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DEBATE-COMMENTARY

Editorial

Interoperability: What Is It, How Can We Make It Work for Clinicians, and How Should We Measure It in the Future?

As the result of the federal incentive program, electronic health records have been widely adopted in the United States, with levels of adoption exceeding 90 percent in both the inpatient and outpatient settings (Henry et al. 2016). However, it is clear that health information exchange has lagged behind (Holmgren and Adler-Milstein 2017). Further, we have been disappointed to date in the lack of impact that this technology has had on health care delivery. Adoption of electronic health records did not consistently improve quality according to data gathered after Stage 1 of meaningful use (MU) (Kern et al. 2013; Samal et al. 2014). Transition from Stage 1 to Stage 2 of MU did not consistently produce the expected improvements in quality (Levine et al. 2017). There are many reasons that quality is not getting better so far with the new technology, but one is that health information exchange performance has lagged far behind performance on most other MU objectives (Holmgren and Adler-Milstein 2017).

Interoperability has been defined by the Institute for Electrical and Electronics Engineering in the IEEE Standard Computer Dictionary as "the ability of two or more systems or components to exchange information and to use the information that has been exchanged" (1991). That is different from health information exchange (HIE), which merely requires an ability to share information electronically. Notably, you can have HIE without true interoperability—the latter requires an ability to use shared data, and not just exchange information.

Both adoption of EHRs—which implies electronic collection of information—and interoperability—suggesting you can move data around when you need to—are important. Early economic models of electronic health record adoption suggest the vast majority of financial benefits occur if interoperability is present. For example, a study by the Center for Information Technology Leadership (CITL) suggested that the country would save $78 billion annually if health information exchange was in place, for a number of reasons including the reduction of redundant tests (Walker et al. 2005). A key finding of the CITL work was that nearly all the benefit comes when coded data are exchanged—if only uncoded information, like PDFs of test results, is exchanged, then there is little if any financial benefit. Another RAND model looking at savings associated with both interoperability and EHR implementation projected financial benefits of $81 billion annually from electronic record implementation and networking (Hillestad et al. 2005). Not envisioned in 2005 was the opportunity for the development of novel clinical services built using interoperable data resources, such as high-fidelity "apps" to help patients with the care of chronic conditions.

Clinicians understand information exchange from their experiences in practice. For example, primary care physicians often want to review key pieces of information like the results of a stress test performed in an emergency department (ED) or the findings of a biopsy from a remote hospital near where a patient spends the winter. Sometimes a Summary of Care Record (SCR) is available, but it may or may not include key information like a new diagnosis of a myocardial infarction after the stress test in the emergency department. Less obvious, but perhaps not less important, are the benefits of granular data —like a change in patient's creatinine level during a hospitalization. Each of these examples illustrates exchange, but one relies on a free text interpretation of a diagnostic stress test, one relies on a coded problem in the problem list, and one relies on a detailed free text discharge summary, coded laboratory data, or both. All of these types of data are now commonly exchanged between health care settings, although rarely are all transmitted in toto.

This is not to say that much progress has not been made. We now have a single standard for many key types of clinical data, as well as standards like the Summary of Care document that enable summaries to be sent. But we still need to begin to assess how often these summaries are received, whether the

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data are intelligible to providers, and whether providers can find information when they need it, but perhaps more important, to find things that they do not know they need. In our EHR today, outside information is often available, but it is almost never accessed because so much of it is redundant with what is already in the EHR; even important new findings are not highlighted and would often be missed.

Interoperability has worked well in other areas in our digital economy. You can take a bank card from the United States to the other side of the world, and in most places, extracting money from a cash machine is reasonably straightforward. But health care information is different than banking in many ways. First, it is much more complex—most inpatient electronic records today include over 5,000 variables, and new variables are added all of the time. It has been hard to develop standards for all of these data elements, and even more difficult to ensure that the standards are actually implemented consistently (Hammond 2005; Hammond, Jaffe, and Kush July 2009; Schuff 2014; Ratwani et al. 2015, 2017). The current state of affairs lags far behind banking —in most communities in the United States today, you cannot access a radiology scan from another hospital in the same town or city, much less one from another country. Generally, even if you are able to find a piece of information, you have to know you are looking for it and actively "pull" the information.

The largest and most rigorous academic studies in the United States on the extent of exchange and interoperability have been carried out by Adler-Milstein and colleagues (Adler-Milstein, Bates, and Jha 2011; Furukawa et al. 2014; Adler-Milstein, Lin, and Jha 2016; Holmgren and Adler-Milstein 2017). The current study in HSR (Lin, Everson, and Adler-Milstein 2018) represents the latest in this series. These authors have provided a very useful assessment of the extent to which exchange and interoperability are (or are not) progressing. The main metric in this particular analysis is the rate of SCR exchange during transitions from hospital settings. Their key finding was that SCRs were electronically exchanged in an average of 41 percent of transitions. While that is a start, it is still a low proportion, especially considering that 85 percent of hospitals reported the capability to electronically exchange data and providers attesting to Stage 1 MU have generally reported performance in the 90–100 percent range (Wright et al. 2014).

In the big picture, this figure should be 100 percent, regardless of the provider organization. In the Lin study, 5 percent of hospitals are already sending SCRs 90–100 percent of the time. The authors explored factors correlated with the 156 hospitals which were sending SCRs over 80 percent of the time and found that hospitals with Cerner or McKesson were less likely to be in the high-performance group. Government-owned hospitals and nonprofits were more likely to be in the high-performance group.

In terms an assessment of interoperability, any analysis relying on a single metric like SCR exchange necessarily has important shortcomings. Using this measure, we cannot determine data types and formats included in the SCRs, or whether the data were coded. We also cannot determine whether the recipients received the SCR's, and most important, whether the recipients were able to extract the information they needed from a clinical perspective. Furthermore, as the authors noted, this study was limited to hospitals although the majority of SCR recipients were outpatient providers, and so this study is only looking at one side of the exchange.

There are several ways in which interoperability rather than exchange could deliver clinical benefit without overwhelming clinicians. First of all, new information could be "pushed" rather than "pulled" to providers. This should be done in a way that shares information seamlessly and only generates clinical alerts selectively in terms of the volume of messages and the selection of the person targeted for the information (rather than sending the same information to multiple people). High volumes of messages and sending the same information to multiple people are both associated with lower likelihood of response to the information (Singh et al. 2009; Murphy et al. 2012).

Second, as mentioned previously, coded data are superior to uncoded data, but data standards are not yet functioning in a clinically beneficial way. For example, there are many ways to code very similar problems, so reconciliation of two versions of a problem list is still a manual process. ICD-10 has added a layer of specificity to codes that is not clinically meaningful and slows clinicians down with additional clicks, rather than creating the infrastructure to automatically aggregate and organize diagnoses according to clinical meaningfully categorizations (Feblowitz et al. 2011; Agha et al. 2014). Even coded laboratory data, which have been transmitted in standardized formats for decades, can contain nonstandard data elements. For example, in a project where we extracted numeric estimated glomerular filtration rates and numeric urine albumin-to-creatinine ratios, our laboratory information system output nonstandard text strings for ">60" and "Below Assay"(Samal et al. 2017).

From the policy perspective, the main approach to promoting interoperability has been certification. Vendors are required to certify their products for the hospitals and providers who use them to qualify for meaningful use incentives. But this system can be gamed. In a shocking case, eClinicalWorks, one of the largest U.S. HIT vendors in the outpatient setting, agreed to pay $155 million in fines to settle a False Claims Act lawsuit. The government alleged that the company hard-coded the 16 medication codes that were required for certification and did not load the thousands of RxNorm codes describing most medications (Gottlieb, Maida, and Polacheck 2017). Without these codes, no eClinicalWorks customer could have exchanged medication-related information successfully with other providers. The extent to which such gaming is commonplace is uncertain. This episode has eerie parallels to Volkswagen's gaming with respect to auto emissions, which was long-standing. This clearly flouted U.S. regulations and resulted in a $2.8 billion fine (Snavely 2017).

An alternative or complementary regulatory approach would be to set up conformance testing, in which messages including key data like laboratories, medication lists, problems, and radiology results are sent to a third party for independent validation of interoperability. Several use cases should be specified to validate the transmitted messages. The first step of validation would be to compare the data in the sender's EHR with the data in the interoperability document to ensure accuracy and completeness. Problem lists, for example, should include all entries without duplicates. The next step would be to view the data in the receiver's EHR in the same way that an end-user would normally interact with the information in a clinical setting. This would not resolve all interoperability measurement issues. However, conformance testing would improve the likelihood that some key pieces of data are coded and intelligible across platforms, and it would make it harder to game the system.

There is ample precedent for this type of role for the federal government in establishing standards. For example, in the early 1800s, there were issues with the divergence of weights and measures used in different port city customs houses. An 1832 report to the U.S. Senate led to the development of the Dearborn balance and centralized assessment of the weights and measures from several customs houses, which was an early example of conformance testing (Congress, Gales, and Seaton 1835).

Overall, more research is needed to facilitate interoperability. Specific questions that should be addressed include evaluation of the best metrics for assessing the functionality of health information exchange, how often recipient needs are met, whether providers are able to get the data they need, what approaches can be taken to enable reconciliation of aggregate data like problem lists and medication lists, and the use of analytics to identify important new information in these data streams. To ensure that expected cost savings are realized further downstream, we must evaluate the impact of transmitted data on the efficiency of care, in terms of reducing redundant testing and its associated harms to patients and facilitating new models of care such as "hospital at home." Studies could address how often key pieces of data are found or missed, and time-motion studies could assess the speed with which data can be accessed. The utility of the data for clinical care and for health services research should be compared to the current state. Qualitative work is needed in addition to quantitative analyses, addressing questions around the usability of data that have been exchanged.

In conclusion, while there has been great progress in HIT adoption, in both the inpatient and outpatient settings, information exchange and interoperability remain poor. Using interoperability to improve clinical care, clinical decision support, and performance measurement will require substantial investments in data normalization and evaluation for specific use cases. These efforts will likely require a stronger push from the federal government. The new 21st Century Cures legislation took a big step in this direction by prohibiting data blocking by either providers or vendors. The ONC will also continue to target interoperability (Rucker 2017).

We have made a huge investment as a nation in HIT, which promises to be one of the keys to improving value in health care. Much more work is needed to get to the next level with respect to health information exchange, but there is light at the end of the tunnel with respect to interoperability. The end game will be getting information to clinicians and patients in ways that improve care.

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Appendix SA1: Author Matrix.