

cumstances (such as when a vendor creates a PHR specifically for a covered entity), vendors such as Microsoft and Google are not covered by HIPAA. Microsoft says it will seek patients' consent before sharing data with third parties, but none of these application suppliers are covered by HIPAA. Whatever the business model for PHRs, lawmakers should require that the consumer user be clearly informed about the identity of the system's operator and the financial terms of any direct or indirect use of patient data.

It's difficult to predict what roles Google, Microsoft, and health plans will play in the PHR marketplace in the long run. There aren't major technical barriers to entry, but data sharing will require the development and adoption of technical and content standards — and a desire on the part of physicians and patients to contribute information to commercial repositories, with their growing contin-

gents of third-party application developers. Since the majority of physicians still don't have electronic medical records, and patients often seek care outside their providers' delivery system, these stand-alone PHRs may serve as data intermediaries. However, if the Obama initiative to replace paper records with interoperable EHRs in the next 5 years succeeds, the landscape will change dramatically, and the need for intermediaries may disappear.

Users of integrated PHRs have demonstrated that creating shared records for patients and their health care team can enhance patients' ability to become active partners in their own health care.⁵ This is a try-it-you'll-like-it type of innovation. As physicians increasingly adopt EHRs, we expect community interest in PHRs to grow organically. Ultimately, it will no doubt become difficult for physician groups to survive in the marketplace without them.

Dr. Tang reports serving on the Google Health advisory council. No other potential conflict of interest relevant to this article was reported.

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1. Steinbrook R. Personally controlled online health data — the next big thing in medical care? *N Engl J Med* 2008;358:1653-6.
2. Tang PC, Ash JS, Bates DW, Overhage JM, Sands DZ. Personal health records: definitions, benefits, and strategies for overcoming barriers to adoption. *J Am Med Inform Assoc* 2006;13:121-6.
3. National Committee on Vital and Health Statistics. Privacy and confidentiality in the nationwide health information network. 2006. (Accessed March 6, 2009, at <http://www.ncvhs.hhs.gov/060622lt.htm>.)
4. Tang PC, Black W, Young CY. Proposed criteria for reimbursing eVisits: content analysis of secure patient messages in a personal health record system. *AMIA Annu Symp Proc* 2006:764-8.
5. Tang PC, Lansky D. The missing link: bridging the patient-provider health information gap. *Health Aff (Millwood)* 2005;24:1290-5.

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No Small Change for the Health Information Economy

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The economic stimulus package signed by President Barack Obama on February 17 included a \$19 billion investment in health information technology. How can we best take advantage of this unprecedented opportunity to computerize health care and stimulate the health information economy while also stimulating the U.S. economy? A health care system adapting to the effects of an aging population, growing expenditures, and a diminishing primary care workforce needs the support

of a flexible information infrastructure that facilitates innovation in wellness, health care, and public health.

Flexibility is critical, since the system will have to function under new policies and in the service of new health care delivery mechanisms, and it will need to incorporate emerging information technologies on an ongoing basis. As we seek to design a system that will constantly evolve and encourage innovation, we can glean lessons from large-scale information-

technology successes in other fields. An essential first lesson is that ideally, system components should be not only interoperable but also substitutable.

The Apple iPhone, for example, uses a software platform with a published interface that allows software developers outside Apple to create applications; there are now nearly 10,000 applications that consumers can download and use with the common phone interface. The platform separates the system from the functional-

ity provided by the applications. And the applications are substitutable: a consumer can download a calendar reminder system, reject it, and then download another one. The consumer is committed to the platform, but the applications compete on value and cost. The Facebook social networking site is another example: it allows users to connect their core accounts to applications that add value for them, from family-tree builders to programs that track flulike symptoms or encourage blood donation. And of course, there is the Web itself, which supports myriad applications — some proprietary, some not — many of which interoperate. For example, users with a personalized Google home page can populate it with widgets from Yahoo. Again, all these programs compete with each other and can be substituted for one another, entirely and modularly.

The platform approach to software design can be used to create and sustain an extensible ecosystem of applications and to stimulate a market for competition on value and price. We believe that the Department of Health and Human Services (DHHS) should encourage the development of such a platform for health care — one that will support applications for communication and computation that span the domains of clinical care, public health, and research. There are early-stage examples of platforms in health care already. For instance, the emerging model of personally controlled health records (PCHRs) is based on a platform that has been adopted by Microsoft and Google, as well as by the Dossia consortium of large employers for its rollout of

Categories of Substitutable Applications with Selected Examples.*	
Purpose of Application	Examples
Medication management	Prescribing Clinician-order entry Medication reconciliation Drug-safety alerts
Documentation	Structured text entry Dictation
Panel management	Disease management Appointment and testing reminders Care instructions Results notification Patient behavior modification
Quality improvement	The Healthcare Effectiveness Data and Information Set (HEDIS) Management of patient transfer and transition
Administrative tools	Billing Referral management Risk stratification
Communication	Doctor-patient communication Multispecialty or team communication Patient support Patient or clinician social networking
Public health reporting	Notifiable disease reporting Biosurveillance Pharmacosurveillance
Research	Clinical trial eligibility Cohort study tools Electronic data capture for trials
Decision support	Laboratory-test interpretation Genomics Guideline management
Data acquisition (subscription)	Laboratory data feed Dispensed medication feed Personally controlled health record data feed Public health data feeds (e.g., local context for infectious diseases)

* The proposed platform would allow a clinical practice or hospital to select the combination of applications that are most useful for the local environment. As alternative applications are developed by competitors, the existing ones may be replaced, or new ones added.

the Indivo product to employees of consortium companies.¹ There is now an active marketplace of enterprises building PCHR applications.

We take it as a given that health care software must be interoperable and secure and must protect patient privacy. But these qualities are not sufficient to pro-

duce an optimal system, which must evolve on a health care platform that extends beyond PCHRs to include other critical infrastructural components, such as medical-practice-based electronic health records (EHRs) and applications that support the complex communication required in health care. We believe that such

a platform should have a number of additional key characteristics.

First, there should be liquidity of data. The platform and its applications should reduce impediments to the transfer of data, in an agreed-upon form, from one system to another. In the banking industry, the automatic teller machine (ATM) is predicated on highly standardized, simple operations. Participation requires at least a minimal amount of data liquidity — ATMs enable consumers from virtually any bank to withdraw money, although only some ATMs can provide a given consumer with his or her account balance.

Second, there should be substitutability of applications (see table). The system should be sufficiently modular and interoperable so that a primary care provider could readily use a billing system from one vendor, a prescription-writing program from another, and a laboratory information system from yet another. Individual systems do not need to perform all functions. (Analogously, a customer cannot apply for a mortgage at an ATM.)

But substitutability goes beyond interoperability. Just as consumers may swap out applications on their iPhones, physicians should be able to readily replace one referral-management system with another. Companies are beginning to offer modular services driven by common data elements found in claims, EHRs, and PCHRs.²

Third, the platform should be built to open standards, accommodating both open-source and closed-source software. Though installation of open-source software is not free, its use decouples the software code from implementation and integration

tasks and facilitates customization, extension, and innovation.

Finally, just as evolution requires variety in order to create ecosystem niches, a platform that supports diverse applications will lead to a robust health information economy. This architecture reduces dependence on individual systems by allowing competition and “natural selection” for high-value, low-cost products. This approach contrasts sharply with design of a national system by committee. Like standards, system design must be driven by successful, real-world innovations; an incremental and iterative process is more likely than a wholesale advance prescription to be successful.³ The platform model allows disruptive technologies to emerge and enables evolution to proceed organically. New companies and players that will contribute to transformation must be recognized and welcomed.

The DHHS could promote the creation of such a system by taking certain actions in terms of regulation, the creation of incentives, and the evaluation of results. Although the platform we envision would support a free marketplace of products and ideas, oversight and regulation are important. The DHHS should ensure that the dominant driving force is the maximization of health and that adequate privacy protection is in place. We must decide as a society what kinds of transactions such a system would be permitted to support. For example, should the platform permit direct-to-consumer advertising or procurement of samples for research?

At the same time, federal incentives should be offered to providers to make use of health information technology in clinical

decision making and in efforts to improve the quality of care and acquire population data for public health. The design of incentives should be built on a realistic respect for physicians' time and effort in order to avoid turning physicians into scribes. A positive step would be to reduce demands for excessive documentation to support billing and medicolegal defense, so that valuable data-entry efforts could serve nobler goals.

In addition, the DHHS should institute a transparent process for evaluation of the platform, individual applications, and the effects of the system on outcomes (health, patient safety, and public health), process measures (physicians' workflow), and costs (of the information technology as well as the provision of health care that relies on it). Ideally, the platform would support applications that would readily allow trials and observational studies of the technology and of therapies and delivery models, promoting what the Institute of Medicine calls a learning health care system.

To get started on this platform, the DHHS should demonstrate at least the kind of interoperability and substitutability that banks have instituted with ATMs. For example, can we produce a medication list for every American that can be obtained through standards-based,⁴ interoperable, substitutable applications? It would be a catalytic investment on the part of the government to ensure that such functionality is comfortably seated on a platform that stimulates evolution and competition among contending, substitutable applications.

Medicine is increasingly becoming a knowledge and information

industry, but it did not invent information technology or the Web.⁵ It makes sense to draw on other sectors' successes in making this type of transition, and they teach us that if we are to use information technology to improve health care, the variety of practice sizes and styles needs to be complemented by collections of information functions that are packaged on a consistent platform. The applications enabling these functions should be as substitutable

as different stethoscopes in a doctor's office.

Drs. Mandl and Kohane are the developers of Indivo, an open-source personally controlled health record that has been deployed at multiple locations, including through the nonprofit entity Dossia. In the past, Dr. Mandl received support from Children's Hospital Boston to guide the translation of Indivo technology to a Dossia environment. No other potential conflict of interest relevant to this article was reported.

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1. Mandl KD, Kohane IS. Tectonic shifts in the health information economy. *N Engl J Med* 2008;358:1732-7.
2. Goedert J. Time to roll for SafeMed. *Health Data Manag* 2008;16:47.
3. Diamond CC, Shirky C. Health information technology: a few years of magical thinking? *Health Aff (Millwood)* 2008;27:w383-w390.
4. Kibbe DC, Phillips RL Jr, Green LA. The continuity of care record. *Am Fam Physician* 2004;70:1220, 1222-3.
5. Stead W, Lin H, eds. *Computational technology for effective health care: immediate steps and strategic directions*. Washington, DC: National Academies Press, 2009.

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Screening for Prostate Cancer

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 A video is available at NEJM.org

In two large randomized trials, researchers examined the effect of annual prostate-specific antigen (PSA) screening on the rate of death from prostate cancer and found that it was small and was offset by false positive diagnoses (study results available at NEJM.org). On February 27, 2009, the *Journal* hosted a debate about the clinical implications of these findings, the risks and benefits of screening, and the best way to advise patients about undergoing PSA testing. Should these studies change practice? Watch the video, participate in the poll, and contribute your thoughts at NEJM.org.