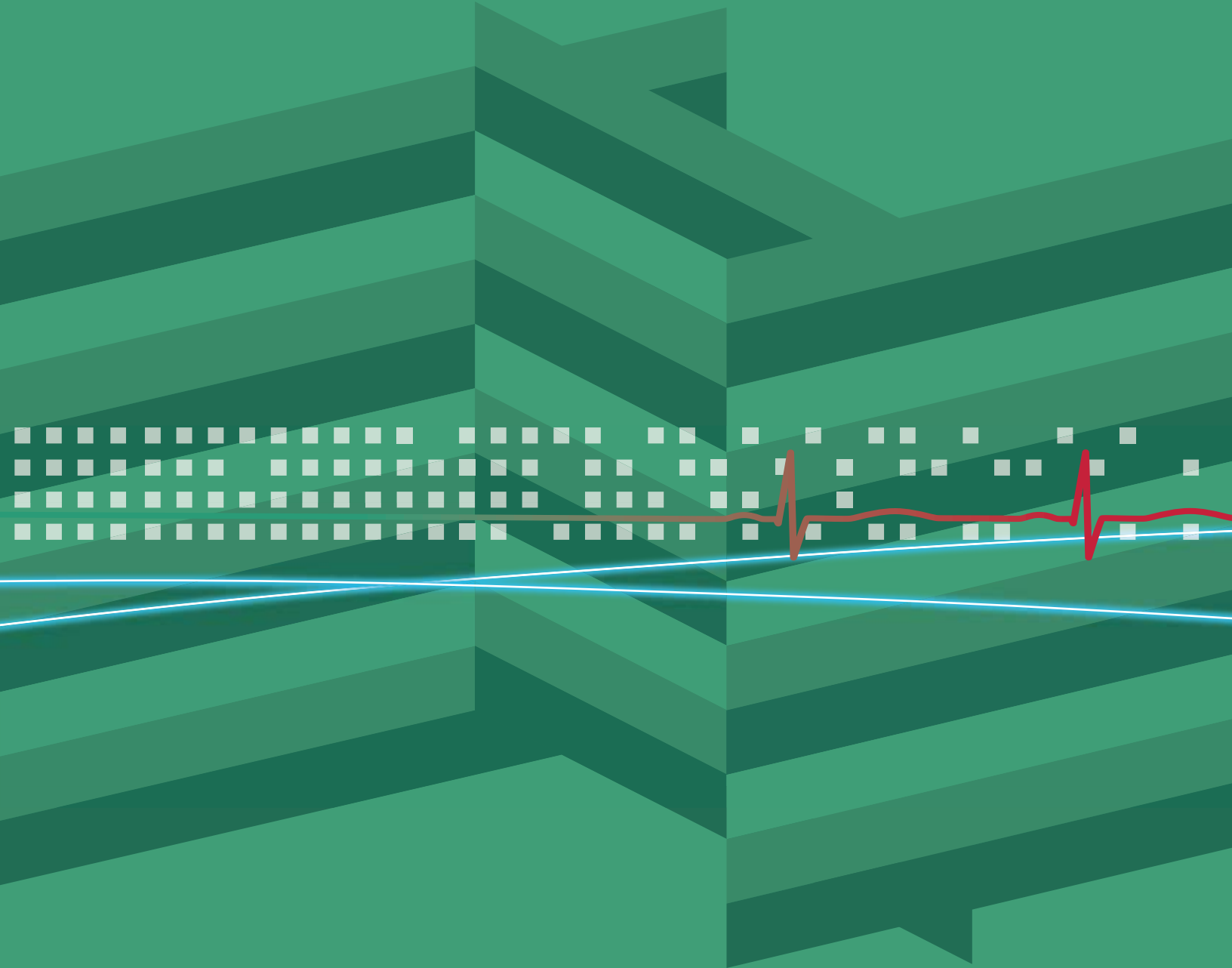


Clinical Guidelines for **Telepathology**

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1. Introduction

This is a working draft of clinical guidelines for telepathology written with the expectation that others will rewrite it and add to it. To keep this document generally applicable it steers clear of technical specifications or implementation issues and concentrates on the responsibilities of the pathologist in telepathology.

2. Scope

For the purpose of this document, Telepathology will be defined as electronic, multimedia communication between pathologists for the purpose of primary diagnoses and diagnostic consultation second opinion. It may also be extended to include similar diagnostic communication between other physicians (non-pathologists) and a laboratory staff by qualified laboratory personnel – trained technicians, technologists, or a pathologist’s assistants – and a remote pathologist and when the laboratory personnel is under the supervision of a pathologist.

The concepts discussed in this document should be generally applicable to all three types of telepathology; static (store and forward), dynamic (synchronous), and hybrid (static-dynamic) implementations.

3. The Practice of Telepathology: Responsibilities of the Pathologist

Pathologists have been sending each other cases for diagnostic second opinion for many years. This collaboration has traditionally involved the sending of stained slides, unstained slides, tissue blocks, wet tissue, pathology reports and cover letters via courier or through conventional mail. The system has worked well, and is the “gold standard” by which diagnoses are compared between institutions. In defining guidelines for second opinion telepathology, pathologists should borrow, whenever possible, from the workflows and responsibilities set up in the courier based system.

Guidelines for primary opinion telepathology should be driven from best practices in conventional laboratory procedures. It is understood that pathologists often work in central offices geographically separated from both the clinics (where cytology and surgical samples are obtained) and the histology laboratories (where cytology preparations and tissue are processed and slides are made).

Sections 3a and 3b detail proposed responsibilities of pathologists and laboratory personnel in both primary diagnosis telepathology (section 3a) and second opinion telepathology (section 3b). Though the discussion is framed in a telepathology environment involving multiple institutions, the responsibilities are similar if telepathology occurs within a single institution.

a. Primary Diagnosis Telepathology

In telepathology, specimens at a referring site are diagnosed by pathologists

at a remote site. In primary diagnosis telepathology, the diagnostic effort and responsibility resides entirely with the pathologist at the remote site.

The medical responsibilities for a site initiating a telepathology session for primary diagnosis, are similar to those of a laboratory sending glass slides by courier or conventional mail to another pathologist for primary diagnosis in a traditional environment. These include:

1. The laboratory must identify the case appropriately. Traditionally this has meant, at a minimum, local accession number and the patient's name as well as some indication of what material has been sent (the number or slides, blocks, reports, etc.) In the telepathology environment this must be extended to the appropriate documentation of images and information sent.
2. The laboratory must insure that all appropriate clinical information is conveyed to the remote pathologist. Traditionally this has usually meant an appropriately filled out requisition and/or the surgeon's operative report, however it can include additional information (for example, X-rays in bone pathology cases) or direct access to the clinicians involved depending on the situation and pathologists medical judgment. If, in the judgment of the pathologists involved, the system cannot provide adequate clinical information to the remote pathologist, telepathology should not be used to render a diagnosis or telepathology should be supplemented by other mechanisms.
3. The laboratory must insure that the remote pathologist has adequate access to appropriate diagnostic material. In a practice setting in which primary telepathology diagnoses are rendered, and a pathologist is not present at a referring site, a methodology must be employed which insure that video sampling of gross tissues and glass slides is inclusive.
4. In addition to the medical responsibilities discussed above, the laboratory has responsibilities for data handling, archiving and security as discussed below.

i. **Technicians, Technologists and Pathologist's Assistants in Primary Diagnosis Telepathology**

Pathologist's Assistants, technologists and technicians have traditionally worked under the supervision of Pathologists in anatomic pathology laboratories. Appropriately trained personnel (pathologist's assistants, technologists and technicians) should be able to present cases and relevant materials, via telepathology, to other pathologists at remote sites.

1. Presenting Personnel should be adequately trained in the use of telepathology equipment and the limitations of telepathology

2. A pathologist should supervise the support personnel, and support personnel should have access to other pathologists throughout the telepathology session.

ii. **Responsibilities of the Pathologist in Primary Diagnosis Telepathology**

In primary diagnosis telepathology, diagnostic effort and responsibility resides entirely with the pathologist at the remote site. If the remote pathologist supervises referring site, the pathologist takes on the roles and responsibilities of both referring and consulting pathologist in Section

b. **Second Opinion Telepathology**

In second opinion telepathology, diagnostic effort and responsibility resides with both the pathologists at the local site (referring pathologist) and the pathologist at the remote site (consulting pathologist).

i. **Responsibilities of the Referring Pathologist**

The medical responsibilities for a pathologist initiating a second opinion telepathology session are similar to those of a pathologist sending glass slides by courier to a consulting pathologist in a traditional environment. These include:

1. The referring pathologist must identify the case appropriately. Traditionally this has meant, at a minimum, local accession number and the patient's name as well as some indication of what material has been sent (the number or slides, blocks, reports, etc.) In the telepathology environment this must be extended to the appropriate labeling of images and documentation of the number of images sent.
2. The referring pathologist must insure that all appropriate clinical information is conveyed to the consulting pathologist. Traditionally for second opinion this has usually meant a cover letter and a copy of the referring pathologist's report, however it can include additional information (for example, X-rays in bone pathology cases) depending on the situation and the referring pathologist's medical judgment. If in the judgment of the referring pathologist, the telepathology system proposed for the consultation can not, adequately provide all of the appropriate clinical information to the consulting pathologist, telepathology should not be used for the consultation or telepathology should be supplemented by other mechanisms.
3. The referring pathologist must insure that the consulting pathologist has adequate access to appropriate diagnostic material. One of a pathologist's cardinal responsibilities is to appropriately sample specimens so as to arrive at the accurate

diagnosis. The pathologists traditionally sub-sample gross specimens into blocks, and those blocks are then sub-sampled in the creation of slides. In traditional courier based consultations, it is not uncommon to have, on the judgment of the referring pathologist, only a subset of slides sent to the consulting pathologist. In some implementations of telepathology, a further level of sub sampling in which images representing selected fields from a slide are sent to the consulting pathologist. In these implementations, it is the responsibility of the referring pathologist to select these fields appropriately.

4. The referring pathologist must render a final report on a case. As in traditional pathology consultations, it is the responsibility of the referring pathologist, when receiving an opinion from a consulting pathologist, to reconcile his or her understanding of the case – and any clinical or pathological information not available to the consulting pathologist – with the opinion of the consulting pathologist and then reach an appropriate diagnosis. This responsibility should also exist in consultations based on telepathology. The use of telepathology should not relieve the referring pathologist of the responsibility to render a final report on a case.
5. In addition to the medical responsibilities discussed above, the referring pathologist has responsibilities for data handling, archiving and security as discussed below.

ii. **Responsibilities of the Consulting Pathologist**

A pathologist receiving a case via telepathology has a number of medical responsibilities similar to those of a pathologist receiving a case via courier:

1. The consulting pathologist should insure that he/she has received all materials sent by the referring pathologist. This has traditionally been done, in the courier-based model, by comparing the material listed in the cover letter (or other documentation) to the material received.
2. The pathologist must insure that appropriate standard operating procedures are in place at the referring site to insure that all the clinical information or pathologic material (tissue, blocks, etc.) necessary to adequately examine a case is available. If in the judgment of the consulting pathologist, the telepathology system proposed can not provide the necessary information to the consulting pathologist, telepathology should not be used for the consultation or telepathology should be supplemented by other mechanisms. If clinical information deemed necessary by the consulting pathologist is not

available by any mechanism, an unqualified opinion should not be rendered.

3. In the traditional courier-based consultation, it is the responsibility of the consulting pathologist to determine if the material sent by the referring pathologist is of adequate quality to render a diagnosis. For example, it has been up to the consulting pathologist to determine if the slides proffered were adequately cut and/or stained. The quality needed for a diagnosis depends directly on the skill of the consulting pathologist and the diagnostic question involved. Consistent with the traditional, courier-based practice, it is the responsibility of the consulting pathologist to determine if the image quality is adequate for diagnosis. If the consulting pathologist feels that image quality and/or video image sampling are not adequate, he/she should request that the glass slides and or blocks be sent for analysis. This is consistent with traditional, courier-based practice.
4. The consulting pathologist should transmit his/her opinion/diagnosis to the referring pathologist in a mutually agreed upon manner. Observations that could effect patient care in a time sensitive manner should be transmitted directly to the referring pathologist.
5. In addition to the medical responsibilities discussed above, the consulting pathologist has responsibilities for data handling, archiving and security as discussed below.

4. Training and Quality Control

a. Training of Pathologists

Because the effectiveness and accuracy of telepathology depends critically on the skill and judgment of the pathologist, both referring and consulting pathologists practicing telepathology should be trained in telepathology.

1. Training should occur on the individual systems that the pathologist uses.
2. Training should also occur in general telepathology/imaging principles and limitations.

The implementation of this training is an issue that requires discussion and consensus. Possibilities could include general web-based seminars and tests supported by the ATA, CAP, USCAP, etc. followed by practical examinations provided by the same organizations. (The CAP has similar programs ongoing for standard glass slide pathology.)

b. Training of Technicians, Technologists and Pathologist's Assistants

In an environment in which a technologist, a technician, or a pathologist's assistant is supervised by a local or a remote pathologist, he/she should be trained specifically in telepathology techniques.

c. **Quality Control**

Pathologists providing consultation by telepathology should be required to have at least 10% of their cases re-examined by another pathologist, comparing the transmitted images to the microscopic slide and any discrepancies should be noted.

5. Documentation and Archiving

The telepathology interaction is a vital part of a patient's care and as such must be documented in the medical record. To this end:

- a. A diagnostic consultation by telepathology shall generate a formal report by the consulting pathologist. This report shall become a permanent part of the patient medical record. It is recommended that all reports, letters, clinical information and possibly static (still) images transmitted from the referring site to the pathologist as part of the telepathology encounter should be archived at the consultant's institution. This practice is consistent with that applied to courier based consultations.
- b. All reports, letters, clinical information and static (still) images involved in a diagnostic consultation by telepathology, as well as the consultant's report, shall be archived as part of the medical record at the referring institution. This practice is consistent with those applied to courier based consultations. (Because image archiving requires special equipment not available at all institutions, the referring institution may allow the consulting institution or a third party to archive telepathology information, as long as the archiving is done under the rules of the referring institution.)
- c. The telepathology encounter, and the general opinion of the consulting pathologist, shall be documented in the final report of the referring pathologist. This practice is consistent with those applied to courier based consultations.
- d. Dynamic, real time images generated during a telepathology session need not be archived. Static (still) images shall be archived at that same image quality, file size and format that was used in the telepathology encounter. Static (still) images should be archived for at least as long as the glass slides involved in the case.
For cases in which diagnoses are based exclusively by static images, the entire image file should be archived.

6. Data Integrity and Security

By its nature, the telepathology encounter involves transmission and storage of confidential patient information. Though it is understood that no security system is foolproof and that the specific security mechanisms needed will depend on the specific telepathology implementation, parties engaging in telepathology shall insure

that the telepathology system provides reasonable privacy and confidentiality by security measures including:

- a. **Message Security:** A telepathology shall occur over secure networks, or shall be adequately encrypted. It is the responsibility of the consulting laboratory to provide a secure station for receiving diagnostic reports. Verifiable digital signatures may be allowed.
- b. **System Authentication:** When appropriate, the system should authenticate itself unambiguously to all users, for example, using a third party certificate and private key.
- c. **User Authentication:** The referring pathologist, consulting pathologist and all other persons using the system (administrators, assistants, etc.) shall be adequately authenticated to each other and to the system. This authentication should involve, at a minimum, a user name and password.
- d. **Activity Logs:** All accesses to the system shall be logged by user and by case. The logs shall be reviewed on a regular basis and the review documented.
- e. **Access Restriction:** Within the security policy of the individual institution, the system should limit access to legitimate users.
- f. **Archiving:** The system shall have adequate back up and archive mechanisms in place.