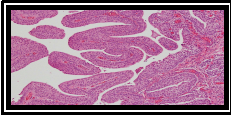


**GUIDELINES FOR ESTABLISHING A TELEPATHOLOGY SERVICE
FOR ANATOMIC PATHOLOGY USING WHOLE SLIDE IMAGING**

**September 21, 2012
v. 13**

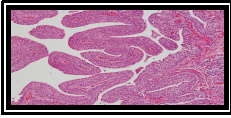


Telepathology Guidelines

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Telepathology Guidelines

Glossary of terms

Digital Pathology

The use of digital imaging and telecommunications technology to facilitate the capture, sharing, transfer and/or storage of image-rich pathology data, and related data for the purposes of diagnosis, education, quality assurance and research.

Telepathology

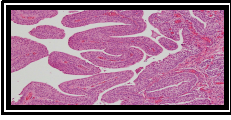
The practice of digital pathology, in which the pathologist views digitized or analog video or still images, and renders an interpretation that is included in a formal diagnostic report or documented in the patient record.

On-site

On-site is where the request for a diagnosis or a second opinion originates. The on-site pathologist is the one who requests the consultation or referral to a pathologist at a remote location. The on-site surgeon is the one who asks for an intraoperative consultation to a remote pathologist.

Remote site

The remote site is where a pathologist views the images and provides the consultation, to the on-site pathologist or surgeon. The remote site pathologist is the one who receives the requests and provides the diagnosis.



Telepathology Guidelines

Introduction

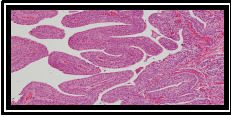
The following guidelines have been developed upon request from the president of the Canadian Association of Pathologists. The objective is to provide Canadian pathologists with baseline information on how to implement and use telepathology in Canada. A working group composed of pathologists, technologists, and healthcare administrators from across Canada was created to oversee the development of these guidelines (see Appendix A for participating members). The expected outcome is to facilitate an organized approach to the rational adoption of telepathology in Canada.

While there are different modalities and applications of telepathology, this document will focus on one modality used in anatomic pathology for intraoperative pathology consultation – frozen section, expert or second opinions, and quality assurance. This modality, called whole-slide imaging (WSI), has shown great improvement in recent years and has the potential to deliver important benefits to the healthcare system, the laboratory, the pathologist and the patient. One such benefit is the potential to provide similar pathology consulting services throughout the country regardless of the size of the institution or location.

These guidelines will deal with clinical-administrative issues of implementing a specific WSI telepathology program for quality assurance, preliminary diagnosis, select primary diagnosis and diagnosis consultation or second opinion in anatomic pathology. These guidelines do not address other modalities and applications that could be used to develop digital pathology programs in the anatomic and clinical pathology laboratories. For example, programs for haematopathology, microbiology, tumour boards, education and research as well as technical and/or standard-related issues are not covered in this document.

This document was systematically developed and based on available medical literature and clinical experience. It is designed to provide information to assist decision making regarding this technology. It is not intended to define a standard of care and should not be construed as doing so. The committee members do not expect this document to replace clinical judgment, and expect that judgment in individual cases will be made by the physician with appropriate regard to the individual circumstances. The committee members do not warrant that adhering to these guidelines will produce a successful outcome in every case.

Current ongoing projects in Canada are listed in appendix B



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Telepathology

Telepathology is part of the spectrum of digital pathology. The College of American Pathologists (CAP) defines telepathology as “the practice of pathology, in which the pathologist views digitized or analog video or still image(s), and renders an interpretation that is included in a formal diagnostic report or documented in the patient record”. It is used as an electronic, multimedia communication between pathologists, surgeons and other laboratory personnel for the purpose of primary diagnoses and diagnostic consultation or what is commonly called a “second opinion”.

A key benefit of telepathology is the ability to reduce the physical boundaries of the laboratory where the sample is processed (on-site) and the location of the assessment / interpretation of the sample at the remote site. Telepathology can provide a means to increase efficiencies in the healthcare system by making pathology consulting services available in regions that have a reasonable telecommunication infrastructure.

Current Usage in Canada

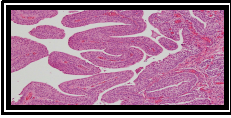
Telepathology for primary diagnosis in the anatomic pathology laboratory has not yet become the current practice for a number of reasons. Some of these are:

1. The rapid evolution and complexity of some of the technologies.
2. The limited amount of experience with telepathology and validation projects in Canada.
3. The high cost of acquisition and access to funding for telepathology.
4. The lack of standards to support integration, workflow alignment and routine operations.
5. The absence of remuneration for telepathology.
6. The size of the images may significantly impact networking capabilities.
7. Device approvals by Canadian authorities may not be in place.

Telepathology Outside Canada

There are some efforts to provide an international collaborative site for the exchange of medical knowledge, group discussion and distant teaching. One such site is iPath at the University of Basel (<http://telemed.ipath.ch/ipath/>). Such sites are excellent for collaboration but have limited use for a local healthcare network where patient confidentiality, reporting, liability and pathologist’s remuneration are important elements.

Increased use of telepathology systems, and its inherent collaborative nature, may eventually bring to the forefront such issues as cross-border professional liability, data protection and security as well as remuneration. This may require international treaties and standards to be developed and it is too early at this stage to contemplate if such a situation is realistic, at least in the short term.



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Applications of Telepathology

Primary diagnosis via telepathology refers to a first opinion diagnosis rendered on an image obtained from tissue sections processed from a paraffin block (Hematoxylin and eosin section, special stains, immunohistochemistry, in situ hybridization) in anatomic pathology. In primary diagnosis telepathology, the remote pathologist is responsible for ensuring that quality slides are prepared and that all the necessary information to render a diagnosis is available and reviewed.

Intraoperative consultation (IOC) via telepathology refers to a preliminary diagnosis / opinion rendered from image(s) of a frozen tissue section that has been processed rapidly during surgery. This may include macroscopic (e.g. gross tissue images) and / or microscopic images.

Second opinion / consultation via telepathology refers to the formal review of a primary diagnosis by a remote pathologist rendered from the digital image(s), and relevant clinical information, used to make the primary diagnosis. The need for a second opinion can be related to the complexity of the case, the type of case (e.g. malignancies that require a second opinion prior to rendering a primary diagnosis), the level of expertise and / or the availability of required resources e.g. technical.

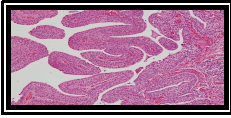
Potential Benefits of Telepathology

For the pathologist:

- Reduced travel
 - Ability to work anywhere and anytime.
- Enhanced access to expertise and diagnostic tools:
 - Sub specialist experts.
 - Multiple opinions.
 - More precise measurements (based on the use of digital tools).
 - Quality digital images representative of the entire specimen on a glass slide that can be viewed repeatedly, annotated and stored for future use.
- Improved turnaround times for interpretations
 - E.g. faster access of immunohistochemical stains.
- Increased collaboration (pathologists, surgeons, laboratory technicians/technologists).
- Improved job satisfaction:
 - The potential to improve workload distribution.
 - Reduced isolation for pathologists working in remote regions.
 - Enhanced access for education and quality assurance activities.
 - Skills development and maintenance.

For the healthcare system and the patient:

- Increased efficiencies due to:
 - Reduced lost or broken slides.
 - Reduced costs related to pathologist travel and/ or specimen transportation (although specimen transportation to the primary processing laboratory is maintained in most situations).



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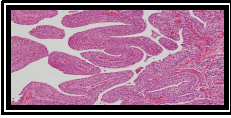
- Improved access to diagnostic materials.
- Diminished interruption of service due to the availability of the pathologist.
- Decreases in patient transfers and two-step surgeries.
- Enhanced recruitment and retention of local surgeons and / or pathologists especially in remote regions.
- Improved quality of service through enhanced:
 - Access to expertise for consultation and education.
 - Collaboration between pathologists.
 - Improved turnaround times.

Technologies used in telepathology

Telepathology is an emerging field that is expected to continue to evolve. Technologies currently used in telepathology include:

1. Static Image Systems.
2. Streaming Image Systems (video streaming).
3. Whole Slide Image Systems.

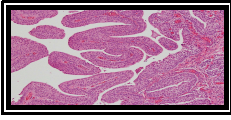
1. **Static imaging** involves the capture and storage of still microscopic or macroscopic images with a digital camera attached to a microscope or a macroscopic platform and the subsequent transmission of the digitized images captured via the internet/intranet. Static imaging is the simplest and most mature modality of telepathology. While the least expensive of the telepathology systems, its application and benefits are considered limited because the whole slide(s) image is not represented and there is dependence on the operator at the on-site for image selection. Its use is limited to specific and selected clinical situations.
2. **Streaming imaging** involves the continuous transmission of images (video streaming) from a microscope or macroscopic platform captured through a digital streaming camera (such as a static digital camera with streaming software or a digital video camera). Control of the streaming image is by the on-site personnel unless a robotic microscope is used. In this situation, the observer at the remote site controls the microscope. Streaming allows the remote pathologist to see as much of the specimen on the microscopic slide as required in order to render a diagnosis. In most situations there is a two way communication to facilitate the discussion between the on-site and remote pathologists. Initially, streaming was thought to be more labor intensive than other telepathology solutions as it required the sender and receiver to view the images concurrently. However, experience shows that in certain situations, it may be less labour intensive because it does not require the time and possible use of an intermediary to scan a slide and, for very high resolutions like haematology, it may help to select the proper field.
3. **Whole slide imaging (WSI)** involves the use of an automated microscopic glass slide scanner that captures serial images from the entire specimen located on a microscope glass slide. These images are 'stitched' together by a complex algorithm to create a virtual image of the entire specimen on a microscope slide, which is then stored and can



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be viewed remotely via image management software. Whole slide imaging is the newest and considered the most complex of the telepathology solutions currently available. The advantage of this modality is its ability to create “virtual” slides of the entire specimen that can be stored, retrieved and shared indefinitely and simultaneously by multiple users with approved access. The challenges associated with this technology include the cost of ownership, lack of multi-planar focusing for cytology, lack of information technology (IT) infrastructure and storage, need for increased resources to physically scan glass slides, the speed of image acquisition and image resolution requirements for some users. Change management, including integration into current processes and end user adoption and validation requirements for new technology are challenges as well.

At this point in time, WSI appears to be the most promising modality for certain applications in the anatomic pathology laboratory. As a result, the guidelines contained within this document focus on such applications.



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Whole Slide Imaging in Anatomic Pathology

Components

Telepathology systems can be comprised of multiple components which are determined by the type of examination required. In anatomic pathology the two primary examinations conducted are macroscopic examination (macroscopy) and microscope examination (microscopy).

Macroscopy refers to the visual examination and manipulation of the surgical specimens before the selection of the representative sections for microscopy, for example, a frozen section during an intraoperative consultation. In telepathology, this can be achieved by the use of an audio-visual system which permits the on-site clinician (surgeon, pathologist, pathologist's assistant or laboratory technologist) and the remote pathologist to discuss the preparation of the specimen. This system is generally composed of a grossing table, a specialized videoconferencing system (camera, monitor and pointing system) and an appropriate lighting arrangement along with a reliable mode of telecommunication (e.g. speaker phone, intercom etc). Some of these systems permit the remote pathologists to annotate the screen to show what areas to prepare. The on-site clinician can see these annotations on a screen which helps prepare the specimen in such a way that facilitates an accurate diagnosis.

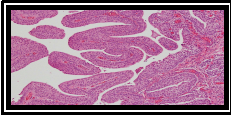
Microscopy refers to visual examination of whole slide via digitized images. The key components include:

- Scanners.
- Viewers.
- Image management software.
- Image analysis tools.

Scanners provide the means to capture the whole slide digital image, and each scanner varies in the resolution of the image and the speed for digitization. A scanner's capacity can range from units that can scan 1 to 10 slides to larger systems that can accommodate up to 500 slides or more. Scanning times vary depending on the size of the area scanned and the magnification required. Currently, the scanning time for a 15 x 15 mm specimen ranges from 2 minutes using a x20 objective to up to 10 minutes using a x40 objective.

Viewers are monitors that permit viewing the digitized images. Viewers must be of adequate size and resolution to provide the necessary details (color and resolution) for the consulting pathologist to interpret the image.

Image management software provides the unifying link for on-site and remote sites. This software also can be configured to reflect the appropriate workflows as well as providing storage and retrieving functions. The software thus becomes the true expression of a pathology network and its workflows. The ease of use and stability of the software are essential for the



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pathologists to adopt and use WSI for primary diagnosis or to render expert/second opinion. Such software should ideally have the capability of linking with other clinical systems such as a laboratory information system via accepted standards such as HL7. Without this linkage, an alternative solution should be found to limit time consuming manual data entry that is subject to clerical error.

Image analysis/computer-aided diagnostics tools have recently been developed to interpret/quantify immunohistochemical staining to identify rare events, count mitotic figures or grade malignant tumours. The accuracy and applicability of the interpretative tools is under investigation. These tools are not in the scope of this document.

Network Configurations

There are three configurations which are emerging: point-to-point, centralized and decentralized. A **point-to-point** setting usually involves two sites (on-site and remote site), which are linked only during the consultation process. In a **centralized** setting, there are multiple remote sites and one on-site (primary) site, which is the sole provider of the diagnostic or consultation service. In a **decentralized** setting, there are multiple sites which can act as on-site and remote sites depending on the circumstance.

The underlying principle for configuring a telepathology network is providing the image and its relevant information to the appropriate remote pathologist in a timely manner.

Implementation

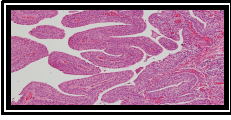
Key considerations when implementing telepathology solutions are changes to the roles, responsibilities, processes and workflow. They include and are not limited to, the following recommendations.

For the on-site, it is recommended to:

1. Maintain procedures for identifying the specimen as per current laboratory protocol.
2. Provide all the relevant clinical information at the time of the consultation and when asked for by the remote pathologist.
3. Obtain the remote pathologist's report and integrate the information into the final report issued at the on-site.
4. Store the remote pathologist's report as per laboratory protocol.
5. Ensure that all laboratory personnel are trained for telepathology and understand its use and its limitations.

For the remote site, it is recommended to:

1. Ensure that all the material and information required for a diagnosis has been received and that additional materials (slides, blocks, tissue, images, etc.) are accessible if necessary.
2. Request additional information if required.
3. Request the glass slide and/or blocks, if the image quality is inadequate or if additional special studies are necessary for diagnosis or patient management.
4. Establish how preliminary results will be transmitted to the on-site.



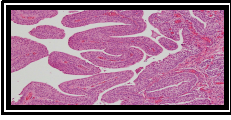
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5. Complete the remote pathologist's report and ensure the on-site pathologist receives a copy.

Challenges

Challenges associated with implementing whole slide imaging solutions are related to the relative infancy of this technology. They range from a lack of established best practices and standards to the technical limitations of the solutions themselves and acceptance of the technology.

1. Currently, Canada is in the early stages of implementing this technology and its use for patient care has been limited to niche applications in a few centres. While these centres have shared their institution-specific protocols and experiences, there are currently no widely accepted best practice guidelines (or standards) that apply to the different modalities and applications of telepathology or to each institution contemplating the use of this technology. In addition, only a few limited validation studies examining the use of WSI for some specimen/tissue types in surgical pathology have been conducted. Robust best practices and standards will eventually be developed as more centres implement telepathology and as image standards, such as the recently established DICOM supplement 145 (August 2010), are implemented by vendors and adopted.
2. The scanners and viewing systems do not easily allow a pathologist to perform multi-planar focus adjustments to accommodate for variations in the thickness of tissue on glass slides. This limitation has been identified as a reason to avoid using these systems to evaluate cytology slides for diagnostic purposes. The quality of images produced by the various WSI solutions (available as of 2012) is directly affected by the quality of the histologic slides that are placed in the scanners. Generally speaking, the focusing algorithms used by these devices cannot accommodate for poor quality histology (tissue folds, chatter artefact from poor microtomy, mounting media issues such as dried mounting media with dirt on top of coverslips or air bubbles underneath coverslips). Poor histology generates images that are inadequate for diagnostic purposes. The technology is, however, rapidly evolving and the issue of fine-focus adjustment will no doubt be overcome.
3. When telepathology is used for primary intraoperative pathology consultation (frozen section diagnosis) in the absence of an on-site pathologist, training of laboratory staff in terms of inking and identifying resection margins, orienting tissue sections and/or selecting areas to be sampled from large specimens etc. is a key component for the implementation of a telepathology program. In addition, technical staff must be familiar with the scanner, imaging software and be able to trouble-shoot technical problems during a time-critical procedure.
4. To operate at a high level of availability and effectiveness are both major technical and financial challenges. These can be achieved in a number of ways, but the final configuration will depend on the designated use (intraoperative pathology consultation versus second opinion) and the available funding.



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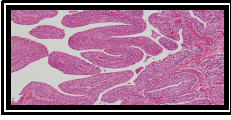
5. Whole slide images are large, typically larger than MRI or CT digital images. As a result, networks used for telepathology to transmit large files within the required timelines without resulting in image distortion and/or degradation may have constraints depending on the network architecture. Image storage requirements will be high and may vary between applications and jurisdictions. Policies and processes should be established based on regional requirements.
6. Change management and acceptance of telepathology are among the biggest issues and require a highly coordinated effort between teams working in different sites. Pathologists and surgeons at different sites as well as pathologists and laboratory staff of different laboratories must learn to work together and communicate after implementation

Validation

Validation refers to the demonstration of equivalent diagnostic performance between digital pathology systems and light microscopy (i.e. the same pathologist will make the same diagnosis with both approaches when examining the same specimen – both macroscopic and microscopic). Each organization implementing telepathology for clinical diagnostic purposes should carry out a validation study to establish the accuracy, safety and reliability of the system.

The following is a list of draft statements that is currently in the stages of being edited and finalized by the College of American Pathologists Center Work Group for Validating Whole Slide Imaging (WSI) Systems for Diagnostic Purposes in Pathology. It speaks to validation of imaging systems / solutions in the clinical and anatomic pathology laboratory. Once this list has been finalized and approved by the College, a full whitepaper will be published in the Archives of Pathology and Lab Medicine (this is planned for late 2012):

1. All institutions or practices considering the implementation of Whole Slide Imaging (WSI) technology for clinical diagnostic purposes must carry out their own validation.
2. Validation for each diagnostic application such as reading intraoperative consultation (frozen section) slides, reviewing immunohistochemistry slides etc. is necessary.
3. The validation study should closely emulate the real-world clinical environment (e.g., include the same workflow process, equipment, etc.).
4. Validation of the entire whole-slide imaging system should be performed.
5. A pathologist adequately trained to use the whole-slide imaging system must be involved in the validation process.
6. Validation of whole-slide imaging systems should involve specific types of specimens such as fixed versus frozen tissue, cytology slides, haematology blood smears and their preparations, but not necessarily all specific tissues, diseases, microscopic changes or diagnoses.
7. The validation process should include a sample set of approximately 100 cases that reflects the spectrum and complexity of specimen types and diagnoses likely to be encountered during routine operation.
8. Digital and glass slides should be evaluated in random order to minimize order effect.



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9. A washout period of approximately three (3) weeks should occur between viewing digital and glass slides.
10. The validation process should ensure that all of the material present on a glass slide, or purposefully selected area(s) on a slide to be scanned, are included in the digital image.
11. Measurable outcomes should establish diagnostic concordance between digital and glass slides for the same observer.
12. Approval of whole-slide imaging systems should be limited to the conditions under which validation occurred. Re-validation is required whenever a significant change is made to any component of the whole-slide imaging system. Significant changes refer to new scanners or the introduction of mobile viewing devices such as iPads, smartphones etc.
13. Documentation should be maintained recording the method, measurements and final approval of validation for the whole-slide imaging system to be used in the clinical laboratory.

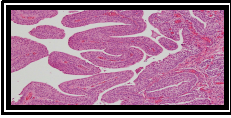
Collaboration and Communication

Telepathology requires a high degree of coordination and collaboration between pathologists, surgeons and technical staff and high confidence levels between them are required to ensure the quality and reliability of the collective work. The value of education, training and practice increase as the process is more complicated and its potential impacts are greater.

Between the digital pathology team and IT support personnel. Dedicated IT support staff should be identified to assist with the planning and implementation of a telepathology system. The IT staff should be involved at the beginning of any planning process and have a clear understanding of the clinical applications / use cases for which the system will be used (e.g. time sensitive applications such as intraoperative consultations or less time-sensitive functions). There should be a clear plan for emergency IT support if the telepathology system will be used outside of regular hours.

Between the remote pathologist and the surgeon on-site. In the case of an intraoperative pathology consultation, the communication between the on-site surgeon and the remote pathologist is of utmost importance. Ideally, the surgeon should be the contact person on-site and must be available for the macroscopic examination of the specimen, unless the specimen is very small and will be examined histologically in total. The remote pathologist may require the surgeon to provide key clinical information and show exactly where the lesion is. Therefore, surgical colleagues should be engaged early on in the implementation process of an intraoperative consultation telepathology program.

Between the remote pathologist and laboratory personnel on-site. Close interaction between the remote pathologist and on-site laboratory personnel is important to identify and help to solve technical problems, and to collaborate on the implementation of new technical developments. The remote pathologist may be involved in dissection and sampling of gross surgical specimens by on-site laboratory staff.



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Appropriate protocols should be developed and the remote pathologist may assist the on-site laboratory staff for dissection and sampling of the specimen to avoid misunderstanding about the nature and site of origin of the tissue blocks. Photomicrographs should be taken as necessary to allow the remote pathologist to evaluate the gross specimen. Interactive (audio and video) macroscopy should be strongly considered for telepathology situations where large, complex specimens are encountered on a regular basis. Any laboratory archives of relevant previous reports and slides must be available to the remote pathologist before an intraoperative consultation.

Training

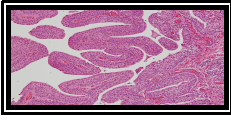
Training on the use of the new telepathology system and new workflow procedures is a key element of a successful implementation and for successful change management. Adequate attention and time should be devoted for all personnel involved (on-site and remote) as workflows and clinical procedures may have to be revised. Care should be taken to make sure that reasonable timelines are set. Training should not be rushed, but offered on a timely basis and shall be completed before the service is operational and before a user is permitted to use the system.

Quality Management

A successful telepathology service must incorporate various elements of quality management, including a systematic process to review consultations and primary diagnoses performed via telepathology. Effective quality assurance processes are an integral component of patient safety. The ultimate goal of quality assurance activities is to improve practices and procedures within the health care system. As a successful telepathology service is based on collaboration between on-sites and remote sites (which may transcend different healthcare regions), maintaining quality becomes an important element and a challenge. It is only through quality management that multiple sites can collaborate and exchange information in a confident and secure fashion.

Here are some elements of quality management:

- A steering committee should oversee the project implementation and be comprised of the key stakeholders such as medical, laboratory clinical/technical and IT representatives.
- Relevant policies should be reviewed and revised (i.e. slide retention, storage location of the final report, etc.) on a regular basis.
- Appropriate levels of documentation of hardware and software as well as administrative and clinical procedures must be made available to all participating sites.
- A practical reporting and troubleshooting process should be developed.
- A systematic process to regularly review consultations and primary diagnoses performed via telepathology should be implemented; for example, a review of a minimum of 10% of all consultations and diagnosis made by telepathology is recommended by the American Telehealth Association (ATA).
- Documentation of key performance parameters such as turnaround time and diagnostic concordance for frozen sections, % of cases deferred to glass slide review and the reasons for such deferrals, % of slides that require re-scanning, etc.



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- Pathologists who are involved in instituting a telepathology program at their health care facility should consider the establishment of a properly constituted quality assurance committee for the purpose of conducting whole-slide telepathology reviews.

Privacy and Security

As most telepathology systems involve the capture and management of personal patient information, an evaluation process to establish if confidentiality and security principles are respected should be completed before the service is implemented. This process is usually done via a Privacy Impact Assessment (PIA) study which focuses on data workflow within the software and hardware environment and how this workflow meets jurisdictional privacy laws and regulations in place at the provincial and national levels. In addition, a Security Threat Risk Assessment (STRA) may be required. Most IT professionals are familiar with such a process and can provide support. Because pathologists may be providing telepathology services across jurisdictions, pathologists should be aware that multiple privacy statutes may apply (e.g. privacy legislation of the provinces/territories in which the patient and physician are located, Canada's *Protection of Personal Information and Electronic Documents Act*, etc.)

Workload Considerations

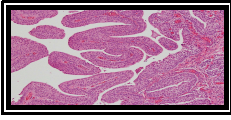
Telepathology encourages collaboration between different pathology laboratories and, therefore, may be viewed as a threat to many pathologists who fear an increased workload. Currently, for certain analyses, telepathology requires additional time compared to the use of the microscope. The need for additional analysis time is likely to diminish as acceptance and utilization of telepathology increases within the clinical and academic domains. Therefore, it may be important that appropriate financial compensation be negotiated within each jurisdiction.

Documentation and Archiving

As in a standard pathology practice, a formal report must be made by the remote pathologist and this report may become part of the patient medical record. It is recommended that all reports, letters, clinical information and images transmitted between the on-site and remote sites be archived at either the on-site or remote institutions or both depending on the jurisdiction's requirements. The on-site shall be the single source of truth (SSOT) for all digital images it generates.

Retention policies need to be established for the storage and archiving of whole slide images as well as for dynamic, real-time images generated during a telepathology session (intraoperative consultation, macroscopy supervision). If, for any reason, only part of the image can be saved, there should be a clear policy supporting this decision.

Because pathologists may be providing telepathology consultations across jurisdictions, pathologists may need to meet the record keeping requirements for more than one jurisdiction. In this regard, remote pathologists will want to ensure their record keeping practices are consistent with the requirements specified in the relevant legislation and College policies for the province/territory in which the pathologist is located, as well as the province/territory in which the patient is located. Such requirements may include the need to retain the whole-slide images in the medical record, as well as the remote pathologist's formal report.



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Technical Support

Technical support is essential to any operational computer system which supports a clinical process.

Local support

Local technical and biomedical support should be readily available to pathologists and staff encountering any technical problem during telepathology activities, especially time-sensitive applications.

Regional and/or jurisdictional support

A coordinating centre or some form of regional or jurisdictional support group or policy should be available to help each participating site obtain vendor support and appropriate training for the telepathology personnel. Telepathology is an evolving technology and thus requires ongoing attention and care.

Equipment maintenance

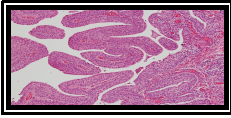
An appropriate equipment maintenance program should be in place in each participating site which may include spare equipment for quick replacement. Complete records for service and preventative maintenance should be kept in accordance with any applicable laboratory accreditation requirements.

Liability

Telepathology raises unique liability issues. As such, pathologists will want to follow a prudent course of action when using telepathology, which may include consulting with other facilities who are using the technology to determine how it is used there (see "*Medico-legal issues arising from new health-care technologies*" available online at: www.cmpa-acpm.ca).

Pathologists who have questions about their liability and liability protection when treating patients through telepathology, are encouraged to contact the Canadian Medical Protective Association (CMPA) for advice. Pathologists considering using telepathology will be interested in reviewing the CMPA's publication "*CMPA assistance in legal matters arising from telehealth: Technology makes location of physician less relevant*" (published March 2006, revised August 2008 and March 2009), which sets out some guiding principles for the purpose of determining members' eligibility for CMPA assistance in the practice of telehealth. This publication is available online at: www.cmpa.acpm.ca.

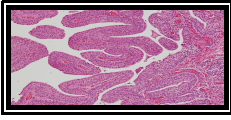
In general, the CMPA's approach to assisting members with matters related to telehealth is consistent with its approach to assisting members of other matters. In this regard, the CMPA will generally assist its members in the event of medico-legal difficulties arising in Canada as a result of professional work done in Canada. Although the patient and the member may not be in the same province/territory at the time of the telehealth encounter, if the legal action is brought in Canada, the member is generally eligible for CMPA assistance. The CMPA will not generally assist where a telehealth encounter occurs between a patient located outside of Canada, regardless of whether the legal action is brought in Canada or elsewhere.



Telepathology Guidelines

Licensure

The remote pathologist involved in primary diagnostic sign out must have complied with all applicable licensing requirements in the jurisdiction involved in the telehealth encounter. If the remote pathologist and the on-site patient are located in different jurisdictions, an inquiry with the College in the jurisdiction where the patient is located is necessary.



Telepathology Guidelines

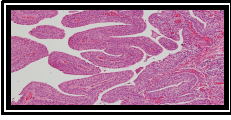
Conclusions

This paper provides general guidelines for pathologists or institutions wishing to explore or implement telepathology. Practitioners are encouraged to experiment with telepathology as the current technology can provide significant benefits to the patient, the pathologist and the healthcare system. Such experimentation will also identify difficult issues/challenges that might be unique to their practice environment. While the technology by itself generates much excitement, the real work, and subsequent benefits, lies in change management, workflow alignment and collaborative teamwork.

Practitioners are encouraged to discuss with fellow pathologists about telepathology, especially project directors of the main projects currently in operation in Canada.

As more and more of such projects are developed, requirements for specific telepathology standards will evolve and help the proliferation of this approach. Robust best practice guidelines can then be developed from the collective experience of many different institutions and practice situations.

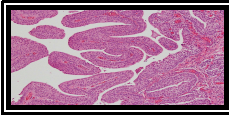
As this technology is still evolving, it is planned that this document will be reviewed on a regular basis.



Telepathology Guidelines

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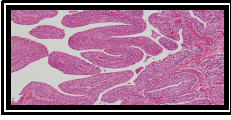
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Telepathology Guidelines

Appendix A - Committee members

Name	Organization
Chantal Bernard	Montreal Children's Hospital, Québec
S.A. Chandrakanth	MBBS, MD.,FRCP (C), Staff Pathologist, Chair of Telepathology Committee, Dept. Of Pathology & Lab Medicine, Health Sciences Centre, Newfoundland
Ian Scott Cornell	MD,FRCP(C), Medical Lead, FHA Telepathology Project, Director, Surgical Pathology , Royal Columbian Hospital, New Westminster, British-Columbia
James Dalton	CEO, Eastern Ontario Regional Laboratory Association
Andrew Evans	Staff Pathologist and Director of Telepathology, University Health Network, Toronto General Hospital, Toronto, Ontario
Bertha M. Garcia	Vice Dean, Education, Schulich School of Medicine and Dentistry, The University of Western Ontario, London, Ontario
Chris Godin	Formerly Manager of Information Services and Technology, Eastern Ontario Regional Laboratory Association
Marek Godlewski	MD., MSc, FRCPC, Assistant Professor, Pathology Dalhousie University, Clinical Department Head Saint John Regional Hospital, Horizon Health Network, New-Brunswick
Gerard H. Jansen	MD, FRCPC, The Ottawa Hospital, Ottawa, Ontario
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Said Louahlia	CHR Rimouski Neigette, Québec
Lisa Manning	MLT, BSc (Hon), Pathology Technical Director, Diagnostic Services of Manitoba
Raymond Maung	MD, FRCPC, MBA, Regional Medical Director of Laboratory Services, Interior Health Authority, British-Columbia
Lisa Moore	RT, BMLSc, Manager, Laboratory Informatics, Vancouver Island Health Authority, British-Columbia
Joanne Phillely	ART, MBA, PMP, Senior Clinical Analyst, Laboratory Diagnostics and Blood Services Branch, Ministry of Health, British-Columbia
Jack Slatnik	Site Lead , Royal Alexandra Hospital , Alberta Health Services
John Srigley	MD, FRCPC, FRCPA[Hon.], Chair, National Pathology Standards Committee Canadian Partnership Against Cancer, Professor, Dept. of Pathology and Molecular Medicine, McMaster University
Bernard Têtu	Committee Chairman , Medical Director, Eastern Québec Telepathology Project and Professor of Pathology , CHU de Québec, Québec
Alain Thibault	Director, Process, Systems/Logistics Management Eastern Ontario Regional Laboratory Association
Woo Je Jo	BSc(hon), MD, FABP, FCAP, FRCPC, Pathologist, Alberta Health Services Red Deer Regional Hospital Center
Donald Daniel Picard	Canada Health Infoway
Hannah Cracower	Canada Health Infoway



Telepathology Guidelines

Appendix B - Current telepathology projects in Canada

The following projects have developed a very good understanding of what is required to plan and implement telepathology for patient care. Their experiences have also given them insight into the applications and limitations that can be of help for those considering telepathology projects:

- British Columbia uses telepathology for select education, quality assurance and consultation (including frozen sections) purposes.
- University Health Network in Toronto uses telepathology to provide diagnostic services (predominantly primary frozen section interpretation) within their sites in Toronto as well as to colleagues in Kingston and communities in Northern Ontario.
- RUIS de l'Université Laval operates telepathology in 21 sites for diagnostic and second opinion and educational functions. Funding to expand this system to 15 new sites across the province has recently been approved.
- The University of Manitoba implemented a scanner for select educational, quality assurance and consultation purposes.
- "EORLA – Eastern Ontario Regional Laboratory Association" is in final validation stages for its Reference Lab Telepathology program. Telepathology (frozen sections) is used at The Ottawa Hospital Civic, and Riverside sites communicating to the central pathology hub located at the Ottawa General Hospitals. Plans to incorporate other regional EORLA lab sites are planned for end of 2012.