling of the specimen.

In the post-analytical phase, free communication between the clinician and pathologist is often essential in the formulation of diagnosis, prognosis and treatment strategies at the local site, and in ensuring that the referral site pathologist fully understands what information is important to the clinical team in each case. Urgent or significant unexpected findings should be transmitted to the local clinician without delay, in compliance with protocols in force at the local site.

Adequate understanding of the language of the local site by the referral site is essential, including idiomatic use and specialist vocabulary.

Liability in law

A Service Agreement must clearly define and document the legal arrangements and responsibilities between the referring and interpreting sites. This agreement must be available for inspection by laboratory staff at local and referral sites, and by patients.

A patient who suffers damage or loss as a result of an alleged error by a cross-border pathology service should not be required to litigate in a distant jurisdiction. It should be possible to seek any legal redress from the local site.

All those involved must comply with all data protection and privacy standards and legislation as laid down at the local site. Policies and procedures for security of patient identification and image data must be documented.

Measures to safeguard the system against intentional or unintentional corruption of specimens and data must be in place. There should be a system to document and authenticate the electronic transmission of the report so as to prevent fraud or loss of confidentiality.

Secondary uses of pathology specimens or data

Any use of specimens or data for research or any other purpose other than direct patient care must be documented and must comply with the normal requirements for practice at the local site.

Staff training and maintenance of local skills

There is a risk that large scale cross-border pathology referrals will undermine pathology services in countries or regions where a high proportion of the workload is outsourced. Consequences include the deskilling of entire regions, inability to train pathologists or laboratory scientists to meet local needs, and inability to conduct research into regionally important diseases. The presence of a well-educated and appropriately credentialed pathology workforce operating from accredited laboratories with the ability to provide internationally recognized pathology training programs is necessary for optimal patient care and should be considered a strategic national resource.