

Standards to Support Information Systems Integration in Anatomic Pathology

Christel Daniel, MD, PhD; Marcial García Rojo, MD, PhD; Karima Bourquard, PhD; Dominique Henin, MD, PhD; Thomas Schrader, MD; Vincenzo Della Mea, PhD; John Gilbertson, MD; Bruce A. Beckwith, MD

• **Context.**—Integrating anatomic pathology information—text and images—into electronic health care records is a key challenge for enhancing clinical information exchange between anatomic pathologists and clinicians. The aim of the Integrating the Healthcare Enterprise (IHE) international initiative is precisely to ensure interoperability of clinical information systems by using existing widespread industry standards such as Digital Imaging and Communication in Medicine (DICOM) and Health Level Seven (HL7).

Objective.—To define standard-based informatics transactions to integrate anatomic pathology information to the Healthcare Enterprise.

Design.—We used the methodology of the IHE initiative. Working groups from IHE, HL7, and DICOM, with special interest in anatomic pathology, defined consensual technical solutions to provide end-users with improved access to consistent information across multiple information systems.

Traditional anatomic pathology laboratory information systems (LIS) collect and manage data on a complex workflow from specimen collection to report creation. In recent years, anatomic pathologists have begun to use images to document various steps in the diagnostic process. Because imaging systems and traditional LIS are not typically integrated, information and image acquisition often involves error-prone and time-consuming double data entry. Orders, images, and reports are spread out over different systems that do not interoperate. Although standardization efforts conducted by standardization bodies, such as Health Level Seven (HL7)¹ and Digital Imaging

and Communication in Medicine (DICOM),² are progressing to provide integration solutions, HL7 or DICOM messages usually contain many optional or ambiguous data fields so that being DICOM or HL7 compliant does not guarantee simple and direct integration. In this sense, the goal of the Integrating the Healthcare Enterprise (IHE) initiative is specifying how data standards should be implemented to meet specific health care needs and making systems integration more efficient and less expensive.³ The IHE process is based on working groups that include both health care providers and information systems vendors. Within domain-specific technical frameworks, IHE defines “integration profiles” that are real-world situations describing exchange of information called *transactions* from various functional components of a distributed health care environment called *actors*. Integrating the Healthcare Enterprise, which has developed in North America, Europe, and Asia, provides implementation guides for transactions by using established industry standards such as DICOM or HL7. The annual definition cycle of new profiles by users and suppliers—ending in the organization of international platforms of interoperability tests (called “connectathons”)—confers its unique efficiency, transforming basic standards into “plug and play” solutions. Prior integration profiles developed for radiologic imaging have been very successful.⁴

Conclusion.—The IHE anatomic pathology working group has defined standard-based informatics transactions to support the basic diagnostic workflow in anatomic pathology laboratories. In further stages, the technical framework will be completed to manage whole-slide images and semantically rich structured reports in the diagnostic workflow and to integrate systems used for patient care and those used for research activities (such as tissue bank databases or tissue microarrays).

(*Arch Pathol Lab Med.* 2009;133:1841–1849)

Multiple localized efforts have been launched previously to try to address portions of this issue in anatomic pa-

Accepted for publication January 16, 2009.

From ADICAP; INSERM, UMR_S 872 eq20 and Université Paris Descartes, Paris, France (Dr Daniel); the Department of Pathology, Hospital General de Ciudad Real, Ciudad Real, Spain (Dr Rojo); Normalisation, GMSIH, Paris, France (Dr Bourquard); the Department of Anatomic Pathology, ADICAP, AP-HP, Paris, France (Dr Henin); the Department of Pathology, Charité, Berlin, Germany (Dr Schrader); the Department of Mathematics and Computer Science, University of Udine, Udine, Italy (Dr Della Mea); the Department of Pathology, Harvard Medical School and Beth Israel Deaconess Medical Center, Boston, Massachusetts (Dr Gilbertson); and the Laboratory Medicine Department of Pathology, North Shore Medical Center, Salem, Massachusetts (Dr Beckwith).

The authors have no relevant financial interest in the products or companies described in this article.

Reprints: Christel Daniel, MD, PhD, ADICAP-INSERM, UMR_S 872 eq20, Université Paris Descartes, 15 rue de l'école de médecine, 75006 Paris, France (e-mail: christel.daniel@spim.jussieu.fr).

thology. In Europe, in 1996, the ADICAP (Association for the Development of Informatics in Cytology and Pathology), with the collaboration of different software vendors, proposed a European de facto standard for image folders.⁵ In the United States, the Association for Pathology Informatics' Laboratory Digital Imaging Project tried to establish an open access, voluntary use specification for sharing images generated in anatomic and clinical pathology laboratories. In 2005, ADICAP, GMSIH (a group promoting the modernization of hospital information systems in France), SEAP (Spanish society of anatomic pathology), SEIS (Spanish health informatics society), and IHE-Japan launched the IHE pathology initiative in Europe.⁶ Relying on this experience, these associations now aim to promote the use of international standards (DICOM, HL7) in the development of information systems in anatomic pathology.

This article presents a use for the IHE methodology in the anatomic pathology domain to more fully integrate anatomic pathology laboratories into the electronic health care environment. We first describe the IHE anatomic pathology efforts to model the anatomic pathology workflow and to define consensual technical solutions to provide end-users improved access to consistent anatomic pathology orders, reports, and images across all hospital information systems.

We also describe the joint efforts of the IHE anatomic pathology group, DICOM working group 26, and HL7 anatomic pathology special interest group to define a common specimen model to consistently identify and describe specimens in both HL7 and DICOM transactions.

METHODS

Working Groups and Sessions

The ADICAP, GMSIH, SEAP, and SEIS solicited the following participants to work on the IHE anatomic pathology technical framework: 11 practicing pathologists and hematologists; 7 informatics technology professionals; and 8 vendors from France, Spain, Italy, Germany, Japan, and the United States. The IHE anatomic pathology working group conducted 13 working sessions between September 2005 and May 2008.

If errors in existing standards or the need for extensions are identified, IHE's policy is to report them to the appropriate standards bodies (HL7 or DICOM) for resolution within their conformance and standards evolution strategy. American, European, and Japanese groups agreed that, although specific DICOM objects are defined for anatomic pathology, modification and/or extension are necessary for 2 main reasons. First, the DICOM model did not initially describe specimens in sufficient detail or associate images with specimens with enough precision for the complexity of anatomic pathology practice; and second, some pathology-related image formats (whole-slide images, multispectral images, flow cytometry, etc) do not have applicable DICOM information object definitions. To address these issues, a specific DICOM pathology working group (WG26) was created in December 2005.⁷

Meanwhile, the HL7 laboratory special interest group began working on a comprehensive messaging model for specimens and a new special interest group (the anatomic pathology SIG) was established to investigate the complex relationships between specimens, observations, protocols, and documents in anatomic pathology.

To date, 8 IHE anatomic pathology–DICOM WG26 joint working sessions have been organized to create the DICOM specimen identification and description module. Joint meetings between the IHE pathology working group and HL7 pathology SIG have also been conducted.

Understanding the Workflow and the Needs

The IHE anatomic pathology working group first described the workflow in the anatomic pathology laboratory and precisely defined the structure and content of the data flow involved in the business processes such as order entry, specimen processing, image acquisition, and report creation. Since anatomic pathology is a specimen-centric activity, a key issue was agreeing on the way to identify and describe specimens that are the subject of 1 or more procedure steps in the laboratory workflow.

Creating the IHE Anatomic Pathology Technical Framework

The aim of IHE anatomic pathology group was to extend the IHE initiative to anatomic pathology laboratories and to their information, automation, and imaging systems and equipment. According to the IHE methodology, this IHE working group created the first version of IHE anatomic pathology technical framework. An IHE technical framework in a given domain identifies the workflow, the IHE *actors* (ie, functional components, application roles) and describes how the *transactions* (ie, appropriate messages exchanged between them) are implemented by using well-established health care data standards. This description is organized into functional units called *integration profiles* that highlight their capacity to address specific clinical needs.

The IHE anatomic pathology technical framework is organized in 2 volumes. Volume 1 provides a high-level view of the domain, identifying actors and transactions. Some of the actors and transactions can be reused from existing profiles described within the radiology, laboratory, or information technology technical frameworks, whereas others need to be specifically defined to achieve integration in the anatomic pathology domain. Volume 2 provides a detailed technical description of each transaction and its messages.

RESULTS

Anatomic Pathology Workflow

The diagnostic process in anatomic pathology is based on visual interpretation of cells and/or tissues. Despite being based on visual interpretation, the diagnostic process differs from that in radiology since the subject of an examination is usually a specimen (not a patient) and a single diagnostic study may involve multiple images of multiple related specimens (parts, blocks, and/or slides) captured with many different types of imaging equipment (Figure 1). In some cases, an image can include more than 1 specimen or even tissue from more than 1 patient (eg, tissue microarrays).

The diagnostic process in anatomic pathology also differs from that in clinical pathology because it relies extensively on visual morphology and spatial relationships. This makes imaging a crucial tool in anatomic pathology.

The 4 main steps of the anatomic pathology workflow are order management, specimen processing, image acquisition, and report creation. Information systems in anatomic pathology laboratories (laboratory information systems or LIS, image acquisition stations, tissue banking databases, etc) gather textual data and images produced along the diagnostic process from specimen reception to report creation. Integrating these different information systems components requires sharing a coherent definition of the domain entities involved in the information flow such as order, case, specimen, image, and report.

Order Management.—In the case of computerized order entry, the order for the anatomic pathologic examination is communicated between the *order placer* (of the order entry system of the hospital information system or HIS) and the *order filler* (of the LIS). Quality assurance

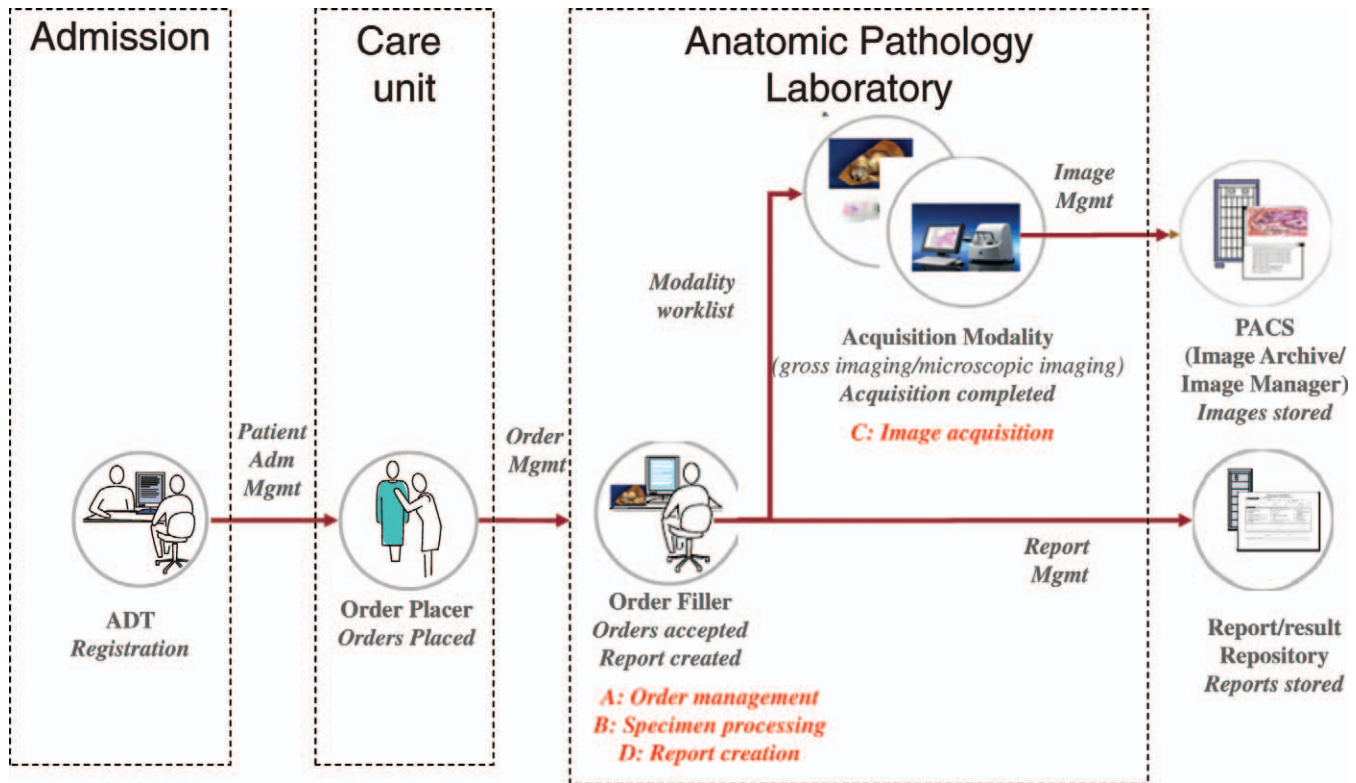


Figure 1. The 4 main steps of the anatomic pathology workflow. A, Order management. B, Specimen processing. C, Image acquisition. D, Report creation.

about order forms provides a list of important items: order identification (order ID); order date and time; identification of the ordering physician; and the ordering care department (including callback telephone number), patient identification (medical identification number, name, visit number, etc), identification of the care unit of the patient (if different from the ordering care department), and priority of the order (date and time when the results are expected to be available). These items are either “required” or “required if available” in the order transactions. An order, such as histopathologic examination of a colon biopsy, usually results in 1 report with associated codified, billable acts.

For each order, the basic or special techniques involved in the processing of the corresponding specimen(s) may require different devices (immunohistochemistry “automaton,” slide-staining machines, image acquisition modality

(eg, digital camera). A procedure step is the smallest unit of work in the workflow performed by a person or a machine (automaton, image acquisition modality, etc) on an object (specimen, tissue sample, tissue section, etc). In the anatomic pathology laboratory environment, the *order filler* of the LIS also identifies the set of procedure steps that have to be performed in the process of fulfilling the order. Figure 2 depicts an example of the breakdown in procedure steps of an order for anatomic pathology examination of specimen(s).

Specimen Processing.—A specimen is defined as a physical object (or a collection of several physical objects), which is considered by the anatomic pathology laboratory as a single, discrete, uniquely identified unit that is the subject of 1 or more procedure steps in the workflow. A specimen may include multiple physical pieces, as long as they are considered a single unit in the workflow. For ex-

```

P0734567: PATIENT Patricia (PATIENT)
OR345: Examination of breast tumor resection and lymphectomy (ORDER with Order Placer NP)
DP07130: Examination of tumor resection and lymphectomy (ORDER with Order Filler NP)
DP07130-A: Gross examination and dissection of the tumor resection (PROCEDURE STEP)
DP07130-A-1: Block creation from the tumor (PROCEDURE STEP)
DP07130-A-1-1: H&E microscopic slide creation (PROCEDURE STEP)
DP07130-A-1-2: HER2 microscopic slide creation (PROCEDURE STEP)
DP07130-A-1-3: H&E microscopic slide creation level 1 (PROCEDURE STEP)
DP07130-A-1-4: H&E microscopic slide creation level 2 (PROCEDURE STEP)
DP07130-A-1-5: H&E microscopic slide creation level 3 (PROCEDURE STEP)
DP07130-A-1-6: Unstained microscopic slide creation (PROCEDURE STEP)
DP07130-A-2: Block creation from the tumor (PROCEDURE STEP)
DP07130-A-2-1: H&E microscopic slide creation (PROCEDURE STEP)
DP07130-A-3: Block creation from the tumor (PROCEDURE STEP)
DP07130-A-3-1: H&E microscopic slide creation (PROCEDURE STEP)
DP07130-A-4: Block creation from the upper margin, red ink (PROCEDURE STEP)
DP07130-A-4-1: H&E microscopic slide creation (PROCEDURE STEP)
DP07130-A-5: Block creation from the lower margin, blue ink (PROCEDURE STEP)
DP07130-A-5-1: H&E microscopic slide creation (PROCEDURE STEP)

```

Figure 2. Detailed breakdown of the procedure steps of a clinical order for anatomic pathology examination of specimen(s). In typical anatomic pathology practice, 3 levels of specimen preparation are conventionally identified: part, block, and slide. One or more blocks may be sampled from each part and 1 or more slides may be sampled from each block for different staining techniques.

ample, when multiple fragments of tissue are placed in a cassette, most laboratories would consider that collection of fragments as 1 specimen (1 “block”). Specimens are sampled and processed during the workflow. Sampling can create new (“child”) specimens. For example, in typical anatomic pathology practice, 3 levels of specimen preparation are conventionally identified: part, block, and slide. One or more blocks may be sampled from each part and 1 or more slides may be sampled from each block. These child specimens are full specimens in their own right (they have unique identifiers and are direct subjects in 1 or more process steps in the workflow). This property of specimens (that can be created from existing specimens by sampling) extends a common definition of specimen that limits the word to the original object received for examination (eg, from surgery). However, child specimens can and do carry some attributes from ancestors. For example, a tissue section cut from a formalin-fixed block remains formalin fixed, and a tissue section cut from a block dissected from the proximal margin of a colon resection is still made up of tissue from the proximal margin. A description of a specimen, therefore, may require description of its parent specimens.

Specimen containers play an important role in laboratory diagnostic processes. In most, but not all, process steps, specimens are held in containers. Sometimes the container becomes intimately involved with the specimen (eg, a paraffin block), and in some situations, such as examining tissue under the microscope, the container (the slide and coverslip) become part of the optical path. Containers are often made up of components. For example, a “slide” is a container that is made up of the glass slide, the coverslip, and the “glue” that binds them together.

A specimen must have an identifier that defines it as a unique subject in the laboratory workflow. Containers have identifiers that are important in laboratory processes (including imaging processes such as whole-slide imaging). In LIS, 3 levels of specimen preparation are conventionally identified: part, block, and slide (Figure 3).

A part is the uniquely identified tissue or material collected from the patient and delivered to the anatomic pathology laboratory for examination. Examples of parts would include a lung resection specimen, colon biopsy specimen at 20 cm, peripheral blood sample, cervical biopsy specimen, and cervical cells obtained via scraping or brush. A part can be delivered in a wide range of containers, usually labeled with the patient name, medical record number, and a short description of the specimen such as “cervical biopsy at the 2-o’clock position.” At accession, the anatomic pathology laboratory creates a part identifier and places it on the container. The container therefore conveys the part’s identifier in the laboratory.

A block is a uniquely identified container, typically a cassette, containing 1 or more pieces of tissue dissected from the part (“tissue dices”). The tissue pieces may be considered, by some laboratories, as separate specimens. However, in most laboratories, all the tissue pieces in a block are considered a single specimen.

A slide is a uniquely identified container, typically a glass microscope slide containing tissue or other material. Common slide preparations include “tissue sections” created from tissue embedded in blocks (1 slide typically contains 1 or more tissue sections coming from 1 block); “touch preps” prepared by placing a slide into contact with unprocessed tissue; and “dispersions,” which are

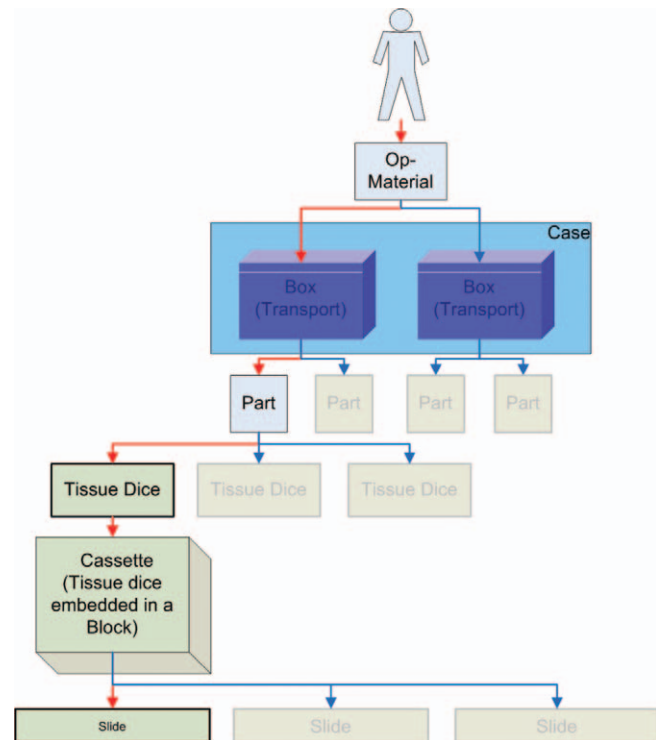


Figure 3. In typical anatomic pathology practice, 3 levels of specimen preparation are conventionally identified: part, block, and slide. There is 1 specimen per container; the value of the specimen identifier (ID) and container ID will be the same.

thin layers of cells created from a suspension, such as liquid-based cytology preparations.

A specimen is defined by decisions in the anatomic pathology laboratory workflow. For example, multiple tissue sections cut from a single block and placed on the same slide are considered a single specimen (as single unit identified by the slide number). However, if the histotechnologist had placed each tissue section on its own slide (and given each slide a unique number), each tissue section would be a specimen in its own right.

In many laboratories that have 1 specimen per container, the value of the specimen identifier (ID) and container ID will be the same (Figure 3). However, there are use cases in which more than 1 specimen is present in a container. During processing, more than 1 tissue item may be embedded in the same block within the same cassette but come from different clinical specimens (parts) (Figure 4). These may represent different lymph nodes embedded in 1 cassette or different tissue dices coming from separately submitted parts (eg, proximal margin [part A] and distal margin [part B]) also placed in the same cassette. To maintain each sample as separate specimens (to maintain their identity), the LIS can give them different IDs and record the physical method of differentiation/identification (eg, the tissue from part A is inked blue and the tissue from part B is inked red). In this case, the specimen IDs must be different from each other and from the container (cassette) ID. If a section is made from the block, each tissue section will include fragments from 2 specimens (red and blue). The slide (container) ID will be different from each tissue section ID, which will be different from each other. If the slide is imaged, a single image with more than 1 specimen may be created, but the different specimens

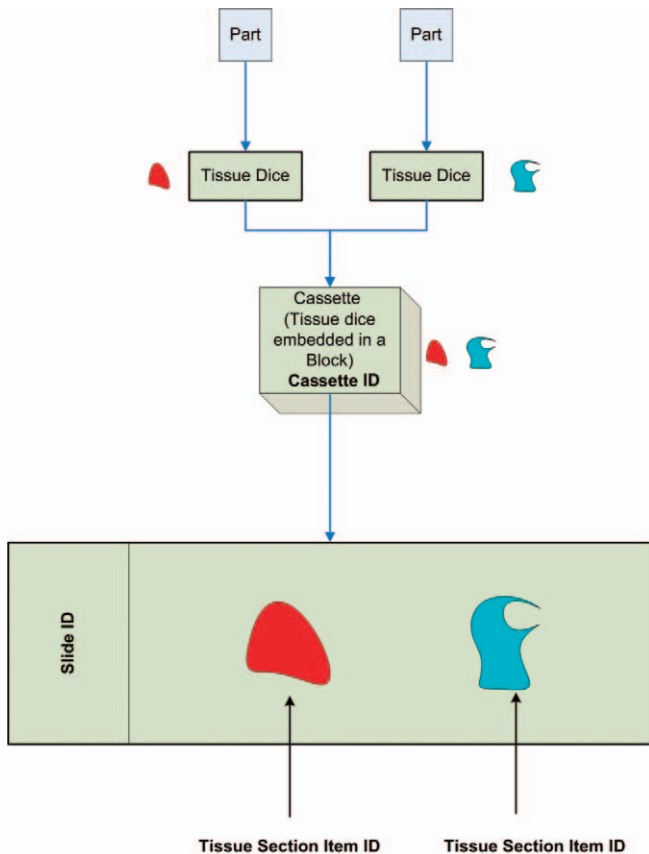


Figure 4. Two specimens from different parts. The specimen identifiers (IDs) must be different from each other and from the container (slide) ID.

must be identified and unambiguously localized within the container.

In cytology, the different directions of smears might represent different parts (eg, portio cervix in gynecologic smears) (Figure 5). The specimen IDs must be different from each other and from the container (slide) ID. The specimens may be localized, for example, by descriptive text such as “short direction smear” or “long direction smear.”

Slides created from tissue microarray (TMA) blocks have small fragments of many different tissues coming from different patients, all of which may be processed at the same time, under the same conditions, by a desired technique. These are typically used in research. Tissue items (spots) on the TMA slide come from different tissue items (cores) in TMA blocks (from different donor blocks, different parts, and different patients) (Figure 6). Each specimen (spot) must have its own ID. The specimens may be localized, for example, by x-y coordinates or by a textual column-row identifier for the spot (eg, “E3” for fifth column, third row). If the TMA slide is imaged as a whole—for example, at low resolution as an index—it must be given a “pseudo-patient” identifier (since it does not relate to a single patient). Images created for each spot should be assigned to the real patients or research subjects.

Image Acquisition.—Digital Imaging and Communication in Medicine defines a hierarchy of concepts related to medical imaging workflow. The highest level is the *study*, which, for anatomic pathology, contains all infor-

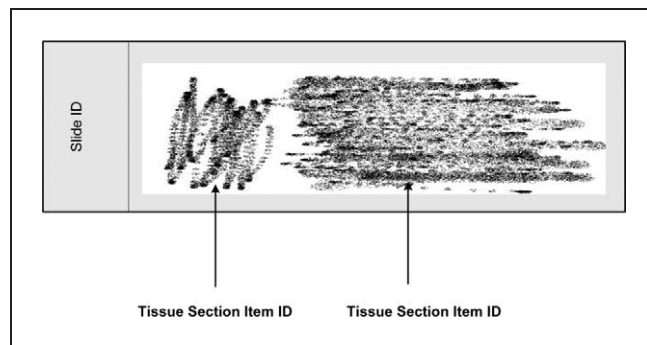


Figure 5. Two specimen smears from different parts on 1 slide. The specimen identifiers (IDs) must be different from each other and from the container (slide) ID.

mation (images and text) collected in the process of fulfilling a given order. The study comprises 1 or more *series*. Each series contains 1 or more images. Each study may contain images acquired by different modalities (gross imaging, microscopic imaging, etc). A new series is created whenever an imaging procedure step is performed on a new specimen or by a new type of equipment. Since image acquisition in anatomic pathology is a specimen-centric activity, a key issue was agreeing across standards (HL7 and DICOM) on the way to identify and describe specimens that are the subject of images.

Before the start of this work in 2005, DICOM had several information object definitions useful in anatomic pathology including the *visible light photographic image for gross specimens* and the *visible light slide-coordinates microscopic image* for slide-based microscopic imaging. However, these information object definitions did not have a strong mechanism for describing the specimen being imaged or associating a particular specimen with a particular image. In fact, while the relationship between patient and image is straightforward in other imaging fields and accurately captured by DICOM objects, in anatomic pathology there is a need for a new specimen module that formally defines specimen attributes at the image level.

To have LIS and digital imaging systems interoperate, it is critical that they all be able to reference a particular specimen according to the same model before associating it with 1 or more reports or images. Therefore, IHE anatomic pathology and HL7 pathology working groups contributed to the DICOM WG26 efforts to define the specimen module in a new DICOM supplement (number 122). The specimen module defines formal DICOM attributes for the identification and description of specimens when said specimens are the subject of a DICOM image. In supplement 122, the “DICOM Model of the Real World” has been extended for specimen with the addition of the objects “specimen,” “container,” “component,” and “preparation step.” The relationships of these new objects to each other and existing DICOM real world objects are shown in Figure 7. Attributes of the specimen, container, component, and preparation step objects are represented in the specimen module, which is focused on critical specimen information necessary to interpret the image.

Specimen attributes include attributes that (1) identify the specimen (within a given institution and across institutions); (2) identify and describe the container in which the specimen resides as well as each component of the container if required (eg, a “slide” is a container that is

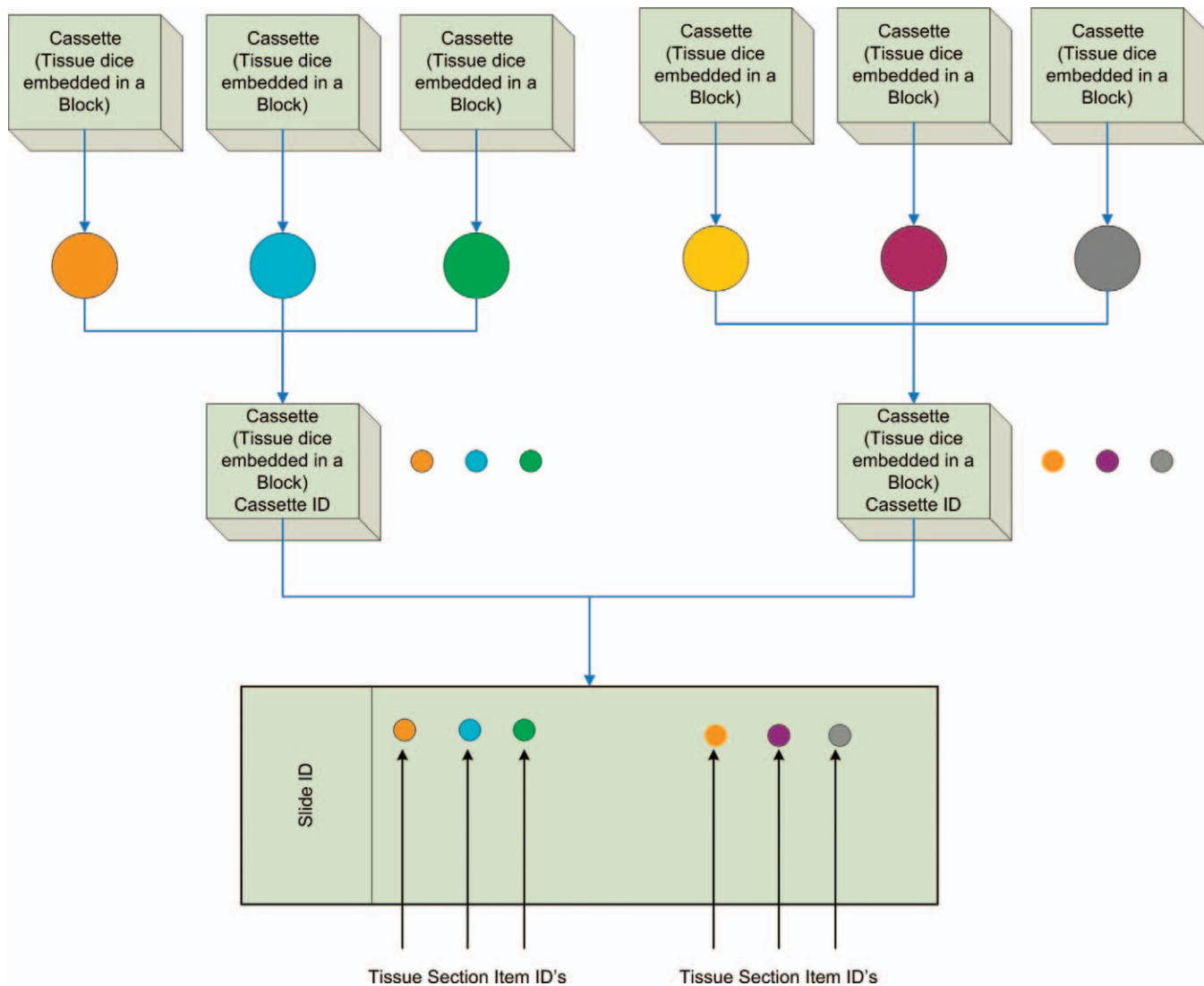


Figure 6. Different specimens from different parts and different patients. The specimen identifiers (IDs) must be different from each other and from the container (slide) ID.

made up of the glass slide, the coverslip, and the “glue” that binds them together); (3) describe specimen collection, sampling, and processing; and (4) describe the specimen or its ancestors when these descriptions help with the interpretation of the image. The specimen module distinguishes the container ID and the specimen ID, making them different data elements to allow maximal flexibility for different situations. Even though the full history of specimen processing is not required in every instance, specimen attributes allow that processing history to be encoded. However, a unique specimen identifier is useful to link a subject specimen to its processing history as managed by an LIS. Attributes that convey diagnostic opinions or interpretations are not within the scope of the specimen module. The DICOM specimen module does not seek to replace or mirror the pathologist’s report.

The specimen module has been harmonized with the HL7 v2 SPM segment and the HL7 v3 specimen domain information model.

Report Creation.—Studies about quality assessment of reports provide lists of mandatory items and stress the positive role of checklists to enhance the reporting pro-

cess.^{8–10} According to “evidence-based pathology,” only features that are reproducible and relevant—with demonstrated diagnostic or prognostic significance—should be reported in description.¹¹ Since 1993, the Association of Directors of Anatomic and Surgical Pathology has published recommendations for pathologic reporting.⁸ In addition, national initiatives (College of American Pathologists’ ad hoc committee on report standardization in the United States and the efforts of the Cancer Institute and French Society of Pathology in France) aim at defining templates for structured reports in anatomic pathology.¹² A generic model of structured reports can be derived from these templates. A pathology report is a clinical document and should have all of the dimensions of a clinical document (author, date/time, patient ID, etc). It might include findings and their supporting evidence expressed, for example, in structured data, free text, and images. Observations should be tied to specific specimens and procedures to laboratory manuals. A crucial issue is to identify a technical solution to handle templates of structured reports including findings and their related supporting evidence.

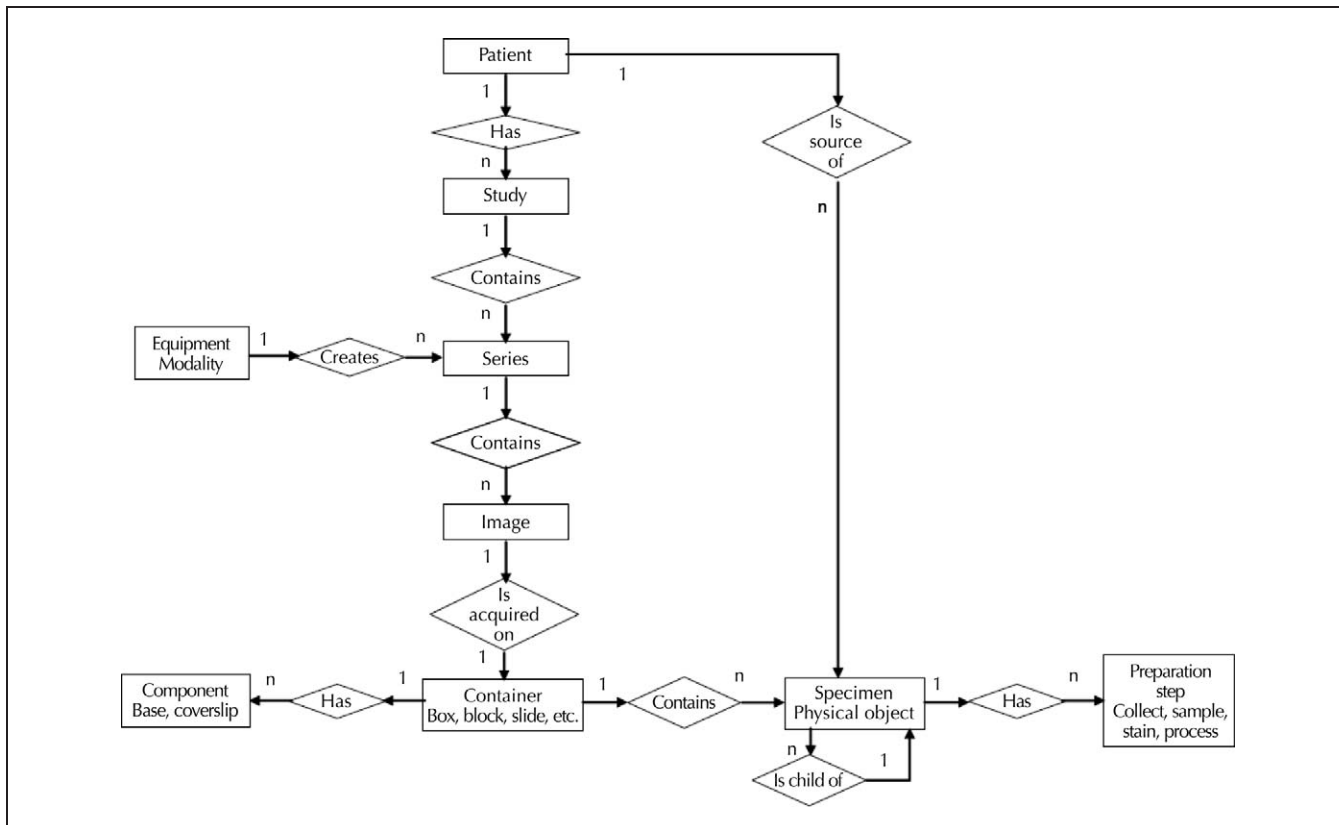


Figure 7. The “DICOM Model of the Real World” extended for specimens with the addition of the objects “specimen,” “container,” “component,” and “preparation step.”

Currently there are 2 candidate approaches for implementing structured reports. The HL7 group has defined the clinical document architecture, which is an XML (eXtensible markup language)–based design for interoperable clinical reports. In addition, the DICOM committee has defined the structured reporting classes for transmission and storage of clinical documents. Efforts are currently underway to harmonize these approaches, which should result in a system that will allow a wide variety of information systems to create and consume such information in a manner that is both human-readable and amenable to computer processing.

IHE Anatomic Pathology Technical Framework

The integration profile “Anatomic Pathology Workflow” was proposed for a first IHE anatomic pathology cycle to establish the continuity and integrity of basic pathology data acquired for examinations ordered for an identified inpatient or outpatient. It focuses on the main transactions of the ordering, reporting, and imaging aspects of the workflow. The “Anatomic Pathology Workflow” integration profile involves 8 actors and specifies 10 transactions to maintain the consistency of ordering and specimen management information in anatomic pathology images and reports (Figure 8). For each transaction, the workgroup proposes the use of the most suitable format—HL7 (version 2 or 3) or DICOM.

Placer order management (PAT-1) contains all the HL7 messages required between the *order placer* (a component of HIS) and the *order filler* (component of LIS) for the management of the life cycle of the order. Its main goal is to

keep a consistent vision of the order, content, and status between the 2 actors. Sometimes the specimens may arrive in the anatomic pathology laboratory without any order. Pathologists are also sometimes responsible for collecting the specimens. In these cases, the transaction *filler order management* (PAT-2) contains all the HL7 messages required by the *order filler* (of the LIS) to send the notification of a new filler order to the *order placer* (of the HIS).

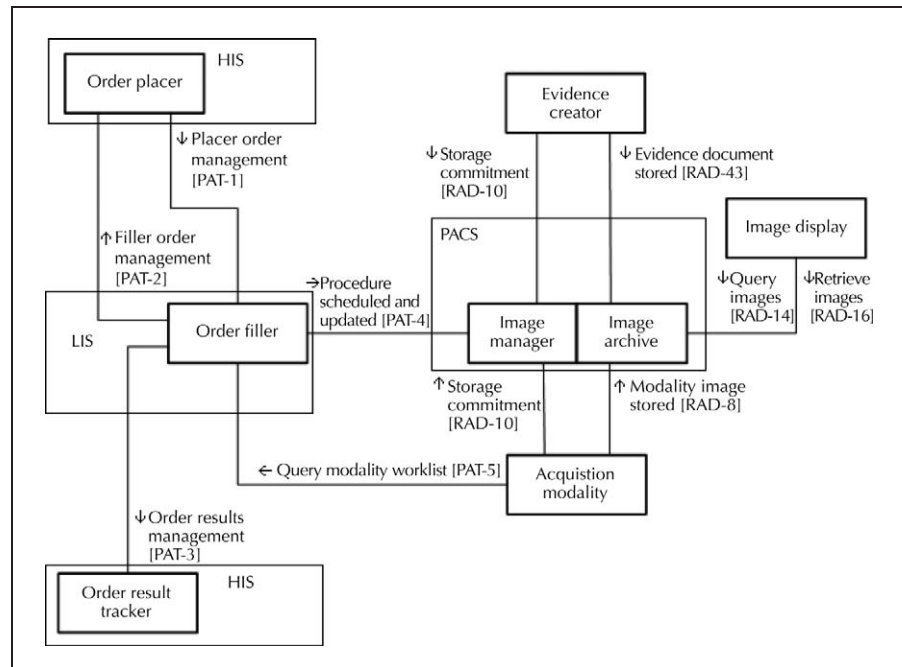
For each order, image acquisition may require different modalities (gross imaging, microscopic imaging, etc). *Query modality worklist* (PAT-5) is based on a DICOM query to the *order filler* (of the LIS) entered at the *acquisition modality*. In case of a general query, the list of scheduled imaging procedures with the associated patient and specimen information is returned to the *acquisition modality*. In case of a query using the barcode identifying a given specimen as the source of an imaging procedure (either part or slide), the specific information about this specimen is returned.

The *procedure scheduled and updated* (PAT-4) allows the *order filler* to send updated information about the order to the *image manager*.

Order results management (PAT-3) carries the report and report status or changes (ie, corrections, cancellations) from *order filler* (of the LIS) to the *order result tracker* (of the HIS).

The transaction *modality image stored* and *evidence document stored* are based on 2 transactions already defined in the radiology domain (RAD-8 and RAD-43, respectively) and allows an *acquisition modality* or an *evidence creator* to send acquired or generated images to the *image archive* (of

Figure 8. "Anatomic Pathology Workflow" involving 8 actors and specifying 10 transactions to maintain the consistency of ordering information and specimen management in anatomic pathology images and reports. The transaction prefixes, PAT and RAD, denote their origin. HIS indicates hospital information system; LIS, anatomic pathology laboratory information system; PACS, picture archiving and communication system; PAT, anatomic pathology; RAD, radiology.



the picture archiving and communication system [PACS]). The transaction *storage commitment* is also based on a transaction already defined in the radiology domain (RAD-10). Thanks to this transaction, the *acquisition modality* or *evidence creator* is able to request that the *image manager* confirm ownership for the specified DICOM objects (images or evidence documents or any combination thereof) stored in the *image archive*, thus allowing the sender to delete those objects. The transaction *query/retrieve images* (RAD-14/RAD-16) allows the querying of the *image manager/image archive* (of PACS) for retrieving and displaying the images.

COMMENT

Quality assessment studies in anatomic pathology show that each of the different steps from specimen collection to report editing may be a source of errors and that integration of information systems supports error reduction.⁹ This work, done in the framework of the IHE anatomic pathology initiative, consisted of defining the needs of systems integration in anatomic pathology, especially between imaging systems, traditional anatomic pathology LIS, and HIS. The IHE anatomic pathology working group has defined standard-based technical solutions for system integration for the basic diagnostic workflow in anatomic pathology laboratories. The results are a new integration profile, "Anatomic Pathology Workflow," proposed for a first IHE cycle in anatomic pathology and covering the steps from order to report. The anatomic pathology technical framework, specifying the use of the most suitable format for each transaction—HL7 (version 2 or 3) or DICOM—has been published for trial implementation.

The main contributions of this work consisted in analyzing the specificity of the anatomic pathology workflow with regards to laboratory and radiology workflows and in defining the structure and content of the information flow involved during the 4 main steps of this workflow: order management, specimen processing, image acquisition, and report creation. Since image acquisition in ana-

tom pathology is a specimen-centric activity, a key issue was agreeing across standards (HL7 and DICOM) on the way to identify and describe specimens that are the subject of images.

A common specimen model and a specimen module including critical specimen information necessary to interpret the image were defined in the DICOM supplement 122. The specimen module has been harmonized with the specimen description in HL7 version 2 or 3 information constructs. The intent for the DICOM specimen module is not to duplicate all the HL7 features, but rather to provide sufficient linkages so that the DICOM images can fit into an overall anatomic pathology laboratory environment that may use HL7 version 2 or 3 messages for workflow management (orders and observations).

Although the main output of the anatomic pathology workflow is a timely and clear report of a diagnostic opinion, there will be increasing desire to associate images as evidence for textual reports. Therefore, the integration profile "Anatomic Pathology Workflow" includes the issue of archiving images in a picture archiving and communication system (PACS). Indeed, the main advantage of using DICOM standard instead of proprietary file formats is to store anatomic pathology images in PACS, like radiologists or cardiologists do, and therefore to distribute these images to clinicians through the same viewers that they use for other medical images. The DICOM WG26 is currently addressing the issue of archiving large whole-slide images in PACS, and the specific DICOM objects that will be defined in the near future will probably challenge the existing DICOM viewers.

Integrating the Healthcare Enterprise technical frameworks are continuously maintained and expanded on an annual basis. Each year, the anatomic pathology technical committee develops supplements to the current stable version of the technical framework to support new functionality identified by the planning committees and issues them for public comment. After the public comment period, an updated version of the technical framework for

“trial implementation” is published to be used by vendors in developing trial implementation software for the annual *Connectathon*. The anatomic pathology committee also considers change proposals to the trial implementation version of the technical framework.

Two additional integration profiles have been proposed for the next cycle that will be dedicated to the management of semantically rich structured reports and also to the integration of systems used for patient care and those used for research activities (like tissue bank databases or tissue microarrays).

Because IHE is organized and driven by professional organizations representing both health care providers and information systems vendors, it is able to use a simple and common language in the technical framework that provides a comprehensive guide for a coordinated implementation of information standards to achieve integration processes. It is our hope that this work will lead to greater adoption of standards within the anatomic pathology community, allowing a proliferation of systems that will seamlessly interoperate, similar to the experience in the field of radiology, in which imaging equipment and information systems from multiple vendors routinely work together, providing a rich environment for clinical imaging activities.

We would like to thank the members of the IHE anatomic pathology working group for their substantial input to the IHE anatomic pathology technical framework: (1) practicing pathologists Dominique Henin, MD, PhD (ADICAP, AP-HP, Paris, France); Frédérique Capron, MD, PhD (ADICAP, AP-HP, Paris, France); Bettina Fabiani, MD (ADICAP, AP-HP, Paris, France); Jean-Marc Guinebretière, MD (Centre René Huguenin, ADICAP, France); Marcial García Rojo, MD, PhD (Hospital General de Ciudad Real, Ciudad Real, Spanish Society of Health Informatics-SEIS, Spain); Ernesto Moro (Universidad Rey Juan Carlos, Madrid, Spanish Society of Pathology-SEAP, Spain); Thomas Schrader, MD, PhD (La Charité, Berlin, Germany); John Gilbertson, MD (Harvard Medical School and Beth Israel Deaconess Medical Center, Boston, Massachusetts); Bruce A. Beckwith, MD (Laboratory Medicine Department of Pathology, Salem, United States); Luis

Goncalves, MD (Hospital de Evora, Portugal); Ikuo Tofukuji, MD (Takasaki University of Health and Welfare, Japan); (2) informatics technology professionals: Karima Bourquard, PhD (GMSIH, Paris, France); Christel Daniel, MD, PhD (AP-HP, INSERM, AD-ICAP, Paris, France); Vincenzo Della Mea, PhD (Department of Mathematics and Computer Science, University of Udine, Udine, Italy); François Macary (GMSIH, Paris, France); Carlos Peces (SESCAM, Spain); Miguel Angel Laguna, PhD (HGCR-SESCAM, Spain); Eric Poiseau, PhD (IHE, Rennes, France); and (3) vendors: Didier Adelh (Samba Technologies, Meylan, France); Jean-Christophe Cauvin, PhD (Medasys, Gif, France); Emmanuel Cordonnier (Etiam, Rennes, France); Jacques Klossa, PhD (Tribv'n, Châtillon, France); François Lecertisseur (Technidata, Bourg-lès-valence, France); Damien Mazoyer (Infologic, Montbonnot, France); Takashi Okuno (Olympus Medical Systems, Japan); Harry Solomon (GE, Chicago, Illinois).

This study was supported by the following grants: FISCAM BR-CCM-2006/03, COST Action IC0604 Euro-Telepath, ADICAP.

References

1. Health Level 7. Health Level 7 Inc. <http://www.hl7.org>. Accessed December 21, 2008.
2. NEMA. DICOM 3 standard, NEMA and global engineering group. <http://www.nema.org>. Accessed December 21, 2008.
3. IHE. IHE International. <http://ihe.net>. Accessed December 21, 2008.
4. Henderson ML, Dayhoff RE, Titton CP, Casertano A. Using IHE and HL7 conformance to specify consistent PACS interoperability for a large multi-center enterprise. *J Healthc Inf Manag*. 2006;20:47–53.
5. Klossa J, Cordier JC, Flandrin G, Got C, Hemet J. A. European de facto standard for image folders applied to telepathology and teaching. *Int J Med Inform*. 1998;48:207–216.
6. Le Bozec C, Henin D, Fabiani B, Schrader T, Garcia-Rojo M, Beckwith B. Refining DICOM for pathology—progress from the IHE and DICOM pathology working groups. *Medinfo*. 2007;12:434–438.
7. DICOM Standards Committee, NEMA. DICOM strategic document, version 8.1, July 9, 2008; e35–e38. Available at: <http://medical.nema.org/dicom/geninfo/Strategy.pdf>. Accessed December 21, 2008.
8. Nakhleh R, Coffin C, Cooper K. Association of Directors of Anatomic and Surgical Pathology. Recommendations for quality assurance and improvement in surgical and autopsy pathology. *Hum Pathol*. 2006;37:985–988.
9. Nakhleh RE. Patient safety and error reduction in surgical pathology. *Arch Pathol Lab Med*. 2008;132:181–185.
10. Zarbo RJ, Meier FA, Raab SS. Error detection in anatomic pathology. *Arch Pathol Lab Med*. 2005;129:1237–1245.
11. Fleming KA. Evidence-based cellular pathology. *Lancet*. 2002;359:1149–1150.
12. Valenstein PN. Formatting pathology reports: applying four design principles to improve communication and patient safety. *Arch Pathol Lab Med*. 2008; 132:84–94.