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Moderator: Sarah E Wheeler; Experts: Darci R. Block, Dustin R. Bunch, Jamie Gramz, Edward Ki Yun Leung, David S. McClintock, and J. Mark Tuthill.
Clinical Laboratory Informatics and Analytics: Challenges and Opportunities.
Clin Chem 2022; 68(11):1361-67. https://doi.org/10.1093/clinchem/hvac157

Guest: Dr. Sarah Wheeler, an Associate Professor at the University of Pittsburgh, Department of Pathology, and Medical Director of Clinical Chemistry at Children's Hospital and at Mercy Hospital of the University of Pittsburgh Medical Center.

Bob Barrett: This is a podcast from *Clinical Chemistry*, sponsored by the Department of Laboratory Medicine at Boston Children's Hospital. I'm Bob Barrett. Health informatics is the science of how to use data, information, and knowledge to improve human health and the delivery of healthcare services. In laboratory medicine, informatics and data analytics use multiple sources of data to improve all aspects of the clinical laboratory, from workflow and personnel to result interpretation. With increasing healthcare information complexity and integration, interoperability issues have become apparent. Collaboration among informaticians, information technology professionals, and laboratorians is critical to ensure that health information systems can utilize and report clinically meaningful laboratory data in addition to providing interoperable data streams for furthering research, education, and innovation in healthcare.

In a Q&A feature appearing in the November 2022 issue of *Clinical Chemistry*, six panelists discussed these issues and other challenges and opportunities for informatics and laboratory medicine. That Q&A feature was moderated by Dr. Sarah Wheeler, who is our guest in this podcast.

Dr. Wheeler is an Associate Professor at the University of Pittsburgh, Department of Pathology, and Medical Director of Clinical Chemistry at Children's Hospital and at Mercy Hospital of the University of Pittsburgh Medical Center. So, first of all, Dr. Wheeler, what is clinical laboratory informatics and how does that differ from clinical laboratory data analytics?

Sarah Wheeler: Great question. So, clinical laboratory informatics can include everything around data and information in the clinical laboratory. This can be everything from laboratory information technology, data presentation in the electronic medical record, collecting data, storing data, harmonizing data collection and presentation. The list really gets further along. Data analytics is really more specifically a subset of clinical laboratory informatics, and that's when we take data and turn it into actionable knowledge. So that can cover many applications from basic turnaround time graphs and

thresholds to using machine learning to create new diagnostic results from existing clinical assays.

Bob Barrett: So what are some of the operational challenges that we still face with providing high quality interpretable laboratory data to clinicians and patients?

Sarah Wheeler: Within the QA, I really love how Dr. Tuthill indicates this. He says that just the ability to view laboratory data within the EMR [electronic medical record] right now in an interpretable fashion is a challenge. So data display within EMR has really had little improvement with physicians often looking at just essentially large spreadsheets of numbers that happen to be flagged red if they're outside of what's considered a normal threshold, or blue if they're within that normal threshold. And to add to that complexity, a lot of patients will see physicians across different medical centers or have their laboratory work done at multiple locations, and that really causes discontinuity in the presentation of their data. Often it's considered a win just if these results actually show up as numbers in the patient chart rather than as scanned copies.

And given the current data capabilities and data presentation in other industries, that's a tragically low bar for us to be excited about. And Dr. Block also indicates that there are areas that are really ready for standardization that could be great for steps in making these results more universally interpretable, such as results nomenclatures. So we often will describe things as positive, reactive, or present. Those are all meaning the same thing, and converging on results nomenclature that can be used everywhere would really be a step in the right direction.

At a more technical level, Drs. Bunch and Leung also note that it's really difficult for labs to even get access to their own data. Often, we have to wait for some sort of distilled report and that can be cumbersome to have changed to include updated information that might be needed, and it's also usually run on a batch schedule. So that means we can't always use it for our emergent needs, which thankfully aren't always super common, but as we've seen in the evolution of COVID, can pop up more frequently than we would like. Part of the reason that we so often defaulted to reports historically is the complexity of our information systems. To extract data from our systems, we often need to use multiple data mining tools to access various decentralized databases that are in use for all of the information we need access to.

For example, in a recent project to ideally assess possible over utilization of a test in the emergency department, we needed to get access to our LIS, the clinical operations system, which would then give us information about ED volumes and staffing. We needed to look at the EMR for

preliminary and final diagnoses, the financial system to assess the potential billing or inability to bill for the test, and then ideally, we would have looked to perform some natural language processing in the EMR to be able to find out if the test was actually mentioned in the clinical notes as part of the differential diagnosis decision. To add to this, every system also has different refresh rates and levels of accuracy, but really, at the end of the day, we want to provide actionable health information to those who will use that information.

So currently, that means we have several audiences for our data and as Dr. McClintock points out in the Q&A, we can't provide different information formats for all of these audiences. So healthcare providers, patients, and other sections within pathology, and other departments within the organization all use data produced by the laboratory, but they have very different needs for their proper use of this data.

It would be ideal if we could provide a patient report that integrated all of the laboratory testing with any appropriate laboratory comments about the interpretation of the test and then also a section for the ordering clinician to provide their thoughts and interpretation for the patient. Separately, if we had a provider facing report, that could contain information about who to contact if they have questions regarding unusual results, laboratory interpretation of groups of tests that are often performed for differential diagnoses, or suggestions for additional testing that should be performed, and then also helpful visualizations of the patient test that could provide a longitudinal view of the patient's health.

Reports that might go from the medicine to anatomic pathology could include only the relevant tests for the differential that's being assessed and may include probability scores or lab interpretation that could be integrated into the AP reports. So we have many interoperability challenges to overcome before we can provide this needed level of personalized data presentation. But really, in the current era of ever-increasing amounts of data, it's becoming increasingly important that we address this.

Bob Barrett: Are there areas in laboratory medicine where we're lagging in our use of data to drive improvements?

Sarah Wheeler: The short answer is "definitely." On the operational side of laboratory medicine, Mr. Gramz points out in the Q&A that there are several tools that we're just beginning to implement to allow for continuous improvement without the need to create lots of manual reports to track things. Informatic solutions that have kind of this real time component for monitoring key performance indicators are becoming much more common in some laboratory areas, and they can help us improving things like exception management, staffing, and

other data driven decisions that can improve our processes from an operational standpoint. An area that continues to be somewhat challenging is point-of-care testing. So, Dr. Leung indicates that there are far fewer tools for accessing that data compared to what we may have for, say, our core laboratories, but this is an area that has hundreds and sometimes thousands of operators within a single hospital system, and we are responsible not just for them performing the testing, but also for all of the regulatory compliance in that. So it's really a critical area where we need data driven improvements for both operations and patients' care. But really beyond this kind of basic descriptive analytics that we've just talked about, where we look at kind of what's happened in the laboratory, it's also critical that the clinical laboratory moves into higher level analytics. So, Drs. Bunch and McClintock discussed that we want to assess what will happen in the lab, so this predictive analytics, and then also how can we make things happen, which we also referred to as prescriptive analytics.

To do that, we need access to our data, which, as Dr. Block discusses, is really not the norm in most of our systems. We are operating within systems that were built to move test tubes in real time and provide numbers, rather than to really be queried for data export and manipulation. So to move to higher level analytics, we'll require resource allocations that unfortunately aren't always currently a priority for systems.

Bob Barrett: How do you think we can best improve the clinical laboratory and the practice of laboratory medicine through informatics and analytics?

Sarah Wheeler: A theme that's running through all of the responses from all of these experts has really been that our goal is to get the right information to the right person at the right time. And doing that requires so much more than just running the test. It's all of the data that has to be managed for making it possible for the physician to order the correct test, to ensuring that quality control material is training properly to avoid any instrument issues use, and also getting the data with the proper units, flagging, and format into the electronic medical record and now patient portals as well.

Ideally, we could have separate presentations of our results for different users as we've talked about, but there's so much that can be done, from exponentially improving error detection and predicting instrument issues to increasing workflow efficiency. And aside from kind of the operations side of things, we've also got opportunities for significant clinical value adds through increasing result interpretability, providing clinical decision support for result interpretation, creating computational assays that can provide personalized

clinical diagnostics, and improve patient understanding of their clinical laboratory test results.

Bob Barrett: Well, finally, Dr. Wheeler, what hurdles do clinical laboratories face in improving their use of informatics and data analytics and how can we collaborate to overcome them?

Sarah Wheeler: I would say data, data, and probably data. It's really--getting our hands on the data is really important and I should probably also add the same for resources in general. Accessing data and the resources to improve informatics and perform data analytics really remain our most common challenges throughout our organizations. Most organizations really don't sufficiently invest in clinical laboratory informatics teams for these teams to do much more than just kind of keep our lights on. Additionally, we have a lack of laboratorians that have either data science backgrounds or feel comfortable working in informatics. So we really need a stronger and more robust pipeline for clinical laboratory personnel to be conversant in the analytics side of things, in addition to the larger umbrella of informatics, so that we can drive operational as well as clinical analytics improvements.

And really, collaboration is such an important addition to this conversation because so much of this work is an intersection of our organizational IT structures, clinicians, and the clinical laboratory, and we need a lot of collaboration to actually get this ball moving in the right direction. Being involved in both organizational and national discussions on central IT and clinical informatics initiatives is really important for us as laboratorians, and we should be working to have representation at these committees and meetings. It's honestly going to take a village for us to move to truly utilizing all of the data we create to provide the best possible patient care through process-based as well as higher level analytics. And so we have to be engaged in these collaborations with all of these groups.

Bob Barrett: That was Dr. Sarah Wheeler from the University of Pittsburgh. She was the moderator of a Q&A feature on challenges and opportunities in clinical laboratory informatics and analytics appearing in the November 2022 issue of *Clinical Chemistry*. I'm Bob Barrett. Thanks for listening.