AMERICAN TELEMEDICINE ASSOCIATION

CLINICAL GUIDELINES FOR TELEPATHOLOGY

AUGUST 2014

Acknowledgements

The American Telemedicine Association (ATA) wishes to express sincere appreciation to the ATA Telepathology Guidelines Work Group and the ATA Practice Guidelines Committee for their invaluable contributions in the research, writing and development of the following guidelines.

Telepathology Clinical Guidelines Work Group (Alphabetical Order)

Chair: **Liron Pantanowitz**, MD, Associate Professor of Pathology and Biomedical Informatics, University of Pittsburgh Medical Center, Department of Pathology

Work Group Members

Kim Dickinson, MD, MBA, MPH, Senior Medical Director Integrated Oncology – Irvine, LabCorp, President, Digital Pathology Association

Andrew J Evans, MD, PhD, FRCPC, Staff Pathologist and Associate Professor, University Health Network, Laboratory Medicine Program, Toronto General Hospital

Lewis Hassell, MD, Associate Professor of Pathology, Director of Anatomic Pathology, Department of Pathology, University of Oklahoma Health Sciences Center (OUHSC)

Walter H. Henricks, MD, Medical Director, Center for Pathology Informatics, Staff Pathologist, Pathology and Laboratory Medicine Institute, Cleveland Clinic

Jochen K. Lennerz, MD, PhD, Staff Pathologist, University Ulm, Institute of Pathology, Albert-Einstein-Allee, Germany

Amanda Lowe, Director of Business Development, Visiopharm

Anil V. Parwani, MD, PhD, MBA; Division Director, Pathology Informatics, Staff Pathologist Shadyside Hospital, UPMC, Pittsburgh, PA

Michael Riben, MD, Director of Anatomic Pathology Informatics, Pathology, MD Anderson

COL Daniel Smith, MD, PhD, Chairman, Department of Pathology, Keesler AFB

J. Mark Tuthill, MD, Division Head, Pathology Informatics, Henry Ford Health System

Ronald Weinstein, MD, Director, Arizona Telemedicine Program and Executive Director, T-Health Institute, University of Arizona

David Wilbur, MD, Professor of Pathology and Director of Clinical Imaging, Massachusetts General Hospital, Harvard Medical School

ATA Practice Guidelines Committee

Chair: **Elizabeth A. Krupinski**, PhD, Professor & Vice Chair of Research, Department of Medical Imaging, University of Arizona

Committee Members

Nina Antoniotti, RN, MBA, PhD, Director of Telehealth, Marshfield Clinic TeleHealth Network

David Brennan, MSBE, Director, Telehealth Initiatives, MedStar Health

Anne Burdick, MD, MPH, Associate Dean for Telemedicine and Clinical Outreach, Professor of Dermatology, Director, Leprosy Program, University of Miami Miller School of Medicine

Jerry Cavallerano, PhD, OD, Staff Optometrist, Assistant to the Director, Joslin Diabetes Center, Beetham Eye Institute

Helen K. Li, MD, Adjunct Associate Professor, University of Texas Health Science Center

Lou Theurer, Grant Administrator, Burn Telemedicine Program, University of Utah Health Sciences Center

Jill M. Winters, PhD, RN, President and Dean, Columbia College of Nursing

ATA Staff

Jordana Bernard, MBA, Senior Director, Program Services

Jonathan D. Linkous, CEO

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.

ATA 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 is to assist practitioners in pursuing a sound course of action to provide effective and safe medical care that is founded 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 indicted when, in the 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. (1)

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.

Acronyms and terms that are commonly used in telepathology are defined in Appendix A. 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. These indications are found in bold throughout the document. **"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.

- **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, email, 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 [Weinstein 1986; Kaplan et al. 2012], and since then there have been many advances and publications [Weinberg 1996; Dervan 1998; Kayser et al. 1999; Wells et al. 2000; Weinstein

2001; Cross et al. 2002; Weinstein 2009; Evans et al. 2010; Williams et al. 2010; Della Mea 2011; Pantanowitz et al. 2012]. 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 have been used interchangeably to refer to telepathology including digital microscopy, remote robotic microscopy, teleconferencing, teleconsultation, telemicroscopy, video microscopy, virtual microscopy, and whole slide imaging [Williams 2010; Weinstein et al. 2009; Weinstein et al. 2012].

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 [Winokur et al. 1998; McLaughlin et al. 1998; Fisher et al. 2001; Evans et al. 2009; Wilbur et al. 2009; Thrall et al. 2011; Nakayama et al. 2012; Gould 2012; Khurana 2012; Collins 2013; Kaplan et al. 2012]. In practice, these digital images are typically linked to patient information including identification/medical record numbers, clinical history, and relevant laboratory and radiology data [Hedvat 2010].

Table 1 summarizes milestones of the many technological advances in telepathology. The primary modes of telepathology include static imaging, dynamic imaging, hybrid static/dynamic telepathology and whole slide imaging.

- Static (store and forward) image telepathology: asynchronous capture of image files for subsequent viewing [Weinstein 1996].
- 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 [Dunn et al. 2009; Kaplan et al. 2002].
- Video microscopy (dynamic): real time transmission (streaming) of images from a video camera for telepathology purposes [Baak et al. 2000; Sinard 1996; Buxbaum et al. 2012].
- Whole slide imaging (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 [Pantanowitz et al. 2011; Cornish et al. 2012; Ghaznavi et al. 2013].
- Multi-modality telepathology: simultaneous utilization of more than one mode of technology (e.g., hybrid robotic microscopy and WSI)[Della Mea et al. 2009].

Table 1. Telepathology system classification [Weinstein et al. 2012]

Imaging System	Year
Real-time Imaging	
Television microscopy	1952
Dynamic-robotic telepathology	1986

Static Image Telepathology	
Store & 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

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 [Yagi et al. 1999]. This revision is an update to the original ATA guideline. More recently, the Canadian Association of Pathologists [Bernard 2014] and the Royal College of Pathologists [Lowe 2013] have also published guidelines for telepathology. The purpose of this document is 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 for Telepathology

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 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.

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 [Doolittle et al. 1997; Krupinski 2010]. 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 [Krupinski 2010]. Users **should** be aware that color in digital pathology images can also be influenced by staining, image acquisition, and software issues [Yagi 2011; Bautista et al 2014].

For the practice of telepathology one can select from a variety of mobile devices [Park et al. 2012; Speiser et al. 2014], 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 & Storage: For the transmission of telepathology images appropriate connectivity, bandwidth and computing capabilities **should** be in place to support the transmitted image type [Romero et al. 2013]. 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) [Marcelo 2000; Krupinski et al. 2012]. 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 [Pantanowitz et al. 2013; Bauer et al. 2013; Jen et al 2013; Evans et al. 2014; Reyes et al. 2014]. 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 [Wilbur et al 2009; Dangott & Parwani 2010; Campbell et al 2012; Stathonikos et al 2013]. 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 [Pantanowitz et al 2011b; Thrall et al 2011; Wilbur 2011].

Intraoperative Consultation (frozen section)

Intraoperative consultation, with or without 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 [Almargo et al. 1996].

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 such as immunohistochemistry, FISH, CISH, 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 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 quality management 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 non-laboratory clinical personnel to identify situations that require adaptation to change their current practice or workflow.

Facility Responsibilities

Standard of Care (SOC)

The SOC 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 (TJC), 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 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 [Wiley et al. 2011].

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 [Pantanowitz et al. 2013].

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 [Pantanowitz et al. 2013].

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) [Giansanti et al. 2008].

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 Assurance

Technical

An ongoing quality management 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 quality management (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 time, 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 minutes.

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, CMS/CLIA, CAP) and their specific policies and guidelines that pertain to telepathology.

Appendix

A: Definitions/Abbreviations

Business Continuity Procedures: Procedures established to ensure, that in the event of a disaster or adverse conditions, business will continue to function.

CAP: College of American Pathologists

CISH: Chromogenic in situ hybridization

CLIA: Clinical Laboratory Improvement Amendments

CMS: Centers for Medicare & Medicaid Services

Digital Pathology: A dynamic, image based environment that enables the acquisition, management, and interpretation of pathology information generated from a digitized glass slide. [https://digitalpathologyassociation.org]

Digital Pathology System (DPS): An image-based computer system that enables the acquisition, management and interpretation of pathology information generated from a digitized glass slide [DPA 2011].

DPA: Digital Pathology Association

FDA: Food and Drug Administration

FNA: Fine needle aspiration

FISH: Fluorescence in situ hybridization

Intended Use: The method or manner in which a product is used on a daily basis [DPA 2011].

Metadata: Data about data. This is structured information describing, explaining, locating, or otherwise making it easier to retrieve, use, or manage information resources. Metadata includes administrative, descriptive, and structural data. Examples of patient identity metadata include name, date of birth, medical record number, and so on.

Mobile Platform: Commercial off the shelf (COTS) computing platform, with or without wireless connectivity, that is typically handheld in nature. Examples of these mobile platforms include mobile computers such as smart phones, tablet computers, or other portable computers. Also referred to as Mobile Devices [FDA mobile guidance document 2013].

Multi-modality Telepathology: The simultaneous ability to utilize more than one mode of practice for the purpose of telepathology (i.e., a hybrid of robotic microscopy and WSI).

Quality Management System: A set of interrelated processes and/or methods that are used to control how quality policies are implemented and how quality objectives are realized.

Robotic Telepathology: The ability to remotely control an image acquisition device (e.g., whole slide scanner), and review acquired images from that device for the purpose of telepathology. Also referred to as dynamic telepathology.

SOC: Standards of Care

Standard Operating Procedures (SOP): A document or instruction that details all steps and activities of a process or procedure.

Static Telepathology: The asynchronous capture of image files for the purpose of telepathology.

Telemedicine: According to the ATA, 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, email, 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.

Telepathology System: The mode or modes of practice (i.e. static, robotic, video, WSI) used for the purpose of telepathology.

TJC: The Joint Commission

Validation: An ongoing process to establish documented evidence that provides a high degree of assurance, that a process or system will consistently perform according to predetermined specifications and quality attributes, taking into account the nature of specimens and techniques that will be encountered [Long et al 2012].

Video Microscopy: The real time (dynamic imaging) transmission of images from a video camera for the purpose of telepathology.

Whole Slide Imaging (WSI): Digitized (scanned) pathology glass slide that has been created on a slide scanner. The digitized glass slide represents a high-resolution replica of the original glass that can then be manipulated through software to simulate microscope review and diagnosis. Also referred to as a virtual slide [DPA 2011].

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For Further Information or Questions: Contact American Telemedicine Association at 202.223.3333 or info@americantelemed.org