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Research and Applications

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Crossing the health IT chasm: considerations and policy recommendations to overcome current challenges and enable value-based care

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ABSTRACT

While great progress has been made in digitizing the US health care system, today's health information technology (IT) infrastructure remains largely a collection of systems that are not designed to support a transition to value-based care. In addition, the pursuit of value-based care, in which we deliver better care with better outcomes at lower cost, places new demands on the health care system that our IT infrastructure needs to be able to support. Provider organizations pursuing new models of health care delivery and payment are finding that their electronic systems lack the capabilities needed to succeed. The result is a chasm between the current health IT ecosystem and the health IT ecosystem that is desperately needed.

In this paper, we identify a set of focal goals and associated near-term achievable actions that are critical to pursue in order to enable the health IT ecosystem to meet the acute needs of modern health care delivery. These ideas emerged from discussions that occurred during the 2015 American Medical Informatics Association Policy Invitational Meeting. To illustrate the chasm and motivate our recommendations, we created a vignette from the multistakeholder perspectives of a patient, his provider, and researchers/innovators. It describes an idealized scenario in which each stakeholder's needs are supported by an integrated health IT environment. We identify the gaps preventing such a reality today and present associated policy recommendations that serve as a blueprint for critical actions that would enable us to cross the current health IT chasm by leveraging systems and information to routinely deliver high-value care.

Key words: policy, health reform, AMIA

BACKGROUND AND SIGNIFICANCE

While great progress has been made in digitizing the US health care system, today's health information technology (IT) infrastructure remains largely a collection of systems that are not designed to support a transition to value-based care. Indeed, the vast majority of hospitals and ambulatory providers have electronic health record (EHR) systems, yet many continue to use fax and phone to exchange health information across the care continuum.[1] In addition, the pursuit of value-based care, in which we deliver better care with better outcomes at lower cost, places new demands on the health care system

that our IT infrastructure needs to be able to support. Provider organizations pursuing new models of health care delivery and payment are finding that their electronic systems lack the capabilities needed to succeed. The result is a chasm between the current health IT ecosystem and the health IT ecosystem that is needed. Both the technologies themselves and the application of those technologies and the data they contain urgently need improvement to support the transition to value-based care. The existing obstacles are largely not knowledge barriers, but execution barriers. That is, we know what needs to be done but not necessarily how best to do it in terms of which specific actions should be pursued by which specific stakeholders. And while the barriers to successful execution are considerable and require coordinated multistakeholder action, they could, and should, be tackled with concerted, nonheroic efforts.

In this paper, we identify a set of focal goals for which near-term achievable actions to meet those goals would enable the health IT ecosystem to better meet the acute needs of modern health care delivery. These goals were identified in discussions that occurred during the 2015 American Medical Informatics Association (AMIA) Policy Invitational Meeting, held September 17–18, 2015. In this paper, we advance these goals by making high-level policy recommendations that could serve as a blueprint for future policymaking. We purposefully avoided consideration of a long-term vision made possible with breakthrough advances in technology, a major policy overhaul, or other changes that are either uncertain or very difficult. Instead, goals and associated policy recommendations are presented in 3 sets that reflect the differing needs of stakeholder groups essential to the delivery of value-based care.

To illustrate the chasm and set the stage for our recommendations, we created a vignette from the multistakeholder perspectives of a patient, his provider, and researchers/innovators; the vignette is included as a Supplementary Appendix to the paper. It describes an idealized scenario in which each stakeholder's needs are supported by an integrated health IT environment that is ubiquitous. That is, aspects of the idealized scenario exist today in certain places within our delivery system (and these demonstrations informed development of the scenario), but they are typically confined to a given provider or delivery system rather than widespread across our delivery system. We identify the gaps that prevent the idealized scenario from being a widespread reality today, and present associated goals and actionable policy recommendations that should be urgently pursued to help cross the current health IT chasm by leveraging systems and information to improve care processes and outcomes within a value-based framework.

SECTION 1: PATIENT PERSPECTIVE

In the vignette, patients have full and ready access to their data, can actively contribute to their care, and can easily participate in research. Despite progress in patient-centered care and participant engagement in research, key gaps remain between the vignette and our current health IT ecosystem (Table 1).

Policy recommendations

Due in large part to federal requirements under the EHR Incentive Program, also known as Meaningful Use, >96% of hospitals[4] and >50% of physicians[5] have some informatics tools they need to enable patient access to health information, contribute to their care, and engage in research. Additional functionalities will be required beginning in 2018 for hospitals participating in Meaningful Use (MU) and for eligible clinicians participating in the merit-based incentive payment system, such as requirements meant to spur more contribution of patient-generated health data (PGHD) and patient access to data through application programming interfaces (APIs). While API efforts hold promise, they are nascent and uncertainties remain about how their technical specifications and governance will inhibit or facilitate patient data access.

Similarly, efforts such as OpenNotes are helping patients access and contribute to their own records and have been found to improve care quality and patient engagement,[6] but standards for PGHD are generally nonexistent. Facilitation of patient participation in research is also lacking. Most commercial EHRs lack key functionality required by a registrar-based consent process,[7] and they do not readily allow for prospective clinical trial participation based on patient characteristics. The ability to reuse data and biospecimens for research presents a great opportunity to advance biomedical science at relatively lower cost to patients and society. However, this too remains challenging, as it is unknown what percentage of hospitals participate in biobanks or what percentage of patients are asked to participate.[3]

To cross the health IT chasm from a patient perspective, policy development and coordinated policy execution is necessary to (1) improve patients' access to data created at the point of care as well as data generated by mHealth and related technologies, (2) enable patient participation in and contribution to care delivery and health management, (3) more readily engage patients in research, and (4) positively identify, authenticate, and match patients with their data.

Improve patient access to clinical data

The Health Insurance Portability and Accountability Act (HIPAA) grants patients the right to electronic copies of their health information. To date, federal policy has encouraged use of patient portals and "Blue Button" functionality, which provide patients with select information usually covering medications, allergies, and some labs and claims information.[8] An emerging set of policies will soon encourage the use of APIs to provide access to patients.[9] However, these approaches presuppose what data patients want and will need for health maintenance, wellness, and research.[10] HIPAA should be modified or clarified to state that patients have a right to all data maintained by a covered entity's designated record set[11] or, alternatively, digital copies of their legal medical record.[12] Further, EHR certification and health care system accreditation should be tied to making it easy for patients not only to obtain their data, but to obtain the data in a manner that preserves "computability" and standardization such that the data can be readily transferred to and consumed by other health IT systems with little or no need for further processing.

Improve patient access to data generated by mHealth and related technologies

A new framework is needed to fit today's highly connected world. HIPAA should be strengthened and extended, in particular to accommodate the broader set of data and stakeholders that are relevant to patient health, such as data from the use of Fitbit and Apple Watch. A recent government report indicated that a burgeoning sector of technology applications routinely handle patient data without being considered covered entities or business associates, and that such "non-covered entities" (NCEs) "may collect, share, or use health information about individuals in ways that may put such data at risk of being shared improperly."[13]

Indeed, better understanding and enforcement of HIPAA, which emphasizes the patient's right to data access, could help shift today's paradigm away from one that makes data access difficult. However,

Table 1. Overview of vignette and associated gaps from the patient perspective

Typical patient experience in the not-too-distant future	Gaps between the current patient experience and the future
1. Patient schedules an appointment with his primary care provider online via the patient portal. The patient can access and transfer medical history and records from his previous provider online prior to the scheduled visit.	1. Most health care providers have not enabled patients to schedule appointments online[1] or provide past medical records electronically.
2. Patient receives an e-mail prior to the appointment that directs him to update his active medication list, family and past medical history, and allergy information. The patient completes an online health risk assessment and enters the issues he wants to discuss with the provider.	2a. Most health care providers have not enabled functionality to allow patients to submit patient-generated data online.[1] 2b. Standards for patient-generated health data are immature or, in many instances, nonexistent.
3a. After the provider sees the patient and sends him to a specialist, the patient meets with a patient navigator, who asks about his interest in participating in a clinical trial.	3a. Only a small proportion of patients receive clinical trial information from their primary physician.[2]
3b. The patient navigator asks the patient about granting permission for storage of his information and residual blood for researchers developing new diagnostic tests and treatments.	3b. It is rare for health care providers to participate in biobanks.[3]

Table 2. Goals and policy recommendations to address gaps in the patient domain

Domain	Goal	Policy recommendations
Patient	Improve patient access to clinical data	Clarify HIPAA to state that patients have a right to all data maintained by a covered entity's designated record set or to a digital copy of their legal medical record through guidance by the Office for Civil Rights. Include in EHR certification and provider accreditation that patient data is transmitted in a manner that preserves computability.
	Improve patient access to data generated by mHealth and related technologies	Extend HIPAA or HIPAA-like requirements to noncovered entities. If not politically viable, convene industry stakeholders to develop coordinated "codes of conduct." Monitor widespread and persistent market failures to address data inaccuracy and poor usability that put patients at risk.
	Enable patient participation and contribution to care delivery and health management	As the market for mHealth and other consumer-facing applications matures, encourage multistakeholder coordination of standards within classes of patient-generated health data and eventually incorporate into health IT certification standards.
	More readily engage patients in research	Through public-private collaboration, pursue a digital infrastructure, including commercial EHRs, that enables machine-readable consent and specimen tracking and alerts clinicians and patients about available research opportunities. Incentivize clinicians and health care systems to partner with researchers to identify potential clinical research candidates using tools such as phenotyping algorithms.

it is likely that new federal policy is needed for NCEs commensurate with policies for covered entities and business associates, with strict, enforceable, and substantial penalties for noncompliance. Absent congressional action on NCEs, efforts to develop industry codes of conduct should be reconsidered and prioritized.[13]

Achieving an environment in which access to a broad scope of health-related data, facilitated by appropriate privacy and security protections, will not be sufficient to ensure that data are also accurate and usable. Indeed, broader access, even if secure, could introduce new risks, especially for technology that is not regulated. While accuracy issues exist for data both within EHRs and generated by consumer devices,[14–16] the resulting harm is not yet known. Policymakers should therefore monitor these issues and identify areas where market forces may not be sufficiently strong to protect consumers.

Enable patient participation in and contribution to care delivery and health management

PGHD can come in many forms, and federal policy has thus far rightly been vague in prescribing specific kinds of PGHD to be reported. This approach should continue until a set of technologies and data types takes hold in the market and is proven to improve care outcomes. However, the government is in a position to help lower barriers to entry by encouraging development of harmonized standards for various classes of PGHD, such as PGHD emanating from wearables that transmit disease-specific data. Should such standards be deemed sufficiently mature, they could be incorporated into a future edition of certified health IT so that all EHRs can readily accept such data. Additionally, the federal government could help advance patient participation in and contribution to care by ensuring that patients have minimum-level assurance of privacy protections and addressing emergent risks associated with data inaccuracy and poor usability, as described in the mHealth recommendation above.

More readily engage patients in research

Widespread adoption of EHRs has reinvigorated a conversation over how best to engage patients as participants in research and ensure that they have information on potentially relevant clinical trials. Indeed, the Precision Medicine Initiative[17] seeks to enroll 1 million patients within the next 2 years, and several efforts at the National Institutes of Health and the Food and Drug Administration have sought to improve access to clinical trial information and opportunities to engage in research.[18] Additionally, the federal government has proposed modifying current human subject protections for use of biospecimens and patient data for research.[19] These proposals, when finalized, must streamline participation, not complicate it. Consent management should be facilitated by a digital infrastructure that enables machine-readable consent and specimen tracking.[20] Further, more emphasis should be placed on developing and testing ways to alert clinicians and patients about available research opportunities. Approaches such as clinical trial alerts, analogous to clinical decision support mechanisms that can identify when a patient's EHR aligns with clinical research eligibility criteria, are now supported by some EHRs and have been shown to be effective, but are underused.[18–23] Both of these informatics challenges are ripe for public-private collaboration. Large-scale initiatives, including those directed by Sage Bionetworks, the Genetic Alliance, and the Global Alliance for Genomic Health, are piloting various approaches to electronic consent.[24] The federal government should seek to highlight the most promising approaches and to understand how commercial EHRs could perform such functionality. Additionally, the federal government should consider ways to incentivize clinicians and health care systems to partner with researchers to identify potential clinical research candidates using tools such as phenotyping algorithms, in order to make generation of evidence a routine part of practice.[25–28]

Table 3. Overview of provider-perspective vignette and associated gaps

Typical provider experience in the not-too-distant future	Gaps between the current provider experience and the future
1. Prior to the patient visit, the provider can access critical new test results and reports, relevant biomedical literature, and all patient information provided by the patient and previous providers within the EHR.	1. Lack of standardized APIs limits clinician access to external data and knowledge, advanced analytics, and other tools to provide patient-specific cognitive assistance integrated into the clinical workflow.[29]
2. Upon conducting the physical exam, the provider completes the note before leaving the exam room, using a template based on the patient's profile and containing prepopulated information. The provider then generates an online specialist referral.	2. Providers typically must complete substantial documentation and abstraction to meet external requirements, in particular reporting of clinical quality measures.
3. Prompted by review of the patient note, the specialist wants further information about the patient's risk based on family history. The specialist consults an online phenotyping algorithm, which returns a predictive analytic result indicating patient risk.	3. Knowledge-based tools using standard APIs are not widely available, and it is rare for health systems to encode and implement the required clinical knowledge in the form of clinical decision support.[30]

SECTION 2: PROVIDER PERSPECTIVE

In the vignette, providers have full and ready access to patient data, spend minimal time on documentation, and easily consult knowledge-based tools through APIs to facilitate patient care. Despite progress in clinical decision support and efforts to streamline quality reporting, significant gaps remain between the vignette and our current health IT ecosystem (Table 3).

Policy recommendations

A networked health care system does not yet exist, and as a result, clinicians do not have access to prior information about their patients or the ability to draw on the ever-expanding knowledge bases relevant to clinical decisions. Adding to the clinician burden is the fact that uncoordinated demands are put on clinical documentation for an ever-expanding number of purposes.[31] To cross the health IT chasm from a provider perspective, policy development and coordinated policy execution are necessary to (1) enable interoperability within an API context, (2) develop and implement a documentation-simplification framework, and (3) pursue a documentation-relevant reimbursement redesign.

Enable interoperability within an API context

Multiple stakeholders have argued that APIs are necessary for the next evolution of health IT to enable access to health information by patients and clinicians and improve interoperability. Policymakers have heeded this advice by requiring federally certified health IT to develop and publish APIs as part of the 2015 edition. In the near term, federal officials must ensure that APIs are standards-based and published in the public domain, so that they do not carry forward the siloed legacy of EHR systems. Second, APIs certified by the federal government should include a core set of data elements, similar to the MU clinical dataset, for example. This core needs to be profiled by groups that capture clinical data in practice and use the data in research and clinical decision support, extended over time through a community-endorsement process. Such a process should solicit input from clinical societies to determine the minimum dataset appropriate for associated clinical conditions, such as querying an institution for pediatric data with an American Academy of Pediatrics–endorsed standard dataset. In the context of care delivery, specialty societies are well positioned to describe the data that matter to their constituencies and could therefore work with the informatics community to play a critical role in specifying the data elements that APIs should expose. Of particular value is to establish forums for proactive conversations between specialty societies, informatics experts, standards developers, and health IT vendors. Subsequently, a federal partner, such as the National Library of Medicine, should house and manage metadata crosswalks once standardization across clinical societies for common datasets has been established. Both of these tasks, ensuring that APIs "work" in practice and defining core data elements, are substantial and challenging. APIs are early in the hype cycle, and many nontechnical challenges need to be addressed for them to deliver on their potential.[32] In terms of core data elements, as both the scope and depth of data grow, it will be increasingly hard to identify a core set of data needed for clinical care. Instead of being daunted by these challenges, we need

Table 4. Goals and policy recommendations to address gaps in the provider domain

Domain	Goal	Policy recommendations
Provider	Enable interoperability within an API context	Federal officials work to ensure that APIs are standards-based and published in the public domain as a component of the federal Health IT Certification Program. APIs include core data elements that have received community endorsement resulting from collaborations between specialty societies, informatics experts, standards developers, and health IT vendors. The National Library of Medicine should house and manage metadata crosswalks once standardization across clinical societies for common datasets has been established.
	Develop and implement a documentation simplification framework	Develop an empirically based regulatory compliance framework for documentation simplification that assesses costs and benefits of standardizing and collecting specific data elements, places higher value on elements with minimal collection burden, and places higher value on documentation that supports patient care and improved outcomes.
	Develop and implement quality measure simplification	Deconstruct quality measures in the electronic environment by developing common data elements required for quality measurement, resource use, and research. Collect, extract, and report use of a common data model of elements that are of high value to multiple stakeholders.
	Pursue documentation-relevant reimbursement redesign	Revise evaluation and management coding guidelines and consider removing prescriptive components of time-based billing. Aggressively pursue alternative payment models that have demonstrated benefits to cost and quality.

to recognize their magnitude and be willing to pursue the associated ambitious policies that may be required to address them, in particular, applying more aggressively constraining data standards and ensuring adherence to those standards across health IT products.

Develop and implement a documentation-simplification framework

If poor interoperability and usability are symptoms of our current health care system, a primary component of the disease must be documentation requirements, driven by reimbursement, legal, quality, research, and public health purposes that do not directly contribute to point-of-care encounters. To address this unsustainable paradigm, we need an empirically based regulatory compliance framework for documentation simplification. This framework should inform a drastic overhaul and simplification of quality measurement, ensure availability of coded clinical data from EHRs for quality assessment and clinical decision support, and guide a redesign of reimbursement requirements.

The 2011 AMIA Policy Invitational focused on clinical documentation, and it was the consensus at that meeting that "in the move to a technology-enabled healthcare environment, the main purpose of documentation should be to support patient care and improved outcomes for individuals and populations and that documentation for other purposes should be generated as a byproduct of care delivery."[33] A set of guiding principles for clinical data capture and documentation was produced along with other relevant recommendations as an output; these should further define the parameters and scope of a documentation-simplification framework.[33]

Develop and implement quality measure simplification

One of the primary aims of the documentation-simplification framework should be quality measurement. Therefore, we should begin to pursue quality measurement simplification, informed by the documentation-simplification framework. This could be done by deconstructing quality measures in an electronic environment by developing common data elements (CDEs) required for quality measurement, resource use, and research. Examples include the National Library of Medicine CDE Resource Portal[34] and the Centers for Medicaid and Medicare Services Assessment Data Element Library.[35] CDEs will enable data collection, extraction, and reporting using a common data model in which each element is deemed as high value to multiple stakeholders. A potential goal could be to make gathering >95% of the data elements for quality reporting automatic or a byproduct of clinical documentation.[36] This approach could also inform measures beyond quality. Measures required under the Medicare Access and CHIP Reauthorization Act should similarly be held to a standard of high levels of evidence and value. Specifically, measures associated with the Advancing Care Information performance category and Clinical Practice Improvement Activities represent additional opportunities to simplify data collection using common data elements.

Pursue documentation-relevant reimbursement redesign

Another function for which the framework could be leveraged is to address what is referred to as general "note bloat." The initial focus could be on evaluation and management guidelines to address inefficiencies for clinicians at the point of care. The Centers for Medicaid and Medicare Services should focus on evaluation and management coding guidelines as a way to revise and simplify documentation and consider removing, or clarifying, the prescriptive components surrounding time-based billing. As we move to value-based care, the justification for detailed documentation guidelines should become less important to payers. The US Department of Health and Human Services should encourage using different approaches to documentation, such as a "delta" note, care team note, or interdisciplinary treatment plan. These efforts could be funded through Center for Medicare and Medicaid Information demonstration projects and could initially use requirements outlined by the Medicare Modernization Act of 2003 as a blueprint.[37]

Table 5. Overview of researcher- and innovator-perspective vignette and associated gaps

Typical researcher and innovator experience in the not-too-distant future	Gaps between the current researcher and innovator experience and the future
1. A researcher within the health system receives an alert that a patient met the criteria for a clinical study, and the patient agrees to participate after going through the informed consent process with the patient navigator. Pertinent historical patient data are accessed for the study.	1. Access to patients and their clinical data to support research is rarely well integrated into clinical care.
2. When the patient is later admitted to the emergency department for a condition that disqualifies him from the study, the emergency department physician and study coordinator communicate about the case and the patient is removed from the study.	2. Patients typically lack the ability to learn about and decide how they want their data to support research and then execute on those decisions in a scalable way.
3. The patient is directed to a new health system–approved app that helps him track and report key health data intended to improve congestive heart failure management. The app not only provides data to the patient's care team, but is also connected to a knowledge cloud that delivers personalized analytics and enables him to donate it for research as part of the Precision Medicine Initiative Participant Technologies Center.[38]	3. The health app environment is immature, with few safeguards for safety and effectiveness and limited integration of apps into clinical care or research.

SECTION 3: RESEARCHER AND INNOVATOR PERSPECTIVES

In the vignette, researchers and innovators can readily access complete patient data and engage patients by integrating research and innovations into clinical care. Today, clinical care, research, and innovation typically occur in silos without integrated data or processes, resulting in substantial gaps between the vignette and our current health IT ecosystem (Table 5).

Policy recommendations

The federal government has invested, and continues to invest, substantial sums to build research networks, such as PCORnet,[39] the National Center for Biomedical Computing,[40] the Clinical and Translational Science Awards Program,[41] and the Precision Medicine Initiative Cohort Program.[42] However, smaller-scale research embedded in provider organizations faces burdensome regulatory requirements as well as challenges in integrating research requirements into clinical care processes. We have also not yet created an environment that can foster an expanding ecosystem of innovative health applications and analytics that are both safe and effective. Most innovators develop applications absent clear standards or protocols, or a sustainable pathway for retrieval of patient data. To cross the health IT chasm from the researcher and innovator perspectives, policy development and coordinated policy execution are necessary to create a policy framework for research and innovation and to develop and implement an app-vetting process for safety and effectiveness.

Table 6. Goals and policy recommendations to address gaps in the researcher and innovator domain

Domain	Goal	Policy recommendations
Researcher	Create a policy framework for research and innovation	Create a cross-agency collaboration to produce a framework that includes "common rule" updates to facilitate secondary use of data for research, common Data Use and Reciprocal Support Agreements, common enforced technical functionalities and specifications based on standard APIs, and data portability from HIPAA-covered entities.
	Develop and implement an app vetting process	Create a public-private collaboration to develop a process that ensures a minimum level of privacy, security, safety, and effectiveness while not hampering innovation.

Create a policy framework for research and innovation

First, we need collaboration among federal agencies to create a policy framework that will assure all stakeholders that the appropriate data are being used for appropriate reasons, under actively agreed-upon terms or circumstances with appropriate patient consent. As described in Table 6, the framework should include policies to aid data access, to enable more research conducted by HIPAA-covered entities[19] and provide necessary standardization. Developing a policy framework supported by technical standards will help sustain "big data" research, which is often dependent on discovery absent a clear hypothesis, and will allow patients to participate with the innovation community in developing effective and usable technologies.

Develop and implement an app-vetting process for safety and effectiveness

Second, we recommend that federal officials and private-sector stakeholders develop a process for vetting health applications to ensure a minimum level of privacy, security, safety, and effectiveness while not hampering innovation. To speed progress, specialty societies or medical colleges could play a role in maintaining trusted sources of the knowledge base (eg, clinical guidelines) used for development of applications and algorithms by innovators, absent or alongside more rigid government regulation. This could be part of a clinical practice improvement activity under the merit-based incentive payment system, which incentivizes novel approaches to improve care.[43] In the future, broadening consideration beyond apps

to enable integration of algorithms and other analytics tools/outputs along with shareable knowledge will help ensure that vetted technologies are widely available and their future iterations improve from a solid foundation.

CONCLUSION

There is little doubt that a chasm exists between the health IT ecosystem we have today and the one we need to routinely deliver high-value care. In this paper, we argue that we know how to cross the chasm in a way that meets the distinct needs of diverse stakeholders who are essential to health system transformation. Importantly, the key goals that would enable such a transformation are shared across stakeholders, and they center on minimally burdensome capture, access, and use of standardized data. It is therefore imperative that substantial new policy efforts are targeted at these goals. Our specific policy recommendations offer a blueprint to guide future policymaking to achieve these goals. However, after almost a decade of policy-driven efforts to drive adoption and use of EHRs, the desire for another ambitious set of policy efforts is limited. Thus, the real challenge in front of us is a simple one: recognizing that our work to build a value-enabling health IT ecosystem is only half done and that incremental progress is not a viable option.

CONTRIBUTORS

Based on content from the 2015 AMIA Policy Invitational, all authors contributed to development of the vignette and policy recommendations.

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COMPETING INTERESTS

There are no competing interests.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* online.

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