Tracking in Anatomic Pathology

Liron Pantanowitz, MD; Alexander C. Mackinnon Jr, MD, PhD; John H. Sinard, MD, PhD

Bar code–based tracking solutions, long present in clinical pathology laboratories, have recently made an appearance in anatomic pathology (AP) laboratories. Tracking of AP “assets” (specimens, blocks, slides) can enhance laboratory efficiency, promote patient safety, and improve patient care. Routing of excess clinical material into research laboratories and biorepositories is other avenues that can benefit from tracking of AP assets. Implementing tracking is not as simple as installing software and turning it on. Not all tracking solutions are alike. Careful analysis of laboratory workflow is needed before implementing tracking to assure that this solution will meet the needs of the laboratory. Such analysis will likely uncover practices that may need to be modified before a tracking system can be deployed. Costs that go beyond simply that of purchasing software will be incurred and need to be considered in the budgeting process. Finally, people, not technology, are the key to assuring quality. Tracking will require significant changes in workflow and an overall change in the culture of the laboratory. Preparation, training, buy-in, and accountability of the people involved are crucial to the success of this process. This article reviews the benefits, available technology, underlying principles, and implementation of tracking solutions for the AP and research laboratory. (Arch Pathol Lab Med. 2013;137:1798–1810; doi: 10.3858/arpa.2013-0125-SA)

The reason for the success of several well-known companies (eg, Walmart, FedEx, Apple, Toyota) is related in part to their adoption of a lean manufacturing process, prioritization of supply chain and logistics (eg, tracking products in real-time), planning quality into their business processes, employment of quality control measures to enhance their products and processes, and utilization of metrics (information) for risk reduction and handling of resources. Moreover, these firms are innovators in emerging technologies that support their initiatives and are not afraid to leverage automation and computing. Pathology laboratories are beginning to adopt a similar “manufacturing philosophy” and have turned to informatics to facilitate this process. Table 1 compares traditional to modern processes in the anatomic pathology (AP) laboratory. In the AP laboratory one of the major tools driving this revolution is the use of bar codes in tracking solutions. Bar codes have been used in many other areas of health care, including the blood bank, pharmacy, medical records, materials management, and at the point-of-care. Bar coding has been used in the clinical pathology laboratory for decades. From this clinical pathology experience we have learned that it is feasible to have labeling and tracking begin at the time of specimen collection and not just at accessioning, that bar codes support robotics and automation, simplify specimen sharing to perform multiple tests, and can help reduce staffing needs. Furthermore, several clinical pathology laboratory information systems (LIS) have evolved to accommodate foreign (ie, outside client) bar codes and have shifted toward adopting universal bar codes (eg, ISBT 128 global standard for transfusion medicine services). Bar coding is now recommended as an evidence-based “best practice.” This article reviews the benefits, available technology, and underlying principles of tracking solutions for the AP laboratory. Things to look for in commercially available tracking solutions are highlighted and implementation of this technology is addressed. The article also discusses the importance of tracking in the research laboratory.

BENEFITS OF TRACKING

Tracking begins with associating each asset to be tracked with a machine-readable identifier. Trackable assets in the laboratory include requisitions, patient specimens, and their derivatives such as tissue blocks (cassettes) and glass slides. Machine-readable identifiers are typically bar codes. Bar codes allow rapid, accurate entry of an asset identifier into a tracking system, recording the person doing the scanning, date/time, and potentially, the location at which the asset was scanned. When scanning is associated with a change in asset status (eg, marking a block as embedded), the asset can be tracked through its production and use in the laboratory. There are several good reasons to implement tracking. Tracking data can be used to locate the history of any asset, making it possible to investigate any problems associated with its production or use. It can provide up-to-the-minute information about the current status of an asset. Moreover, tracking assets in the laboratory can provide real-time detection of workflow bottlenecks. Another benefit of...
Laboratory misidentification errors may be 12 mistakes that are falling behind. However, there is a trade-off between higher levels of control and complexity; the more the tracking solutions seek to control the workflow, the greater the complexity needed to allow users to deal with the exceptions, which inevitably surface in the daily operations of a histology laboratory.

One of the major advantages of a tracking system is its ability to help eliminate labeling errors and maintain optimal patient safety, thereby reducing medical-legal liability. Errors from misidentification in the laboratory may result in an adverse event that causes serious patient harm (ie, a sentinel event). Studies have shown that up to 0.7% of specimens have problems related to specimen identification.14 Laboratory misidentification errors may be due to preanalytic (eg, mislabeled specimen), analytic (eg, mixing up tissue blocks or slides), or postanalytic (eg, incorrect report sent) errors.15,16 A Q-Probes study in 2011 involving 136 institutions provided information on a total of 1811 mislabeling occurrences, showing that overall mislabeling rates were 1.1 per 1000 cases (1.0 specimen, 1.7 blocks, and 1.1 slides).17 The work locations at which these errors occurred were as follows: 21% before accessioning, 12% at accessioning, 22% at block labeling, 10% during gross pathology, and 30% at tissue cutting.12 These error rates are not that surprising given the fact that mislabeling is known to be associated with manually labeling items, handwritten items, and batching of tasks.18 To overcome these problems, laboratories formerly incorporated additional time-consuming steps to ensure proper asset identification, such as the use of multiple identifiers and/or the introduction of many cumbersome checkpoints into their workflow. However, these extra steps unfortunately often remain error prone and “work-arounds” may result when problems remain unfixed. Implementing a tracking solution to support work process standardization in the AP laboratory has been shown to resolve such issues. For example, at Henry Ford Hospital in Detroit, Michigan, pathologists reported a 62% decrease of overall misidentification case rate, 92% decrease in slide misidentification defects, and 125% increased technical throughput at their microtomy workstations after bar codes were introduced.19 Similar successes attributed to implementing bar codes in the AP laboratory have been reported at other institutions including the University of Pittsburgh Medical Center in Pittsburgh, Pennsylvania,20 and Yale University School of Medicine in New Haven, Connecticut (Figure 1).

Table 1. Comparison Between Traditional and Modern Processes in the Anatomic Pathology Laboratory

<table>
<thead>
<tr>
<th>Old Processes</th>
<th>New Processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual workflow</td>
<td>Automation</td>
</tr>
<tr>
<td>Handwriting</td>
<td>Bar codes and RFID</td>
</tr>
<tr>
<td>Manual data entry</td>
<td>Automatic data capture</td>
</tr>
<tr>
<td>Batch-match work</td>
<td>Continuous processing</td>
</tr>
<tr>
<td>Just-in-case strategy</td>
<td>Just-in-time strategy</td>
</tr>
<tr>
<td>Logs for tracking</td>
<td>Real-time tracking</td>
</tr>
<tr>
<td>LIS-linked data</td>
<td>Web-based dashboards</td>
</tr>
</tbody>
</table>

Abbreviations: LIS, laboratory information system; RFID, radio frequency identification tag.

Table 2. Tracking Software Complexity

<table>
<thead>
<tr>
<th>Level</th>
<th>Capability</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Auditing</td>
<td>Posts events for each asset (what, when, who)</td>
</tr>
<tr>
<td></td>
<td>Allows audit trails (when was asset last seen)</td>
</tr>
<tr>
<td></td>
<td>Workflow analysis</td>
</tr>
<tr>
<td>II. Constrained workflow</td>
<td>Assures use of the appropriate asset at the appropriate time</td>
</tr>
<tr>
<td>III. Drive workflow</td>
<td>Promotes patient safety</td>
</tr>
<tr>
<td></td>
<td>Identifies delayed assets in real-time</td>
</tr>
<tr>
<td></td>
<td>dynamic to-do lists</td>
</tr>
</tbody>
</table>

Figure 1. Graph showing the steep decline in errors following the implementation of a bar code tracking solution in the anatomic pathology laboratory at Yale in New Haven, Connecticut.
Available technologies to implement tracking in the AP laboratory include bar codes, and more recently, radio frequency identification (RFID) tags. Bar codes are optical machine-readable representations of data where each character (data element) is represented by patterns (bars, blocks, spaces). There are 2 different bar code types (Figure 2), namely, 1D (linear) and 2D (eg, DataMatrix, MaxiCode, QR code). The 1D bar codes can be numeric (eg, Codabar, UPC) or alphanumeric (eg, code 128). The advantages of using 2D bar codes are that they contain higher data density (eg, more characters), produce smaller bar codes, allow omnidirectional scanning, and result in fewer scan and printer failures. Parameters other than bar codes that are important to take into consideration when labeling assets include space for additional human readable data or text, font, colors, and resistance to damage. For example, it is often best to avoid certain colors (eg, dark red, aqua, or blue) that can make it difficult to reliably read bar codes. The Clinical and Laboratory Standards Institute AUTO12-A document offers guidance about standard human-readable elements to appear on specimen labels and specifies the exact locations, fonts, and font sizes of these elements. A bar code scanner with a photo sensor is used to read bar codes and transmit captured data to a linked computer (Figure 3).

Radio frequency identification tags (transponders) are small electronic devices that when affixed to an asset can store unique codes or characters about that asset (Figure 4). They are similar to bar codes, but do not necessarily require a user to physically locate and scan the tag. Radio frequency identification readers scan tags by using radio frequency signals. Table 3 compares bar code technology to RFID tags. Radio frequency identification is more rugged than bar codes (eg, easier to read and has a near flawless read rate), has greater capacity, allows data to be updated, and allows many tags to be simultaneously identified, which supports batch-related workflow. Passive RFID tags draw power from readers to activate their chip’s transmitter. Active RFID tags have a transmitter and their own power source (eg, battery), offer a wider read range (up to 18 m), and transmit data faster, but are often bigger and cost more. Currently, RFID technology is more expensive than bar codes and there are limited vendors offering complete AP tracking solutions. Also, there is a measurable failure rate detectable with RFID tags under the harsh conditions in an AP laboratory.

When selecting software, a laboratory should certainly consider a tracking module already integrated with its LIS (if available), or opt to use middleware from a third-party vendor designed for this purpose (eg, Vantage, Cerebro, OmniTrax, CheckMate, Histology Tracking System or HTS). Some laboratories have successfully built their own tracking solutions. Interoperability is essential, not just with the LIS, but also with instruments to be used in the laboratory (eg, printers, autostainers, cytology liquid-based devices). Some middleware solutions use proprietary bar coding systems that may be difficult to align with an existing tracking solution, causing laboratories to either abandon labeling and tracking certain aspects of their testing process (eg, immunohistochemistry), or have them resort to placing 2 different bar codes on slides. Tracking software should be...
flexible (easy to configure), easy to maintain, and simple to use (eg, offer screen prompts). It is important to take into consideration what platforms will be used so that appropriate applications are installed on desktop computers, touchscreens, mobile computers, and/or handheld devices. Depending on the software selected, licenses may be needed for individual workstations. Laboratory information systems and middleware solutions are also available for verification (ie, to match specimen and cassette bar codes, or match block and slide bar codes) (Figure 5) and to generate alerts (eg, visual/audio) when there is a mismatch.

**Hardware**

Hardware for tracking solutions includes computers, printers, and scanners. These devices will need to be placed wherever scanning of bar codes is required (eg, accessioning area, grossing benches, microtomy stations, pathologists' offices). It is important to determine up-front the minimum specifications (eg, microprocessor and random-access memory needs) for these computers. There is a wide array of available bar code scanners (readers) including contact wands that resemble a pen, laser scanners with triggers, and those with charge-coupled devices that can take flash photos of bar codes. They each use different technology for reading and decoding a bar code, and most can read a variety of bar code symbologies. The scanner chosen should be capable of reading the type of bar code to be used (ie, 1D or 2D); 2D bar codes require image readers. Scanners can be wireless, wired (tethered), or fixed (mounted). Fixed scanners typically allow hands-free and high-speed scanning. It is also important that scanners be correctly configured to exclude unused symbologies, to avoid any scan errors.

Printers may be needed for labels, cassettes, and slides. Printed adhesive labels can be used for labeling specimen containers, accompanying paper requisitions, and glass slides. Durable labels that use thermal technology are favored because they can withstand harsh environments. They may need to withstand thermal (eg, microwave) and/or chemical (eg, xylene) exposure (Figure 6). Damaged labels may wash off, erase, or darken. Candidate labels selected by a laboratory should ideally first be tested in their own environment (eg, processed over a weekend to determine if they remain intact). For biorepositories where frozen tissues undergo long-term storage, label indelibility is particularly important. Depending on the volume of printed labels needed and the space available, laboratories can choose between industrial or desktop label printers (Figure 7). When evaluating printing appliances, important attributes to consider include the overall device footprint, print quality (eg, 600 dots per inch), durability, label programming language versatility, and compatibility with the intended bar code symbology. Thermal transfer label printers use printer ribbon, whereas direct thermal label printers print directly onto labels and hence do not use ribbons. The latter printers may be easier for laboratory staff to maintain.

<table>
<thead>
<tr>
<th>Table 3. Comparison Between Bar Code and Radio Frequency Identification (RFID) Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Bar Codes]</td>
</tr>
<tr>
<td>Requires line-of-sight alignment</td>
</tr>
<tr>
<td>Reduced read speed</td>
</tr>
<tr>
<td>Limited stored data</td>
</tr>
<tr>
<td>Limited to read-only</td>
</tr>
<tr>
<td>Exposed to external damage</td>
</tr>
<tr>
<td>Read individually</td>
</tr>
<tr>
<td>Manual scanning</td>
</tr>
<tr>
<td>Holds identification data</td>
</tr>
</tbody>
</table>
When purchasing a cassette printer there are several factors to be considered other than the instrument’s footprint (Figure 8). Cassette printers can have a single hopper (ie, 1 magazine that holds cassettes) or multiple hoppers (eg, up to 12 magazines that hold cassettes with different colors). These printers can be expandable and typically are capable of providing rapid, high-quality, and permanent printed bar codes on cassettes. Many cassette printers require a dedicated computer for operation. Since LIS connectivity is essential, printers will ideally need to be interfaced (linked). These interfaces may already be prebuilt and require minimal customization. Printers with more hoppers may involve more complex interfaces. Several glass slide printers are also available. Devices that print adhesive labels to be stuck onto the slide can become expensive in the long run, and this requires extra labor with the potential for error (eg, sticking the incorrect label on the slide). Some instruments use laser etching directly onto the slide, but this may create glass dust. Finally, some laboratories may prefer to use thermal transfer printers that allow data and bar codes to be printed directly onto glass slides. Before introducing printers into the workflow process, the slide capacity (ie, how many slides the printer holds) and throughput (eg, slides per minute) should be balanced with the expected workload to prevent having to repeatedly interrupt production in order to reload the printer.

**WORKFLOW**

Workflow in AP begins with obtaining the specimen from the patient. Implementing bar coding at this early stage of the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories. For those laboratories that have an outreach computer solution, tracking can start with an electronic order entry. This requires that the electronic health record where a test order is placed be interfaced to an electronic order entry. This requires that the electronic order entry have an outreach computer solution, tracking can start with the specimen’s life cycle, albeit ideal, is usually outside the purview of most laboratories.

**ACCENSIONING**

Accessioning occurs when the specimen arrives in the laboratory. At the receiving area, laboratory staff enter cases into the LIS where they then get assigned unique accession numbers. If the specimen (or its container) does not yet have a bar code recognized by the LIS, then laboratory staff will need to print and label it with one. Introduction of bar coding at this early step negates the need for users to handwrite labels, alleviates downstream manual key entry into the LIS, and reduces the potential for mismatches when workflow becomes busy and demanding. Placing bar codes on both paper requisition forms and specimen container labels is common practice. Owing to time constraints during a frozen section, many laboratories may opt not to accession their cases at the time of intraoperative consultation. Accessioned cases get passed on to prosectors for gross examination and transfer of tissues into plastic cassettes. Scanning a bar code on the requisition and/or specimen container should open the correct patient’s case in the LIS, allowing the user to verify that the label is appropriate for this asset. Printing bar codes directly onto cassettes with unique block numbers just-in-time and only when needed helps avoid preprinting, sorting, and distribution. Just-in-time in this context refers to the label and asset being generated at the same time. However, cassette printers should be set up so that they are also able to print on-demand and handle batch printing. Ideally, technologic equipment including computer monitors (eg, touchscreens) should be ergonomically accessible at grossing workstations. Computer screens and keyboards can be attached with mobile arms. This may require a cassette labeler at each grossing station. There are cassette printers available with a small footprint that can fit at grossing stations.

There are several steps involved when tracking assets as they enter and leave the histology laboratory (Table 4). Work centered around the microtome, where many cassettes, tissue ribbons, and slides are handled, is an area at high risk for mismatch errors. This can be addressed by having histotechnologists scan blocks, print slide labels, or use etched slides. Bar codes at this stage can greatly help drive standard protocols, for example, informing the user of the exact number of sections to be cut for particular biopsies. Instructions for the histotechnologist need to be easy to view. Slides for them to use need to be printed just-in-time and/or on-demand. A tracking solution can be implemented so that slides, or trays containing slides, can again be scanned when they are delivered to pathologists, and also during sign out at pathologists’ workstations.
The last step in the AP workflow involves the storage and retrieval of specimens, blocks, and slides. A tracking solution for this purpose needs to facilitate quick and easy operation, while at the same time providing accurate documentation. Custodians in pathology need to know which pathology specimens can be discarded and which are to be retained (e.g., held for teaching purposes). Retrieval of specimens (e.g., gross specimens to take additional tissue sections, or Papanicolaou test vials for add-on human papillomavirus tests) can be time-consuming. Software that offers virtual trays/racks can greatly improve locating stored specimens or assets by recording their exact location (e.g., room, shelf, cabinet, drawer, tray). Therefore, as long as assets get scanned, their receipt and checkout from storage can be recorded.

**DASHBOARDS**

Many laboratories rely on a status monitor (“manager’s view”) within their tracking system to visually check the status of all assets and to quickly identify bottlenecks in the overall specimen workflow. These so-called dashboards allow users to view at a glance, in the form of a table or spreadsheet (Figure 9), the status of various activities and/or assets such as stains (e.g., which stains have been ordered, stained, delivered, or are missing) or blocks (e.g., which blocks are to be grossed, processed, embedded, cut, or stored). From these displays users can immediately determine the total pending workload in the laboratory and see how that workload is distributed across the production chain, anticipating how much work may be coming their way. Each tracked step can display the volume of cases and length of time these have been at each step. Colors can be used for this purpose: green for appropriate status, yellow as a caution for possible delay, and red as an alert for overdue cases. Rules can be applied for how long a specimen should spend at each tracking event. Histology laboratories may have such dashboards displayed on large mounted TV screens. In such cases it will be important to make sure that the software product allows users to resize windows for these large wall-mounted displays. Apart from providing real-time or near real-time tracking, other features some laboratories may find useful with dashboards are the drill-down capability of the tracking solution to view details for specific assets of interest, flexibility to define and track their own monitors (e.g., stains, blocks, divisions), receiving e-mails for alerts, and the option to view dashboards on the Web.

**RESEARCH LABORATORIES**

The need for specimen tracking in a research laboratory or biorepository (tissue bank) is as relevant and important as it is in the clinical laboratory setting. Similar to a clinical histopathology laboratory, a research pathology laboratory engages a complex workflow strategy to serve a broad number of users (clients) in order to process a variety of samples and specimens. A research laboratory may perform some clinical testing in the form of routine histologic processing for consult cases, testing for clinical trials, or conduct esoteric/specialized clinical testing such as immuno-histochemistry or molecular diagnostics. Therefore, research laboratories will experience similar enhanced efficiency, productivity, quality control, and safety measures by developing and implementing methods and tools to track and manage specimens throughout the entire testing process.

A critical step toward implementing a robust specimen tracking system is to clearly define and establish a consistent workflow process in the research laboratory. This in itself poses a challenge due to the inherent variety of each research project, that is, the scope of specimens, size of projects, work requests of investigators, and the “final product” for each project, as well as the potential mix of daily clinical cases sometimes handled with research projects. As with any complex process, defining and establishing a consistent workflow is an ongoing process that will undergo continuous refinement and optimization. Nonetheless, a laboratory director or manager needs to develop some form of specimen tracking from the moment laboratory operations commence. If the research laboratory is newly established and/or the laboratory director is...
relatively inexperienced, specimen tracking is typically done manually until the workflow processes becomes consistent, which can take as long as 6 to 12 months. As the workflow processes become further established, defined and functional, it then becomes a good time to implement an electronic LIS with the capacity to be modified to accommodate future growth as the research laboratory matures and evolves.

Research laboratories in pathology departments are frequently core laboratories serving clients within their department, as well as researchers from across the institution seeking to use human specimens to validate their previous findings. Workflow in a research histopathology laboratory generally parallels workflow in a clinical histopathology laboratory: specimens are received and accessioned; a work requisition is created; samples are processed in the laboratory; results or productivity is reviewed; and reports and/or invoices are generated (Figure 10). Policies governing the accessioning of samples are also accordingly similar. All materials are accessioned promptly upon arrival to the research laboratory. At this stage the specimen identification number and date received are entered into a database. Biobanking software is available that uses an internal sequence or “wheel” to generate unique identifiers for samples.28 A primary accession number is assigned that serves to link the specimens to the principal investigator/project, the work order, and any additional products that are generated in the process, such as purified DNA, slides, blocks, and images. A work requisition is established, and the samples along with any documentation are physically transferred to the laboratory where work is performed. Often, additional accession numbers are generated after assignment of the primary accession number; for example, DNA or RNA “prep” numbers may be generated if DNA or RNA is extracted as part of the work requisition. These secondary accession numbers, in turn, need to be linked to the primary accession number. Once work for the project is completed, the final products, such as immunohistochemistry stains, purified DNA, and reports from digital image analysis, are organized and prepared in a suitable manner to be returned to the requesting investigator. At the same time, invoices and other final reports (eg, productivity reports, accounting reports) are created and sent to the appropriate individual for further processing. Tracking specimens throughout this process is challenging, particularly as additional products are generated throughout the workflow. Managing specimen tracking is greatly facilitated by implementing an electronic LIS.

Identifying an LIS that is suitable for a research laboratory poses a unique set of challenges. There are essentially 2 options: develop a user-designed (ie, laboratory-developed) LIS or purchase a commercial LIS. The former option is potentially less expensive and provides precisely defined functionality, yet requires a large investment of time and information technology resources, neither of which may be available to the laboratory director or manager. The second option is potentially more expensive, but offers an immediately operational software solution to the specimen-tracking problem. This latter scenario further underscores the critical importance of establishing a consistent

<table>
<thead>
<tr>
<th>Table 4. Block- and Slide-Tracking Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process Step</strong></td>
</tr>
<tr>
<td>Tissue processing</td>
</tr>
<tr>
<td>Embedding</td>
</tr>
<tr>
<td>Microtomy</td>
</tr>
<tr>
<td>Staining (including immunohistochemistry)</td>
</tr>
<tr>
<td>Case assembly</td>
</tr>
<tr>
<td>Case delivery</td>
</tr>
<tr>
<td>Slide review</td>
</tr>
</tbody>
</table>
and detailed laboratory workflow process, as this is essential for identifying an appropriate software solution for specimen tracking. The major challenge to using a commercial LIS to track specimens in research laboratories arises from the fundamental difference in the manner by which clinical specimens and research specimens are accessioned, and the subsequent work requisitions that are assigned in each respective laboratory. Patient specimen(s) accessioned in a clinical laboratory are derived from a single patient no matter how many specimens there may be (eg, some cases such as autopsies can have dozens of parts), and all these specimens are linked to each other and the patient by a single accession number. On the other hand, specimens submitted for research projects are generally derived from many different patients (Figure 11). As such, these specimens are not linked to a single patient, and instead a surrogate for the patient needs to be assigned. This typically is the principal investigator. Despite the fact that the specimens submitted to either a clinical or research laboratory are very often physically identical (ie, formalin-fixed, paraffin-embedded block or Optimal Cutting Temperature-embedded tissue specimens), the way in which these 2 types of specimens are managed by an LIS is different, and this difference can lead to significant challenges tracking the specimens in the laboratory. Most commercially available pathology LIS systems are designed to work well in clinical practice. However, their capability for managing research samples becomes compromised owing to the fact that research specimens are often linked to each other and the principal investigator by the primary accession number. Thus, in the research setting the patient is replaced by the principal investigator in this situation. Under this model, the LIS often assigns a part number to each specimen (eg, block A1) instead of maintaining the original specimen name (eg, S-08-12345 A6). Consequently, the user may have a difficult time managing these aliases and may be required to keep a master list or key linking the alias part numbers to the actual specimen names. This increases the complexity of tracking research specimens in the laboratory during the workflow process and can potentially lead to inefficiencies in the form of extra work, rekeying of information, and sample mix-ups. One option for successfully using a commercially available LIS for tracking research specimens is to work directly with the vendor to develop a custom-designed module that can accession research blocks derived from different patients under a single accession number (Figure 12). This can allow the user to track individual specimens by their original name versus a generic part number. It also enhances workflow because work orders are clearly assigned to individual research specimens and the proper work order is executed. Furthermore, it is possible to link other important data elements to the project, such as institutional review board–approved protocol numbers, which facilitates compliance with yearly audits and other reports that may be required by the local institutional review board. Lastly, generating
invoices and other business reports is facilitated, which increases productivity and improves forecasting expenses during budget preparation.

IMPLEMENTATION

Planning and Resources

Implementation of a tracking system involves planning, systems analysis and design, developing procedures, and training. As with most other information technology projects, a major challenge will be balancing the competing expectations of different stakeholders regarding cost, time, and scope of the project. Laboratories that have AP tracking solutions will testify that implementation is demanding, almost always requires some customization, and can become protracted because it involves not only technology but also addressing workflow and the culture of the laboratory. At the outset, workflow will need to be evaluated and possibly modified, to allow assets to proceed with no or limited manual operator intervention. It is important to determine which critical steps in the workflow will become trigger points for asset tracking where assets are labeled and/or bar codes are scanned. Limits (eg, minimum time duration) will need to be established that define failure of assets to progress to their next logical step. Plans should make sure the tracking solution is scalable to handle potential future growth in volume and flexible should certain equipment become obsolete or as new devices (eg, whole-slide scanners that read bar codes) are acquired. A staged approach is recommended and more likely to be successful. For example, a laboratory may decide not to bar code all assets at once (eg, requisitions, containers, cassettes, slides, reports) or phase in only portions of their workflow at a time (eg, first cassettes in the gross room, then processing, then embedding and so on; NOT first biopsies, then resections, cytology cell blocks, etc, which will result in multiple simultaneous workflows in the laboratory). Implementing the system slowly will help address and fix problems before the entire laboratory is affected. A downtime procedure should be developed. During busy times in the laboratory the system is likely to be stressed and if something fails (eg, a printer breaks down) the entire tracking system can be brought to a standstill. A few years ago there were no off-the-shelf AP tracking solutions for laboratories from which to choose. Today,
there are several software and hardware vendors, as well as consulting firms, with experience in this area. There are several costs that will need to be included in the budget for a tracking solution (Table 5). For a start, it is important that there be enough workstations (computers) with appropriate peripheral devices (eg, printers, scanners) to prevent delays. However, apart from these obvious direct costs it is important to be aware that there may be several indirect costs (eg, consulting fees or purchasing custom furniture for workstations, such as flexible arms for mounted monitors and keyboards).

### Technology and Infrastructure

Implementation involves software installation, hardware deployment, configuring interfaces, and establishing network connectivity. The functionality of new appliances needs to be validated. The information technology department and most likely vendor technical support staff will need to be involved. Apart from ensuring that there is adequate space for computer equipment, printers, and/or bar code scanners near work areas (eg, grossing benches, microtomes), it is important for all workstations to have network access. Wireless access offers the flexibility of moving workstations around when needed; however, there may be interference from other equipment, Wi-Fi connections can occasionally drop on devices located near the edge of a network’s wireless signal range, and wireless networking is prone to some security issues (eg, malicious intrusion) and thus may not be an option at some institutions. Sensitive computer equipment may also need to be strategically placed away from blood and fluids. Hardware components (eg, cassette labelers) today typically come with existing interfaces to link with many laboratory information systems. However, there is no true “plug and play” in the health care environment. Therefore, some customization will be required. Laboratories may be frustrated to find out that certain instruments (eg, immunohistochemistry auto-stainers) may be incompatible with their tracking system.

### Hidden Practices

For tracking software to be used effectively for controlling workflow, all assets need to be included. Most blocks/slides follow a standard workflow path through the laboratory. However, there are several common “hidden” practices (ie, exceptions to standard workflow) in the AP laboratory that may disrupt workflow and hence derail a tracking solution. “Hidden practices” does not refer to covert actions by staff, but rather to the production, use, or distribution of assets (mainly slides) about which the computer system is unaware. Table 6 lists several hidden practices that will need to be identified and addressed before implementation of a tracking system. These will need to be either eliminated or formally integrated into the tracking process. The consequence of not doing so is that it may foster a culture that the tracking software is “optional” and can be circumvented if necessary.

### Laboratory Staff

“Buy-in” from all users will be a key component to successful implementation. Histology staff may feel that bar coding is being implemented because they are making too many mistakes. Scanning assets at various steps is “new work,” may take longer, and introduces conceptual workflow change (eg, changing from batches to single-piece workflow). Savings and efficiency of the tracking solution comes from the total solution, where more work in one area yields much less in another. Time is saved by staff not wasting their time looking for work lists or logs to check off, not wasting time looking for missing assets, or repeatedly filing and pulling blocks. Mislabeling errors that occur after implementation are likely to be judged a major offense. Staff will therefore need to be well trained, and policies and procedures should be in place and enforced to ensure the tracking system is used properly. Individuals will need to overcome a learning curve, and in order for the solution to work compliance will be vital. Human noncompliance rather than technologic issues is frequently the cause for a tracking solution to fail.
specimen content identification errors. A label with a bar or tracking system can prevent specimen laterality or associated with the asset they are to represent. No bar code assure that the correct bar codes are used and remain that appropriate procedures and processes be in place to the bar codes, not the specimens themselves. It is crucial assets and managing paperwork).

are also direct (eg, reduction in overtime hours) and indirect ''histology staff, and histology staff feel more analyzing and standardizing workflow is crucial. Variability work with future devices they may want to acquire. does not lock them in; for example, their bar codes should equal. Laboratories should go with a tracking solution that tracking solutions may be available—they are not all created tracking solution. While 90% control can be achieved significant changes in workflow.

CONCLUSIONS

Implementation of a tracking solution can be logically divided into 3 technical domains: methodology, technology, and most importantly, but often overlooked, the culture of the laboratory. People and not technology or devices are usually the driving force behind quality. A variety of tracking solutions may be available—they are not all created equal. Laboratories should go with a tracking solution that does not lock them in; for example, their bar codes should work with future devices they may want to acquire. Implementation is not as simple as purchasing hardware and/or software and installing it. Associated costs and hidden practices need to be considered. Also, preparation by analyzing and standardizing workflow is crucial. Variability in workflow breaks the association between status and location, defeating the tracking system. Therefore, careful examination of the workflow with elimination of inappropriate variability can significantly improve the success of a tracking solution. While 90% control can be achieved relatively easily, 100% control is far more difficult to accomplish. One of the major setbacks at present is that a universal bar code to support interoperability in the laboratory is not available on the market. Further advances in this field are anticipated, with better collaboration among vendors and tracking solutions to begin at the time of specimen procurement. Finally, additional literature is needed to hear from diverse laboratories about their tracking implementations, benefits, and setbacks.

References


Table 5. Costs Associated With Tracking Software Implementation

- Cost of the software
- Additional “seat” licenses for LIS (if integrated)
- IT personnel, time, management, leadership, maintenance
- Many bar code scanners
- Label printers
- Cassette labelers
- Slide printers
- Computers at each microtome/embedding station
  - Computers, monitors, keyboards
  - Network lines, electricity
  - Reconfiguration of workstations, furniture (eg, mounting arms)
- Significant changes in workflow
  - Productivity, resistance, training, compliance

Abbreviations: IT, information technology; LIS, laboratory information systems.

Table 6. Hidden Practices That May Impede a Complete Tracking Solution

- Reembedding and reprocessing blocks
- Slides produced from reembedded blocks
- Ordering stains on unstained slides
- “Bonus” or extra sections
- Negative controls that accompany immunostains
- Repeated special stains or immunostains
- Three levels ordered on 1 slide, but that do not fit
- Frozen section slides
- Cytology direct smears
- Broken/destroyed slides
- Blocks/slides from outside labs
- Archival material (pre-bar codes)


Liron Pantanowitz, MD; University of Pittsburgh Medical Center

John H. Sinard, MD, PhD; Yale University School of Medicine

Liron Pantanowitz, MD, obtained his medical degree from the University of the Witwatersrand in South Africa. He did an anatomical and clinical pathology residency at Beth Israel Deaconess Medical Center, Harvard Medical School in Boston, Massachusetts, followed by hematopathology and cytopathology fellowships. He served as the director of Pathology Informatics at Baystate Health in Springfield, Massachusetts, for 5 years. Dr Pantanowitz is currently an associate professor in the departments of pathology and biomedical informatics at the University of Pittsburgh. At the University of Pittsburgh Medical Center, he is the director of the pathology informatics fellowship, as well as the associate director of the Pathology Informatics Division and director of the FNA Clinic. Dr Pantanowitz cofounded and serves as an editor-in-chief of the Journal of Pathology Informatics. He is a section editor for digital pathology for the Archives of Pathology & Laboratory Medicine. He is also the current president of the Association for Pathology Informatics. He chaired the Digital Pathology Working Group for the College of American Pathologists (CAP) to develop recommendations for the clinical use of whole-slide imaging. He is also on the Standards and Guidelines Committee of the American Telemedicine Association. Additional memberships include the Digital Pathology Association, International Academy of Digital Pathology, Society for the Internet in Medicine, and previously, the CAP Diagnostic Intelligence and Health Information Technology Committee and Healthcare Information and Management Systems Society. Dr Pantanowitz is an author of the ASCP Pathology Informatics Case Reports (formerly CheckSample), serves on several committees for cytopathology associations, and is on the editorial board of several journals. He is widely published and is the lead editor of the recently published textbook entitled Pathology Informatics: Theory & Practice.

John H. Sinard, MD, PhD, did his undergraduate training in biochemical sciences at Harvard, Cambridge, Massachusetts, and then obtained MD and PhD degrees from the Johns Hopkins University School of Medicine, Baltimore, Maryland. Following that, he did an anatomic pathology residency at the Yale-New Haven Medical Center, Connecticut, and then joined the faculty at Yale where he has been ever since, working his way up to the rank of professor. His first book, Outlines in Pathology, has been used by residents for many years to prepare for the pathology board examination. His second book, Practical Pathology Informatics, was the first informatics book devoted to anatomic pathology. During his time at Yale, Dr Sinard directed the Autopsy Service for 16 years and the Residency Training Program for 6 years. He is currently the associate director of Anatomic Pathology, and still directs the Ophthalmic Pathology Service. He founded and directs the Pathology Informatics Program at Yale, which is well known for developing custom software for clinical use. He serves on the Medical Records and Clinical Information Committee and the Medical Directors Leadership Council for Yale-New Haven Hospital. Outside of Yale, Dr Sinard has served on many committees for the College of American Pathologists (CAP) and for the College of American Pathologists Electronic Case Series Program. He has also been a member of the Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee for the US Food and Drug Administration.
Alexander C. Mackinnon Jr, MD, PhD, Medical College of Wisconsin, Milwaukee

Alexander “Craig” Mackinnon Jr, MD, PhD, attended the University of Colorado, Boulder, where he majored in molecular, cellular, and developmental biology. Following undergraduate studies, he attended Northwestern University in Evanston, Illinois, where he studied the neurotoxic properties of β-amyloid fibers. He then enrolled in an MD/PhD program at the University of Illinois, Urbana-Champaign (UIUC). His thesis at UIUC focused on the assembly of muscle sarcomeres during embryonic development using the genetic model Caenorhabditis elegans, which is a tiny nematode. He then did an anatomic pathology residency at the University of Chicago, Illinois, followed by a postdoctoral fellowship studying cardiogenesis during mouse embryogenesis. This was followed by a clinical fellowship in molecular genetic pathology at the University of Chicago and Evanston/NorthShore Hospitals. Dr. Mackinnon joined the Department of Pathology at the Medical College of Wisconsin in 2010 where he established and directs the Clinical and Translational Research Core Laboratory. He also serves on the department’s residency committee and the Institutional Review Board Committee at the Medical College of Wisconsin. Dr. Mackinnon has served on 2 committees for the Association for Molecular Pathology: the Training and Education Committee and the Membership Affairs Committee. He recently edited a textbook on pediatric neoplasia.