Abstract

This article presents a case study in designing, developing, and implementing a web-enabled reporting application for the anatomical pathology (histopathology) department of a tertiary care teaching hospital in India. The article describes workflows, requirements assessment, and implementation methods that the investigators adopted for deploying the solution. The primary focus of the study was to demonstrate the requirements assessment performed, the strategies adopted, and the challenges encountered during the development and implementation. The study demonstrates a successful deployment as well as successful adoption of healthcare information technology by the end users. Factors that played a crucial role in adoption included the combination of people, processes, and technology. The lessons learned from this study would help application developers design efficient systems that suit the requirements of the end users while keeping in mind the ever-changing need for workflows and scalability in a developing country.

Keywords: health information technology, anatomic pathology, design, development, implementation

Introduction

The origin of anatomic pathology has no clear demarcation in the history of medicine. Some attribute it to the time of the invention of the microscope in the 17th century AD.¹ Some evidence dates to the 17th century BC in ancient Egypt, where the Edwin Smith Papyrus and the Papyrus Ebers contain accounts of information on bone injuries, trachoma, ulcerating lumps, and other conditions.²⁻⁴ The importance of pathology in modern medical practice must not be understated. Pathological reports are used in the diagnosis and treatment of an ever increasing range of clinical conditions. They have become an integral part of clinical decision making, with some studies indicating that a large percentage of decisions affecting patient management involve a pathological investigation.⁵ Pathology is also an integral part of postmortem studies to identify cause of death. Hence, justifiably, an anatomic pathology report is also known as “the final diagnosis.”

With the computerization of medicine, it was only a matter of time before electronic capabilities were put to use in reporting and archiving anatomic pathology studies. The introduction of computers in reporting pathological specimens is not uncommon. However, the use of computer technology has been mainly restricted to commercially available word processors. Although information is captured digitally, the stored information is of little value for research, mainly because
the format of information captured is primarily unstructured textual data, the mining of which requires significant efforts.

The modern anatomic pathology laboratory has many concerns to address, ranging from recording patient demographics to noting gross and microscopic findings of specimens, formulating and authorizing reports, disseminating reports to end users, archiving reports and specimens, regulating workflow, and maintaining overall quality and turnaround time.6–7

Laboratory information systems (LIS) are not a new concept either. The origins of LIS can be traced back to the 1970s, but the first generation of LIS that enabled laboratories to utilize automated reporting tools was introduced only during the early 1980s.8 The next generation of LIS emerged in the early 1990s with the evolution of personal computers. By 1995, server technology architecture had grown severalfold, which allowed for the development of web-enabled systems that enabled laboratories and researchers to extend the reach of their operations.9 Between 1996 and 2002, additional functionality such as wireless networking, standardization of code sets, and standards for data exchange emerged.10

Just as pathology has been broadly categorized into anatomic pathology and clinical pathology, LIS also come in different flavors with specific roles. Some systems are built to interface directly with laboratory machines to import results and automate reporting, whereas others are built to handle narrative data. Anatomic pathology is one specialty that involves narrative data. Standards and specifications for image management, report management, and terminologies have been suggested in previous studies.11–13 Digital Imaging and Communications in Medicine (DICOM) is an international imaging standard that "defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use."14 It is used in almost every imaging modality, such as radiology, cardiology, and radiotherapy, and in anatomic pathology.15 Anatomic Pathology Structured Report (APSR) and Anatomic Pathology Reporting to Public Health (ARPH) are report management standards that provide templates for, respectively, building surgical pathology reports and transmitting reports to public health organizations.16 Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT) is a terminology standard used in anatomic pathology.17 New standards are also being developed for web browsers. One such standard has been the introduction of HTML5. HTML5 can support rich graphical user interfaces, reduces the necessity for additional plug-ins, and provides better error handling.18

The current study focuses on the implementation of an anatomic pathology information system in a tertiary care teaching hospital, the methodology adopted, and the challenges that were encountered.
Methods

Study Setting

The application was implemented in the Department of Anatomical Pathology of St. John’s Medical College Hospital, a 1,250-bed tertiary care teaching hospital in Bangalore, India. The hospital imparts formal training in medicine, nursing, and other allied health science fields. The anatomical pathology department is located within the medical school and comprises 15 core clinical pathologists. In addition to them, the department includes student pathologists who undergo formal training for three years. The department reports about 11,000 pathological specimens annually, most of which are biopsies.

Current Workflow

The department receives samples from inpatient and outpatient departments of the hospital. Most of the inpatient samples arrive with a barcode that is generated from the hospital’s information system. A small number of samples come in as external samples referred from other hospitals or practitioners. Samples received are segregated into various categories based on the nature of the study, such as biopsies, antinuclear antibody (ANA) studies, double-stranded DNA (dsDNA) studies, and so forth. A unique identifier consisting of a combination of alphanumeric characters is assigned to each sample. This sample number is used throughout the lifespan of that particular report. These details are entered into category-specific registers for future reference. Furthermore, if the sample happens to be a biopsy, it is sent to the grossing room, where a pathologist observes the gross specimen and notes the findings. Pieces of tissue (referred to as bits) are sampled and sent for processing when the specimen is large.

After grossing, the specimen is sent for processing, at the end of which a paraffin block is obtained. This block is sliced and mounted on a slide for microscopic examination. A worklist, wherein slides are allocated to the pathologists for reporting, is created on paper. The leftover paraffin blocks are stored for an indefinite period in bags marked with the year. Glass slides are kept for 20 years in case of biopsies and 10 years in case of cytology or fine-needle aspiration cytology (FNAC).

The entries are also stored in registers to facilitate cross-referencing, tracking, and indexing. On average, the department secretaries collectively spend six to seven hours a day managing the processes of cross-referencing, tracking, and indexing. The pathologist notes the findings and shares the final impression on paper. Sometimes the report is authorized by multiple pathologists. These notes are handed over to a pool of typists who transcribe the notes onto a computer. Printouts of reports are reviewed by the pathologist for validation and authorization. The final reports are segregated into various sections and transported back to the hospital by a human courier. The courier is responsible for handing the reports over to a central laboratory or the medical record...
department (for inpatient and outpatient reports respectively). The respective department staff collect these reports from either the central laboratory or the medical record department (see Figure 1).

### Challenges

In the existing system, many processes were manual, time consuming, laborious, and prone to transcription errors. The average turnaround time for biopsies was two to three days, which is within the benchmark specified by the national accreditation body but could certainly be improved. The time taken for reports to reach the clinicians within the inpatient wards depended on the human courier delivering the reports. Instances were reported in which clinicians received the wrong reports, reports were lost in transit, or reports were not traceable.

The department also saves the specimens (one month for specimens; paraffin blocks are stored indefinitely) and reports for future reference. If a repeat investigation on a patient occurred a few years later, the department secretaries would look through the archives, which were mainly ledger books, to retrieve the reports from previous investigations. This manual process was time consuming and was made worse if a patient had several pathology investigations during the past years. The probability of retrieving all past reports was poor in this scenario. The retrieval process was done using a complicated process of cross-referencing by maintaining multiple registers. The average time required to pull out previous reports was anywhere from 30 minutes to three hours. The current processes were exposed to risks associated with storing data physically, such as environmental degradation, fires, and natural disasters.

Sometimes, a single report required multiple levels of validation and authorization; therefore, it proved difficult to create worklists and allocate reporting duties to pathologists on a daily basis.

### The Solution

After a thorough and detailed requirements analysis, a browser-based application was designed and developed, keeping in mind the complex workflows of the department. The other options that were considered included a client-server architecture and stand-alone applications that would run on individual computers. However, these options were ruled out because they were not feasible, were not scalable, or involved legacy technology that was not sustainable and not as easy to use as the browser-based application would be.

### Components of the Information System

The application consisted of four components. The first was a browser-based application that would be the data entry tool. This application also served as the interface that would allow other end users such as physicians to view reports through their computer terminals. The second layer consisted of
a relational database management system (RDBMS). MySQL database, an open-source RDBMS, was used in this instance. The third component was the operating system (OS). CentOS, which is an open-source software variant of the Linux operating system, was selected because it had vast community support groups and forums to help troubleshoot issues. The final component was the hardware, which consisted of server hardware and end-user interfaces, which in our case were a combination of thick clients and thin clients. A thick client is a fully featured desktop computer that is connected to a network. A thin client, on the other hand, functions as a normal personal computer but typically lacks a hard drive, extra ports such as I/O ports, and an optical drive.

Requirements Analysis

The first step in the process of developing a reporting system was to study the workflow. After this study was completed, the pathologists were interviewed to understand their requirements. After several iterations, the functional, software, and quality specification documents were created. Some of the key requirements that emerged from the discussions were as follows:

1. Workflow-related requirements
   - Sample reception status/date/time in the lab to be captured
   - Automated numbering of samples based on sample type and type of investigation to create unique sample IDs
   - Ability to create subsample IDs from the primary sample
   - Ability to control nomenclature of sample IDs
   - Ability to incorporate clinical notes

2. Application-specific requirements
   - Ability to access the application from anywhere within the institute
   - Ability to create worklists for reporting allocation
   - Ability to flag the status of reporting, such as "in progress," "pending," and "completed"
   - Ability to display the names of individuals who have been assigned the responsibility to report
   - Ability to electronically authenticate the end user, thereby removing the necessity of physical signatures
   - Ability to create templates and aut populate normative data, thus saving time by reducing typing needs
   - Ability to store, locate, and retrieve previous reports with ease
   - Ability to save the reports in universal formats such as PDF
   - Ability to search for reports using a combination of data such as the first few letters of the patient name, the medical record number of the patient, and so forth
   - Ability to filter reports by test category
• Ability to create preliminary reports
• Ability to create supplementary reports if there is a need to add to or modify finalized reports
• Ability to upload patient documents such as previous reports
• Ability to upload images/photographs with the report

3. Assumptions

• End users who are comfortable using computers
• Availability of uninterrupted power supply and network connectivity

4. Challenges/constraints

• Replicating the real-world complex workflow of the department within a computerized system

The information technology (IT) workflow for the proposed system is described in Figure 2.

Prototype Development

The browser-based application was coded using a widely used open-source general-purpose scripting language for web development called PHP and other scripting languages such as HTML5, Cascading Style Sheets (CSS), and JavaScript. The database was built using MySQL. The time taken from requirements analysis to deploying the prototype was around four months. This phase included development and testing from the development teams as well as end-user acceptance testing, troubleshooting, and bug fixing. Every update made to the application was tested thoroughly by the end users.

The application is currently hosted on two x86 Intel processor-based tower servers with 4 GB (gigabytes) RAM and a 500-GB hard drive on each machine. The servers run in high-availability (HA) mode. The application will eventually be migrated from the existing server environment to servers running on virtual machines. The application can be accessed using Internet Explorer 9, Mozilla Firefox version 16 and above, and Google Chrome browsers.

End-User Feedback and Acceptance

End-user acceptance was obtained with several iterations of testing and troubleshooting that occurred while the development team worked on improving the form and functionality based on pathologists' feedback.

Implementation

Computers were deployed in the department to provide access to the application. Each departmental user, including the technicians, secretaries, and pathologists, were provided with a
username and password to access their worklist and report the samples assigned to them. Multiple training sessions were conducted on-site until the end users were comfortable using the application.

## Results

The application helped streamline many workflow-related issues such as generating sample IDs, which is now an automated process; creating worklists for pathologists and accountability for signing off on reports; transmitting completed reports to end users; and maintaining a clear audit trail of reports. The application provided greater visibility on the status of reports, which helped expedite the process of completing overdue reports. The time taken for cross-referencing was greatly reduced when compared to the manual process of searching through books and ledgers. A subsequent study showed that the time taken to cross-reference 50 randomly selected samples was 37 minutes using manual searching and 22 minutes using the computerized process respectively (see Table 1). Now that the data are entered online and available on demand, the processes of manual cross-referencing, tracking, and indexing have been completely eliminated. This change saved a collective six to seven hours of work among the department secretaries. Because the department staff were comfortable using computers, the effort required for adoption of the system was minimal. For users who still preferred the traditional pen-and-paper method, office secretaries transcribed the reports, which were then vetted by the pathologist and electronically signed.

The system architecture has been designed to be scalable in order to accommodate the addition of image management and viewing modules at a later time. Because speed and flexibility were of essence, we used HTML5 to ensure that the application would take advantage of modern browsers and run efficiently.

Future enhancements planned for this system include the ability to archive and store images and the ability to exchange information with the hospital’s information system. Other innovations in the lineup include voice recognition, e-mail alerts for pending and overdue reports, print flags to track the number of times a report has been printed, and the incorporation of SNOMED CT or another appropriate terminology for coding diagnoses. We have also proposed to incorporate machine learning in order to identify patterns and assist in decision making.

## Discussion

The transition from a paper-based process to a system that involves minimal use of paper has been exceptional, as evidenced by informal discussions held with all the stakeholders, namely the pathologists, clinical end users, laboratory technicians, and department secretaries. We have come a long way since traditional paper-based systems. The success of such an implementation depends on various factors, the most important one being human resources. It is essential to have buy-in from
all stakeholders. In this instance, the pathologists’ proactive initiative ensured that their requirements were captured and translated into the application. The hospital's professional services team, consisting of physician informaticists and management professionals, contributed by serving as a liaison between clinical users and the development teams, thus effectively bridging the gap between medical knowledge and information technology. Because the pathologists were used to typing reports on a word processor, there were no issues related to adoption of the new system.

Success also depended on the technology that was chosen. The system included many innovations, such as the use of a browser-based system using HTML5 coding rather than a traditional client-server system, which provided much-needed flexibility to end users, namely the pathologists and the clinicians, who could type and view reports from practically any computer within the hospital’s local area network (LAN). A combination of the right people, processes, and technology therefore influenced the positive outcomes of this implementation.

Other available applications offer numerous functionalities beyond the scope of the application presented here, such as radio-frequency identification (RFID) tracking, image processing, and decision support, but the costs to acquire these are prohibitive in a developing economy. A global shift toward the digitization of data is in progress, but the data will be of little value without the support of good analytics. Subsequent versions of the application will have a greater proportion of structured data fields to enable further analytics, and natural language processing (NLP) algorithms will be developed to mine unstructured data.

**Conclusion**

Implementing the web-based system for pathology reporting has shown significant benefits, such as on-demand availability of reports, reduction in the use of stationery such as paper and ledger books, and increased overall efficiency of the department by eliminating redundant tasks that were being performed prior to the implementation of this system. The biggest challenge, however, was replicating the real-world workflow of the department. Preliminary analyses suggest that the application has indeed been able to capture most of the requirements, which is probably one of the biggest reasons for the successful implementation. It is highly recommended that this model be replicated in similar resource-constrained settings.

Future versions of the application will include programs to mine unstructured data and offer decision support to help clinicians achieve better outcomes.

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Notes


9. Ibid.

10. Ibid.


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