

### Raymond D. Aller, MD, and Hal Weiner

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### Document-management systems worthwhile if you go extra mile

As health care is increasingly “going digital,” document-management software is increasingly going into the pathology lab, but selecting and implementing such systems can be an arduous task.

The benefits of document-management software are numerous and can range from ensuring that all lab professionals have access to the most recently updated versions of policies and procedures to seeing who approved those documents and who attested to reading them. Due to features such as these, digital document-management systems ultimately improve efficiency and patient care, says Brian Jackson, MD, medical director of informatics at ARUP Laboratories, Salt Lake City. However, he adds, the first couple of years after installing the new software can be rough because these systems tend to be complex and require considerable data entry.

“What you lose is the convenience of being able to keep documents in MS Word files on your computer, where it’s really easy to go in and change things,” Dr. Jackson says. “But the ease of editing in that scenario is what causes version-control problems.”

While ARUP made the right decision by implementing document-management software, explains Dr. Jackson, the laboratory had to hire administrative personnel to support the product. “At our lab, we had to create a whole new category of clerical employees that we call document-control specialists, who enter, manage, and archive the documents. We have a number of these individuals gathered throughout the lab.”

To ease the transition from paper to paperless, J. Mark Tuthill, MD, who has given conference presentations on electronic document management, offers a number of recommendations. As with any lab system purchase, laboratory management should begin by forming a working group to assess the lab’s needs and vet potential vendors and software products, suggests Dr. Tuthill, head of the pathology informatics division at Henry Ford Health System, Detroit. At Henry Ford, this group consisted of representatives from all of the health system’s labs, as well as a number of medical directors from various hospitals in the network.

“The more people you have, the more opinions you get, which can be challenging,” Dr. Tuthill says. “But if you don’t have enough opinions, you will miss something.” Involving multiple stakeholders in the selection process also increases their engagement and the likelihood they will embrace change when the software is rolled out.

Once the working group has narrowed the list of software vendors to no more than a handful, Dr. Tuthill recommends that it send those companies requests for proposal that include numerous questions about the technology platform, security and administrative considerations, and documentation features. In the latter category, he says, the questions may range from “Is electronic searching supported?” to “Can an index be created automatically?”

"One of the things we liked about MasterControl [Henry Ford's document-management software] was the ability to replicate binders electronically so that it's easy to find, index, and create a table of contents for documents," Dr. Tuthill continues. The software also allows for various degrees of access and a hierarchy of electronic signatures "so the appropriate leaders can sign off and place the documents in production, while employee users can attest that they've read the document in question and note the changes and updates." The vendor's reputation for responsiveness to user feedback was another important factor, Dr. Tuthill says.

Ross Simpson, MD, a pathologist at Park Nicollet Methodist Hospital, St. Louis Park, Minn., advises labs to consider software that can assist in implementing ISO 9001 document-control processes when shopping for a document-management system. "Some vendors have document software more gauged to website content or publishing and do not understand . . . the workflows needed for ISO 9001-compliant document control processes," he explains.

No less daunting than selecting a document-management system is implementing one, says Dr. Tuthill. He learned firsthand that establishing precise document-naming conventions "is probably the most challenging part of doing document management. Everyone had to agree. And we had to come up with a standard that was flexible enough to be expanded upon." Flexibility is essential, he emphasizes, because it's impossible to anticipate all of a lab's documentation needs and compliance requirements going forward.

Henry Ford used document-naming guidelines in the ISO 9000 and CLSI quality management standards as a starting point. "These guidelines provide an outline for various organizational functions and document types," says Dr. Tuthill. "We then created local naming conventions and abbreviations." For example, a document related to a procedure would include the abbreviation "PRO" in its name, while a document about facilities and safety would be identified with the abbreviation "SAF." Abbreviations indicating document types include "pol" for policy and "prs" for process, among others. "So, for example," Dr. Tuthill explains, "the informatics procedure for the cytology department entering an addendum would be named inf-palm-cyp-7.51-pro8: copath procedure and addendum procedure."

It's important to establish document-naming conventions at the outset or searching for documents will be more difficult than it should be, says Dr. Jackson. "You need to have an administrator who champions this from the beginning." Having an administrative champion for the new system also helps ensure staff buy-in and thorough training.

For a large laboratory such as Henry Ford, it's also critical to set a feasible schedule for implementation, says Dr. Tuthill. To avoid becoming overwhelmed, "we gave each of our labs its own month for migrating documents into the new document-management system," he adds.

At the same time, the lab needs to consider if and how it should create new policies specific to electronic document management before the system goes live. For example, says Dr. Tuthill, if a lab employee at Henry Ford prints out part of a document, the pages will be marked automatically with the date and time. Per the lab's policy, those pages must be thrown out within 24 hours to prevent the circulation of uncontrolled copies. This rule is part of a policies and procedures document that governs the management of files in the system and includes instructions for how documents will be updated and by whom.

For institutions that choose to use only electronic documents, having a policy or plan for what to do when the hospital's network goes down is also crucial, says Dr. Simpson, who notes that Park Nicollet had two network outages last year. Because of the possibility of such events, the hospital system had provided copies of the documents on thumb drives, which were periodically updated, to each of its sites. "Those were utilized during the unscheduled network downtimes," he explains. "Other options that were evaluated but are not yet implemented include directly storing a copy of the policies in selected computers on a nightly basis."

Implementing document-management software in a stepwise fashion allows each component to be evaluated and refined if necessary, Dr. Tuthill concludes. Lower priority functionality can be added later, and features that have not proved valuable can be discontinued. For example, he explains, one of the best attributes of MasterControl is that it keeps track of which documents are nearing their expiration date and who has to review them. But

laboratories at Henry Ford were receiving an excessive number of emails alerting them to upcoming deadlines.

“We ended up turning off the email notification,” Dr. Tuthill says. “It was just too noisy for this process. However, we do use email alerts for updated documents requiring signatures.” —*Carolyn Schierhorn*

## **HHS releases guidance on ransomware attacks**

The HHS Office of Civil Rights has released HIPAA guidance to help health care entities better understand and address the threat of ransomware attacks.

The guidance, available on the Health and Human Services website, describes ransomware and how it works. It also explains how to minimize the chances of a ransomware attack, spot the signs of an attack, implement security incident responses, and mitigate the consequences of an attack.

As a general rule, HHS discourages organizations from paying a ransom because paying cyber criminals doesn't guarantee health care entities will regain access to their data. Furthermore, hackers may launch additional attacks on organizations that meet their demands.

“After systems have been compromised, whether to pay a ransom is a serious decision,” the guidance says, “requiring the evaluation of all options to protect shareholders, employees, and customers.”

## **McKesson alters IT business**

McKesson Corp. recently announced plans to divest the majority of its information technology business by entering a joint venture with Change Healthcare Holdings, a supplier of software, analytics, and network solutions.

The new company will combine Change's operations with most of McKesson's Technology Solutions division, including McKesson Health Solutions, Imaging and Workflow Solutions, Business Performance Services, and Connected Care and Analytics.

“The new organization brings together the complementary strengths of McKesson Technology Solutions and Change Healthcare to deliver a broad portfolio of solutions that will help lower health care costs, improve patient access and outcomes, and make it simpler for payers, providers, and consumers to manage the transition to value-based care,” the companies reported in announcing the deal.

The partnership excludes, among other McKesson businesses, the company's Enterprise Information Solutions division, which markets core hospital information systems, such as Paragon, as well as its RelayHealth pharmacy technology business. However, McKesson reports that it is exploring “strategic alternatives” that may result in the sale of its enterprise information solutions business.

“We appreciate the critical importance of the electronic medical record and other core information systems to the success of our provider customers,” Pat Blake, executive vice president and group president, McKesson Technology Solutions, said in a statement. “As we embark on building a new, EMR-agnostic technology company with Change Healthcare, we believe that it is in the best interest of our customers to identify a strategic alternative that will allow for more focus on core provider information systems. We are committed to supporting our customers as we evaluate these options, ensuring a smooth transition through this process.”

## **Leica sample-tracking system added to Psyche products**

Leica Biosystems has integrated its Cerebro sample-tracking system with Psyche Systems' WindoPath laboratory information system and NucleoLIS molecular lab system.

Cerebro “measures and monitors performance metrics,” Puneet Sarin, vice president and general manager of Leica

Biosystems Pathology Imaging Business, said in a statement.

Among the features of WindoPath and NucleoLIS are customized result reports and the capability to place orders online.

[\*\*Leica Biosystems\*\*](#), 800-248-0123

[\*\*Psyche Systems\*\*](#), 800-345-1514

## **Agilent buys iLab Solutions**

Agilent Technologies and iLab Solutions LLC have signed a definitive agreement under which Agilent will acquire substantially all the assets of iLab, a provider of cloud-based solutions for core laboratory management.

“Using iLab’s offerings, customers can easily and accurately book time in shared facilities to bill and invoice for projects, to manage studies, to generate reports and business intelligence, and to schedule instrument reservations across multiple projects,” according to a statement from Agilent, a provider of laboratory instruments, software, and services.

iLab Solutions provides laboratory management services to universities, research hospitals, and other institutions worldwide.

[\*\*Agilent\*\*](#), 800-227-9770

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