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Sarah E. Wheeler

Darci R. Block

Dustin R. Bunch

Jamie Gramz

Edward Ki Yun Leung

See next page for additional authors

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Q&A

Clinical Laboratory Informatics and Analytics: Challenges and Opportunities

Moderator: Sarah E. Wheeler [a,*]
Experts: Darci R. Block [b] Dustin R. Bunch [c] Jamie Gramz,[d] Edward Ki Yun Leung,[e] David S. McClintock,[f] and J. Mark Tuthill[g]

Introduction

The American Medical Informatics Association defines biomedical and health informatics as the "science of how to use data, information, and knowledge to improve human health and the delivery of health care services." More specifically within 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, integration and interoperability issues have become readily apparent between health information systems, bringing to the forefront questions about the validity of data exchange and basic data access. Most data generated within the clinical laboratory are of high quality, well annotated, and structured discretely, however turning these data into useful and actionable information can be a difficult data analytics bridge for many to cross. Instrument and laboratory information system (LIS) vendors are beginning to aid in the creation of generalized reports for common laboratories questions; however, this still falls short of the potential of the clinical laboratory to bring more actionable information to hospital leadership, clinicians, and patients. Collaboration among informaticians, information technology (IT) professionals, and the laboratorians is critical to ensure our health information systems can utilize and report laboratory data clinically, in addition to providing interoperable data streams for furthering research, education, and innovation in healthcare.

To discuss these and other challenges and opportunities for informatics in laboratory medicine, we have invited several experts to share their experiences.

Can you describe the areas of the clinical laboratory where you have seen the most improvement by the increased use of informatics and data analytics?

Darci Block: The COVID-19 pandemic is a case in point for the value of informatics. It certainly was not easy, and there were many lessons learned, but the ability to monitor case rates and predict surges was all thanks to the mighty efforts of clinical laboratorians who became overnight experts of SARS-CoV-2 testing and informatics and data analytics (whether they knew it or not). We also learned that when our collective attention is focused on a single threat, the response can be very targeted and efficient in execution. We accomplished a tremendous amount in a relatively short duration because of this laser focus.

[a]Associate Professor of Pathology, University of Pittsburgh School of Medicine; Medical Director of UPMC Mercy and UPMC Children's Hospital Automated Testing Laboratories, Associate Director of UPMC Presbyterian Clinical Immunopathology Laboratory, Pittsburgh, PA, USA; [b]Assistant Professor of Laboratory Medicine and Pathology, Mayo Clinic Rochester, MN. Co-director of Central Processing and Central Clinical Laboratory, Vice Chair of Informatics for Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, MN, USA; [c]Assistant Director Clinical Chemistry and Co–Director Laboratory Informatics, Nationwide Children's Hospital, Assistant Professor – Clinical, College of Medicine, The Ohio State University, Columbus, OH, USA; [d]Head of Digital Applications for Laboratory Diagnostics, Siemens Healthineers, Tarrytown, NY, USA; [e]Director, Core Laboratory, Department of Pathology and Laboratory Medicine, Children's Hospital Los Angeles. Assistant Professor of Clinical Pathology, Keck School of Medicine of USC, Los Angeles, CA, USA; [f]Senior Associate Consultant, Division of Computational Pathology and Artificial Intelligence, Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, MN, USA; [g]Division Head, Department of Pathology and Laboratory Medicine, Henry Ford Health System, K-6 Pathology, Detroit, MI, USA.
*Address correspondence to this author at: Clinical Laboratory Building, 3477 Euler Way, Rm. 4025, Pittsburgh, PA 15213, USA. E-mail wheelerse3@upmc.edu.
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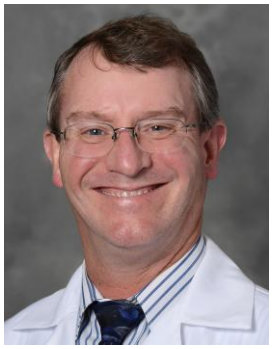
Dustin Bunch: At this time, laboratory operation activities are receiving the largest benefits from laboratory data streams in the form of internal and external quality metrics. Most laboratories are monitoring turn-around-times, volumes, QC (quality control), and infection metrics either through reports and/or dashboards, and have mandatory reporting to federal, state, and local entities.

David S. McClintock: I thought this would be an easy question; however, it wasn't—clinical laboratories have benefited from an increased awareness and use of informatics for decades, with incremental changes over time leading to numerous diagnostic, operational, and quality improvements. For example, we have seen improved interfacing and coordination of laboratory instrumentation and automation, most recently in the areas of molecular testing, microbiology, and point-of-care testing. Data-rich analytics are driving laboratory operations more and more, in addition to laboratories seeing minor gains in interoperability with greater adoption of standards such as Logical Observation Identifiers Names and Codes (LOINC) and unique device identification (UDI).



J. Mark Tuthill: Clearly, automation of manual processes has had the most direct impact in the clinical laboratory. The impact of business analytics is now having direct impact on the laboratory as well. Because of the use of descriptive analytics, predictive analytics, and artificial intelligence, laboratories have a much deeper understanding of their workflow and any deviations and thus can respond in ways not previously available. I believe this will continue to develop in the future into next-generation automation and laboratory efficiency.

Edward Ki Yun Leung: The areas for which I have seen the most improvement by the increased use of informatics are in the core or integrated laboratory environments with total laboratory automation. Vendors are providing tools, usually at a middleware level, where data from the instruments can be analyzed and presented on dashboards for laboratory staff and management. The dashboards can be successfully used in different ways such as monitoring turnaround time, identifying bottlenecks in laboratory operation workflows, optimizing staffing resources to support changes in testing volumes throughout the day, and supporting test utilization programs.

Jamie Gramz: Standardization, improved efficiency, and reduction of hands-on time are key improvements made possible with lab informatics. Informatics has accelerated the laboratory's ability to generate, aggregate, and analyze data and has been the key enabler in operationalizing data through use of automation, while also helping labs to offset the growing shortage of laboratory professionals in the US and other countries around the world. Whether it be the transformation of tests ordered by a physician into the autonomous handling of samples throughout the preanalytic, analytic, and postanalytic processes or the use of autoverification to streamline the evaluation, review, and reporting of patient results, informatics is helping to drive the timely delivery of actionable patient information that medical laboratories provide.

What are some of the operational challenges we still face with providing high-quality, interpretable laboratory data to clinicians and patients?

J. Mark Tuthill: There are multiple factors that impact the quality and interpretability of laboratory data by clinicians and patients. First, the ability to see, understand, and read these data in an easy fashion has been challenging. Most laboratory reports are very flat, textual, and are not summative. Nor is there interpretive guidance provided: "You got the number, figure it out." This is not helpful. We need better graphical

displays of laboratory data for patients and clinicians. In addition, because laboratory results produced by different laboratories may have different reference intervals or completely different result values, it can be very difficult for clinicians and patients to interpret results across different healthcare systems. So providing interoperable, interpretable results is only part of the challenge.

Dustin Bunch: Foremost is data access, which is the most common barrier for those that want to do data science. As a community, we have not created a culture where it is normal to routinely access raw data. Historically, if data were available, access to those data came through distilled reports. Another issue is the number of people trained to process and/or interpret the data available in clinical laboratories.

Edward Ki Yun Leung: Some of the current operational challenges we face that impact high-quality, interpretable laboratory data include decentralized databases and the need of multiple different data mining tools to extract the data. Both may have significant impact on the fidelity of the final data. In the current healthcare environment, data are stored in multiple systems such as electronic health records (EHR), laboratory information systems, clinical decision support systems, clinical operations and analytics software and systems, revenue cycle management systems, and software systems that support clinical trials and research. Each of these systems may have different levels of accuracy and refresh rates. In addition, each system may require a different data mining tool to extract the data. High skill-set requirements may be needed to effectively use these tools to extract, combine, and format the data.

Jamie Gramz: Interoperability has come a long way over the past 10 years with completion of the 3 stages of meaningful use: driving EMR (electronic medical record) integration including data capture and sharing (2012), advanced clinical processes (2014), and improved outcomes (2016). And as a patient, I appreciate being able to quickly see my lab results in the patient portal app as soon as they are released from the laboratory. Providing patients with immediate and transparent access to their health information was an important achievement and great step forward. But in today's consumer-driven society empowered by the internet, it introduces a new set of challenges as patients try to understand and interpret the meaning of their lab results, potentially even attempting to self-diagnose medical conditions. This may create new opportunities for laboratories to provide support for lab test result interpretation and expanding patient portal apps to include access to relevant and accurate information as a logical next step.

Darci Block: Clinicians and patients seem most interested in having all "relevant" health record information in one place that is easy to reference and digest quickly. It makes shopping for healthcare more feasible and streamlines the experience when a mountain of paper results and records do not need to be synthesized at each stop. To that end, it seems like a simple thing to pull laboratory results into a single system or viewer from any place a patient has lab testing performed to support this endeavor. However, operationally the methods of standardizing results (via LOINC and other standards) have not completely overcome the challenge for reasons I am not altogether sure of. Additionally, results nomenclature (e.g., positive = "P," "+," "detected," "reactive," "confirmed," "present") remains a ripe opportunity for standardization to consolidate meaning in such collections of results.

David S. McClintock: I like to think of laboratory informatics as how we best deliver the right clinical laboratory information to the right person, at the right place, at the right time, and in the right way. With that in mind, clinical laboratories are still far behind in delivering the "right" laboratory information to the right person. We still provide a single result or interpretation in a one-size-fits-all approach, with each lab formatting their results in different ways that can confuse both patients and clinicians alike. Unfortunately, our current lab information systems do not allow us to send multiple versions of results for multiple purposes (although, to be fair, downstream HIS [health information systems] can't ingest differing versions of the same result either), which means it will be a long time before we can tailor our reports to meet the specific needs of the customer/right person (e.g., patient, primary care physician, subspecialty clinician, etc.).

Are there areas in laboratory medicine where we are lagging in our use of data to drive improvements?

Jamie Gramz: A common one is the slow adoption of analytic solutions to help monitor performance, with many labs still following tedious and time-consuming steps to collect the data needed to manually generate reports. Automating this process with informatics solutions that provide real-time analytic reports to monitor the common key performance indicators that most labs measure could be a "low-hanging fruit" opportunity to help drive continuous improvement. Real-time analytics solutions can make it easier for labs to assess performance, identify inefficiencies, and drill-down to determine the root causes of problems. Whether it be to monitor internal metrics like turnaround time, throughput, and exception management or to investigate complex issues like identifying the leading sources

of sample integrity issues, analytics should be a key tool used by the laboratory to help make data-driven decisions for improvement.

J. Mark Tuthill: The biggest area where we are lagging in our use of data is widespread access to all varieties of data and the ease of access to that information. Once data is available, the ability to display that data in meaningful ways, to the correct people, at the correct time, is the next challenge. Typically, the laboratory has relied on paper data outputs to respond to workflow challenges or defects/deviations in the laboratory testing process. This is true in both preanalytic, analytic, and postanalytic processes. Replacing static, paper-based reports with dynamic, real-time dashboards is still in its infancy in many laboratories, particularly for real-time dashboards that would have direct day-to-day impact on workflow and patient care activities beyond simple "turnaround times."

Darci Block: In my experience, I would say all areas of laboratory medicine lag because access to data, even the most basic data within the laboratory information system, not to mention instrument and middleware data, is limited; these systems were designed to drive workflows and keep track of specimens in real time and not really designed to be queried and exported for further manipulation. It's also very frustrating because we know the information is there but seemingly just out of reach.

Edward Ki Yun Leung: One area where we are lagging in our use of data to drive improvements is in point-of-care testing (POCT). POCT is very different when compared to laboratory testing. Different vendors may have their own software and/or system for their own devices, and a POCT program may have 2 to 3 (or even more) different vendors. It is not uncommon for a POCT program to use a POC middleware solution to interface the different software and/or systems to the LIS and/or EHR. When compared to the clinical laboratories, there are not as many tools to mine, extract, format, analyze, and present the data. Another area in POCT where we are lagging in our use of data is in testing personnel management, especially for larger programs where there can be more than 1000 POCT users. For each user, we need to manage the education, licensing, training, and competency documentation. This can be very challenging and resource intensive because the information may be in paper format and in multiple databases.

Dustin Bunch: The Gartner Model Data Science Continuum states as complexity increases the institutional value increases. Currently, clinical laboratories are lagging in all areas when it comes to high-complexity/high-value applications of data science. The lab tends to be in the low complexity/low-value region, using only descriptive analytics (what happened) and diagnostic analytics (why it happened). To grow data analytics in the clinical laboratory, we need to move into the high-complexity/high-value applications, which deal more with predictive (what will happen) and prescriptive analytics (how can we make something happen).

David S. McClintock: While labs are well versed with descriptive analytics (what happened in your lab?), most are not equipped to progress to higher level analytics, such as diagnostic analytics (why did X happen?), predictive analytics (what will happen in the lab and when?), and prescriptive analytics (how can we make X, Y, and Z happen in the lab?). In general, deriving more value from your data equates to increasing resources and tools. Diagnostic analytics requires broader integration of operational and diagnostic data, including ways to achieve both real-time awareness of events and mechanisms to act on them. Predictive and prescriptive analytics build upon diagnostic analytics, adding further integration of larger data sets with machine learning/artificial intelligence tools. Overall, increasing analytics efforts requires substantial funding and resource allocations, which unfortunately hasn't been a pressing priority for clinical laboratories, pathology and laboratory medicine departments, and larger enterprise healthcare systems alike.

What hurdles do clinical laboratories face in improving their use of informatics and data analytics? How can we collaborate to overcome them?

David S. McClintock: Resources, resources, resources! Overall, we need to invest more in informatics people, processes, and technology. Clinical laboratories, and their larger enterprise institutions, don't overwhelmingly fund laboratory informatics positions or appropriately size their LIS and middleware clinical business analyst teams. Additionally, clinical laboratories need to increase their awareness of broader informatics initiatives and challenges, both locally in their institution/region and nationally. Laboratory leadership, in addition to any pathology/laboratory informatics clinicians and staff, needs to engage with their own central information technology and clinical informatics groups to ensure they have a seat at the table—this allows the labs to both understand immediate issues at hand and contribute to the larger discussion about IT and informatics initiatives.

Edward Ki Yun Leung: A hurdle we face in improving the use of informatics is support and resources. Traditional laboratory staff may have limited knowledge

and experience with informatics, and informaticians may have limited knowledge and experience in laboratory medicine. Both will be needed for the successful implementation of informatics that will be useful in laboratory medicine. We will need hospital and laboratory leadership to collaborate and invest the proper resources to support this model.

Darci Block: To improve something, you need to have a basic understanding of what you are dealing with, how it works, and what rules it tends to follow. Laboratorians should start asking and answering—What is informatics? What does it do and how does one participate? In my role as vice chair of informatics, I have settled into a role as steward of IT and other project resources for our department. The hurdle is keeping up with the volume and pace of desired change, which requires strict and disciplined prioritization from top leadership and efficient and lean processes for getting work done, engaging the right groups at different times, while maintaining adequate quality practices and control measures. I serve as a liaison to translate a need or desire from the lab requestors to IT teams that are responsible for maintaining, optimizing, and/or implementing systems to meet both groups' expectations. I think we can overcome hurdles by fostering open dialog within an organization but also between organizations to collaborate and learn best practices and lessons learned from one another.

Jamie Gramz: Understanding what is available and where to start is a common challenge. With many diagnostic companies offering feature-rich informatic solutions designed to address a variety of lab challenges, it can be difficult to determine which solution will work best in your environment. When weighing the various solutions, determine which potential improvements will have the most significant impact to the laboratory and the stakeholders you serve. Are there mission-critical initiatives related to patient care? Do you need to prioritize compliance issues, such as result reporting or QC? Should initiatives that help to optimize the use of lab staff or laboratory consumables be considered next? If your operations are in good shape, would implementing robust, real-time analytics be the next step to further improve performance?

Dustin Bunch: The future of data science in the clinical laboratory will have to move away from a single institution application and move to applications gathering data from regional, national, and international hospital data sets. There are currently many barriers to achieve this, but there have been strides made to make this happen with things like common data models such as the Observational Medical Outcomes Partnership from observational health data science and informatics, better LIS interaction, and nationally supported databases.

J. Mark Tuthill: I believe the biggest hurdle the laboratory faces in using informatics is related to the lack of human resources with data science backgrounds and experience. Without dedicated personnel with experience in business analytics as well as staff members who recognize the value of using analytics to drive workflow processes, we are hampered by lack of time and effort. Thus, what needs to be improved is the pipeline for analytics analysts, training and education of clinical laboratory scientists, as well as PhDs, pathologists, and residents who support operations across the laboratory enterprise.

An additional new consideration for the clinical laboratory is the use of wearable devices, devices that continuously measure analytes (e.g., glucose) and laboratory testing in home-care settings. These are disruptive forces that will require new informatics solutions. As these developments are in their infancy, we don't have much experience yet. Should these data be integrated back to the electronic medical record? the LIS? other systems? What level of detail, how long should continuously monitored data be stored and retained? How is quality assurance accomplished with such devices? While I am raising questions more than answers, these points may frame future requirements.

Are there tools that vendors offer or could create to help clinical laboratories with limited resources improve their use of laboratory data?

Jamie Gramz: Most in vitro diagnostics vendors provide IT solutions to help manage patient and quality control testing, but some offer additional products that can add value in helping the lab overcome key challenges. Inventory management solutions can simplify the consumable check-in process, track reagent consumption, and help automate the reordering process. Implementing an inventory management solution can help reduce costs and avoid low or out-of-stock inventory situations to enable lab staff to spend time performing more meaningful tasks. Equipment monitoring and alerting solutions can enable centralized oversight and control of analyzers and automation systems in multiple laboratories from a single workstation. Analytics and reporting solutions can make it easier to monitor performance, identify inefficiencies, and investigate root causes of problems.

J. Mark Tuthill: Relevant to business analytics, there are vendors that will provide analytic solutions that connect directly to the laboratory information system and help support laboratories in these business processes. However, these tools rely on clean data that is readily available to these tools. Typically, third-party vendors do not have access to the laboratory information systems and do not have deep knowledge of the laboratory information systems organization or its database. Thus, they

rely on the laboratory to provide personnel to assist them with deployment of these tools. Lack of personnel again becomes the bottleneck. Once analytics tools, reports, and visualization are deployed, they can be leveraged widely by the laboratory with relative ease and low-level support. The vendors of instruments and automation lines are also working to make such tools basic offerings in the platforms, so, at times, it is a process of discovering what you may already have. Consultants can also be employed to help laboratories understand capabilities they may already have.

Darci Block: It would be great if vendors could assist efforts to open regular dialog between customers using common systems (analytical equipment and instruments as well as IT systems and applications). How great would it be if instead of feeling like Christopher Columbus sailing the ocean blue, you could learn from the experience of others who have already navigated this path and similarly share your experience to hopefully prevent mayhem for someone else?!

David S. McClintock: Yes, vendors can start by creating tools for labs to easily access their data, both for internal application and for third-party (export) use. Moving to modern programming practices is also key, primarily so vendors can better meet increasingly complex laboratory informatics needs, conform to modern IT infrastructures, and avoid debilitating cyberattacks by adopting current cybersecurity measures. Other ways vendors can help laboratories include: 1) enabling non-word processor based reporting tools to allow for easier configuration and interoperability with other systems; 2) creating basic descriptive analytics and dashboarding tools within the application to support lab workflows; 3) better integration of standards, e.g., LOINC/UDI/Systematized Nomenclature of Medicine, within their applications to promote interoperability; 4) support for modern interfaces and web services, including HL7 FHIR[a]/SMART on FHIR,[b] so labs can create or purchase apps that plug in to existing software and create new functionality; 5) many, many more.

Edward Ki Yun Leung: Professional organizations such as the American Association for Clinical Chemistry, the American Society for Clinical Pathology, and the Association for Pathology Informatics are great resources for laboratory professionals and informaticians to learn about each respective discipline. Even though there are educational materials, courses, bootcamps, and conferences offered by each of these organizations, vendors can provide additional support and resources to enhance these programs and partner with these organizations. Currently vendors are providing informatic tools that work well within their own systems; however, laboratories rarely use one vendor for their entire test menu. Vendors can help by developing tools that make it easier to interface and use the data between different systems and databases.

Dustin Bunch: Vendors could help by allowing their software to seamlessly integrate data science modules into their LIS and make it easy to integrate noncommercial/academic-based algorithms. This may require the software to be able to natively communicate with current data science languages such as python and R or to actively link to processing pipelines.

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

Edward Ki Yun Leung: We can best improve the clinical laboratory and the practice of laboratory medicine by expanding and educating informatics to staff at the laboratory technologist level. Informatics is extremely valuable to laboratory operations. Once staff are more knowledgeable and comfortable with this, informatics can be integrated into routine laboratory operations and their daily workflow. They will be able to experience the benefits of informatics, provide practical feedback on the tools, and contribute to the future development of the field. We will be able to present the right information, to the right person, at the right time.

Dustin Bunch: The lab will be better able to detect errors, especially if we incorporate preanalytical and postanalytical data into our workflows. We should be able to predict instrument issues before failures that create unscheduled downtimes similar to industrial manufacturing companies. In addition, data science can help improve laboratory efficiency, but this is dependent on many factors. My favorite goal of data science in the lab is to increase data interpretability. The number and variety of tests are ever increasing, which increases the complexity of interpretation. If the laboratory is able to simplify interpretation, this would be a win for the clinicians and patients. This can also be applied to simplifying charts for public consumption, allowing patients to understand their information better.

J. Mark Tuthill: There are several areas that we need to address and consider in how we can best improve the laboratory diagnostics using informatics. First and foremost are workflow processes. Using informatics tools to model and understand workflow and then design laboratory efficiency by creating standard work is step 1. Once workflow tools have been put into place, laboratory information technology needs to be applied in an organized, concerted fashion. This will have direct

operational impact on laboratory cost, efficiency, and effectiveness of personnel. Thus, the laboratory information system is key and remains key to effective laboratory testing as well as improving the practice of medicine. Once workflow has been improved and laboratory information system technology is in place, we can begin to use analytics and modeling to not only assess our workflow activities and our laboratory efficiency but begin to apply these tools in sophisticated ways. For example, artificial intelligence can be used to not only help understand laboratory testing patterns but to help understand variations in laboratory testing that suggest variations in outcomes or cost of care. Such algorithms are in their infancy. Moving past business analytics into clinical analytics is the ability to use clinical information in actionable ways that impact patient care; this is the next level of effort that laboratories can make. This will enable diagnostic tools such as multianalyte assays that are able to create laboratory "values" and "laboratory diagnosis" based on algorithms that infer this information from simple testing results.

David S. McClintock: The future of clinical laboratory informatics lies in 1) getting access to *all* laboratory data, not just orders and results; 2) organizing that data into discrete data sets that address specific operational and clinical needs; and 3) using that data with innovative artificial intelligence techniques, both within and external to the laboratory, to optimize operational workflows, automate manual tasks, and create/deploy computational assays to drive personalized therapeutics for patients and provide novel insights on clinical diagnostics. A better understanding of, and improved integration with, enterprise/institutional IT strategies is also important so clinical laboratories can stay aligned with major central IT initiatives to adopt new technology, modernize platforms, and improve cybersecurity. As more groups move to the cloud, labs will have to adapt to how instrumentation interfaces are configured, how they access and backup data, and how they validate their LIS and other lab applications.

Jamie Gramz: Although laboratory testing has evolved immensely over the past 20 years to become highly automated, reliable, and efficient, there has not been much advancement in the area of clinical decision support (CDS). There remains a tremendous amount of human variability involved in the manual, cognitive process of ordering and interpreting lab tests. Today, physicians are tasked with not only ordering the appropriate tests for a patient but also interpreting lab test results. Introducing services to provide support for lab test result interpretation, test ordering recommendations, and predictive models to help enable the early identification of patients at risk of specific diseases are scenarios where laboratory-based CDS could help. Informatics solutions for CDS and the increased use of machine learning and artificial intelligence will be key enablers to help the laboratory expand the value it provides today to go beyond the traditional reporting of test results and reference intervals.

Darci Block: To see the full effect it will take a village. Leadership that listens but also makes definitive and strategic decisions to guide initiatives that will fulfill intended outcomes and business longevity. Governance groups that are knowledgeable of systems and processes that can provide oversight and policies that when followed make the best use of systems so that data is cleanest and in its most meaningful formats. Integrated user groups that identify and strategically address issues and challenges as they arise and provide input into what works and what does not. And finally clinical laboratories that produce the data must be good stewards of this resource to have any hope of improving human health and the delivery of healthcare services.

Nonstandard Abbreviations: HL7 FHIR, Health Level 7 Fast Healthcare Interoperability Resources; SMART on FHIR, Substitutable Medical Applications, Reusable Technologies on Fast Healthcare Interoperability Resources.

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