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Research Article

Use of contextual inquiry to understand anatomic pathology workflow: Implications for digital pathology adoption

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Abstract

Background: For decades anatomic pathology (AP) workflow have been a highly manual process based on the use of an optical microscope and glass slides. Recent innovations in scanning and digitizing of entire glass slides are accelerating a move toward widespread adoption and implementation of a workflow based on digital slides and their supporting information management software. To support the design of digital pathology systems and ensure their adoption into pathology practice, the needs of the main users within the AP workflow, the pathologists, should be identified. Contextual inquiry is a qualitative, user-centered, social method designed to identify and understand users' needs and is utilized for collecting, interpreting, and aggregating in-detail aspects of work. **Objective:** Contextual inquiry was utilized to document current AP workflow, identify processes that may benefit from the introduction of digital pathology systems, and establish design requirements for digital pathology systems that will meet pathologists' needs. **Materials and Methods:** Pathologists were observed and interviewed at a large academic medical center according to contextual inquiry guidelines established by Holtzblatt *et al.* 1998. Notes representing user-provided data were documented during observation sessions. An affinity diagram, a hierarchal organization of the notes based on common themes in the data, was created. Five graphical models were developed to help visualize the data including sequence, flow, artifact, physical, and cultural models. **Results:** A total of six pathologists were observed by a team of two researchers. A total of 254 affinity notes were documented and organized using a system based on topical hierarchy, including 75 third-level, 24 second-level, and five main-level categories, including technology, communication, synthesis/preparation, organization, and workflow. Current AP workflow was labor intensive and lacked scalability. A large number of processes that may possibly improve following the introduction of digital pathology systems were identified. These work processes included case management, case examination and review, and final case reporting. Furthermore, a digital slide system should integrate with the anatomic pathologic laboratory information system. **Conclusions:** To our knowledge, this is the first study that utilized the contextual inquiry method to document AP workflow. Findings were used to establish key requirements for the design of digital pathology systems.

Key words: Anatomic pathology, contextual inquiry, workflow, digital pathology

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BACKGROUND

The pathologist's workflow in the practice of anatomic pathology (AP) has traditionally been a complicated manual process where pathologists microscopically examine stained slices of formalin-fixed, paraffin-embedded tissue affixed to glass slides. These findings are consolidated and interpreted by the pathologist in the context of the clinical representation and other laboratory or radiographic studies and a diagnosis is rendered and reported, a process defined as sign-out.

With advances in information technology and the evolution of the electronic medical record (EMR), the pathologist have been able to record specimen encounters in greater detail, to more easily manage and distribute final reports, and more accurately bill for procedures performed. The AP laboratory information system (APLIS) is being increasingly utilized by the pathology department to manage these tasks.[1] Currently, many members of the pathology and histology departments regularly interact with these computerized information systems throughout the workday, including administrative assistants, transcriptionists, histotechnologists, and pathologists. Vendors of these commercially available electronic systems struggle to design and provide a single solution for many different AP workflows.

While workflow enhancements provided by the move to computerized systems have collectively improved workflow efficiency, the pathologist's individual enhancements have been diluted. Anecdotally, some pathologists even avoid direct interaction with these new electronic information systems by using older, "legacy" technologies. For example, many pathologists still use tape dictation instead of using "newer" technologies such as voice-recognition software because, despite greater costs, these "older" technologies still provide a more time-efficient workflow. Furthermore, the rising trend of subspecialization within the practice of pathology, i.e., subspecialists review, interpret, and report only cases related to their subspecialty, offers a higher rate of expertise for case interpretation, but also offers the opportunity of a workflow tailored to a specific organ system. For example, workflow in dermatopathology (characterized by high volume of cases, smaller number of slides per case, and smaller tissue sections) is markedly different from soft tissue pathology (characterized by lower volume, greater number of slides per case, and larger tissue sections). Unfortunately, the "one size fits all" approach of current APLIS systems does not provide for customization of each subspecialist's workflow.

In parallel, recent rapid advances in the technology of scanning and digitizing entire glass slides, known as whole slide imaging or digital slides, promise to replace the microscope and glass slides as a tool for the pathologist in sign-out workflow.[2,3] Digital slides and their supporting pathology information management software have the potential to efficiently support workload distribution and reduce the errors caused by the current manual exchange of paperwork and glass slides from the histology lab to administrative support and finally to the pathologist. To be adopted by pathologists, a "digital slide/digital pathology system" comprised of digital slides and supporting information management software to manage the information in these slides would need to provide compelling workflow advantages over the current "glass slide system" comprised of a microscope and glass slides.

Inefficiencies that exist in the current AP workflow may potentially be alleviated by a digital slide system. However, identifying these inefficiencies and designing a new system using digital slides is a complex task. It first entails a detailed understanding of the AP workflow and needs of the key user, the pathologist. Many social, qualitative methods, such as interviews, focus sessions, and surveys, can be utilized to collect feedback from users to help identify requirements for engineering or/and designing new technology/systems. However, all these methods depend on the user's ability to clearly articulate his/hers needs, an inherently difficult action. Holtzblatt *et al.* developed and designed contextual inquiry as a user-centered, qualitative method that can help gather unarticulated knowledge about work, collect low level details of work that have become habitual and invisible, and provide data about structure of work practice rather than market characterization.[4] Using the contextual inquiry method, members of the design team gather detailed design data while they observe users at their workplace doing their work. Observers employ a "master-apprentice" model, whereby the users teach the observers how their work is performed, while the observers ask questions about the work and document their observations and discussions using notes. Artifacts, i.e., physical objects and forms used to accomplish work tasks, are discussed and collected for future reference. If possible, multiple carefully selected interviewees are recruited for the contextual inquiry sessions. About 10–20 interviews are usually sufficient for an analysis. Once all contextual interviews are performed, data is consolidated from all the interviews to provide a representation of work across all users.[4]

Contextual inquiry can uncover aspects of workflow important to software and device design that cannot be discovered by other techniques, such as surveys or focus groups.[5] A small number of studies reported the use of contextual inquiry for design of medical devices and information systems within the hospital/medical environment.[5-9] To date, several studies focused on AP workflow, but none utilized social techniques to observe the pathologist's workflow.[10-16] To our knowledge, the following study is the first study to document contextual

inquiry models in AP workflow. The objectives of this study are to apply the contextual inquiry method to: (1) provide formal documentation of the routine sign-out workflow of pathologists at a large academic medical center; (2) identify inefficiencies and problems within the current glass slide-based AP workflow that can be possibly improved by the introduction of digital pathology systems; and (3) provide guidelines for key design requirements of new digital pathology systems.

MATERIALS AND METHODS

Contextual inquiries and modeling sessions were conducted according to guidelines suggested by Holtzblatt *et al.*[4]

Observations

Pathologists from a single large academic medical center were observed/interviewed while conducting routine sign-out service. In academic pathology practices, pathologists typically perform a subspecialty-based sign-out service as they review only cases related to their subspecialty. To reflect this trend, pathology subspecialists representing the most common subspecialities at academic pathology centers were selected for the observation sessions.

Initial observation sessions were conducted with all selected pathologists. Several follow-up sessions were conducted to observe sign-out of cases that required additional stains and, therefore, were not signed out during the initial sessions. Each initial observation session lasted 2–3 hours and each follow-up session lasted 1–2 hours. The volume of reviewed cases at each session varied according to case complexity, subspecialty, type of specimen, number of interruptions, and pathologist.

Observations were conducted by a team of two researchers. Both researchers were graduate students; one researcher was a practicing dermatopathologist. During each session, the researchers employed a master-apprentice model while the pathologist (the "master") was performing sign-out service. Researchers carefully collected information about artifacts, sources of information, tasks and sequences of tasks, and interruptions. Researchers documented their findings utilizing notes representing user-provided data. "Breakdowns" (i.e., anything that interrupted the user from accomplishing his work) and potential design ideas were captured as well. No personally identifiable patient or pathologist/ interviewee information was documented or collected.

Interpretation

Affinity diagram

Following the completion of each observation session, researchers conducted an interpretation session to review their user-provided notes and capture them as "affinity notes." Interpretation sessions occurred within 72 hours of the initial observation session. To help identify common issues, work patterns, and needs, affinity notes were arranged into hierarchical categories based on common themes in the data to create an "affinity diagram." Following the conclusion of all observation and interpretation sessions, all affinity notes were used to create a consolidated affinity diagram.

Models

To help visualize the work process and provide context to the data, five graphical models were created following each observation session. At the conclusion of all sessions data was consolidated and five consolidated models were developed.

The flow model captured the flow of physical artifacts as well as data and communication between the key users and other individuals and/or groups and information systems. The sequence model documented the main work tasks, activities and actual steps that users performed to accomplish various work tasks. Different steps performed by different users to conduct an identical activity were documented and represented as different strategies. In addition, the triggers for each work task, as well as breakdowns in the ongoing work, were captured. The artifact model documented and described the physical objects (devices and/or forms) that supported the work. Each artifact model included an image of the artifact and provided information about its usage, intent, and in-detail description of the artifact parts important for usage. The cultural model captured the general policies, values, relationships and other factors that impact the user's workflow and decision-making. The physical model captured the physical layout of the work environment as documented via drawings or photographs. Breakdowns documented in the affinity notes were provided in the sequence, flow, and artifact models.

RESULTS

A total of six pathologists, all board certified subspecialists, including two dermatopathologists, two genitourinary pathologists, and two breast/obstetrics and gynecology (OB/GYN) pathologists, were observed in the study. Pathologists experience varied and included >10 years (n = 1), 5-10 years (n = 3), and <5 years of experience (n = 2). Each pathologist was observed in an initial contextual inquiry observation session (total six initial sessions); two follow-up sessions were conducted. The number of cases that was examined by the pathologist during a single observation session ranged from <15 to >30.

Affinity Diagram

A total of 275 affinity notes were recorded; 16 notes were repeated, resulting in a total of 254 distinct affinity notes. Notes that were conceptually similar were grouped into 75 third-level categories, further categorized into

24 second-level categories, and finally into five main categories. The main categories were technology, communication, synthesis/preparation, organization, and workflow. The full consolidated affinity diagram is provided in Table 1 in Supplement A.

Of 254 affinity notes, 54 notes were documented as breakdowns. Majority of breakdowns were recorded in three main categories: organization (n = 15), communication (n = 13), and workflow (n = 11). Of the seven breakdowns recorded in the technology category, six were attributed to the APLIS. The number of breakdowns also differed by subspecialty bench: 25 breakdowns occurred on the dermatopathology bench, 16 on the breast/OB/GYN bench, and 13 on the genitourinary bench.

Models

Flow Model

The AP workflow is comprised of a specimen life cycle, initiated by the clinician with the removal of a specimen from the patient, and terminated with the receipt of a final pathology report at the clinician's office. The flow model [Figure 1] describes all users involved in the specimen lifecycle and their responsibilities, as well as all systems utilized to support this work. The model documents the flow of artifacts and communication between the various users and systems utilized during the specimen life cycle.

As shown in Figure 1, the pathologist is the key user within the AP workflow, communicating with all individuals/groups and information system involved in the specimen lifecycle. The pathologist interacted with a total of 10 individuals/groups including histotechnologists at the histology and immunohistochemical (IHC) labs, gross room/pathology assistants, pathology residents/fellows, pathology colleagues, pathology experts at other institutions, and support staff (including courier, medical transcriptionist, and administrative assistants). A total of four information systems, including the APLIS, EMR, radiology information system, and reference resources were involved. A total of 18 artifacts including specimen, cassettes, requisition sheet, glass slides (including hematoxylin and eosin (H and E)-stained and IHC-stained slides, blank slides, slides assigned for quality assurance (QA), slides sent to archive), final report, accession log, clinical/surgeon notes, and dictation/transcription notes were exchanged [Figure 1].

The overall events in the specimen life cycle, which serves as the basis for the AP workflow documented within the flow model, are described in detail below.

Procedure and Requisition

The clinician collects specimen/s (e.g., tissue, bone, etc.) from the patient and completes a requisition form. Specimen/s can vary in size, ranging from smaller tissue sections such as biopsies (e.g., needle biopsies) to whole organs removed during surgery (e.g., uterus, large bowel segments, others). Specimen/s and forms are packaged and sent to a predetermined pathology lab.

Accession

The package is received at the histology lab and an accession (instance of receipt of a package) is created in the APLIS. The accession is assigned an accession number. If the package contains several specimens collected from the patient (e.g., several biopsies collected from several body parts), each specimen is defined as a "part." Each accession can thus have multiple parts.

Gross Examination

At the gross room, a pathology assistant examines the specimen/tissue from each part and dictates the macroscopic description of the specimen using a transcription service. The pathology assistant decides which tissue portions are appropriate for further microscopic examination. Larger tissue portions are dissected into smaller portions (no larger than 2.0 × 2.5 × 0.3 cm) and placed into cassettes. Each part can occupy multiple cassettes. The pathologist assistant records a "key" for each cassette which associates a description of the tissue with a cassette number and part number.

Histology

Cassettes carrying specimen sections are placed in formalin. Smaller specimens, such as needle biopsies, fix rapidly and typically require less hours of fixation (about 5 hours) compared to larger, denser tissue samples such as excisional biopsies and surgically removed organs (≥12 hours). Following fixation, cassettes are placed into a tissue processor; during processing, the tissue sections undergo hydration and clearing and are infiltrated with paraffin. Formalin-fixed tissue from each cassette is oriented and placed into a mold and then embedded into a paraffin block. A histotechnologist cuts into the block to create thin slices/sections of tissue and mounts appropriate tissue sections onto glass slides. These initial tissue cuts are routinely stained with H and E. Each slide is labeled with an accession number, part number, block number, and stain type. After H and E staining, glass slides are collated by part, accession number, and subspecialty bench into slide trays and delivered to the appropriate pathologist by a histotechnologist or a courier.

Case Examination

A pathologist (or pathology resident/fellow) receives and reviews the slides. The pathologist quickly glances at the slides within the slide tray to obtain important information about the case prior to examining each slide under the microscope. Frequently, at this stage, the pathologist is able to deduce specimen and procedure type based on the specimen shape, number of blocks, number of slides per block, stain type, and sometimes even determine a preliminary diagnosis. The pathologist then proceeds and examines the slides using the microscope. If additional clarification on findings provided by the

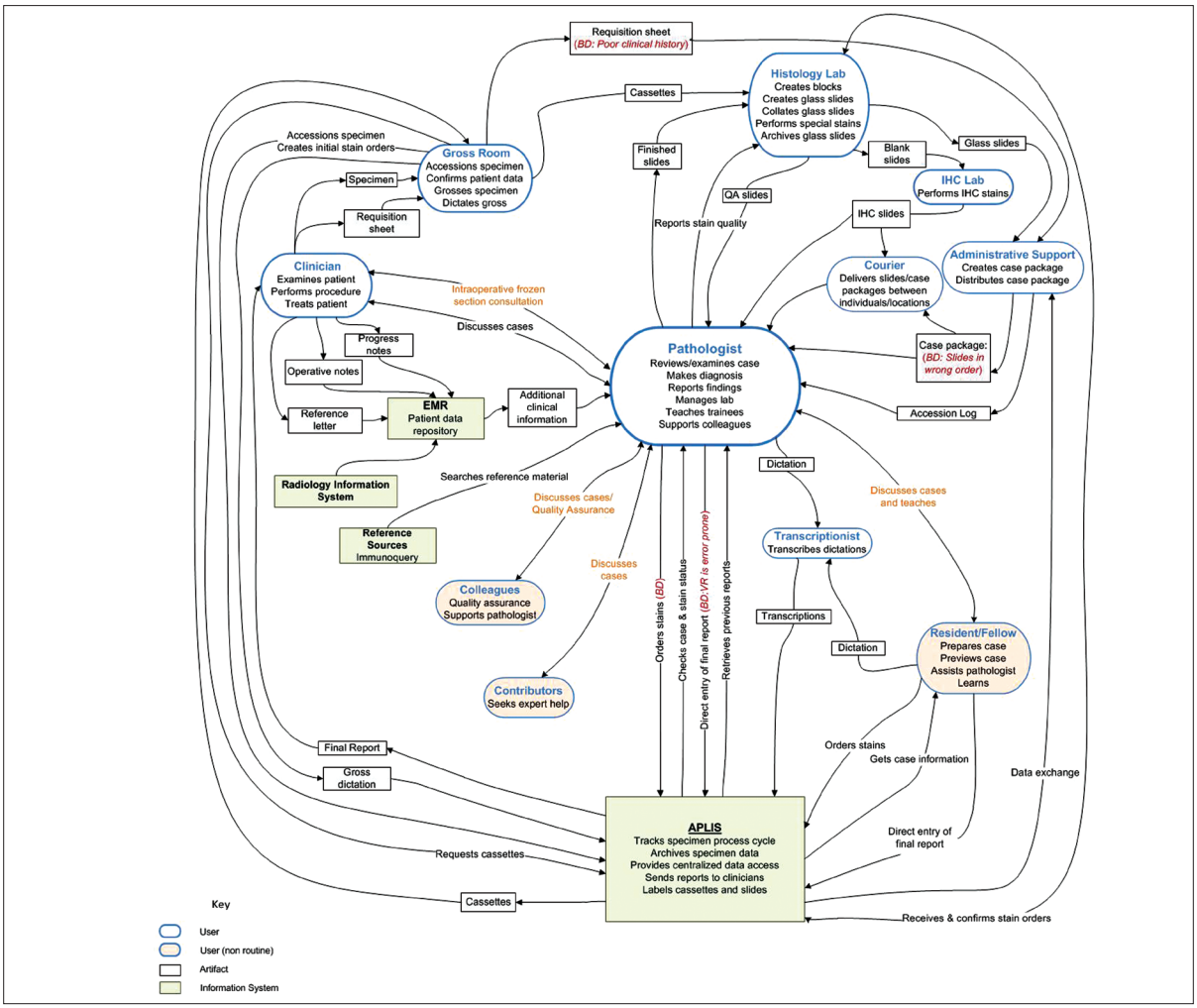

Figure 1: Consolidated flow model. APLIS = anatomic pathology laboratory information system; BD = breakdown; EMR = electronic medical record; IHC = immunohistochemistry. The consolidated flow model documents the flow of information and artifacts between all users involved in the AP workflow. As shown, the pathologist is the main user in the AP workflow. Circles represent individuals and/or well-defined user groups; rectangles represent information sources and artifacts and items of communication. Sections of the AP workflow that are not part of the routine sign-out workflow are indicated (orange). Breakdowns in the flow of information or artifacts are indicated in parenthesis (red)

initial slides is required, additional stains (i.e., special and/or IHC stains) and cuts are ordered via the APLIS. For interpretation of complex specimens the pathologist retrieves additional clinical information from various sources, including lab results from the EMR, operatory notes from the surgeon, letters of correspondence from other physicians, and radiology reports.

Creation of Final Report

The pathologist dictates or types a final report that communicates a final diagnosis into the APLIS. Once a pathologist signs-out a case by typing in a password the final pathology report is memorialized as a permanent part of the patient's medical record. An addenda is created if additional stains are examined after case sign-out or if the pathologist has to provide additional explanations or information per the clinician's request.

The specimen life cycle mentioned above refers to the typical, routine case sign-out, the focus of this study, as well as teaching at the academic center. However, the flow model provided in Figure 1 captures additional, more specific workflows within the AP workflow, such as consultations, quality assurance, and frozen sections. These specific workflows are not discussed in further detail in this study.

Sequence Model

The sequence model captured the ordered steps that the academic pathologist performed to complete a routine case sign-out. The consolidated sequence model provided in Table 2 in Supplement B combines findings from six individual sequence models prepared for each individual pathologist observed in the study. The consolidated sequence model contains four major sections, based on four major overall intents/tasks conducted during routine sign-out and their respective triggers: 1. Prepare

for the day's workload (trigger: arrival of case packages to pathologist); 2. Make and deliver diagnoses (trigger: cases organized and ready for review); 3. Obtain more morphological information about a case (trigger: decision point during case examination that requires additional morphological information to clarify findings); and 4. Aggregate slides with different stains for a case in review (trigger: arrival of slides with pending stains to pathologist). The main activities during sign-out included: "Estimate the day's workload," "gather and organize information relevant to a case," "examine a case," and "communicate a diagnosis." Tasks that were subloops triggered during the activity "examine a case" included "order additional stains" and "organize materials for cases pending additional stains."

The task that required the highest number of steps was "make and deliver diagnoses." A total of 41 abstract steps were performed (and documented as strategy 1) during two activities—"examine a case" and "communicate a diagnosis." Steps used to conduct the activity "examine a case" were remarkably similar between pathologists, with only small variations (presented as extra steps in strategy 2), such as "annotating slides with felt tip pens." The activity "communicate the diagnosis" involved similar number of steps in the dictation strategy ($n = 10$) (strategy 1) and direct text entry strategy ($n = 8$) (strategy 2). When pathologists decided that progressing to the next step in the activity "examine a case" required additional information (such as either ordering additional stains from the histology lab, ordering additional tissue to be submitted, checking the EMR for additional results or notes, and/or calling the clinician to request additional clinical information), subloops were triggered. Upon completion of these subloops, case examination was resumed.

Except for the activity "preparing for the day's workload," the majority of activities were performed numerous times throughout the day. Majority of documented breakdowns were related to the inability to monitor case status, missing materials or relevant information, and problems with the APLIS.

Cultural Model

The consolidated cultural model, provided in Figure 2, identified the general policies, values, constrains, relationships, and other factors that influence the academic pathologist's workflow and decision-making. The main goal of the pathologist was to provide accurate diagnosis, delivered to the client, the clinicians, in a timely manner. A pathologist's reputation among clinicians was measured by both the quality of the reported diagnoses and timeliness of reporting. Although the pathologist wanted to verify that his/her provided diagnoses were carefully crafted, complete, and error-free prior to finalizing the report and sending it to the clinician, he/she also wanted to reduce turnaround time. The pathologist was also required to comply with documentation policies and standards throughout the specimen lifecycle, especially in the creation of the final report. The academic pathologist relied on other users within the AP workflow to achieve this goal: the histology lab and courier to support specimen processing and delivery of slides as soon as possible, while the residents and/or fellows to help analyze the slides and provide a diagnosis. The APLIS, used by the pathologist to communicate with other users, manage/track specimen, and construct and provide the final report, played a critical role in the pathologist work. The APLIS was frequently a major cause for frustrations.

Physical Model

Details of the pathologist's office/working area are provided in Figure 3. The workstation typically consisted of a desk equipped with a microscope (single or multi-headed) and a computer with access to the APLIS. Glass slides provided within slide trays and accompanied by paperwork were delivered to the workstation. The pathologist performed all activities required to complete sign-out while sitting at the workstation. The microscope and computer, as well as packages of cases/slide trays being reviewed were within arm's length. Newly arrived unmatched slides/cases and slide trays of cases pending either additional stains, quality assurance review or other action items (for example, call clinician) were within the pathologist's sight but usually not within arm's reach.

Artifact Model

A total of eight artifacts were collected and included in this model: the microscope, slide tray, glass slides, requisition sheet, accession log, glass slide annotations, paper working draft, and the final report. All eight artifact models are provided in Supplement C; three key artifacts will be discussed in further detail below.

Microscope

The optical microscope was the tool used by pathologists to examine microscopic glass slides. The microscope has several controls utilized by the pathologists to examine the field of view. Microscope settings (including eyepiece, stage, and lighting) were maintained from day to day. However, some pathologists optimized settings at the beginning of the day to minimize the number of minor adjustments required while examining slides throughout the day. The most commonly used controls were the magnification changer, the fine focus knob, and the condenser. Microscopes were typically equipped with multiple lens objectives, providing various options for tissue magnification. The Pathologist used low magnification objectives (i.e., 2× and 4×) to obtain an overview of the tissue and to screen for areas of interest. Medium magnification objectives (i.e., 10× and 20×) were used to confirm findings seen at low magnifications and to identify additional areas of interest on the slide. High magnification objectives (i.e., 40× and

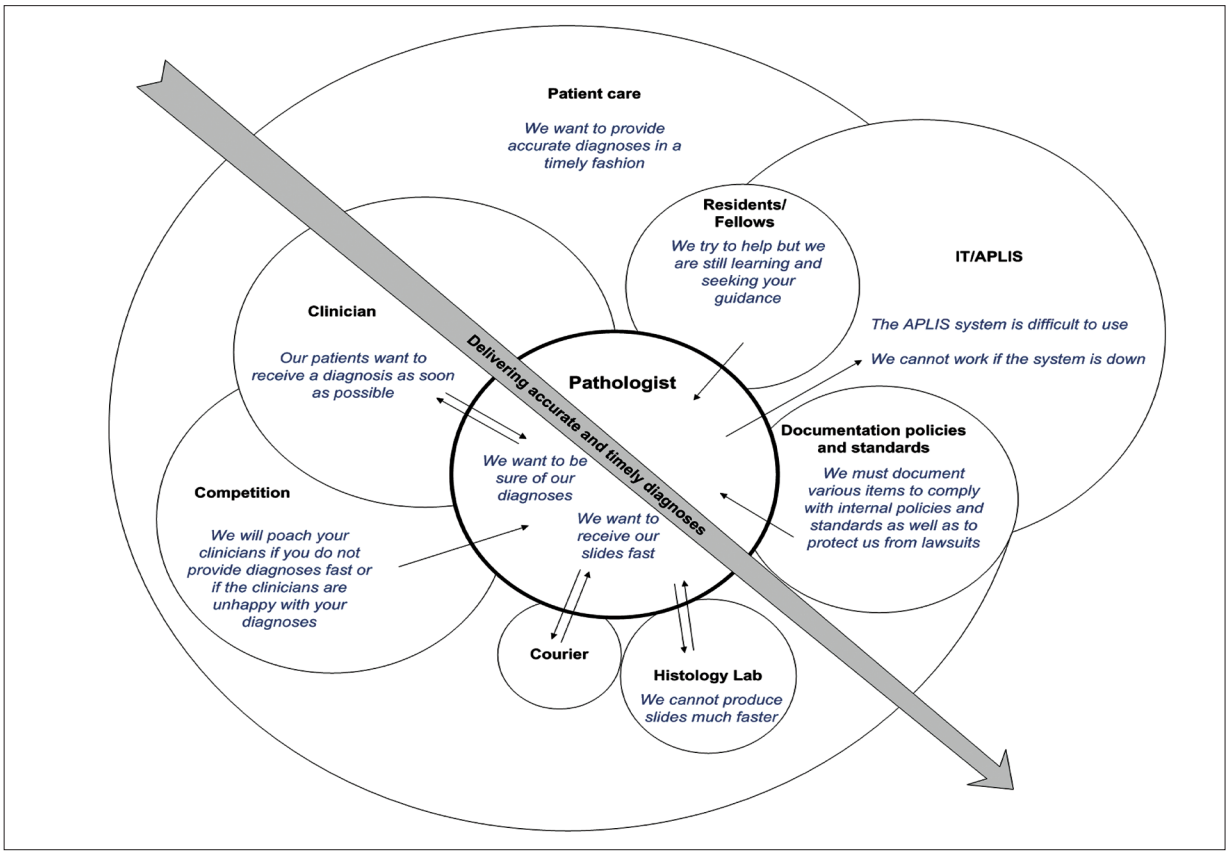

Figure 2: Consolidated cultural model. The cultural model shows the main influences on the academic pathologist. The arrow represents the main goal of the pathologist (deliver accurate and timely diagnoses). The various factors affecting the pathologist—values (patient care, competition), policies, information systems/resources (IT/APLIS), and other users within the AP workflow (clinician, histology, resident/ fellow, courier)—are all represented as overlapping circles. Text in italics describes the main concerns for each influencing factor

60×) were used to confirm findings obtained at the low and medium magnifications and to examine in detail cellular morphological features.

Glass Slides

Pathologists reported that they typically examine hundreds of glass slides daily. The number of slides for each case ranged from as few as one or two slides prepared from a single specimen part to as many as 60 or more slides prepared from multiple specimen parts. Each slide had a label, typically a sticker that provided the pathologist with information about the accession number, part and block number, and stain type. Frequently, pathologists were able to identify stain type by a quick, visual scanning of the tissue. While slides produced by the histology laboratory were fairly consistent, occasionally variations occurred. Standard protocols were developed and implemented by the histology laboratory to limit the number of tissue pieces that may be placed within each cassette, as well as the number of sections/ slices that may be placed on each slide. Tissue was affixed near the center of the glass slide.

Glass Slide Annotations

Pathologists marked the glass slides with a fine-tip, felt-tip pen. These markings indicated important findings on specific slides that should be included in the final report. In addition, they helped the pathologist perform rough calculations for prognostic factors and match regions of interest on different slides.

DISCUSSION

Anatomic surgical pathologists' workflow has arguably not seen any major changes since the introduction of IHC stains. However, the workflow is mature and has undergone many refinements throughout its history. Nonetheless, we noted much inefficiency in the AP workflow and identified a large number of step/processes that may improve following the introduction of a digital slide system, as identified below:

Case Management

Keeping track of cases and their related glass slides was a routine task that required significant time and attention. Furthermore, as case volume increased, the logistics of the tracking process became more complicated; hence the process had poor scalability. Matching slides to cases was constantly required throughout the day. No effective method was available to track the status of pending stains, frequently resulting in "orphaned" slides. Pathologists were very vigilant about potential specimen

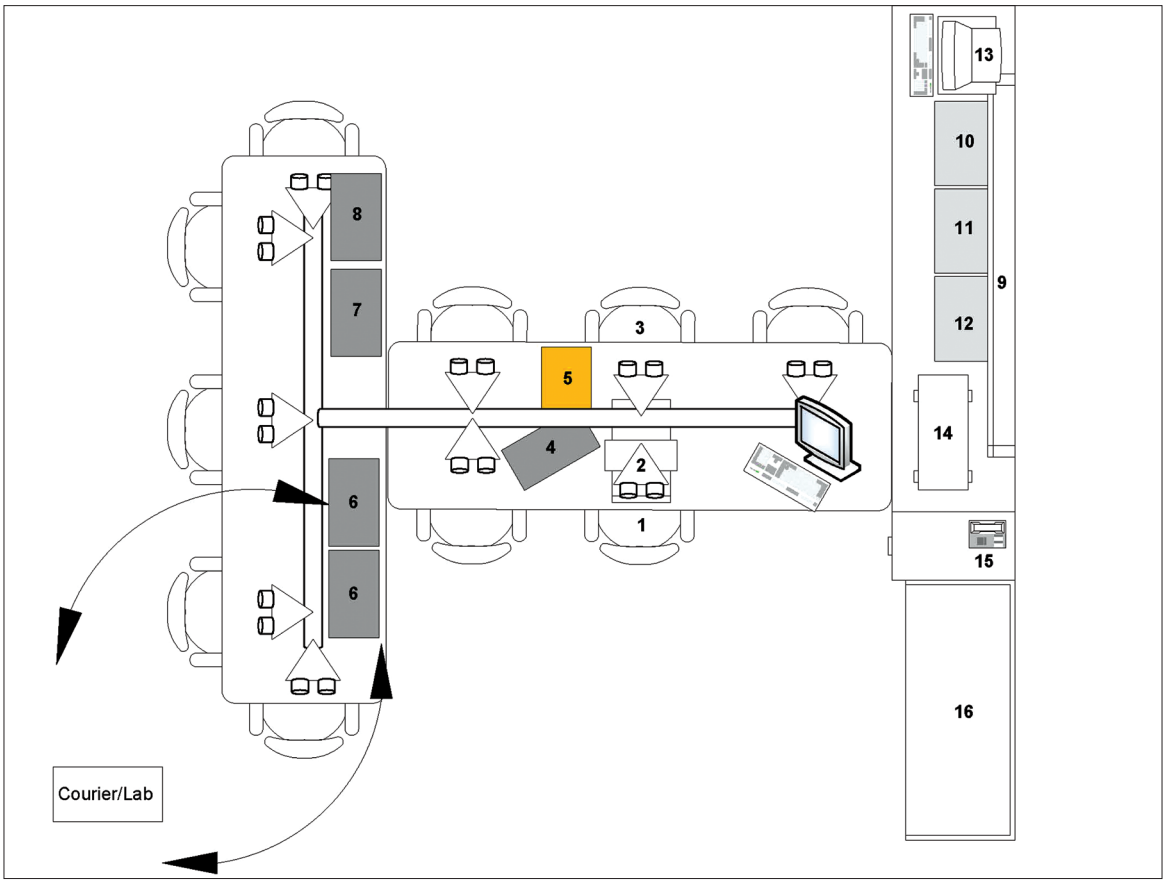

Figure 3: Consolidated physical model. The physical model provides details of the pathologist office/working area. 1. attending pathologist's seat; 2. multiheaded microscope; 3. primary fellow/resident's seat; 4. slide trays of cases currently being examined; 5. working drafts/requisition sheets; 6. new slides are dropped off and completed slides are picked up; 7. cases pending quality assurance review; 8. cases set aside for other purposes; 9. large monitor screen (connected to APLIS); 10. cases pending IHC stains; 11. cases pending special stains; 12. cases pending additional tissue re-cuts and levels; 13. computer workstation used by fellows/residents; 14. computer workstation used to access the APLIS and EMR; 15. telephone; 16. bookshelf

misidentification errors. If implemented properly, a digital slide system could automatically match and deliver cases, streamline the stain ordering process, and help pathologists perform cross checking for specimen misidentification.

Case Examination/Review

Once cases were assembled and presented to the pathologists, case examination was an extremely efficient process. Pathologists were very skilled at gleaning information about a case from glancing at the slides arranged within the slide tray: pathologists were able to deduce the specimen and procedure type based on the shape of the specimen, the number of blocks, the number of slides per block, stain type, and sometimes even determine the diagnosis without examining the slides under the microscope. Pathologists were very skilled at examining the slides under a microscope: pathologists had an extensive knowledge of staining patterns and a deep understanding of how disease states change these patterns.

Pathologists often had to spend considerable time to retrieve additional clinical information from different sources, such as the EMR or the radiology information system, while reviewing complex cases. A digital pathology system should interface with these information systems, automatically retrieve these data, and present it to the pathologists on an as needed basis. Pathologists also expressed frustration with tedious tasks performed at high magnification, such as identifying mitoses, eosinophils, and microorganisms. The introduction of computer algorithms that can identify these morphologies within a digital slide would likely be adopted by pathologists.

Case Reporting and Developing Relationships with Clinicians

The final report communicated a diagnosis and information that helped clinicians determine a course of treatment for their patients. First and foremost, pathologists wanted their reports to be accurate and complete and to reflect their level of professionalism. The final report was also identified as the primary factor in the development of trusting relationships between pathologists and their referring clinicians. Therefore, pathologists were concerned

about the overall quality of their final reports and carefully crafted their reports. While a digital slide system might improve some aspects of the workflow, the greater potential is to change the way reporting is performed.

APLIS

The APLIS served a large and significant role in driving the pathologist's workflow. However, the APLIS also had a significant role in driving the workflow of other users, including histotechnologists, pathologist assistants, transcriptionists, and administrative assistants. This study focused on the observation of pathologists (and their resident/fellow trainees) while conducting their work. However, the output of work conducted by other individuals and groups involved in specimen life cycle, such as gross examination, receipt and execution of stain orders, transcription, and printing the working draft was also observed and documented. Occasionally, the APLIS also fulfilled the role of a virtual working draft during case review. The APLIS was used to report the final diagnosis although limited to a faxed report sent upon case sign-out. A digital pathology system would need to integrate with the APLIS.

Key Recommendations for Digital Pathology Systems

Based on our findings, we offer 12 concepts important to AP workflow as key guidelines for vendors of digital pathology systems to support design of new digital pathology systems.

1. Pathologists feel "at home" with their optical microscopes and glass slides. This workflow has been refined over hundreds of years and will be difficult to replace. Although digital pathology systems cannot replicate the glass slide examination experience, they need to offer a similar experience when examining the digital slide, as well as offer advantages that offset the digital shortcomings.
2. The functionality of the slide tray should not be disregarded. The slide tray delivers key information to the pathologists just prior to slide examination.
3. Consider the practicality of the paper working draft or a virtual working draft using the APLIS. It provides clinical information critical to case interpretation. It also serves as a place to document and organize the initial thoughts of the pathologists and therefore provides an outline for the final report. The working draft also serves as a to-do list.
4. Pathologists deliver their patient care via their final reports. Their professional reputation largely depends on the accuracy, completeness, and timeliness of their final reports.
5. It is important for pathologists to develop trusting relationships with their clinicians. Good relationships with clinicians cultivate additional referrals.
6. Pathologists like to have a relative idea of the amount and types of cases they will review on a daily basis, to help them plan and prioritize their work accordingly.
7. The manner pathologists plan to approach a case is strongly influenced by specimen type.
8. Pathologists expect their work to be reviewed by other professionals within the healthcare system. They are expected to document not only key diagnoses and important findings but also document the interpretation of stains (for billing purposes) and communication/consultation with other pathologists and physicians.
9. Pathologists use several information sources to support case interpretation.
10. Orientation of tissue within the block and slide is important. Pathologists examine tissue slices while keeping the big picture in mind. They use tissue shapes/morphology, gross examination descriptions, disease markers (e.g., IHC stains), and clinical information (e.g., operatory notes, radiology reports) to provide context to the tissue slices.
11. Pathologists are trained to recognize differences between normal and abnormal tissue based on staining patterns of a large number of stains (but particularly H and E stains) and relate these differences to disease processes.
12. Sophisticated communication between the digital slide system and the existing APLIS will be required.

CONCLUSIONS

To our knowledge, this is the first study that utilized the contextual inquiry method to study routine pathology workflow. Although AP workflow has existed and been refined over several hundreds of years, it still contains much inefficiency. Furthermore, the current AP workflow is labor intensive and lacks scalability. While a fully digital workflow can help improve some workflow inefficiencies, developers of digital slide systems should ensure that the new systems also provide the functionality offered by the current glass slide-based AP workflow. Future studies should be conducted to examine specific workflows within AP, such as quality assurance and consultation workflows, differences between workflows in various subspecialty benches, and explore in more detail pathologists' behavior while using the microscope and glass slides.

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