# Pathology Informatics and Biobanking

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**Julie McDowell:**

While there is a diversity of laboratory information systems available, there is no one system used by biobanks. Furthermore, there is an increased utilization of digital hold slide scanning technology in converting slides made from biobanking into digital whole slide images. In this CAPcast, Duke Health pathology resident, Dr. Richard Davis interviews leading pathology informatics experts, Dr. Raj Dash about biobanking and its integration with various LIS technologies. Dr. Dash is also at Duke Health.

**Dr. Richard Davis:**

Good afternoon, Dr. Dash, it's good to speak with you again.

**Dr. Raj Dash:**

Good afternoon, Dr. Davis.

**Dr. Richard Davis:**

Excellent. So I guess we'll go ahead and jump into it. So my first question, what should biobankers know about information systems and how they impact biobanking practice?

**Dr. Raj Dash:**

Yeah, so that's a good question Dr. Davis. And I think one of the first things to recognize is that there are two kinds of information systems of relevance to biobankers. One is the LIS or Laboratory Information System, and the other that is often used in biobanking is the LIMS or Laboratory Information Management System. And although those two names sound very similar with the only difference being one word and that being management, they're actually focused in very different ways. The LIMS system is very focused on specimens, inventory management, and related processes. Oftentimes a LIMS system is utilized in research laboratories and in situations where there are in fact no patients at all. On the other hand, a laboratory information system really does focus on providing diagnostic results for patients. So they're related, but they're different.

Now, certainly for biobanking, clinical data adds value to those archived specimens, but there's also a need to be able to track the specimen collection process, to track inventory of supplies necessary for biobanking and other details like that. So in that circumstance, both a LIMS or LIS would be a value in a biobanking system. And in fact, many biobanking systems will have an information system devoted to biobanking operations and then that will interface with a lab information system that houses more of the clinical data. There is an overlap of specimen information that needs to be shared between both. I would say at a minimum, with archive specimens in the anatomic pathology world, a pathology report in a de-identified format, potentially depending on IRB protocols is critical to have available for archive tissue. And the relevant clinical lab data may be critical to have in place for liquid biospecimens. In some cases, molecular data might be critical depending on the IRB protocol.

As you might imagine, there are elements of specimen testing that would be present in the LIMS or captured natively in the LIMS for testing that's performed by the biobank or research laboratories. But there may also be many elements of the electronic health record that need to transfer over from the clinical world, the clinical information system into the research information system. Certainly one of the key reasons for correlation of this data is that if there's any discrepancy, for example, between a clinical diagnosis and a research diagnosis, then that needs to be resolved to ensure that there's no harm to patients. Electronic interfaces can minimize the data entry burden, but oftentimes there is a lot of manual work that's required to review data in a clinical system, extract the relevant details and populate it] research information system of a LIMS simply because each IRB protocol of which a biobank may support many is often different. So creating a single interface when there's many different types of data needs for different protocols can be challenging.

Also, there has to be careful thought put into de-identification to support patient privacy as required by HIPAA and to allow the biobank to serve as an honest broker for clinical data for which PHI, protected health information, may only be available to key personnel depending on how the research protocol is written. So kind of a long answer, lots to know, and multiple types of information systems, but some of them are quite advanced and it's not to say that there's not significant amount of automation that is possible.

**Dr. Richard Davis:**

Excellent. Well, in light of that answer, maybe the next two questions can help bring out some of the details in that very thorough answer. So what would you say the current landscape of the use of information system technologies are out there and what should biobankers consider before choosing specific LIS and LIMS technologies?

**Dr. Raj Dash:**

Right. So as with choosing any vendor product, it's good to look at the market to see what vendor has. Not only the current market share, but growing market share. For example, in the laboratory information system world, there have been significant market increase by Epic Beaker in the laboratory information system world. There's many LIMS systems out there as well. They don't have the same size as some of the LIS systems used in clinical care, but there are different products out there to suit different requirements. And so one of the key requirements I feel is that the vendor needs to have financial sustainability, they need to be able to scale to the operation that's required. A large entity like Duke Health and with a significant number of samples being processed every day really requires a robust information system both on the LIS side and on the LIMS side.

Of course, the system also needs to be able to meet the requirements of the biobank, and sometimes a smaller vendor with a more agile software development group can respond to the needs of a biobank better than a larger vendor can, simply because of the ability to customize software. And that needs to be weighed against the cost of the system of course, as well as the financial sustainability of the system in the long-term. Most information systems when they're purchased by an organization, particularly large organizations, they do not change those information systems very often.

Perhaps the last thing to consider is how often that information system is being updated. Something that's updated very infrequently might mean that requirements and optimizations that the biobank is hoping for might not be realized for a long time to come. On the other hand, a system that is plagued with bugs might interfere with operations and updates that occur too frequently might require a significant amount of personnel effort on part of the biobank to continue to support those updates and the downtimes associated with updates to a LIMS or to an LIS system.

Probably the last thing to consider on the current landscape is the growing use of pathology PAC systems and image management systems as the field of anatomic pathology transforms from one largely based on glass slides to digital whole slide images.

**Dr. Richard Davis:**

Excellent. We'll talk about digital whole slide imaging in a little bit. Sort of pivoting off of that last answer. For biobanks that are considering implementing information systems, what are the major opportunities and challenges that occur with implementation as well as with maintaining those information systems?

**Dr. Raj Dash:**

Right. Well, one of the key opportunities is the ability to scale to the amount of data that researchers require alongside their archived biospecimens. And in order to provide this type of robust data, be it genomic, digital, tissue, whole slide images, pathology diagnoses, cancer synoptic data, clinical lab data, the information system is what keeps it all together and allows each individual specimen potentially every encounter if there's a series of specimens being collected over time for a particular protocol to be tracked very carefully, then provided to researchers as needed in a very organized format. Certainly some of the challenges with these types of information systems, be it in the clinical world or in the research world, stems from all the complexities of an electronic system that can manage this type of data. So there's issues with data security. The data needs to be kept secure, needs to be kept behind the firewall, patient privacy needs to be protected as we alluded to earlier.

There's issues with data integrity. There needs to be some thought put into validation of data input field to ensure that there's not misspellings, for example, that can compromise the ability to retrieve information down the line. There's always issues with uptime, keeping the systems running. There are mechanical parts in a computer system and along with electronic parts, cooling fans can fail and the system can go down. And so these are ongoing challenges. Of course, the software which we mentioned before, is always undergoing optimization to fix bugs that are identified by users and to add to the feature set. And while these are on the one hand opportunities for increased functionality, they also represent challenges in that every new feature and upgrade can result in some downtime and can result in new bugs being introduced into the system.

**Dr. Richard Davis:**

So you mentioned digital pathology earlier, and this is a field that has exploded in recent years with the advent of whole slide imaging technologies. How do you see whole slide imaging technology changing the practice of biobanking?

**Dr. Raj Dash:**

So I think that digital pathology is here to stay, pathology PAC systems are starting to mature. There's not many systems out there that I would say are ready for production use in large healthcare environments, but there certainly are some. There are systems outside the United States that leverage these types of information systems for primary clinical diagnosis, leveraging only digital slides as opposed to glass slides. And this is going to provide some opportunities and challenges for the biobank.

So whole side imaging technology allows the biobank to not only bank physical specimens, but to pair those together with digital specimens. And while whole side imaging technology is a key revolutionary, if not evolutionary transformation of the anatomic pathology diagnostic process and underutilized digital component that is of relevance to biobanks is also the gross image. So in many circumstances, having both the gross specimen image along with how it's been triaged and sectioned with parts of tissues submitted into various blocks, which then make it onto glass slides, which then turn into a scanned image. Having that series of steps, processing steps in the manufacturing process, if you will, of a glass slide or of a digital image, can be invaluable to researchers as they perform their experiments, leveraging these tissues.

And one of the key elements associated with biospecimens is understanding the quality of that biospecimen for downstream use. And the way that many of the ways in which quality is assessed to ensure that downstream use and analysis is not compromised is to take a look at the pre-analytic variables. And if the entire process can be captured digitally, where you have date timestamps and you have digital images of exactly how a specimen was processed, it can greatly support credibility and integrity and to the experimental and research processes that follow afterwards downstream of the use of tissue specimens. So I see the tremendous opportunity, although there's a lot more data to be captured and challenges associated with that data capture, I see tremendous opportunities for the biobank to leverage the digital images to support the integrity of its operations, to also leverage the digital images for research in and of itself on that data with the advent of image analytics and AI algorithms.

**Dr. Richard Davis:**

Excellent. So in light of that answer and to sort of sum up our conversation, what does the future hold for biobanking as pathology continues to move deeper and deeper into the digital space?

**Dr. Raj Dash:**

Right. Well, I think one thing that's become clear is that we can't continue to use Excel spreadsheets for our research enterprise any longer. Dedicated information systems are necessary just based on the sheer volume of information and the complexity of information that all needs to be linked together in ways that make the data valuable for a researcher that ensures the integrity of that data and ensures that IRB protocols are being upheld, patient privacy is being protected, and the security of the information is not in question. So I would say that there's a huge opportunity as we move to digital, both in the genomics era with the amount of discreet data that can be cataloged for gene variance, clinical lab data. It has always been discreet and I think has been undervalued and underrated, but because of the sheer volume, hasn't really been able to be taken advantage of by researchers at the level that a human is capable of processing that much information.

But now that we have narrow AI or these artificial intelligence machine learning algorithms able to sift through large amounts of data looking for patterns, I think we can finally take advantage of the large amounts of data or big data that are potentially capable of being managed by the information systems within a biobank, and or ancillary associated clinical information systems that might be interfaced to that biobanking system. So I really see tremendous opportunities and impetus or catalyst to move forward with implementation of these robust information systems in an era of digital pathology, artificial intelligence, and machine learning.

**Dr. Richard Davis:**

Excellent. Thank you very much, Dr. Dash.

**Dr. Raj Dash:**

Very welcome. That was enjoyable.

**Julie McDowell:**

Again, that was Dr. Richard Davis talking with leading pathology informatics expert Dr. Raj Dash. For more information about biobanking, please visit the cap.org and search for Biorepository Accreditation Program.

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