## Newsbytes

### Editors: Raymond D. Aller, MD, & Dennis Winsten

### Tips for archiving LIS data when moving to a new system

December 2023—While many dismiss the saying "Nothing lasts forever" with a simple shrug, those three words may cause angst in those anticipating the demise of their laboratory information system.

The process of archiving LIS data, for such reasons as an LIS reaching the end of its product life or a hospital switching lab systems as part of a merger, can take years and be fraught with headaches, according to Michelle Stoffel, MD, PhD, associate chief medical information officer for laboratory medicine and pathology at M Health Fairview health system, Minneapolis.

Dr. Stoffel should know. Over the past four years, she has worked on multiple data-archiving projects at two institutions. During her clinical informatics fellowship at the University of Washington School of Medicine, she was involved in transitioning to a new EHR and anatomic pathology system. In her role at Fairview, she is helping the laboratory move from operating anatomic pathology, clinical pathology, and blood bank systems to using an integrated EHR-LIS, a project that began before she arrived at the medical center and is nearly finished.

While there is no standard process for archiving lab system data, laboratorians and information technology staff can take steps to make the process flow more smoothly, says Dr. Stoffel, who spoke about end-of-life LIS planning at the Association for Pathology Informatics' 2023 Pathology Informatics Summit, in Pittsburgh.



Dr. Stoffel

Those involved in LIS archiving need to begin by determining what data need to be archived based in part on whether that data are also preserved and accessible elsewhere, she says. Essential patient test results stored in the LIS may also be available in the EHR or backed up in a data warehouse, but large quantities of metadata and other information used for research and operational purposes typically are not incorporated into the EHR. For example, says Dr. Stoffel, a pathology lab may need to preserve quality assurance data or specific details about frozen section concordance with final surgical pathology diagnoses, or even billing and coding information, all of which may not be accessible via the EHR system.

### In Dr. Stoffel's experience, data that laboratories should archive fall into three categories: data to satisfy regulatory and legal requirements, patient care data, and data to support future research or academic needs.

When archiving regulatory-related data, labs must capture not only data to fulfill federal and state data-retention requirements but data to meet CAP-specific data-retention requirements for maintaining accreditation, Dr. Stoffel says. She also advises checking with the hospital's health information management department to identify the types of data that should be retained to satisfy typical requests for medical and legal information.

Before archiving patient care data, an institution's informatics team should work with the lab to determine how the latter will access the archived information, particularly when an LIS and EHR are being replaced simultaneously.

"Are you going to keep the legacy system up and accessible to lab users in a read-only state for a while versus turning off the old and turning on the new system nearly simultaneously?," Dr. Stoffel asks. "In those first days when you are transitioning to a new EHR or LIS, you need to be able to access recent results just in time, so be sure you can see those lab results from the last hour, last day, last couple of days. Often the best way to ensure that is to have both the legacy system and new system available side by side so users can keep taking care of patients while they learn the new system."

At the same time, laboratorians need to be aware that it may not be feasible to transfer all patient test result data to a new system, in which case the lab will have to establish a retention timeframe, such as a five-year or 10-year look-back period or a time limit that meets regulatory requirements, Dr. Stoffel says. Yet for some patient cases, including those involving long-term illnesses, such as cancer, clinicians may need to look back decades, so these types of cases may drive decisions about how much historical patient care data to transfer.

Like pathologists, researchers require access to historical data within the LIS. They often need to extract large amounts of data, such as results for all patients who had a certain condition and underwent a specific test in the past 20 years. This type of information is typically provided in the diagnostic portion of a report, which makes it easier to find, but it can be difficult to design a data-archive interface that can extract data meeting very specific requirements in an aggregate manner, Dr. Stoffel says. "That's where having search functionality that allows users to filter the data they're looking for and extract it is necessary."

Whatever the retention period, she cautions, those involved in a data-archiving project need to communicate it to end users to avoid erroneous assumptions. "Imagine you are doing a chart review and you are assuming that the information you see is the sum total of the patients' data and it's really not."

### Laboratories take a variety of approaches to archiving LIS data, Dr. Stoffel says. Some convert large amounts of historical data into records in the new system, which allows users of the new system to access and query historical data along with more recent patient information seamlessly.

But this approach can be expensive and time intensive, she notes.

Other labs buy or build archiving systems that are locally hosted or hosted in a cloud environment. These archiving systems are typically software applications for accessing data that provide storage capacity tailored to the lab's needs and an interface for retrieving and viewing data in a read-only format and extracting it for operational or research use. Archives solely use read-only formats because they are repositories of historical information, which should not be altered by end users, Dr. Stoffel explains.

Labs that opt for commercial archiving solutions have multiple options, Dr. Stoffel says. Some vendors offer laboratory-specific archiving solutions, while others offer domain-agnostic products. The latter type of company may not have prior laboratory archiving experience, she notes, but many have flexible archiving platforms that can be easily tailored to a laboratory's needs.

Furthermore, some LIS vendors offer archiving solutions specific to their own lab systems. This option potentially could be a simpler way to create an archive that replicates some of the legacy LIS functionality. The legacy LIS vendor would be uniquely positioned to understand how data were stored within its LIS and how that data could best be retrieved, Dr. Stoffel says.

End users generally prefer when the archive looks as similar as possible to the legacy LIS, Dr. Stoffel adds. This means re-creating as closely as possible the look of tools for navigating data, data labels, and the types of reports. However, this may not be possible, depending on the limitations of the archiving software, and it may not be advisable if the legacy formatting will not be intuitive to users of the archive who didn't have experience with the legacy system. Replicating an interface that meets everyone's needs is one of the biggest challenges of the

### The process of extracting and reconfiguring data to fit a new system can be another daunting aspect of LIS data archiving due to the diverse types of data in an LIS.

"Think of a clinical pathology chemistry report, which might have numeric values and reference values with very little text data, and compare that with an autopsy report that might have 20 pages of unstructured text," Dr. Stoffel says. "It may be difficult to create an archive report template that can display very different data formats, so multiple approaches may be needed."

Adding to the challenge, a laboratory typically uses an LIS for decades, and a laboratory's subspecialty areas may have been more siloed years ago and used nonstandardized report formats, for example, Dr. Stoffel says. Therefore, even seemingly small tasks, such as standardizing heading styles for the same type of report for archiving purposes, can be time consuming.

LIS report value settings that have been altered over time can be even more problematic. For example, a chemistry lab test result may have associated reference interval settings that had been configured to apply specific reference interval values to all current reports. Some LIS software applications may overwrite the original settings if the reference intervals are changed over time. In such instances, only the most recent reference intervals may be extracted during the archiving process, and they may appear to apply to all the historical reports too. "This could lead to archiving data that is incorrect if the issue is not recognized and addressed," Dr. Stoffel says.

"Depending on how you are able to extract your data, you might only be able to extract the most recent value, but for regulatory purposes you may need to have the original report values available, as well as an audit trail of any changes to the final report," she says. In that example, the informatics team would have to retrieve the historical data and find a way to make it available in its original form, which could mean creating a PDF of the original report.

Addenda and amendments to laboratory reports are similarly challenging because the time stamps and change trails need to be preserved, Dr. Stoffel says.

IT staff and laboratorians need to work together to ensure archived reports are consistent with the source data. In the archiving project nearing completion at M Health Fairview, the lab team provided checklists of essential data elements from the legacy system that needed to be included in archived reports and research extracts. The LIS archiving team then reviewed each re-created report example with laboratory and research stakeholders to ensure the information was represented correctly.

# The process of archiving data from an LIS in parallel with setting up and implementing a new system to replace the legacy LIS could take three to five years, Dr. Stoffel says.

During that time, IT and lab department staff involved in the undertaking may leave and project requirements may change.

Consequently, Dr. Stoffel suggests revisiting goals annually to make sure the project stays on track. She also advises showing end users a demo or screenshots of the archive as early as possible and then on a regular basis to obtain their feedback and alleviate anxiety about the project. In addition, Dr. Stoffel recommends saving as much documentation as possible, including a detailed list of project requirements, project meeting notes, and even screenshots of legacy system software application user interfaces to remember how they were structured.

Documentation is not only valuable if staff leave before the project ends or if the lab has retained licensing to further configure its archiving system over a set time period, she says, but it will come in handy down the road,

when the lab has to replace its replacement LIS.

"Just because the last life cycle was 20 years," Dr. Stoffel adds, "we don't know for sure if it's going to be that long before we're doing this again."

—Renee Caruthers

### Pramana undertakes new business ventures

The artificial intelligence-enabled health technology company Pramana recently announced collaborations with Caris Life Sciences, Intermountain Health, Gestalt Diagnostics, and Techcyte.

- Pramana reported that it will digitize approximately 1.5 million slides annually under a multi-year agreement with Caris Life Sciences. The companies will integrate Pramana's scanning systems and software with Caris' molecular science and AI tools for comprehensive molecular profiling.
- Pramana announced a multi-year partnership with the nonprofit Intermountain Health system under which the entities will build digital archives for anatomic pathology. As part of the deal, Pramana will digitize approximately 8 million glass slides from Intermountain's biorepository using the vendor's Spectral family of scanners and intelligent-acquisition software.
- Pramana and Gestalt Diagnostics have introduced an integrated digital and AI-powered platform that combines Gestalt's mitotic cell-counting algorithm with Pramana's Spectral family of scanners. The joint solution has an open DICOM (Digital Imaging and Communications in Medicine) interface.
- Pramana has entered a strategic collaboration with Techcyte to provide intelligent volumetric scanning and digital diagnostics solutions for cytology, microbiology, and hematology applications. The collaboration will integrate Pramana's Spectral HT and Spectral M intelligent whole slide imaging systems with Techcyte's AI-powered diagnostics software platform to provide scalable digitization of cytology and microbiology diagnostic workflows, including specimens that are hard to scan.

### NovoPath and PathAI offer webinar on streamlining pathology workflows

NovoPath and PathAI have released a webinar explaining how digital pathology and artificial intelligence can streamline pathology workflows and how some of the largest U.S. laboratories are applying these applications.

The webinar, titled "Digital pathology and artificial intelligence 101: unlocking value from the AP LIS," features Eric Walk, MD, chief medical officer for PathAI; Jim Sweeney, president of PathAI Diagnostics; R. Shawn Kinsey, MD, medical director of PathAI Diagnostics; and Ed Youssef, chief strategy officer for NovoPath.

The webinar is available at www.novopath.com/webinar/webinar-amplify-the-value-of-your-ap-lis.

### Leica Biosystems enhances digital pathology scanner

Leica Biosystems has released three more product features for its Aperio GT 450 digital pathology scanner for the research setting.

The new enhancements include automatic narrow stripe scanning, a quality control feature that triggers the scanner to automatically rescan a slide when the system detects image-quality issues resulting from a tilted slide or tilted tissue; Z-stack scanning, which produces a composite, three-dimensional image that enables users to review slide samples at varying degrees of thickness; and space-saving 20 × magnification.

The scanner is available for research use only.

Leica Biosystems, 312-565-6737

### Ibex Medical Analytics and Roche enter partnership

Roche has reported that it will offer Ibex Medical Analytics' artificial intelligence algorithms for breast and prostate cancer diagnosis via its Navify digital pathology software platform.

Ibex's algorithms, which can be used in prioritizing cases, determining cancer grading and subtyping, and identifying noncancerous entities, are used worldwide but are for research use only in the United States. They are CE-marked for in vitro diagnostic use in Europe for breast and prostate cancer detection in multiple workflows.

Navify and the algorithms run on Amazon Web Services cloud infrastructure.

#### Roche Digital Pathology, 800-428-5074

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