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The IOM's Second Wake-Up Call: The Lab Goes Under the Microscope

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"One death is a tragedy; 98,000 deaths is a statistic."

The Institute of Medicine's often cited 1999 report, To Err Is Human, calculated that 98,000 patients die each year in US hospitals as a result of medical errors. The IOM unsurprisingly characterized this report as a "serious wake-up call," but even that estimate may have been understated as subsequent studies provided plenty of evidence to suggest that 98,000 may in fact be several times too small.

On September 22nd, 2015, the IOM published new findings in its report, Improving Diagnosis in Healthcare, having revisited the topic with a focus on diagnostic errors. They found that to err is indeed human, summarizing their findings as the "second serious wake-up call." The report states that:

- Five percent of U.S. adults who seek outpatient care experience a diagnostic error.
- Postmortem examination research spanning decades shows that diagnostic errors contribute to approximately 10 percent of patient deaths.
- Medical record reviews suggest that diagnostic errors account for 6 to 17 percent of adverse events in hospitals.
- Diagnostic errors are the leading type of paid medical malpractice claims and are twice as likely to result in the patient's death compared to other claims.

Diagnostic errors are defined as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient" across the healthcare continuum. Not only have diagnostic errors been unappreciated when considering care quality, but they are also endemic (with most people experiencing at least one in their lifetime) and sometimes devastating. With the 2015 report, we now have a key cause of the problem identified and recommendations of how to tackle it by consolidating multiple approaches and disciplines with context we can put to work.

As the source of diagnostic data, the laboratory is at the center of avoiding diagnostic errors, and improving the accuracy of diagnoses. The laboratory's importance in solving both problems for healthcare becomes clear when two of the IOM's key recommendations are viewed through a lab-centric lens. These relate to collaboration and IT.

IOM recommendation: Collaboration

The IOM report calls for more effective collaboration in the diagnostic process; first, among pathologists, radiologists, other diagnosticians and treating healthcare professionals; and second, between healthcare organizations and the patients themselves. Industry shifts have made both types of collaboration more important and, yet, more difficult to achieve.

For example, a dramatic increase in the number of tests available

conspire to make physicians' lives more difficult when trying to determine what test to order for their patients. At the public release discussion of the report, it was noted that:

No single physician will know everything about all of these new molecular tests and that's where teamwork will be important, both for selection of the appropriate test and interpretation of them.

Collaboration is key to enable physicians without the requisite knowledge to safely order everything that is necessary and nothing that isn't, to cut down on waste but more importantly provide more accurate diagnoses.

While the effect of this clinical and operational problem spans beyond the lab's purview, it is the laboratory at the intersection of the cause. Physicians in need of guidance for ordering and results interpretation are typically working within transaction-based EMRs that simply give them data, but do not offer suggestions or instructions on what to do with it. Because the laboratory sits at the center of these transactions between the physician, the patient and diagnostic results, it is well-placed to bridge the gap, as identified by the IOM, by going beyond the transaction and helping influence how to act on it. With the right tools, the laboratory can solve the problem by providing guidance to the physician — at the point of the test order.

Another challenge for improved collaboration between healthcare organizations and patients is the industry trend of payment structures shifting to value-based care, as opposed to fee-for-service, and patients more often receiving care outside of the hospital. A recent study projects a 17 percent growth in outpatient services from 2013 to 2023. With a focus on improved overall outcomes, collaboration becomes key to ensure patients follow treatment plans and have access to the most appropriate care. However, with more patients being cared for as outpatients, providers are faced with the challenge of how to connect treatment data electronically, across physical boundaries outside the four walls of the hospital. Again, the laboratory plays a key role as a conduit for meaningful collaboration as this occurs, and there are instances of institutions that have recognized this. For example, Tricore Reference Laboratories, a large reference laboratory in New Mexico, recently announced a new effort to maximize the value of laboratory data across its expanding outpatient community. Their program is aimed at enabling more effective population health, precision medicine and real-time targeted intervention initiatives.

IOM recommendation: Information technology

The IOM report states that health information technology should support patients and healthcare professionals in the diagnostic process, specifically emphasizing the importance of interoperability, usability and clinical decision support, and the free exchange of information on human factors improvements.

No healthcare strategy is complete without an IT strategy, and no IT strategy is complete without interoperability. From the laboratory's perspective, as diagnosis becomes more specialized with complex tests that subdivide existing disciplines, the specificity required in information systems to support this can easily become more siloed. A plethora of information systems across diagnostic specialties are provided by dozens of different vendors. As these numbers increase, so does the challenge of enabling patient-centric collaboration across disciplines. For these reasons, establishing interoperability with laboratory information systems from the beginning is critical. Cross-vendor initiatives are one approach to consider. The Commonwell Health Alliance, an interoperability initiative founded by Cerner, McKesson, Sunquest and athenahealth, seeks to make health data available to individuals and providers regardless of where care occurs. It is these such initiatives that will help positively impact diagnoses through standardization and achieve the IOM's recommendation for

improvement.

For human factors, it has not gone unnoticed that healthcare IT lags in its adoption of user-friendly technology for a number of different end users. A year ago, the American Medical Association called for solutions to EHR systems for physicians that have neglected usability as a necessary, rather than desired, feature, and the AMA's usability framework has very recently called out popular EHR systems for their low usability scores. Earlier this year, a nursing group has called for the identification of a centralized body that focuses on usability for nursing adopted technologies. This is one reason for the low adoption in hospitals of basic EHR systems.

Taking our laboratory-centric view, fewer than 35 percent of U.S. hospitals have automated the specimen collection process carried out by nurses; while labeling errors occur at an average rate of one out of every 1,000 specimens collected during inpatient care, and 10 times more in the ED. Further, fewer than 10 percent of hospitals have extended their blood banking system to a simple automated bedside check between the patient and unit prior to administering a transfusion. When an end user's tasks are considered in context, role-based interactions with IT vary significantly and need to be tailor-made for adoption success. The same principles are even more important when we extend this to a complex clinical decision support system that, for all its advantages, can also introduce diagnostic risk into the decision making process if misapplied. The emphasis in the recommendation must be on IT decision support, not IT decision-making. There is, after all, only so much an algorithm can do.

Summary

The IOM's recommendations on improving diagnostic outcomes are timely and well-aligned with the increasing complexity of diagnostic medicine, the future care settings where diagnostics will take place and the growing use of IT systems to help us diagnose. The report confirms that IT systems alone cannot provide high quality and safe healthcare, but improvements will come only by leveraging a combination of collaborative workflow practices and intelligent interoperable IT systems that appropriately interact with a wide variety of decision-making end users.

Given the breadth of the recommendations, the challenge for healthcare institutions is knowing where to begin. With laboratory medicine at the center of the diagnostic process, an examination of the lab's role as a conduit for improved outcomes is a good starting point. With this approach, we can make the IOM's second wake-up call immediately actionable in a way that can help us avoid diagnostic errors and, perhaps, even eliminate the future need for a third wake-up call.

About the author

Jonathon Northover, J.D., BVC, senior manager, closed-loop solutions, Sunquest Information Systems. With the goal of eliminating manual processes and the potential for error from vein to vein, Jonathon Northover focuses on leveraging information technology to bring the laboratory to the patient bedside. With more than 15 years of experience in the legal, healthcare IT and software startup businesses, he excels at combining workflow best practices, regulatory and technology to bring innovative solutions to market. Jonathon earned his Bachelor of Law degree (L.L.B) and Juris Doctorate (J.D.), with honors, from King's College in London.

This article was written as a follow-up to JoAnne Scalise's article, "To err is human revisited: the lab goes under the microscope."