The Essential Role of Laboratory Professionals

Ensuring the Safety and Effectiveness of Laboratory Data in Electronic Health Record Systems

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PURPOSE

The development of electronic health record (EHR) systems and other health information technologies is changing how laboratory data are transmitted and displayed throughout the healthcare system. The purpose of this paper is to provide an overview of the key areas in which laboratory professionals can contribute their expertise to the development of accurate exchange and display of laboratory data in EHR systems. Thoughtfully designed and rigorously tested EHR systems improve patient care by making it easier to collect, share, and interpret patient data. However, variations in EHR system design, functionality, and ability to exchange data accurately (interoperability) can also cause preventable patient safety risks. Examples of preventable patient safety risks include misdiagnosis, delays in treatment, and inappropriate treatment. These patient safety risks may unintentionally result in patient injury or even death. For the purpose of this paper, an EHR is safe and effective for laboratory data when the display of information and the computer system's behaviors (such as critical result alerts) are developed and implemented to optimally ensure accurate and timely interpretation by the end user.

The purpose of this paper is to illustrate the seriousness of laboratory data-related interoperability issues and display discrepancies in EHR systems, and propose focus areas for action by laboratory professionals to support resolving those issues. Through collaboration, laboratory professionals, clinicians, healthcare executives, medical professional societies, health IT developers, and federal agencies like the Office of the National Coordinator for Health Information Technology (ONC), the Centers for Medicare and Medicaid Services (CMS), and the Food and Drug Administration (FDA), can work together to develop effective solutions to reduce identified patient safety risks in and improve the safety of EHR systems.

BACKGROUND

National efforts are underway to implement EHR systems that can seamlessly exchange health information to improve patient care and, ultimately, population health outcomes.[1] The ONC and CMS have laid the foundation for the rapid and systematic adoption of EHR systems by healthcare systems and providers across the United States through two sets of regulations, the ONC's EHR Standards and Certification Criteria[2] and the Medicare and Medicaid EHR Incentive Program.[3] The ONC and CMS regulations work together and are progressive, meaning the standards and certification requirements and clinical quality measures are related and increase with each stage of implementation. The certification criteria establish the technical specifications that EHR systems must comply with to be certified in order for eligible providers and hospitals to participate in the incentive program. The incentive program promotes adoption of EHRs and the meaningful use of health information technology (IT) by providing payments to eligible healthcare providers and hospitals that demonstrate

1 Healthcare providers and consumers have the potential for greater access to health information through investments in EHRs and a focus on their meaningful use, as described by the Health Information Technology for Economic and Clinical Health (HITECH) Act, as enacted by the American Recovery and Reinvestment Act of 2009.

2 ONC's Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule (45 CFR 170, Stage 1) and Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; (45 CFR 170, Stage 2). Retrieved from http://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17210.pdf and http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf

3 Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule (42 CFR Parts 412, 413, 422 et al, Stage 1) and Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 (42 CFR Parts 412, 413, and 495). Retrieved from http://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17207.pdf and http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf

achievement with established EHR clinical quality measures.[4] The objective is to implement EHRs in three stages over a multi-year period, focusing on 1) data capture and sharing (infrastructure), 2) advanced clinical processes (health information exchange), and 3) improved outcomes (advanced use of data), in 2012, 2014 and 2017, respectively. The actual years of implementation for Stage 2 and Stage 3 may be subject to change if determined appropriate by the U.S. Department of Health and Human Services (HHS), based upon ongoing evaluation of the progress and success of EHR implementation.

Institute of Medicine (IOM)

As the percentage of providers using EHR systems has significantly increased over the last decade,[5] there is concern that EHR system-related patient safety events may also be on the rise. The November 2011 Institute of Medicine report, *Health IT and Patient Safety: Building Safer Systems for Better Care,* noted that the lack of empirical data on the nature and prevalence of EHR system-related adverse patient events makes it challenging to determine the extent of the associated risks to patient safety.[6] However, several patient safety events related to the use of laboratory data in EHR systems are identified in the Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database.[7] This database includes mandatory (for death or serious injury) and voluntary adverse event reports involving medical devices, including events associated with EHR systems. One of these patient safety events is described in this paper to illustrate reported safety concerns.

Clinical Laboratory Improvement Advisory Committee (CLIAC) and the Communication in Informatics Workgroup

In response to concerns and questions raised by members of the Clinical Laboratory Improvement Advisory Committee (CLIAC, an HHS-Federal Advisory Committee) about the extent of the challenges with the usability and interoperability of laboratory data in EHR systems, the Laboratory Science Policy and Practice Program Office,[8] Centers for Disease Control and Prevention (CDC), convened the Communication in Informatics Workgroup (CIIWG) in July 2012. This group included experts[9] in the fields of health informatics, laboratory science, and medical practice. Group members shared their individual experiences with laboratory data-related health IT challenges and described potential patient safety issues that should be addressed. A preliminary report from the CIIWG was presented

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4 For the Meaningful Use objective to incorporate clinical lab test results into the EHR as structured data, an example of a CMS EHR performance measure implemented in Stage 1 (2012) is as follows: More than 40% of all clinical lab test results ordered by the EP, or an authorized provider of the eligible hospital or CAH, for patients admitted during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data. Retrieved from http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/2_Clinical_Lab_Test_Results.pdf

5 Hsiao, C. J., & Hing, E. (2012). Use and characteristics of electronic health record systems among office-based physician practices: United States, 2001–2012. NCHS Data Brief, 111. Retrieved from http://www.cdc.gov/nchs/data/databriefs/db111.htm

6 Institute of Medicine (2012). Health IT and Patient Safety: Building Safer Systems for Better Care. The National Academies Press. The ONC commissioned the IOM to establish a committee to explore how health IT assisted care could be made safer so that the potential benefits of Health IT could be realized. This report is a result of that request. Retrieved from http://www.nap.edu/catalog.php?record_id=13269

7 FDA MAUDE - Manufacturer and User Facility Device Experience. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Search.cfm

8 The Laboratory Science Policy and Practice Program Office at CDC has been renamed The Division of Laboratory Programs, Standards and Services at the time of publishing this paper.

9 The Communication in Informatics Workgroup was convened by CDC's Division of Laboratory Science and Standards in Atlanta, GA on July 11–12, 2012.

to the CLIAC in August 2012.[10] The results of the CIIWG report prompted the CLIAC to send a letter to the Secretary of the Department of Health and Human Services in September 2012 highlighting the potential for serious risks to patient safety in the implementation of EHR systems and offered several high level recommendations to mitigate risks.[11] Based upon the CLIAC recommendations and the CIIWG report, the Division of Laboratory Programs, Standards and Services, now in the Center for Surveillance, Epidemiology and Laboratory Services, decided to develop this white paper.

Patient Safety Organizations (PSOs)

Patient Safety Organizations (PSOs) are also identifying patterns of safety concerns associated with the adoption of health IT.[12] For example, ECRI Institute's (formerly the "Emergency Care Research Institute") *Top 10 Health Technology Hazards for 2013* includes four hazards associated with the adoption of health IT.[13] This is a fourfold increase over the one hazard identified by ECRI's Top 10 list for 2012.[14] In addition, the January 2013 report entitled "ECRI Institute PSO Deep Dive on Health Information Technology", indicates that for health IT (or EHR) associated events, laboratory information systems ranked as the fourth most implicated health IT system, representing 22 of the total 171 (13%) events reported by 36 healthcare facilities over a nine week period.[15] Examples identified by ECRI of problem areas across all health IT systems in the report included: inadequate data transfer from one health IT system to another; data entry in the wrong patient record; incorrect data entry in the patient record; failure of the health IT system to function as intended; and configuration of the system in a way that can lead to mistakes. Recognizing that such errors can occur without health IT systems, there is cause for concern as an occasional error in a health IT system can be replicated very quickly across a large number of patients. Combining documented patient safety events with the anecdotal evidence shared by individual laboratory professionals across the U.S. presents enough concern to warrant further investigation and mitigation.[16]

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10 Clinical Laboratory Improvement Advisory Committee (CLIAC), Report on Communication in Informatics Workgroup, CLIAC August 2012 Meeting Summary. See Presentations and Committee Discussion: Report on Communication in Informatics Workgroup. Retrieved from http://wwwn.cdc.gov/CLIAC/Meetings/PastMeetings.aspx

11 Clinical Laboratory Improvement Advisory Committee (CLIAC) (2012, September 26). 2012 Letter from CLIAC to HHS Secretary regarding Electronic Health Records. Retrieved from http://wwwn.cdc.gov/cliac/pdf/2012_0ct_CLIAC_%20to_Secretary_re_EHR.pdf

12 PSOs are part of a national system for providers to voluntarily report medical errors, near misses, and other patient safety events while having assurance that the information will be protected from legal discovery and kept confidential.

13 ECRI Institute (2012, November). ECRI Institute 2013 Top 10 Health Technology Hazards. *ECRI Institute.* Retrieved from http://www.ecri.org/2013hazards. See hazards 4, 5, 7, and 9.

14 ECRI Institute (2011, November). ECRI Institute 2012 Top 10 Health Technology Hazards. *ECRI Institute.* Retrieved from http://www.ecri.org/2012_Top_10_Hazards. See hazard 5.

15 ECRI Institute (2013, January). ECRI Institute PSO Deep Dive: Health Information Technology. *ECRI Institute.*

16 Communication in Informatics Workgroup (CIIWG) meeting, Centers for Disease Control and Prevention, July 11–12, 2012.

WHITE PAPER AND FOCUS AREAS FOR ACTION

The concerns for potential and real patient harm as shared by individual experts, CLIAC, and PSOs prompted CDC to develop this white paper identifying examples of patient safety risks and highlighting how laboratory professionals' expertise can contribute to the development of safer EHR systems. This paper proposes three focus areas where laboratory professionals can contribute their expertise to the improvement of EHR system design, development, and implementation to address laboratory data-related patient safety concerns. These strategies were developed based upon the input received from the members of the Communication in Informatics Workgroup:

1. **Engagement:** Laboratory professionals can provide laboratory expertise for health IT decision-making in the design, development, and implementation of EHR systems at both national and local levels;
2. **Data Integrity and Usability:** Laboratory professionals can guide and maintain data integrity and usability to ensure that laboratory data are accurately presented in the EHR and available at the point of care; and
3. **Innovation:** Laboratory professionals can partner with stakeholders to stimulate innovation in EHR technology and usability to reduce laboratory data-related errors attributed to the use of EHR systems.

These focus areas are described in further detail below.

#1 Engagement

Laboratory professionals can provide laboratory expertise for health IT decision-making in the design, development, and implementation of EHR systems at both national and local levels.

The intersection of laboratory information management, compliance with laboratory regulations, and the usability of laboratory data within EHR systems is extremely complex. Resolving EHR system issues requires collaboration and significant human and capital investment by professional organizations, regulators, and the health IT industry to ensure the integrity and proper use of laboratory data across the spectrum of patient care settings. Health information system developers and implementers need to understand laboratory information management, exchange, stewardship, and display requirements. Expert consultation with laboratory professionals, as well as clinicians who use laboratory data, is critical to bridging the knowledge gap between clinical practice and EHR system technology design and implementation.

For the reasons cited above, the inclusion of laboratory professional expertise in national health IT policy and standards development is an important factor in ensuring laboratory data are well managed and compliant, and in improving the usability of EHR systems for the benefit of patient care. When developing and implementing health IT policies and standards, it is necessary to engage those who use EHR systems to fully understand the potential patient safety consequences. For laboratory

data, these users include both clinicians and laboratory professionals. The active participation of laboratory professionals as part of multidisciplinary teams is essential to improving the safety of EHR systems by identifying and eliminating laboratory data exchange and display errors, as well as supporting compliance with existing and new federal regulations. Laboratory professional organizations can communicate with federal agencies developing policy, certification, and standards, such as ONC and the National Institute of Standards and Technology (NIST) to determine opportunities and mechanisms for their members to get involved in collaborative, multidisciplinary efforts. Healthcare executives and laboratory leaders can also encourage and support the participation of laboratory professionals in the development of national health IT policies and standards.

Participation by laboratory professionals in the development of institutional health IT policies and standards also helps to ensure that patient safety concerns related to laboratory data are considered and addressed at the local level. Laboratory professional input is important since each organization's circumstances and technologies are unique and vary by clinical setting, such as those seen in a private practice, hospital, or healthcare system. Executive and medical leadership at these institutions can develop a multidisciplinary team, including pathologists and other laboratory professionals, to provide their expertise in the development of such policies and evaluate their potential impact on patient care and outcomes. Laboratory professionals serving on such teams can consider whether their institutions' unique needs are appropriately addressed in the development of these local policies. During the implementation of an EHR system or any clinical decision support technology, these teams can use standardized resources to assess its safety and functionality, such as the ONC funded *Safety Assurance Factors for EHR Resilience* (SAFER) Guides.[17,18] The combination of seeking consultation from a multidisciplinary team and using standardized EHR assessment tools will provide tailored advice to healthcare executives on their organization's specific scope of issues throughout the configuration, implementation, use, and evaluation of health IT systems.

Addressing safety concerns related to laboratory data in EHR systems for rural hospitals and community health centers will be particularly challenging because of limited access to health IT expertise and other infrastructural needs. Such health institutions can benefit from existing programs that allow the sharing of expertise, lessons learned, and benchmarks from healthcare settings across the nation. Existing resources are available that support the improvement and use of laboratory health IT, but laboratory professionals may not be aware of these resources. For example, the Laboratory Interoperability Collaborative provides support to hospital laboratories with the technical aspects of EHR system implementation and complying with Meaningful Use requirements.[19] Regenstrief Institute, Inc. offers a free mapping tool for converting local laboratory coding to LOINC.[20,21] To raise the awareness of these and other available resources, professional societies and federal health agencies,

17 The Office of the National Coordinator for Health Information Technology (2012, December 21). Health Information Technology Patient Safety Action & Surveillance Plan for Public Comment. HealthIT.gov. Retrieved from http://www.healthit.gov/sites/default/files/safetyplanhhspubliccomment.pdf. The SAFER Guides were referenced in the ONC's December 2012 Health Information Technology Patient Safety Action and Surveillance Plan released for public comment and are likely to fill an immediate need for such an assessment.

18 Singh, H., Ash, J., Sittig, D. (2013) Safety Assurance Factors for Electronic Health Record Resilience (SAFER): study protocol. BMC Med Inform Decis Mak. 2013; 13: 46. Published online 2013 April 12. doi: 10.1186/1472-6947-13-46. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3639028/

19 Laboratory Interoperability Collaborative (LIC). Retrieved from http://www.labinteroperabilitycollaborative.org

20 LOINC Mapping Assistant (RELMA®). *LOINC from Regenstrief.* Retrieved from http://loinc.org

21 The use of any product names, trade names, images, or commercial sources is for identification purposes only, and does not imply endorsement by the U.S. Department of Health and Human Services.

such as CMS, FDA, and CDC, can collaboratively develop strategies that will connect laboratories and providers in rural and community health centers with available resources.

The list below summarizes actionable ***engagement strategies*** that can be implemented by laboratory professionals.

Engagement Strategies

Laboratory Professionals and Organizations can:

- Provide laboratory expertise for health IT decision making at national and local levels,
- Serve on policy and standards federal advisory committees and the numerous workgroups that support the ONC healthcare initiatives,
- Monitor and submit comments on proposed rules and guidelines from all areas of government that impact EHR implementation and future EHR data use, including those from ONC, CMS, FDA, NQF, NIST, and AHRQ,[22]
- Foster healthcare executive and laboratory leadership support for staff to participate in national collaborative efforts such as ONC's Standards & Interoperability Framework workgroups and other initiatives,
- Work with ONC, NIST, and the Healthcare Information and Management Systems Society (HIMSS) and other policy, certification, and standards development organizations to determine opportunities for collaboration.
- Institute communication networks for the timely distribution of relevant healthcare information and issues, and
- Improve awareness of and connect providers and laboratories with resources that support the improvement and use of EHR systems.

22 National Quality Forum (NQF), National Institute of Standards and Technology (NIST), and Agency for Healthcare Research and Quality (AHRQ).

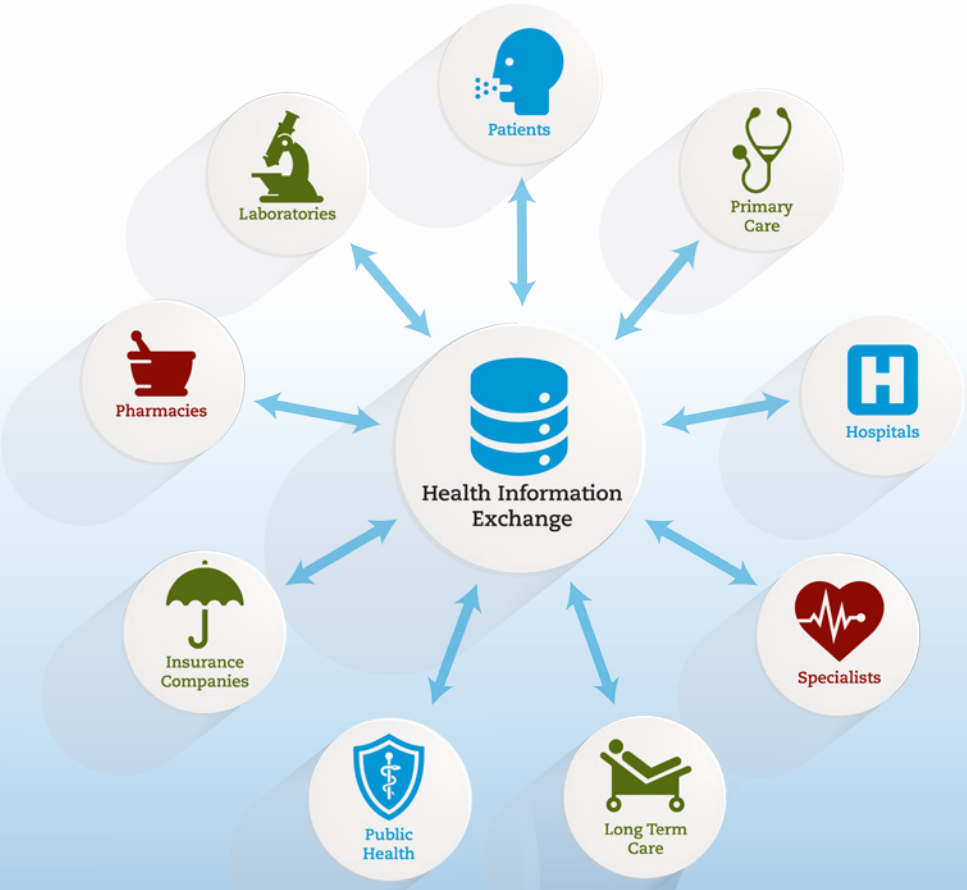
#2 Data and Usability

Laboratory professionals can guide and maintain data integrity and usability to ensure that laboratory data are accurately presented in the EHR and available at the point of care.

Like all medical information, laboratory orders and results contained in EHRs convey information that is inherently private, confidential, and sensitive for patients, their families, and healthcare providers. Patient-specific laboratory data are integral to accurate diagnosis, appropriate treatment, and determining overall patient care decisions. Therefore, assurance is needed that patient-specific laboratory information is provided in a timely manner to the intended recipient, not altered in an exchange between systems (interoperability and fidelity), and displayed in a manner assuring accurate interpretation.

The graphic below shows how laboratory data and other health information can be exchanged with numerous recipients throughout the healthcare system. Laboratory professionals, clinicians, patients, and other stakeholders must be able to trust that the EHR system provides accurate, reliable, and timely information. When this trust is not proven through vigorous usability testing, the resultant patient safety risks can range from negligible to potentially catastrophic. The stories on the following pages illustrate how these consequences can manifest in patient harm.

Health Information Exchange in the Healthcare System



Unconventional Results Display—Delayed Diagnosis and Treatment

A young woman's abnormal Pap smear results went undetected for four years due to a usability issue with her physician's EHR system.[23] *Due to a default setting, the system presented the physician with the patient's previously normal laboratory result and the most recent abnormal result went unnoticed. The young woman's advanced cervical cancer was only detected when she sought treatment for other symptoms that had developed. As a result of the delay in diagnosis and treatment, the young woman had a hysterectomy.*

The EHR system's usability challenge described above was not the sole factor contributing to the sub-optimal care of the patient, but the one that illustrates the need for thorough usability testing when designing, configuring and implementing EHR systems to assure optimized display behavior. Laboratory professionals have specialized knowledge about the test results they generate and the content necessary to inform clinical decisions, and their expertise is critical to developing laboratory data scenarios for usability testing. Laboratory expertise is also needed during the implementation of the EHR system within each organization, such as the physician's office in the example above, to verify that laboratory data are successfully transmitted and accurately displayed on the physician's user-screens. Design, configuration and implementation of an EHR system should include a user-centered assessment of how the new technology will affect existing clinical workflow, and appropriate EHR configuration or workflow modifications being made prior to full implementation. This will ensure that critical steps, such as follow-up for abnormal results are not missed.

23 Singer, S. (2010, June 5). Electronic medical records may cause patient care errors, Florida medical board says. *Palm Beach Post* [Ft. Lauderdale]. Retrieved from http://www.palmbeachpost.com/news/news/electronic-medical-records-may-cause-patient-care-/nL7Yc/

Unexpected Interpretation of "Daily"—Delayed Testing Contributes to Serious Anticoagulant Therapy Risk

The patient story below illustrates how usability errors when ordering a Prothrombin Time/International Normalized Ratio (PT/INR) led to serious patient risk.

A patient being treated with the anticoagulant warfarin was admitted to the hospital.[24] *In order to monitor the patient's warfarin dose, a daily PT/INR test was ordered via the EHR system. Unknown to the clinicians, the EHR system had been programmed to interpret a "daily" draw time at a different time of day than expected. Instead of drawing blood for the test at 6 AM, which was the expected meaning of "daily," the blood would be drawn at 4 PM.*

When the patient's PT/INR value was checked via the EHR system the next day, there was no PT/INR result for that morning nor was there an indication that an order for a PT/INR test was pending. Assuming the PT/INR test had not been ordered, the clinician gave the regularly prescribed dose of warfarin to the patient and reordered the PT/INR test. Later that afternoon, the original daily PT/INR order was drawn and the test results indicated a dangerously elevated PT/INR value indicating a bleeding risk. Once this information was known, the care team was able to adjust the medication dose, lowering the PT/INR. The patient experienced no further symptoms.

Had the patient's PT/INR been performed at the time expected by the ordering clinician, the risk for potentially serious complications associated with excessive warfarin dosing could have been prevented.

The clinician who reported the particular PT/INR incident described above noted that "the computer transformed daily into an oddball time" and that "the average [user] screens…are poorly usable due to deficient format and too many lines of clinically useless information."[25] The usability of EHR system user screens can also contribute to the safety and effectiveness of clinical decision-making and patient care. In this example, there are two usability issues. First, the EHR system was configured with a definition for "daily" that did not match the expectation of the ordering clinician. Second, the content of the user

24 MAUDE Adverse Event Report. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI__ID=1840232

25 *Ibid.*

screen was cluttered. Both issues indicate that there may have been incomplete usability testing and a limited user-centered workflow assessment during configuration and implementation to ensure that the EHR system would support clinical practice expectations.

Patients who rely on laboratory testing to monitor their medication therapy may be particularly vulnerable to errors associated with the interpretation of laboratory orders or results, making even a seemingly minor error potentially life-threatening. The patient case above is one of eight laboratory-related EHR events included in the FDA's MAUDE database at the time of review for this paper. While more data are needed to identify trends and draw specific conclusions, three of the eight reported events (37.5%) were related to anticoagulation therapy. Considering previously documented information on the serious and potentially fatal consequences of PT/INR related incidents,[26] and extrapolating that only a small fraction of EHR incidents are voluntarily reported to the FDA, the percentage is a cause for concern. As stated previously, laboratory professionals have the expertise to assess the usability of EHR system ordering and reporting functions, and should give extra attention to concerns related to high-risk patient testing such as the PT/INR.

Opportunities for Laboratory Professionals to Improve Data Integrity and Usability

Organizations like the ONC, NIST, and HIMSS convene multidisciplinary groups to develop guides[27,28] and other resources to improve the usability, interoperability, and safety of EHR systems. To assess usability during EHR configuration and implementation, the ONC is investing in the development of a series of *Safety Assurance Factors for EHR Resilience* (SAFER) Guides, mentioned previously. These guides, published in January 2014, will assist healthcare providers in assessing the patient safety risks of the ordering and laboratory test result reporting functions in their EHR and other health IT systems.[29] The expertise of laboratory professionals is needed in such assessment efforts to ensure the accuracy and usability of laboratory data in EHR systems.

There are also existing examples of how laboratory professionals are providing their expertise to improve the safety and effectiveness of health IT. A variety of public and private stakeholders with laboratory expertise are currently serving on the ONC's the Laboratory Report Tiger Team and the Standards and Interoperability (S&I) Framework.[30] The Laboratory Report Tiger Team is tasked with making recommendations to ONC that will reduce the cost and burden associated with implementing EHR system interfaces that support laboratory test ordering and results reporting to physician offices. The Laboratory Tiger Team has compiled a list of issues limiting the interoperability and display of laboratory test results in EHR systems. Some examples are provided on the following page.

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26 Public Health Dispatch: Adverse Events and Deaths Associated With Laboratory Errors at a Hospital, Pennsylvania, 2001. *Centers for Disease Control and Prevention*. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5033a4.htm

27 Lowry, S. Z., Quinn, M. T., & Ramaiah, M. (2012). A Human Factors Guide to Enhance EHR Usability of Critical User Interactions when Supporting Pediatric Patient Care. NIST Interagency/Internal Report (NISTIR) - 7865, 46 pp. doi:10.6028/NIST.IR.7865

28 Osheroff, J. A., Teich, J. M., Levick, D., & Et al. (2012). Improving Outcomes with Clinical Decision Support: An Implementer's Guide (2nd ed.). US: Healthcare Information and Management Systems Society. Retrieved from http://www.nist.gov/customcf/get_pdf.cfm?pub_id=911520

29 See the SAFER Guides published on the ONC's website (January 2014): http://www.healthit.gov/policy-researchers-implementers/safer

30 The ONC's Standards & Interoperability (S&I) Framework website: http://www.siframework.org/

Examples of EHR Interoperability and Display Issues

- Hard-coding of data elements in the EHR system, such as reference ranges and units of measure, which can cause errors when the reporting laboratory does not use the same values;
- Truncation of text and long number strings causing incompleteness of data when the laboratory and EHR system have different maximum character limits for fields;
- Chronological versus reverse chronological display of test results causing the most recent reports to display at the end rather than the beginning of a user screen;
- Allowable special characters (e.g., #, &, $) causing unusual system behaviors, such as displaying gibberish or stopping interface communications;
- Inconsistencies in design of alerts, flags, and color-coding between systems causing user confusion; and
- Inconsistencies between the printed version of laboratory reports and the user-screen display causing user confusion.

The Standards & Interoperability (S&I) Framework is a collaborative community of volunteer participants from the public and private sectors who are focused on providing the tools, services and guidance to facilitate the functional exchange of health information. Examples include technical implementation guides for computer interfaces. Recommendations from the Tiger Team have created additional S&I Framework workgroups to address the specific standards needed for laboratory data exchange. A functional behaviors guide for Laboratory Orders and Results Interfaces is currently under development and volunteers are being solicited for a second initiative to create an agreed upon set of laboratory order codes, named the "a LOINC Order Code Project".[31] Laboratory professionals knowledgeable in any key area, including laboratory operations, CLIA or accreditor requirements, or health IT standards, are desirable volunteers for participating on an S&I Framework workgroup.

EHR systems provide significant advantages for managing laboratory information as structured data compared to paper records or electronic versions of paper records. The use of structured data substantially improves accessibility and portability of health information, local and national surveillance programs, and clinical decision support tools. Thus, it is important for laboratory and other healthcare professionals to invest their time and effort now in the development of consensus based information exchange standards. Existing unintended system and display behaviors such as those listed above need to be resolved to fully realize the benefits of EHR systems. To further promote user-centered design features that support clinical practice and workflows, specific laboratory data usability guidance and related resources are needed. Laboratory professionals can seek out and create opportunities to collaborate with other stakeholders to develop guides and practice models to improve EHR systems and Clinical Decision Support (CDS) tools.

31 a LOINC Order Code Project on the S&I Framework Wiki: http://wiki.siframework.org/a+LOINC+Order+Code+Join+the+Initiative

The need to support development of health IT for laboratory data has been recognized by several professional organizations and the CDC. The College of American Pathologists published a white paper with guidance for laboratory leaders regarding laboratory information system interfaces with EHRs.[32] The Association for Pathology Informatics (API) also published a white paper with a companion toolkit for assessing functionality of laboratory information systems, enabling meaningful comparisons between different systems when purchasing decisions are being made.[33] APHL has also published a laboratory informatics self-assessment guide for public health laboratories which is equally applicable to clinical laboratories.[34] An online resource for coding includes the Laboratory Interoperability Collaborative, which was developed by the American Hospital Association and the College of American Pathologists under a grant from the CDC.[35]

The list below summarizes actionable ***data integrity and usability strategies*** that can be implemented by laboratory professionals.

Data Integrity and Usability Strategies

Laboratory Professionals and Organizations can:

- Engage with EHR developers on the development and design of laboratory-related EHR system features, such as critical results alerts,
- Provide laboratory expertise for assessing and improving the interoperability and usability of EHR systems at both organizational and national[36] levels, and
- Facilitate rigorous assessment of the usability of laboratory test ordering and reporting functions in the EHR for high-risk patient testing.

#3 Innovation

Laboratory professionals can partner with stakeholders to stimulate innovation in EHR technology and usability to reduce laboratory data-related errors attributed to the use of EHR systems.

There is a critical need for innovation to improve the usability of EHR systems and benefit patient outcomes. The ONC's EHR certification criteria establish ground level requirements, providing developers the foundation for new and innovative health IT systems. With an infusion of workflow engineering and creative vision in the design and development of health IT, there is an opportunity to bring the future promise of sophisticated analytics into today's healthcare system. Such inventiveness could reduce delays in treatment and potentially save lives, as demonstrated by the following patient scenario.

32 Laboratory Interoperability Best Practices, The College of American Pathologists. Retrieved from http://www.cap.org/apps/docs/committees/informatics/cap_dihit_lab_interop_final_march_2013.pdf

33 A Methodology for Assessing Functionality and Enabling Comparisons Among Competing Systems, Association for Pathology Informatics. Retrieved from http://www.pathologyinformatics.org/toolkit

34 Laboratory Efficiencies Initiative Informatics Self-Assessment Tool, CDC. Retrieved from http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Pages/Informatics.aspx

35 The Laboratory Interoperability Collaborative. Retrieved from http://labinteroperabilitycollaborative.org/index.php

36 National, voluntary participation opportunities include development of health information exchange standards on the ONC's Standards & Interoperability (S&I) Framework: http://www.siframework.org/

Innovation Needed for Earlier Detection of Emergent Conditions

A 10-year old girl presented to the emergency department with vomiting, fever and an elevated pulse rate. She also had multiple bug bites on her legs, some of which were red and swollen from scratching. Based on her symptoms, doctors diagnosed her with the flu and she was sent home. Two hours after she was discharged, her laboratory results revealed an elevated white blood cell count (WBC). This additional information indicated the need to promptly rule out a serious bacterial infection. However, the laboratory result was not reviewed in conjunction with the girl's clinical findings.

The girl's condition worsened and she returned to the emergency department the next day. She was admitted to the ICU with severe multiple system organ failure, placed on IV antibiotics and died shortly thereafter from septic shock and staphylococcal bacteremia.

This patient story illustrates the opportunity and critical need for innovation in health IT. Innovative clinical decision support (CDS) tools can be created to analyze patient records automatically when new information is received in the EHR, such as the elevated WBC in this example. If such CDS tools existed, the reduction in time to diagnosis and treatment for an acute condition could be life-saving. Emergent conditions like sepsis can be detected earlier, prompting clinicians to further evaluate the patient. A UC Davis study performed on retrospective aggregate patient data also concluded that patients at risk for sepsis could be identified for prompt treatment through computerized analysis of clinical indicators.[37]

Innovation in EHR system test result management functionality could also make an immediate impact on patient safety. Some EHR systems include an alert feature to notify physicians of different types of critical situations that require management or immediate attention. When functioning appropriately, these alerts can support the timely interpretation of laboratory test results, which leads to timely diagnosis and treatment of conditions. When there are too many alerts (alert fatigue), or when the alerts do not provide meaningful information, the alerts may have the opposite effect. The implications of electronic test result management tools, like alerts, are just beginning to be understood.[38] A recent study found that current capabilities for test result management are not yet adequate and that new EHR system features will need to be designed and developed to address patient safety issues.[39]

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37 Gultepe E, et al. J Am Med Inform Assoc 2014;21:315–325. doi:10.1136/amiajnl-2013-001815

38 Singh, H., Spitzmueller, C., Peterson, N. J., & Et al. (2012). Primary care practitioners' views on test result. J Am Med Inform Assoc. doi:10.1136/amiajnl-2012-001267. Retrieved from http://jamia.bmj.com/content/early/2012/12/24/amiajnl-2012-001267.full.pdf

39 *Ibid*

Laboratory professionals and other stakeholders can consider being more intentional in supporting the advanced use of information and innovation now so that future EHR systems have intelligent features to help clinicians promptly identify emergent conditions and save lives. A forum for collaboration could be a key strategy to help. This forum could take the form of a national collaboration panel including laboratory professionals, human-factors engineers,[40] health IT designers, informaticians, clinicians, and EHR system users. Laboratory professional organizations can champion collaborative efforts and support research agendas that will provide more detail on the issues surrounding the use of laboratory data in EHR systems, eliminating barriers to the free-flow of information on patient safety risks and EHR system-related errors. Such collaboration could lead to stimulating innovative ways to display laboratory and other data so that the right information is available at the right time and in the right format.

Innovations in health IT are needed now. To enable collaboration, access to data on EHR system-related usability and interoperability errors is needed. More information can help stakeholders understand the scope and context of these errors in relation to patient safety and propose solutions. Unfortunately, there are barriers to the free flow of information regarding EHR system-related errors and related patient safety risks. Non-disclosure agreements and other similar practices of the health IT industry prevent sharing of information on patient safety risks for certain EHR systems.[41] Efforts by the Agency for Healthcare Research and Quality (AHRQ) are currently underway to provide a mechanism for reporting these adverse events related to use of the EHR, but no current forum exists where all stakeholders can collectively learn from the errors of their colleagues' systems.[42]

Legal barriers and the lack of aggregate data on EHR system-related patient safety events limit understanding of the scope and context of errors in EHR systems which, in turn, can limit or delay innovation. More data on real and potential EHR system-related errors are needed from credible, vetted sources to support assessment of EHR systems, identify patterns of safety concerns, and make improvements. In the interim, professional laboratory organizations could encourage laboratories to participate in the assessment of EHR systems and to voluntarily report issues to PSOs that offer confidentiality and legal protection.[43]

Patients also increasingly expect a viable method to access their medical information in a timely, reliable, secure, and private manner. This demand is likely to increase with implementation of the "Patient Access" rule, amending CLIA and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to provide patients access to their test reports. Laboratory professionals can help lead the effort to innovative patient access to laboratory information and can produce guidelines for the design of patient portals. Patients would also benefit from resource materials that would help to educate and inform their healthcare decision-making. Laboratory professionals can partner with

40 Human factors engineering is defined by the Agency for Healthcare Research and Quality's Patient Safety Network as ". . . the discipline that takes into account human strengths and limitations in the design of interactive systems that involve people, tools and technology, and work environments to ensure safety, effectiveness, and ease of use." Retrieved from http://psnet.ahrq.gov/primer.aspx?primerID=20

41 Roth, J. H. (2011). Regulating Your Medical History Without Regulations: A Private Regulatory Framework To Electronic Health Record Adoption. *Boston University Law Review,* 91(6), 2103-2129. Retrieved from http://www.bu.edu/law/central /jd/organizations/journals/bulr/volume91n6/documents/ROTH.pdf

42 IOM, 6.

43 Middleton, B., Bloomrosen, M., Dente, M. A., Hashmat, B., & Et al (2012). Enhancing patient safety and quality of care by improving the usability of electronic health record systems: recommendations from AMIA. *Am Med Inform Assoc.* 2013;20(e1):e2–8. doi:10.1136/amiajnl-2012-001458. Retrieved from http://jamia.bmj.com/content/20/e1/e2. See recommendation 4b.

stakeholders and stimulate innovation by convening experts and developing guidelines for improved patient access to laboratory data.[44] Laboratory professionals can help lead the effort to innovative patient access to laboratory information and can produce guidelines for the design of patient portals. Patients would also benefit from resource materials that educate and inform their healthcare decision-making. Laboratory professionals can partner with stakeholders and stimulate innovation by convening experts, eliminating barriers to the free-flow of information on EHR system-related errors and patient safety risks, and developing guidelines for improved patient access to laboratory data.

The list below summarizes actionable ***innovation strategies*** that can be implemented by laboratory professionals.

Innovation Strategies

Laboratory Professionals and Organizations can:

- Champion collaborative efforts and support research agendas to provide more detail on laboratory data-related patient safety concerns in the EHR,
- Collaborate with human factors engineers, EHR system interface designers, and others to advance innovation and the usability of laboratory data displays,
- Encourage participation in EHR system assessments and voluntary reporting of EHR-related issues to PSOs, and
- Lead innovation in patient access to laboratory information.

44 44: CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports – Final Rule (79 FR 7289): http://www.gpo.gov/fdsys/pkg/FR-2014-02-06/pdf/2014-02280.pdf

SUMMARY

In this early stage of EHR system adoption, laboratory professionals have a unique opportunity to help create health IT systems that enable optimized healthcare decision making, improve the timeliness, consistency and quality of care, add value for providers and patients, and save lives. This paper proposes that laboratory professional organizations and laboratory professionals focus their efforts on the following to benefit the development of a health IT infrastructure and ensure the safe and effective use of laboratory information in EHR systems:

1. **Engagement:** Laboratory professionals can provide laboratory expertise for health IT decision-making in the design, development, and implementation of EHR systems at both national and local levels;
2. **Data Integrity and Usability:** Laboratory professionals can guide and maintain data integrity and usability to ensure that laboratory data are accurately presented in the EHR and available at the point of care; and
3. **Innovation:** Laboratory professionals can partner with stakeholders to stimulate innovation in EHR technology and usability to reduce laboratory data-related errors attributed to the use of EHR systems.

The U.S. healthcare system is transforming at an unprecedented pace with renewed focus on patient wellness, disease prevention, and provider accountability. This transformation is being facilitated by the rapid expansion of health IT, which is bringing new challenges and opportunities for providers and patients with the interpretation and use of laboratory information. Our nation's patients are also our families, friends and loved ones. They deserve our professional commitment to the thoughtful design of and innovation in health IT systems to achieve the future vision and full intent of Meaningful Use. The absence of clinical input in the development and implementation of health IT can produce unintended consequences and jeopardize patient safety.

CONCLUSION

Participation and collaboration are key. National agencies can work together and build consensus on the patient safety priorities.[45] Laboratory professionals and organizations can support the future vision and help improve the overall quality of healthcare for individual patients and the national population. To do so, laboratory professionals can educate themselves on the promises and pitfalls of EHR systems, and proactively engage in creating the solutions essential to sustaining the transformation of the U.S. healthcare system. In the best case scenario, the laboratory profession, laboratory industry, clinicians, and governmental agencies would work together to create and promote the implementation of standards, policies, practices, and services that improve the use of laboratory information throughout the patient encounter.

Understanding and integrating the expertise and perspective of laboratory professionals in the development of EHR systems is critical to ensuring the safety and effectiveness of laboratory data in EHR systems and establishing a solid foundation for a health IT infrastructure to benefit this nation's citizens now and for future generations.

45 Sittig, Dean F., Singh, H. (2012). Electronic Health Records and National Patient-Safety Goals. N Engl J Med. doi: 10.1056/NEJMsb1205420. Retrieved online May 2014: http://www.nejm.org/doi/full/10.1056/NEJMsb1205420

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