

TECHNOLOGY

CLINICAL UPDATE IN CLINICAL INFORMATICS—PART II

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In the August 2018 *SGIM Forum*, we coauthored the first of a series on Clinical Informatics, inspired by a live Clinical Update session at this year's 2018 SGIM Annual Meeting. In brief, each article in this series summarizes key papers in clinical informatics for generalists published within approximately the last year. The complete methods for journal and article selection are described in the August 2018 article.¹

In the previous article, "Clinical Update in Clinical Informatics—Part I," we summarized publications in the year prior the annual meeting that were relevant to a currently popular topic: desktop medicine. In this article, we focus on policy recommendations for electronic health records and health information technology. In the discussion, we highlight real examples of high-level policy changes that impact the health data ecosystem.

Case Vignette

Mr. Shah is a 55-year-old male, with essential hypertension on lisinopril, who moves to Denver, and is experiencing shortness of breath a few times in the past week. He selects a new primary care physician and schedules an appointment. He does not have his medical records from his last physician. He receives a letter in the mail welcoming him to the new practice, containing information about his new doctor and the practice group. Enclosed also is a paper form that has questions about his medical history. He is to complete this and bring it to his upcoming visit.

Policy Recommendations

The vignette describes a common clinical scenario in which a patient and physician express several information needs towards a common task of having an in-person office visit to establish primary care. This vignette is loosely based on one presented in a key paper published by Adler-Milstein et al. in April 2017² that presents high-level policy recommendations as a potential roadmap for health information technology (IT) and electronic health

record (EHR) policymaking. The paper is the result of a policy invitation of the American Medical Informatics Association (AMIA), which assembled clinical informatics experts to outline "goals and near-term achievable actions...to enable the health IT ecosystem to meet the acute needs of modern health care delivery."

Adler-Milstein et al. describe the needs of the health IT ecosystem from the perspective of multiple stakeholders: patients, physicians, researchers, and innovators. For example, the authors go beyond identifying gaps in the patient experience, such as having online scheduling capabilities, electronically transmitting personal health records, or collecting health data (patient-generated health data, or PGHD); to enable these types of functionalities, the authors suggest policy updates, such as clarifying HIPAA requirements to ease patient access to their health records or to their PGHD from wearables and apps. In the vignette, supportive IT infrastructure, incentivized by appropriate policy, would facilitate Mr. Shah's access to his health records and their transmission electronically to his new physician; further, he could easily track his own biometric data and provide medication and health status updates electronically to his new physician.

This paper is aligned with but broader in scope than a position paper that the AMIA EHR Task Force published in 2015 describing the current state of EHRs and making five high-level recommendations about the future of EHRs.³ Many of those recommendations, such as those pertaining to a call for simplifying documentation, refocusing regulation of EHRs, ensuring that EHRs support patient-centered care, and other recommendations, have also been reframed in the 2017 paper partly as issues concerning physicians² and discussed in other organizations' position papers.⁴ Concerning researchers and innovators as stakeholders, Adler-Milstein et al. recommend the development of a policy framework that assures that appropriate data is used for appropriate

continued on page 2

**TECHNOLOGY** (continued from page 1)

reasons, with appropriate patient consent and agreed upon terms.

Finally, an editorial by Labkoff and Sittig in June 2017 focuses on needed safety surveillance of EHRs and clinical decision support (CDS) knowledge sources by proposing the concept of a Health Information Technology Safety Center.⁵ That is, they comment that with the rapid and widespread usage of EHR and CDS systems, a health IT safety center could collect, investigate, and disseminate learnings from challenging EHR-related safety issues.

Discussion

A real-life example of a policy framework relating to appropriate consent for data usage, enacted in May 2018, is the European Union's General Data Protection Regulation (GDPR). The GDPR applies not only to health data but also to all consumer data in the EU—including non-EU organizations who engage in the collection and usage of data from EU-based users. According to the European Commission, with GDPR in place, the general principle is that no data processing is done unless necessary, for example, for reasons of public interest or where the subject has given explicit consent. In practice, this means that companies offering mobile apps, devices, and other healthcare technologies collecting data from EU users must comply with GDPR or risk facing very expensive fines. This includes hospitals and healthcare systems. In the United States, California governor Jerry Brown signed the Consumer Privacy Act, also a digital privacy law, in June 2018; considered a Californian version of GDPR, the law is expected to go into effect in January 2020.

All of these papers touch upon components of a key concept in clinical informatics: the learning health

system. According to an Institute of Medicine report on Digital Infrastructure for the Learning Health System, a learning health system is designed to both generate and apply best evidence in the provision of high-value, patient-centered care, driving scientific discovery as a natural extension of patient care and ensuring innovation, quality and safety in health care. The learning health system should include infrastructure and policies supportive of secondary uses of EHR and other patient data—importantly, with a focus on value for each patient *and* without undue burden on clinicians—such as quality measurement and improvement, safety monitoring, public health surveillance and management, basic and clinical research, and healthcare innovation.

FAIR data principles, published in 2016, can accelerate the achievement of the learning health system. FAIR defines a set of principles to enhance the Findability, Accessibility, Interoperability, and Reusability of all types of digital objects, such as electronic health care records, clinical guidelines, and predictive algorithms.⁶ The FAIR principles suggest, for instance, that such digital resources should have high quality metadata, unambiguous licensing, adhere to data standards, and follow community expectations. The FAIR principles have been widely adopted across global communities, including governments, governing bodies, publishers, and funding bodies. Consequently, these principles offer a sensible framework for the design of digital infrastructures to support the learning health system and its components, towards meeting the data needs of healthcare stakeholders—patients first and foremost, but also healthcare professionals, researchers, and innovators.

The next article in this series will

focus on clinical decision support systems and population health.

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