

## Guidelines

# American Telemedicine Association clinical guidelines for telepathology

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## PREAMBLE

The American Telemedicine Association (ATA) brings together diverse groups from traditional medicine, academia, technology, and telecommunications companies, e-health, allied professional and nursing associations, medical societies, government and others to overcome barriers to the advancement of telemedicine through the professional, ethical, and equitable improvement in health care delivery.

The American Telemedicine Association has embarked on an effort to establish practice guidelines for telemedicine to help advance the science and to assure the uniform quality of service to patients. They are developed by panels that include experts from the field and other strategic stakeholders, and are designed to serve as both an operational reference and an educational tool to aid in providing appropriate care for patients. The guidelines generated by ATA undergo a thorough consensus and rigorous review, with final approval by the ATA board of directors. Existing products are reviewed and updated periodically.

The purpose of these guidelines was to assist practitioners in pursuing a sound course of action to provide effective and safe medical care that is found

on current information, available resources, and patient needs. The guidelines recognize that safe and effective practices require specific training, skills, and techniques, as described in each document. The resulting products are properties of the ATA and any reproduction or modification of the published guideline must receive prior approval by the ATA.

The practice of medicine is an integration of both the science and art of preventing, diagnosing, and treating diseases. Accordingly, it should be recognized that compliance with these guidelines alone will not guarantee accurate diagnoses or successful outcomes. If circumstances warrant, a practitioner may responsibly pursue an alternate course of action different from the established guidelines. A divergence from the guidelines may be indicated when, in the

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reasonable judgment of the practitioner, the condition of the patient, restrictions or limits on available resources, or advances in information or technology occur subsequent to publication of the guidelines. Nonetheless, a practitioner who uses an approach that is significantly different from these guidelines is strongly advised to provide documentation, in the patient record that is adequate to explain the approach pursued.

Likewise, the technical and administrative guidelines in this document do not purport to establish binding legal standards for carrying out telemedicine interactions. Rather, they are the result of the accumulated knowledge and expertise of the ATA work groups and other leading experts in the field, and they are intended to improve the technical quality and reliability of telemedicine encounters. The technical aspects of and administrative procedures for specific telemedicine arrangements may vary depending on the individual circumstances, including location of the parties, resources, and nature of the interaction.

## SCOPE

This guideline is intended to cover clinical applications of telepathology only. For this document, telepathology is defined as the electronic multimedia communication across a network of pathology-related information, between two or more locations for use-cases between pathologists and/or qualified laboratory personnel, and may include involvement by clinicians and/or patients. Examples of clinical applications include primary diagnosis, intraoperative consultations, secondary consultations, and quality assurance that may result in amended cases. The scope of this guideline excludes use-cases specifically for research or education purposes. The recommendations apply to all types of telepathology configurations, regardless of the hardware device utilized, including static (store and forward), dynamic (synchronous), and hybrid static-dynamic implementations.

For this document, there are several terms that need to be defined specifically:

- “Shall, should, may” – this document contains requirements, recommendations, or actions that are identified by text containing the keywords “shall,” “should,” or “may.” “shall” indicates a required action whenever feasible and practical under local conditions. “Should” indicates an optimal recommended action that is particularly suitable, without mentioning or excluding others. “May” indicates additional points that may be considered to further optimize the healthcare process. “Shall not” indicates that this action is strongly advised against period.
- Telemedicine: The use of medical information exchanged from one site to another via electronic

communications to improve a patient’s clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, E-mail, smart phones, wireless tools, and other forms of telecommunications technology.

- Telepathology: A form of communication between medical professionals that includes the transmission of pathology images and associated clinical information for the purpose of various clinical applications including, but not limited to, primary diagnoses, rapid cytology interpretation, intraoperative and second opinion consultations, ancillary study review, archiving, and quality activities.

## INTRODUCTION

The term “telepathology” was introduced into the English language in 1986 by Weinstein,<sup>[1,2]</sup> and since then there have been many advances and publications.<sup>[3-13]</sup> The practice of telepathology involves obtaining macroscopic and/or microscopic images for transmission along telecommunication links for obtaining a remote interpretation (telediagnosis), second opinion or consultation (teleconsultation), quality assurance, education, teaching, self-study, and research (tele-education). A variety of terms has been used interchangeably to refer to telepathology including digital microscopy, remote robotic microscopy, teleconferencing, teleconsultation, telemicroscopy, video microscopy, virtual microscopy, and whole slide imaging (WSI).<sup>[9,11,14]</sup>

With advances in technology and widespread access to the Internet, telepathology is increasingly being used around the world, improving rapid sharing of cases and access to expert pathologists. Telepathology can be used for remote-site interpretation of all types of pathology material including, but not limited to, H&E stained paraffin tissue sections, frozen sections, cytology or hematology slides, microbiology specimens, clinical fluids (e.g. urine), electron micrographs, electrophoresis gels, and cytogenetics images.<sup>[2,15-24]</sup> In practice, these digital images are typically linked to patient information including identification/medical record numbers, clinical history, and relevant laboratory and radiology data.<sup>[25]</sup>

Table 1 summarizes milestones of the many technological advances in telepathology.<sup>[14]</sup> The primary modes of telepathology include static imaging, dynamic imaging, hybrid static/dynamic telepathology, and WSI.

- Static (store and forward) image telepathology: Asynchronous capture of image files for subsequent viewing<sup>[26]</sup>
- Robotic (dynamic) telepathology: The ability to remotely control an image acquisition device (e.g. microscope, whole slide scanner) that is used to view glass slides<sup>[27,28]</sup>

- Video microscopy (dynamic): Real time transmission (streaming) of images from a video camera for telepathology purposes<sup>[29-31]</sup>
- WSI: Digitization (scanning) of a glass slide to generate a digital file that allows the entire slide to be viewed in a manner that simulates microscopy<sup>[32-34]</sup>
- Multi-modality telepathology: Simultaneous utilization of more than one mode of technology (e.g. hybrid robotic microscopy and WSI).<sup>[35]</sup>

Despite many advances and increased utilization of telepathology, barriers exist that have limited its widespread use. These include cost, legal and regulatory issues, technology barriers (e.g. limited resolution, large image files), resistance from pathologists, and above all a lack of standards. Previously, the ATA published guidelines for telepathology in 1999.<sup>[36]</sup> This revision is an update to the original ATA guideline. More recently, the Canadian Association of Pathologists<sup>[37]</sup> and the Royal College of Pathologists<sup>[38]</sup> have also published guidelines for telepathology. The purpose of this document was to provide new and updated guidelines to offer guidance on specific applications, practice, benefits, limitations, and regulatory issues that may arise in the practice of telepathology.

## CLINICAL GUIDELINES

### Technology

The selection of digital imaging systems for clinical use shall be determined at the discretion of the medical director of the pathology facility intending to use them.

The facility shall be responsible for using such devices for food and drug administration (FDA)-approved clinical applications as claimed by the manufacturer. The medical director shall be responsible for employing and validating these devices if they are to be used for non-FDA-approved applications. To date, the FDA has not provided guidance with respect to WSI use for primary diagnosis, but if guidance is issued it should be followed as appropriate.

**Table 1: Telepathology system classification<sup>[14]</sup>**

Imaging system	Year
Real-time imaging	
Television microscopy	1952
Dynamic-robotic telepathology	1986
Static image telepathology	
Store and forward telepathology	1987
Whole slide imaging (automated)	1991
Whole slide imaging (operator-directed)	1994
Multi-modality telepathology	
Hybrid dynamic robotic/static imaging	1989
Whole slide imaging dynamic robotic/static imaging	2011

## Technical Specifications

### Image Acquisition

One may select from a variety of devices to acquire an image, including cameras and scanners.

### Displays

One may use a variety of displays including computer monitors, TV screens, and mobile devices. The viewing device and its associated parameters (e.g. monitor size, resolution, and color) shall accurately display the pathology image to be viewed.<sup>[39,40]</sup> The professional judgment of the pathologist may be used to determine whether or not an image is satisfactory to render a diagnosis.

The consistent presentation of images is essential and is influenced by software, graphic controllers, and display devices. Good visualization of displayed images is achieved when the diagonal dimension of the display distance is about 80% of the viewing distance.

Zoom (magnification) and pan functions should be used for display of the image at the originally acquired spatial resolutions (i.e. direct presentation of acquired pixels on the display pixels).

Viewing devices should be color calibrated. Although there is no accepted calibration standard for color medical displays, there are a variety of options in the literature and it is important to select one that can readily be implemented and maintained on the display of choice.<sup>[40]</sup> Users should be aware that color in digital pathology images can also be influenced by staining, image acquisition, and software issues.<sup>[41,42]</sup>

For the practice of telepathology, one can select from a variety of mobile devices,<sup>[43,44]</sup> including tablets and smartphones, and may be used as long as they can securely display the pathology image to be viewed at an acceptable level of quality.

### Transmission and Storage

For the transmission of telepathology images appropriate connectivity, bandwidth, and computing capabilities should be in place to support the transmitted image type.<sup>[45]</sup> Bandwidth for real-time viewing of images will be higher than for asynchronous transmission.

IT infrastructure for telepathology systems shall facilitate linkage of pathology images with necessary metadata (e.g. identifiers, clinical information, and prior pathology findings).

Adequate storage capacity should be in place if images used in telepathology are to be retained, manipulated and retrieved. A typical WSI captured with a ×20 objective lens typically represents 20+Gb of storage if uncompressed, but after compression, the size is reduced to an average range of 200-650 Mb.

Compression technology may be applied so long as it does not compromise the image for clinical use (i.e. should be “visually lossless” in that it does not change resolution as visible to the naked eye).<sup>[46,47]</sup> Compression is defined as mathematically reversible (lossless) or irreversible (lossy). Reversible compression may always be used as there is no impact on the image. Irreversible compression may be used to reduce transmission time or storage space only if the resulting quality is sufficient to reliably perform the clinical task.

Software should support image acquisition, viewing and, if desired, annotation and workflow (e.g. side-by-side viewing of multiple images).

### Clinical Applications

Telepathology can be used for any of these applications:

#### Primary Diagnosis

Primary diagnosis can be successfully rendered using a variety of telepathology modes on a variety of substrate materials.<sup>[48-52]</sup> There are studies that indicate that there is not always 100% concordance between digital versus glass slide interpretations, however, there is not always 100% concordance between glass vs. glass slides and both inter- and intra-reader variability can vary as a function of case complexity.<sup>[19,53-55]</sup> There are also some studies that show that certain cases (cytopathology in particular) are more challenging to interpret using digital imaging and may, therefore, not be quite ready for primary diagnosis.<sup>[20,56,57]</sup>

#### Intraoperative Consultation (Frozen Section)

Intraoperative consultation, with or without the use of frozen section, can be accomplished by telepathology using a variety of models, including fixed images, robotic dynamic telemicroscopy, video microscopy, and WSI. If an intraoperative consult is performed on a resection specimen or large biopsy specimens, access to imaging of the gross specimen should be available in addition to microscopic imaging materials.<sup>[58]</sup>

#### Rapid Cytology

Rapid cytologic assessment of cytologic samples (e.g. fine-needle aspiration) requires sufficient speed and image resolution to assist with a patient management decision such as whether to obtain further sample, or to direct specimen management. Speed and resolution used should be determined by the consulting pathologist based on their experience and expertise with respect to the specific samples and diagnostic task.

#### Secondary Consultation

Secondary consultation refers to any situation where a primary or initial review (with or without a formal diagnosis) has been performed on the primary materials (gross specimen, glass slides, etc.) and further opinion is sought by means of telepathology tools. Secondary consultation may be either formal or informal,

differentiated primarily by whether or not a written or other formal report is rendered on the consultation. Informal secondary consultations used to direct patient care should not be referenced in the medical record without the knowledge of the rendering consultant. Secondary consultation is distinct from peer-review activity performed for quality assurance purposes. Secondary consultation via telepathology may be used to enhance quality of care by providing access to particular expertise more widely and at a potentially lower overall cost.

#### Special Studies

Telepathology can be successfully used to expand access to specialized services not otherwise available on a cost-effective basis in a given location. These include but are not limited to specialized staining processes like immunohistochemistry, fluorescence *in situ* hybridization, chromogenic *in situ* hybridization, etc., and their appropriate controls if required. Other technical procedures requiring physician interpretation are also amenable to remote interpretation via telepathology tools. Digital images of special studies shall include pertinent patient identifiers and access to appropriate control materials.

#### Archival Review

Archival review for clinical purposes occurs when a case is being reviewed in the context of a new specimen from the same patient or other clinical reassessment of that patient. Availability of digitized materials for archival review should be indicated in some manner in the patient record. Archival material review should be documented to indicate limitations of possible material assessed (e.g. only 3 images were reviewed even though the case had 20 slides originally). The lab should employ a data management system, whereby processes and procedures are defined for short- and long-term image storage, and accurate and timely retrieval of images.

#### Quality Activities

Telepathology tools may be utilized in accordance with local quality management (QM) plans to monitor laboratory and or personnel quality performance on a qualitative or quantitative basis, and should be reviewed according to laboratory standards. Digital pathology tools may be used to provide quality assurance of the diagnostic process itself. This can be done by means of regular diagnostic quality control cases, selected (automatic, semi-automatic, random, or directed) peer review or other means, either prospectively or retrospectively.

Quality assurance of glass slides can be facilitated by digital pathology. Standardization of histology lab output can benefit from the rigor required for slide digitization. Digital imaging when used for visual management of quality control materials should allow trend analysis. Quantitative or qualitative data obtained

from digitized images incorporated into or used as a component of QM systems should be retained for an appropriate period as determined by the referring and consulting institutions.

### **Consensus Conference**

Telepathology enables consensus review peer activity from multiple sites, either contemporaneously or asynchronously. The method employed should be determined by the situation (diagnostic considerations, sample type, speed required, magnifications needed, etc.) and resources available.

### **Multidisciplinary Interactions (Tumor Boards)**

Telepathology enables review of cases for tumor boards and subspecialty conferences at the primary site or remote sites. Telepathology-tool facilitated pathologist-clinician interactions can enhance care by lowering the barriers to slide or other information sharing.

### **Patient Consultation**

Telepathology allows for the remote view of patient's pathology images either solely by the patient or in consultation with the clinical team including the pathologist. Patient access to their digital pathology materials shall adhere to pertinent privacy and security guidelines.

## **Clinical Responsibilities**

### ***Sending (Referring) and Receiving (Consulting) Individuals***

Referring and consulting parties should agree on a minimal acceptable data set that shall accompany digital material such as accessioning number, patient name, and block/slide ID.

The referring individual shall:

- Include all relevant clinical information for the consulting pathologist
- Ensure that the consulting pathologist has access to any necessary and/or relevant current and prior diagnostic material
- Take responsibility that the correct image is being sent, as well as appropriate metadata

Appropriately trained personnel should be able to manage cases and relevant materials being transmitted to either the referring pathologist or consulting pathologists.

A laboratory medical director should be responsible for training the support personnel including trainees and shall be available to the support personnel as needed; responsibilities may be delegated.

### ***Other Clinical Staff Who May be Impacted***

Prior to the implementation of novel telepathology, pathologists should engage nonlaboratory clinical personnel to identify situations that require adaptation to change their current practice or workflow.

## **Facility Responsibilities**

### ***Standard of Care***

The standard of care of the facility shall be defined by the organization and/or other accrediting/regulatory bodies such as the College of American Pathologists (CAP), The Joint Commission, or as is appropriate locally.

The facility should engage the Medical Advisory Committee/board to review and approve protocols around telepathology in situations where a traditional paradigm is substantially changed.

### ***Technical Support***

IT support personnel shall have a basic understanding of the technical requirements for the required workflows and be familiar with aspects of networking, interfaces, and the operating systems involved.

Technical support personnel, including vendors with an adequate understanding of the telepathology systems (hardware, software), should be available to ensure that the systems are operating appropriately.

A technical support plan should match the urgency and critical nature of the use case implemented for telepathology applications.

### ***Functional Verification of Equipment***

The facility shall make sure that technology and instrumentation operate in accordance with manufacturer's specifications.

### ***Accreditation***

The laboratory shall operate in compliance with applicable accreditation criteria.

### ***Privileges***

The Pathology Department, and specifically the Clinical Laboratory Improvement Amendments (CLIA) Laboratory Director (or equivalent) and/or her/his pathologist designee, shall determine which individuals will have privileges to practice telepathology at the institution and any applicable practice settings.<sup>[59]</sup>

### ***Licensure***

The facility performing telepathology shall adhere to the applicable licensure requirements, with respect both to facilities and to pathologists, for their location (s) and those with which they communicate.

### ***Validation***

#### **Technical**

All laboratories implementing a telepathology service for clinical diagnostic purposes shall perform their own validation studies.<sup>[48]</sup>

The validation shall encompass the intended use of the clinical case and setting anticipated to be deployed.

Validation should encompass all components of the telepathology workflow. These should be validated as a single "system."



Revalidation shall be conducted if there is significant change in a component or use-case.

Validation should use prepared human specimen(s) of the specific type that matches the type that will be used for the clinical use-case. Validation for specific tissues, diseases, microscope changes, or diagnoses is not necessary.

A pathologist(s) who has been adequately trained to use the telepathology system shall be involved in the validation process.

The validation process should also include all individuals that will use the telepathology system, including laboratory managers, laboratory staff, and IT personnel.

The validation process should confirm that all of the material present, or purposefully selected areas on the glass slide, is included in the digital image/video.

The validation process should confirm that the video/image being sent is identical to that which is received. However, it should be noted that with lossy compression, the image that results from compression/decompression may not be identical to the starting image but should be “visually lossless” with respect to diagnostic information and/or details/features.

Validation should comply with the most current accrediting standards of the facilities’ regulatory bodies; including methods, measurements, evaluations, and approvals for the telepathology system.

Validation documentation should be maintained for a sufficient period to satisfy regulatory bodies and legal institutions.

### **Diagnostic**

A validation process should include a sufficient number and mix of cases for each application that reflects the spectrum and complexity of specimen types and diagnoses likely to be encountered.<sup>[48]</sup>

### **Training**

Personnel responsible for performing telepathology, using telepathology technology and following telepathology procedures shall be trained in the correct usage and adhere to any relevant Standard Operating Procedures (SOPs).<sup>[60]</sup>

- The training and competency assessment of the staff should be determined by the local SOPs.
- Training procedures should be standardized.
- Training should be documented.

### **Documentation and Archiving**

#### **Reporting of Pathologic Findings**

A diagnostic consultation by telepathology should generate a formal report for the medical record, comprised of either the pathology report or as a documented report of the oral communication. Informal/internal “curbside/

hallway” type telepathology consultations may be documented at the discretion of the pathologists involved and/or in accordance with departmental procedures.

The referring pathologist should document in the formal pathology report that the telepathology encounter occurred, and detail the interpretation rendered by the consulting pathologist at their discretion, and/or in accordance with the institution/departmental SOP.

#### **Disclaimer Statements**

Any disclaimer statements added to the formal report of the telepathology encounter may be facility specific and determined by an organization’s policies.

#### **Logs**

Logs of telepathology interactions shall be tracked as is appropriate to the local requirements and regulations. These logs can be used for clinical purposes, reimbursement records, quality assurance, research, or any other appropriate reason.

#### **Retention Policy**

The retention of associated artifacts of the telepathology event, including telepathology documentation, reports, and captured images shall be retained as is appropriate to the local requirements and applicable regulations.

Images should be retained for an appropriate period as determined by the referring and consulting institutions.

### **Quality Management**

#### **Technical**

An ongoing QM program should address the technical performance of a telepathology system such as image quality, malfunction, network performance, device calibration, data integrity, and image tracking.

Examples of quality metrics that may be monitored include the number of discordant diagnoses due to poor image quality, re-scan rate as a technical quality indicator, and delays in turnaround time due to the technology.

#### **Diagnostic**

A QM program should address the diagnostic performance of the pathologists using the system.

Examples of quality metrics that may be used to assess diagnostic performance include number of misdiagnoses (e.g. discordant glass versus digital diagnoses), delays in turnaround times, and deferral rates (e.g. failure or inability to render a telepathology diagnosis) for users.

A pathologist knowledgeable in telepathology should be appointed to oversee the diagnostic QM program.

#### **Operations**

##### **Maintenance**

The maintenance of the system shall be in accordance with vendor recommendations and other applicable regulatory standards.

The maintenance records shall be retained as per the local regulatory requirements.

#### **Technical support**

The facility should develop telepathology specific business continuity procedures as appropriate for their environment, if such procedures are different from complete downtime/system availability procedures.

The facility should develop downtime SOPs for telepathology that are appropriate for their institutional needs.

#### **Physical Facilities**

Institutions shall ensure that the physical facilities and equipment provided for telepathology applications are adequate for safe and efficient operations; this includes appropriate environmental controls, network infrastructure, physical space, and utilities.

#### **Security and Privacy**

Organizations and health professionals providing telepathology services shall ensure compliance with relevant local, state, and federal (or international if appropriate) legislation, regulations, accreditation and ethical requirements for supporting patient/client decision-making and consent, including protection of patient health information.

All data transmission shall be secure through the use of encryption that meets recognized standards.

Individuals in charge of technology should familiarize themselves with the technologies available regarding computer and mobile device security, and should help educate users with respect to such issues as privacy and security options. If videoconferencing is going to be used (e.g. tumor boards), privacy features shall be available to all participating parties. Privacy features should include audio muting, video muting, and the ability to easily change from public to private audio mode.

When providers use a mobile device, special attention should be placed on the relative privacy of information being communicated over such technology.

Providers shall ensure that access to any patient information stored on any device is adequately restricted. Devices shall require a passphrase or equivalent security feature before the device can be accessed. If multi-factor authentication is available, it should be used. Devices should be configured to utilize an inactivity timeout function that requires a passphrase or re-authentication to access the device after the timeout threshold has been exceeded. This timeout should not exceed 15 min.

Mobile devices should be kept in the possession of the provider when traveling or in an uncontrolled environment. Unauthorized persons shall not be allowed access to sensitive information stored on any device, or

use the device to access sensitive applications or network resources. Providers should have the capability to remotely disable or wipe their mobile device in the event it is lost or stolen. Providers and organizations may consider establishing guidelines for periodic purging or deletion of telepathology-related files from mobile devices.

Protected health information and other confidential data shall only be backed up to or stored on secure data storage locations. Cloud services unable to achieve compliance shall not be used for personal health information or confidential data.

#### **Regulatory Compliance**

Telepathology programs shall be mindful of regulatory agencies (i.e. FDA, Centers for Medicare and Medicaid Services/CLIA, CAP) and their specific policies and guidelines that pertain to telepathology.<sup>[61-65]</sup>

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