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Tectonic Shifts in the Health Information Economy

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In a recent shift in the health information landscape, large corporations are seeking an integral and transformative role in the management of health care information. The mechanism by which this transformation is likely to take place is through the creation of computer platforms that will enable patients to manage health data in personally controlled health records (PCHRs). Two types of large corporations are involved. Technology companies such as Google and Microsoft see business opportunities,¹ whereas Fortune 100 companies in their role as employers^{2,3} see efficiencies and cost savings when patients can securely store, access, augment, and share their own copy of electronic health information. Though this shift in the locus of control of health information is driven largely by a need to provide assistance with clinical care processes, it will also profoundly affect the biomedical research enterprise. We illustrate this shift with a two-part scenario in which a patient fills her PCHR with data from multiple sites of care and then participates in research.

The first part of this scenario involves information integration. The patient, who has inflammatory bowel disease, is treated at a gastroenterology practice and has had an inpatient admission

at one hospital, a visit to an emergency department at another hospital, and test results at a laboratory. She logs into her hosted PCHR at a secure Web site. Since she has established subscriptions to automatic updates from each of these clinical entities, her PCHR is current with copies of those data.

The PCHR enables the patient to authorize access to information (views or even copies of the record) to others, including clinical providers, family members, health care proxies, and researchers, and to intelligent software agents such as a disease-management tool.

The second part of this scenario involves participation in research. Through her PCHR interface, the patient signs up for notification of open research studies on inflammatory bowel disease. Her eligibility is determined by a combination of her demographic characteristics, responses to a brief survey, and the clinical contents of her PCHR (e.g., diagnoses and medications). Five study matches are returned, and she chooses to participate in two. The first match is a randomized clinical trial of a medication with local enrollment at the hospital where she visited the emergency department. She makes an appointment and enrolls

in person. The second study is a noninterventional prospective cohort study from an academic medical center located on the opposite coast. There is a small financial incentive to participate. The patient enrolls in this study with an online consent, agreeing to make select contents of records available to study investigators on an ongoing basis and to answer monthly online questionnaires.

This scenario anticipates a new scale of data liquidity, a gush of information from clinical settings — electronic health records, laboratory information systems, and medication-management systems — into PCHR platforms where health care consumers independently decide about subsequent disclosure. If others follow the lead of major health care institutions such as New York–Presbyterian Hospital, which has committed to allow patients to transfer electronic health information into the Microsoft HealthVault personal health record,⁴ companies that are new to health care may ultimately house and manage an information repository far larger than any in the academic sector. If the project is successful, patients at New York–Presbyterian Hospital will have the opportunity to individually control a copy of their own data. Collectively, they will control a population database hosted by a third party (at New York–Presbyterian Hospital it is Microsoft, and at Cleveland Clinic it is Google). This database will potentially reflect the entire scope of the hospital's services and outcomes, and patients will determine the parties with whom they subsequently share their data.

Such qualitative and quantitative changes in the health information economy will certainly affect our biomedical research system in ways that cannot be fully predicted. We have produced the reference application for this model, known as the Indivo system,^{5,6} and we continue to pursue PCHR-based population-level studies within our academic health center.^{7,8} On the basis of our experience, we consider the potential effects of the success of the PCHR model on the clinical research enterprise. We hope that the clinical research community can respond to these changes in an informed and thoughtful manner.

THE INFORMATION LANDSCAPE

PCHRs are a special instance of personal health records^{9,10} that include portals. Portals are closed

systems that allow patients to view their own clinical data in institutional electronic health record systems or their claims data in payer systems.¹¹ We contend that PCHRs are a disruptive innovation that inverts the current approach to medical records in that they are created by and reside with patients who grant permission for their use to institutions, clinicians, researchers, public health agencies, and other users of medical information. PCHRs use the subscription model,⁶ which facilitates consumer-driven data aggregation (Fig. 1). In some ways, this model, like a health care version of the financial Quicken product, advances the flow of information far more than models requiring interinstitutional data-sharing agreements. Under the subscription model, data from two competing health care networks may reside in the same PCHR without cumbersome agreements between those two networks. The patient asserts a claim to his or her data at each network independently. This consumer-driven model of data aggregation may promote data liquidity far more than competing approaches, such as health information exchanges,¹² which require centralized management of data-sharing agreements between networks and institutions.

On patient approval, companies, governmental and nongovernmental organizations, and health centers can create applications that connect through a programming interface to the major PCHR platforms. These applications should make a PCHR a benefit rather than a chore by enabling services such as the interpretation of laboratory tests, referrals, the provision of customized medical advice, and disease management. How similar this interface (Fig. 1) will be across the major PCHR platforms and how nurturing the various PCHR purveyors will be of patient-directed sharing of data across these platforms remain to be seen.

Clinical research has primarily been the province of and under the control of the health care systems where the patients have received their care. Notable exceptions include studies with broad-based recruitment strategies such as the Framingham Heart Study, which identified subjects through a geographic community, and the Nurses Health Study, which recruited subjects through professional channels. Similarly, PCHRs present a diffusible and scalable mechanism for ready and direct recruitment of cohorts across the boundaries of health systems, managed-care networks, and academic medical centers.

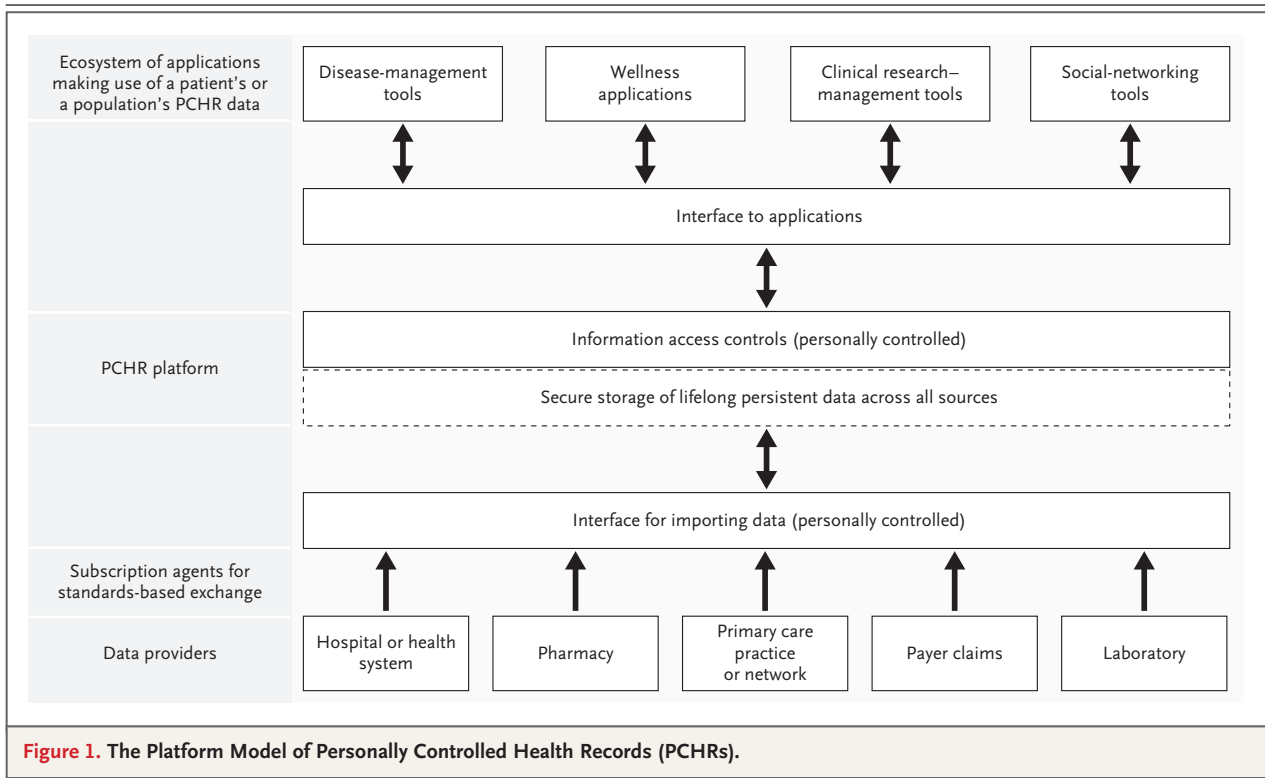


Figure 1. The Platform Model of Personally Controlled Health Records (PCHRs).

KEY ISSUES FOR CLINICAL RESEARCH

If the platform model proves to be successful, the largest, richest, and most up-to-date health care databases will reside on the servers of the companies providing the PCHR platform. If PCHRs are as successful as their proponents project, even large programs such as the National Institutes of Health's multibillion-dollar Clinical and Translational Science Award program may produce smaller, less complete data sets.^{13,14} Extensive clinical data sets used by public health agencies, such as those of the Centers for Disease Control and Prevention (CDC) for health surveillance¹⁵ and the Food and Drug Administration (FDA) for the post-marketing surveillance of pharmaceuticals,¹⁶ may have less population coverage and less complete and specific information than those that could reside in PCHR repositories if they receive widespread uptake and are kept up to date.

A number of key questions arise. For instance, do the PCHR service providers themselves have a research mission? Do they intend to look across PCHRs to make observations about population health or the health of particular cohorts of pa-

tients — for example, patients taking a particular medication? If so, who will have access to the data, for what purposes, and under what sort of regulation? PCHR companies should all clearly define whether and how they will de-identify or aggregate data^{17,18} and how or whether secondary uses of the data sets will be allowed or limited.

Academic medical centers may find themselves struggling to understand these implications before following the lead of New York–Presbyterian Hospital and Cleveland Clinic in making health-system data available to a PCHR company. If they empower their patients by enabling the fluid transfer of health information, does this mean their own researchers will have access to patient data that span institutions and include annotations and supplementary information provided by patients? How would this access be determined? One approach would be to allow individual patients to strictly control access to their data by third-party researchers. As in the scenario above, a consumer might choose to connect her PCHR to a software application hosted by a clinical research organization that enables her to enroll in a clinical trial of a medication. She also might

connect to an FDA postmarketing surveillance program enabling her to contribute her medication, symptom, and outcome data. A consumer also might choose to share information about influenza vaccinations and influenza-like illness with the CDC to augment national surveillance, prevention, and control efforts. Alternatively, she might link her record to a social-networking site, share her data, and engage with patients who have similar conditions.

Another approach would be for the platform company to directly extract data, perhaps de-identified, by polling across PCHRs, removing the patient as the intermediary in the decision. The latter approach is not consistent with a fully personally controlled model⁵ (e.g., in Fig. 1, the layer for information access controls would include control by the PCHR platform company in addition to control by the health care consumer), but it could well be chosen by some commercial vendors. Issues with respect to information privacy are discussed below.

Neither tactic provides the institutional control that academic medical centers, health maintenance organizations, and health networks currently have over their patients' health records. There is a reasonable argument that such control has been parochial and has created inefficiencies in fostering scientific discovery^{19,20} and in delivering high-quality clinical care. Wide-scale sharing of meticulously collected research data is largely still a work in progress.²¹ Nonetheless, if the pendulum swings the other way, an entire generation of clinical researchers in training will find themselves with second-class or no access to the best research resources. For example, a PCHR provider and a partner organization could conceivably, with the best of intentions, generate the largest genetically characterized and phenotyped cohorts, using the PCHR as a vehicle. Indeed, many researchers might have an incentive to work with these PCHR companies to minimize the per capita administrative overhead for their studies or to market research studies directly to consumers with PCHRs.

Whether these new companies will gain access to patients to engage them in prospective studies or even formal therapeutic trials is unknown. Academic medical centers will need to assess whether they will be competing with PCHR vendors even on a local level for the attention and participation of their own patients in research. Public health

agencies will need to understand the structure and value of these new sources of population health data. To the degree that commercial interests have been fast in moving into this new era of management of personalized medical records, personalized medical advertisement, and personalized decision support, regulatory authorities and academic medical centers have been slow in moving their focus beyond the challenges of individual cohort studies and controlled trials.

REGULATION OF PCHR-BASED RESEARCH

Our society should make an informed decision about how the goals of improving health care, and the twin beacons of maximizing patient autonomy while minimizing health risk, should be served in the context of a seismic change in the locus of control, curation, interpretation, and guardianship of patient information. The companies providing PCHRs are not covered entities under the Health Insurance Portability and Accountability Act (HIPAA). Unless this changes, a group of researchers may emerge with identical questions but with restrictions and safeguards quite different from those of their colleagues in academic health centers. For example, within HIPAA-covered entities, there are very clear definitions of what constitutes a limited data set and a de-identified data set²² and what the substantial penalties are for infractions in their use and management.

Consumers navigating the opportunities to share and potentially even monetize their data for research deserve a guidepost such as a certification or a seal of approval with regard to services, software, and projects from a trusted authority. Protections for research subjects in the new, personalized health information economy will arise through a mixture of federal regulation (perhaps, for example, the extension of HIPAA), contractual relationships, certification, and educational programs. Progress in this regard has been slow, even as PCHRs are deployed. Bills introduced in Congress in 2006 and 2007^{23,24} would dictate the structure, governance, and financing of personal health records and PCHRs. However, no legislation has been enacted. The Department of Health and Human Services currently funds a private, nonprofit organization to certify electronic health records with respect to interoperability, quality, and privacy protection.²⁵ Whether this en-

tity will be expanded to certify PCHRs and the software agents and services that connect to PCHRs, whether the industry will attempt to self-regulate or to certify PCHRs, and whether federal laws or regulations will be enacted or amended remain to be seen. Given the posited right of patients to contribute or sell their own data,⁷ consumer protections will need to balance a new degree of patient autonomy with transparency and education with regard to the responsibility and risks of data stewardship. For example, they will need to strike a balance between patient control and a paternalistic protection against coercion and false claims made across the multiple channels of communication that are possible between these new research entities and health care consumers. Since some PCHR platforms may allow advertising based on the content of personal information, including Internet search terms, lessons may be derived from experience with federal oversight of direct-to-consumer advertising of pharmaceuticals.²⁶

Academic medical centers, federal regulators, and PCHR service providers will probably need to collaborate to ensure that institutional review boards or newly configured oversight bodies can establish protocols for recruiting subjects through PCHRs. Exploratory multistakeholder meetings have already begun.^{27,28} Creative and effective online consent processes must be developed and used, since globalization of the research enterprise requires electronic means of researcher–subject interaction. Such consent must reveal clearly and emphatically how identified and de-identified patient data will be handled.

OPPORTUNITIES AND CHALLENGES

We see five important hurdles to overcome if PCHRs are to be used to the full extent of their potential. First, the ready exchange of richer clinical data requires broad agreement on standard data formats. It is encouraging that an emerging consensus^{29,30} is dictating how information is imported to, or exported from, the PCHR — including data-exchange standards recently recognized by the Secretary of Health and Human Services.³¹ Second, entities controlling clinical data systems (e.g., hospitals and practices) have yet to commit to make data available electronically to patients, and to do so, they need cooperation from their

information-system vendors. Third, under the Clinical Laboratory Improvement Amendments (CLIA),³² laboratories must release test results only to authorized persons, which, depending on individual state laws and regulations, may not always include the patient. Hence, in many circumstances, the current form of CLIA can be interpreted as preventing the communication of laboratory results directly to patients.³³ We think that patients have a fundamental right to view and distribute their own data. Fourth, vast amounts of medical information are still stored on paper. Although saving scanned electronic images of paper records in a PCHR is an important step forward, the full promise of PCHRs will not be realized until there is a greater adoption of electronic health records in health care practice settings³⁴ that make structured data available for analysis and computation. Fifth, since in the United States there is no universal patient identifier³⁵ or set of business processes to enable ready authentication of the consumer across the health care system,³⁶ new approaches to establishing identity and trust are needed.³⁷

Despite these challenges, many consumers with PCHRs will soon control a valuable resource — an integrated copy (possibly the only such copy) of their health care information across sites of care and over time as well as the annotations and supplementary information they provide. Under favorable conditions, consumers will benefit considerably as new business models develop, enticing them to engage in research, establishing communication channels between researchers and PCHR owners, and competing for consumer attention over those channels. Just as medicine emerged stronger after Abraham Flexner's 1910 report on medical education,³⁸ our health care system can be made not only safer for patients but more agile in pursuing translational research if we recognize and help steer these shifts in the medical information economy.

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nies. The core PCHR software produced under this contract is made freely available as part of the open-source code base of Indivo. No other potential conflict of interest relevant to this article was reported.

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