Published in final edited form as:

Clin Chem. 2011 February ; 57(2): 196–204. doi:10.1373/clinchem.2010.148668.

Potential for Electronic Health Records and Online Social Networking to Redefine Medical Research

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Abstract

Background: Recent legislation in the US requires that all medical records become electronic over the next decade. In addition, ongoing developments in patient-oriented care, most notably with the advent of health social networking and personal health records, provide a plethora of new information sources for research.

Content: Electronic health records (EHRs) show great potential for use in observational studies to examine drug safety via pharmacovigiliance methods that can find adverse drug events as well as expand drug safety profiles. EHRs also show promise for head-to-head comparative effectiveness trials and could play a critical role in secondary and tertiary diabetes prevention efforts. A growing subset of EHRs, personal health records (PHRs), opens up the possibility of engaging patients in their care, as well as new opportunities for participatory research and personalized medicine. Organizations nationwide, from providers to employers, are already investing heavily in PHR systems. Additionally, the explosive use of online social networking sites and mobile technologies will undoubtedly play a role in future research efforts by making available a veritable flood of information, such as real-time exercise monitoring, to health researchers.

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" Author Contributions:All authors confirmed they have contributed to the intellectual content of this paper and have met the following 3 requirements: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; and (c) final approval of the published article.

Authors' Disclosures or Potential Conflicts of Interest:
Employment or Leadership: C.A. Brownstein, PatientsLikeMe.
Consultant or Advisory Role: None declared.
Stock Ownership: C.A. Brownstein, PatientsLikeMe.
Honoraria: None declared.
Expert Testimony: None declared.

Summary: The future confluence of health information technologies will enable researchers and clinicians to reveal novel therapies and insights into treatments and disease management, as well as environmental and genomic interactions, at an unprecedented population scale.

INTRODUCTION

The recently enacted Health Information Technology for Economic and Clinical Health (HITECH)[6] Act in the US, part of the 2009 economic stimulus package, provides $27 billion over 10 years for the adoption of electronic health records nationwide (1). By 2012, Medicare and Medicaid reimbursement will be tied to whether a healthcare provider implemented “meaningful use” of electronic health records (EHRs) (2). Integrated EHRs, once mostly limited to large health maintenance organizations (HMOs) and academic health systems (3), are expected to become a reality of clinical practice, in a move considered akin to the Medicare/Medicaid adoption of electronic billing for prescriptions. As part of the “meaningful use” implementation of HITECH, healthcare providers will be required by 2012 to make patient EHRs available on request in a format that can become part of a personal health record, further opening up the closed management of health records to patient involvement and control (4).

Recent developments in patient-oriented care, most notably with the advent of health social networking and personal health records (PHRs), have greatly expanded patient’s involvement in their medical decisions and management. In addition to the use of the Internet for diagnosis help and research on medications, patients are increasingly turning to social networking Web sites, such as TuDiabetes (www.tudiabetes.org), to manage their self-care and seek advice. Some of these Web sites, such as PatientsLikeMe (www.patientslikeme.com), enable patients to monitor their symptoms and therapy regimens over time. This information can be shared with other users, allowing for comparison of novel side effects and treatment regimens. With integration of such data into PHRs and personally controlled health records (PCHRs), the ability to conduct research into patients’ behavior, treatments, and environment greatly expands (5). The surplus of information generated by such tools is already of great interest to pharmaceutical companies and public health researchers (6, 7).

The plethora of real-world health information available from these varied data sources will increase the ability of health researchers to perform translational research, better understand clinical effectiveness of therapeutics, and open doors to increased understanding of environmental and behavioral influences on disease. Challenges remain before the use of EHRs and PHRs for health outcomes research can reach its full potential, including proper study design and ability to better understand bias in these new data sources (e.g., how are companies ensuring that a representative sample of users are reviewing a product or treatment, and not just those who feel strongly in favor of it or against it). The details of wide-scale adoption of EHR systems, their interoperability, and quality assurance remain unresolved. Yet, with the implementation of the HITECH Act and continuous developments on the Internet, researchers and clinicians must prepare themselves for the coming transformations in healthcare. This review addresses the use of EHRs in research, the

potential of PHRs and online social networking to improve health, and what this means for the future of health outcomes and diabetes research.

EHRS AND HEALTH OUTCOMES RESEARCH

Although randomized controlled trials (RCTs) provide the most rigorous method to determine the efficacy of a drug compared to placebo, their finite durations can limit the ability to detect latent health effects in drugs designed for a lifetime, and they are further restricted by their weak ability to obtain clinical effectiveness data and lack of longitudinal comparisons with other drugs available for the same condition (8, 9). Observational studies that harness large-scale EHR and medical records databases have the potential to uncover the effectiveness of drugs in routine care, identify latent adverse events, compare outcomes from several therapies head on, help expand our knowledge base of safe indications (10), and detect adverse drug events (ADEs) in real time (8, 11, 12).

Pharmacovigilance and Adverse Drug Events

The measuring, monitoring, and prevention of ADEs using EHRs and inpatient monitoring systems has been an important area of observational studies (13, 14). As noted above, preapproval trials establish efficacy but cannot provide clinical effectiveness data. Developments in pharmacovigilance have enabled physicians to extend their knowledge of therapeutic safety and contraindications tremendously, even if such systems have largely been limited to government databases and academic medical centers. The long-term scale of such databases, such as the U.S. Food and Drug Administration’s (FDA) Adverse Event Reporting System (15), has yielded important safety profiles of late-arising ADEs, such as dermatological and gastrointestinal ADEs in children from use of antibiotics (16). More recently, large commercial health insurance databases have used active drug safety surveillance systems such as i3 Aperio and helped define safety profiles of new diabetes drugs such as incretins (17). This area continues to be an important component of surveillance research and will only increase with the widespread adoption of EHRs in the coming years.

Signal detection, or the ability to automate ADE warnings with computerized database monitoring systems, is another area of ongoing research and clinical implementation (8, 18–20). One study of such an automated system monitored 36 653 inpatients over an 18-month period and correctly identified 731 ADEs in patients, whereas health professionals only reported 92 (18). A study published by one of the authors showed the potential for automated signal detection through population monitoring to detect early signs of COX-2 inhibitor’s association with myocardial infarction (21). Although there are potential difficulties in translating data entry from physician-based EHRs to accurately detect signals, one study found consistency between natural language processing characterization of patients with asthma with known population characteristics (22), providing further validation of this approach.

Recently, the FDA helped move the field forward with the launch of the Sentinel Initiative, the goal of which is to provide a linked, automated database from multiple sources of all approved drugs (23), and the Observational Medical Outcomes Partnership (24), which aims

to improve the methodologies of surveillance research. These projects should provide a solid foundation for when widespread EHR adoption populates the National Health Information Exchange (NHIE) infrastructure and further expands the ability to perform such studies.

Comparative Effectiveness of Therapeutics

With few exceptions, the vast majority of RCTs compare the efficacy of drugs under trial to that of placebo to gain approval by the FDA. In the routine clinical setting, however, physicians are not tasked with choosing between placebo and a drug, but rather between several drugs for the same condition (25). Pharmaceutical companies typically do not carry out such trials because of a lack of incentives to show that their new product will either be proven only as, or less than, effective than currently available medications (12). Head-to-head trials are mostly government sponsored, with a recent increase, since the passage of Medicare Part D provided an incentive for the government to ascertain comparative effectiveness data (26).

To help overcome some limitations of RCTs and assist in clinical decision-making, comparative effectiveness research using healthcare utilization databases, such as HMO administrative databases, Medicaid data, and EHR databases, can use epidemiological methods to study large and diverse populations of multiple drugs. This method provides the advantage for researchers to select patients of a specific disease and compare multiple drugs for their efficacy while examining the impact of ethnicity, location, age, duration of use, and, hopefully soon, genomics (12). Additionally, it is possible to observe various outcomes from differing drug exposures within the same patient over time, allowing patients to serve as their own control.

Methodological limitations are prevalent in postmarketing comparative effectiveness, and researchers must pay special attention to ensuring that proper techniques for data analysis are used. For example, confounding effects (e.g., inherit bias within physician prescribing by medical specialty) can limit generalizability and must be considered carefully before embarking on any such studies (9, 12). Despite this, the advent of EHRs increases the ease and potential benefits of such studies tremendously.

EHRs in Diabetes Research

EHR-based research on diabetes ranges from surveillance monitoring of treatment regimens to tertiary prevention and disease management efforts (27, 28). Most notably, observational studies using large-scale provider databases in both the UK (29) and Canada (30) provided early human-based evidence of the protective effect of metformin therapy as well as the increased risk of insulin and sulfonylureas on the development of cancer. More recently, the use of EHR-based research for surveillance purposes was demonstrated to be a useful adjunct to RCTs and provide signals of potential ADE in a study by one of the coauthors of a head-to-head comparison of myocardial infarction risk among users with rosiglitazone vs metformin (31). This study demonstrated that EHR-based ADE signal detection systems could have raised early warnings about the excess risk of myocardial infarction associated with rosiglitazone. Another large-scale observational study using the Medicare prescription data agreed with this finding and found pioglitazone relatively safer than rosiglitazone

among the thiazolidinediones (32). In light of these findings, the FDA recently conducted a second review of approved thiazolidinediones on the basis of these findings and that of several other observational studies. On metaanalysis, the FDA advisory committee concluded rosiglitazone therapy is associated with adverse cardiovascular outcomes when compared to other antidiabetic agents and recommended stronger warnings than were previously in place when this first came to light in 2007 (33). The consistency of several observational studies and the strength of their design provided critical confirmation of this substantial risk that was not fully appreciated in the RCT-based drug approval studies.

Hivert et al. (34) used EHRs to predict future diabetes and congestive heart disease among patients in a primary care network. Again, this study looked retrospectively at EHR data focusing on patients with aspects of metabolic syndrome to predict future outcomes based on a defined set of criteria and were able to demonstrate predictive power.

These studies demonstrate the possibility of identifying drug interactions and predisease characteristics either as they are happening, retrospectively, or predicatively, providing a useful resource for both researchers and physicians.

Challenges of EHR Observational Studies

Much has been made of the shortcomings with observational studies and infamous examples of misleading findings—most notably, the controversy over the use of hormones to protect against coronary artery disease in postmenopausal women (35, 36). Past missteps in observational studies for health outcomes could be attributed to confounding by indication, the use of proxies for covariates, and unmeasured patient population characteristics (9). Part of these shortcomings arose from the relatively new and growing nature of the field of epidemiological surveillance studies, considered akin to RCTs of the 1950s (9).

One of the chief shortcomings of observational studies is their lack of randomization, which can lead to bias in both physician and patient selection as well as potential differences in baseline risk factors (37). This lack of randomization and difficulty in quantifying pretreatment patient characteristics can be partially ameliorated through statistical approaches, such as propensity scoring and instrumental variable analysis (38). While epidemiologists are continually making strides in addressing these concerns, the prospect of a national shift to EHRs, with lifelong records and potentially genomic profiles, will allow researchers to effectively randomize observational studies on the basis of real-world treatments. In the near term, addressing such bias as discontinuation rates and movement out of an EHR network will need to be carefully addressed in the design of EHR-based studies.

Beyond statistical and study design challenges, the true historic difficulty in the implementation of these observational studies has been the lack of consistency, reliability, and overall quality of healthcare databases, which were not primarily designed for research (8). Secondary data-use studies often rely on a merging of electronic prescription billing databases with physician-oriented electronic medical records (39, 40). Furthermore, there remain substantial limitations in the use of these data for hypothesis-testing research, especially with the pervasive lack of key confounding variables. The reliance on advanced

natural language processing methods to transform EHRs in structured data with varying success means that current approaches are focused on hypothesis generation.

In this regard, the widespread adoption of EHRs and thrust of the HITECH Act will fundamentally alter the landscape of HER-based studies to a point where the use of datasets with millions of patients will become feasible (41). Additionally, the expansion of EHRs over the next decade will enable focused subpopulation analysis, enable long-term treatment studies, and reduce the need for proxy covariates when controlling for associated risk factors of treatments. Combined with the methodological maturation of the field and emphasis on data quality, the future for HER-based observational studies looks promising.

HITECH Act and Future Potential

The use of large-scale health databases facilitates observational studies by making real-time population data available on the use of drugs, as well as important patient descriptors such as BMI, smoking status, and alcohol use (39). Surveillance studies have historically relied on medical records databases, which often are physician entered and oriented, and administrative databases designed for reimbursement and accounting purposes (39). Although electronic billing of prescriptions is mandated in the US, these prescriptions often lack key information required for studies such as coexisting conditions, ethnicity, health behaviors, and other important confounding conditions that are often noted in physician-oriented medical records (39). While a few large institutions have instituted integrated electronic health records that combine both of these sources of information, (notably academic medical centers and some HMOs), only 1.5% of hospitals in the US have a comprehensive electronic records systems as of 2009 (3).

Conversely, and perhaps complimentary, to the use of pharmacovigilance for the discovery of ADRs and the potential for harm is the ability of EHR database studies to understand the safe use of therapeutics in clinical settings (42). The Netherlands PHARMO database has already shed light on the safe use of statins as well as the conditions for which they are possibly not helpful (10, 43). It is especially important to establish the proper use of therapeutics under multiple-drug regimens. It is also worth noting the potential for EHRs to integrate personal genomics data, which could allow for countless avenues of analysis of drug safety by genotype. The ability of EHRs to assist in this aspect of clinical management rests not only on the breadth and depth of researcher output, but also the management, analysis, and data-mining capabilities enabled by the widespread adoption of EHR databases. With adequate tools, perhaps enabled by third-party vendors, it may be possible in the future for physicians to compare their patient profile and specific characteristics (i.e., genomic data integration such as envisioned by the Informatics for Integrating Biology and the Bedside –I2B2 program (44)) with other patients on the same treatment regimens. This step would enable nonpublished analytical decision-making to be at the hands of physicians nationwide, a major shift that could significantly improve health outcomes.

PHRS AND SOCIAL NETWORKING

Defining PHRs and PCHRs

PHRs vary in definition depending on their use, control, software, and context. PHR systems often include the ability for patients to enter their own health information and gain access to health provider–hosted EHRs, whereas others delineate access through employer portals (45). The American Health Information Management Association defines PHRs as a tool for patients to collect, track, and share past and current health information (46). The underlying intent of all of these systems is to allow patients to have better access and control over their health information and thus increase participation in their own care (45, 47). In this review, a PHR will be considered any system that, at a minimum, allows patients access to their health records via computer.

PCHRs are a subset of PHRs, but with the specific characteristic of the patient as the absolute controller of the PHR. Therefore, the individual patient decides who can read, write, or modify their PCHR. By delineating access through patient consent, even for deidentified or aggregated data, systems using PCHRs hope to allay concerns of data privacy and confidentiality, while at the same time empowering and engaging patients (45, 48). In this review, a PCHR will be considered any system or EHR that gives the patient explicit control over his or her records.

Deployed PHR and PCHR Systems

Large corporations and government-administered healthcare plans are already investing heavily in both the use and development of PHR and PCHR systems. Most notable of these in the private sector are Dossia and Microsoft HealthVault. Indivo (www.indivohealth.org), developed at Children's Hospital Boston, set the groundwork for PCHRs through its open-source development platform and open standards (48), on which the Dossia platform (www.dossia.org), founded by AT&T, Wal-Mart, and others, is based (49). HealthVault (www.healthvault.com), tested in collaboration with New York Presbyterian Hospital, aims to collect and store patient information and also directly upload data from compatible medical devices such as blood pressure and heart rate monitors. Google Health (health.google.com), launched in collaboration with the Cleveland Clinic, aims to allow patients to manage all of their health information from various providers and sources in one place. Other private sector initiatives include Health Record Banks such as Healthbanking.org and Revolutionhealth.com.

In the public sector, the Centers for Medicare & Medicaid Services launched a PHR to allow patients to track services and communicate with providers over the Web (www.mymedicare.gov), while the Veterans Administration is piloting My HealthVet (http://www.health-evet.va.gov) which allows users to self-enter structured medical data, track personal health metrics, and grant access to other users (6). In this sense, the My HealthVet project is essentially a PCHR. Whereas these models may differ in their implementations, they all allow the patient greater access and in some cases control of their own EHR.

PHRS Enabling Patient Feedback, Accuracy, and Efficiencies

One challenge of HER-based research is ensuring complete and accurate data, especially when combining multiple data sources and information created for disparate purposes. By enabling patients to proofread their medical files, PHRs and PCHRs help providers obtain the most comprehensive file possible (50). While some patient-entered data are error-prone (e.g., patient-entered test results), studies have shown that patient recall can reduce duplicative laboratory tests and procedures (51).

Among patients with type 2 diabetes, the use of electronic journals (Web-based survey of patient-entered data) before their visits increased the accuracy of information transmitted to their physician (27). Similarly linked PHRs to provider EHRs resulted in more frequent medication adjustments when patients entered clinical data (52). Some PHR systems allow for patients to add over-the-counter medications and supplements, an often critically missing resource from current EHR-based studies (45). Whereas these studies demonstrate the inherent and unpredictable errors possibly present within paper medical records and EHRs, they also demonstrate potential fixes through greater patient participation. Such additional safeguards could help improve confidence in PHR-based studies.

PCHRs and Patient Participation in Research

One of the more burdensome aspects of EHR-based research is the extent to which caution must be taken to satisfy Health Insurance Portability and Accountability Act (HIPAA) requirements and the various medico-legal hurdles of institutional review boards. While offering myriad protections to patients enrolled in research, the anonymization of data and other requirements has also resulted in a situation where physicians are unable to communicate findings of trials in which the patient is a participant (53). Though RCTs require a certain level of anonymity, to safeguard both privacy and objectivity, such lack of communication from incidental findings could be detrimental. Kohane et al. (53) give the example of a genomewide study during which researchers find polymorphisms among dozens of participants, indicating they may respond favorably to a newly approved drug. Although it may benefit the patients, such a discovery cannot be easily communicated without overcoming significant ethical and legal hurdles. PCHRs represent a unique way to overcome such pitfalls while at the same time better engaging patients and improving research outcomes. With PCHRs, electronic “listeners” can be put into place to allow patients to be notified of ongoing research pertaining to their particular health condition, medications, or even genotype (45, 53). Critically, patients can allow key pieces of their PCHR to be broadcast for use in public health research and then decide if they would like to participate in the research that the “listener” finds. Already, patients have shown a willingness to engage in such systems provided they are largely for public benefit and clearly define how their data will be used (54, 55, 56).

With proper interoperability standards, researchers have the potential to make population-wide queries across multiple PCHR databases with the potential to reach millions of patients across vast geographies. Because there is no central database needed for such queries and patients have authorized access themselves, the potential for privacy breaches and data theft, sensitive in the wake of large-scale consumer credit thefts, are minimized (56). Another

boon to researchers and patients is the fact that this system design allows for enrichment of patient phenotypic data over time, opening up new avenues to research in which individual patient's information can be merged across studies as well as providing healthcare providers with additional information on patients in their care (56).

Health Social Networking and Quantified Self-Tracking

Health social networks (HSNs) are online social networking communities where patients can connect with each other around shared medical conditions. HSNs vary in their capabilities and features: at baseline, all provide emotional support through shared struggle, a few provide physicians to answer questions (57), and some offer quantified self-tracking (QST) (e.g., the symptom and quality-of-life charts at PatientsLikeMe [www.patientslikeme.com]) or alert patients to clinical trials. The emotional support and empowerment engendered by HSN Web sites can improve disease management, facilitate patient-physician communication, and promote psychological well-being (54). All of these aspects are important for health quality research, but perhaps the greatest potential for integrated translational research lies in QST.

QST allow patients to catalog their symptoms, medications, mood, and general condition over time in an analytical and standardized format via the Web. Aggregation of these data at the population level permits research by casual and knowledgeable users, Web site administrators, pharmaceutical companies, and health researchers. Users can share QST data with other community users, compare treatments and responses to drugs, and match to others with similar attributes and conditions (57).

PatientsLikeMe is one of the largest HSN Web sites that has QST and makes available member data for clinical trials, with over 79 000 members as of November 2010 (58). The self-stated goal of the Web site is to help patients improve their (often chronic) condition: "Given my status, what is the best outcome I can hope to achieve, and how do I get there?" PatientsLikeMe has reported a wide range of benefits for patients using its site, including a reduction in risky behavior among HIV patients and reduction of inpatient care among patients with mood disorders (54). In addition to helping patients manage their conditions, PatientsLikeMe has published a variety of research including the following: site of onset links to dominant hands among amyotrophic lateral sclerosis (ALS) patients (59), pathological gambling among ALS and Parkinson patients (60), and others (61).

CureTogether (www.curetogether.com), another HSN with QST features, has over 15 000 members who have contributed over 1.3 million data points covering 625 conditions. CureTogether advocates an Open Source Health Research Plan, modeling its patient community around diseases in a similar fashion to how software programmers developed Linux (62). Much like the collaborative model of PatientsLikeMe, CureTogether is increasingly using its HSN community to verify the effectiveness and compare the use of popular treatments, for example, pain medications and management techniques for Vulvodynia (63).

MedHelp is another HSN that offers QST for a variety of conditions, with a focus on providing health applications (e.g., drug interaction checker), direct communication with

physicians, and QST tools for patients with a wide variety of conditions. MedHelp began in 1994 and currently has over 10 million monthly users as well as a database of self-reported medical data with over 5 million data points (64).

TuDiabetes (www.tudiabetes.org) is an HSN focused on community support for patients with diabetes that currently has over 446 groups organized around various aspects of diabetes (e.g., Animas insulin pump users, athletic diabetics). Recently, TuDiabetes announced collaboration with Children's Hospital Boston to enable QST of hemoglobin A_{1c} values, with the ability to share with other users and display geographically (65). Part of the program is designed to investigate the ability to integrate QST data into PCHR platforms. SugarStats (www.sugarstats.com) is another newly developed Diabetes HSN that allows for QST. A list of innovative Web sites and platforms is included in Supplementary Table 1.

The potential for HSN, and especially QST, to be used in clinical trials has not gone unnoticed. As mentioned previously, PatientsLikeMe sells anonymized data to pharmaceutical companies and researchers. Other HSN sites let their users know of various ongoing clinical trials in which they could participate. Although patients vary in their willingness to share data, many want to know the latest treatments and help advance research on their disease. One striking example of this willingness was observed among the ALS community at PatientsLikeMe. After news spread of the potential benefit of lithium treatments for ALS, one patient gathered 250 PatientsLikeMe ALS volunteers to self-experiment with lithium. Although there are obvious challenges with such studies, it is worth noting that the patients had a larger sample than the original report and, unlike the initial findings, did not appear to demonstrate benefit from lithium (66), which was also the conclusion of a traditional follow-up study (67).

The integration with clinical trials and potential for expanded patient led trials opens up the possibility for patients to share their feedback from clinical trials with the public and other affected users, allow for cross-comparisons of responses, and feed this data into PHRs, all of which open up previously unavailable avenues for research (45, 57).

Automated Tracking of Patient-Entered Data

Because of their ability to receive data streams from multiple sources, EHRs and PHRs also have the potential to continuously track patient health through fully automated processes. Already, physicians use automated health tracking with cardiac monitoring devices and implanted health monitors in telemedicine that enable remote diagnosis (68, 69). As these devices transmit data wirelessly to healthcare providers at specified intervals, they can link to EHRs and facilitate patient tracking as well as completeness of medical files for care management and research. Beyond such invasive devices are technologies already in place, such as pedometers and glucose monitors that could be linked to PCHRs and QST systems to automate self-reporting of activity levels. One such device, FitBit (www.fitbit.com) is an inexpensive, wearable monitor of sleep and activity patterns that syncs wirelessly to the Internet. A recent study found cell phone data entry of activity levels to be as accurate as paper-based methods (70), while applications for diabetics to enter their blood glucose levels into smartphones have been proliferating, with several already developed for both the

Android (71) and iPhone OS (72) platforms. These applications when linked to PCHRs hold great potential for diabetes research and management on multiple levels.

The explosive uptake of smartphones in the US presents unique opportunities to track patient exposure to various environmental hazards and benefits such as parks. The University of California Los Angles participatory urban sensing project (http://urban.cens.ucla.edu) does exactly this by uploading data from GPS-enabled cell phones while giving users their own Personal Environmental Impact Report (57). When this information is connected with Environmental Protection Agency pollution monitoring, similar to how Centers for Disease Control and Prevention diabetes rates were recently associated with Environmental Protection Agency monitoring of particulate matter pollution (73), it could enable researchers to match genotypes with diseases and exposure.

For researchers, the incoming information explosion will require both knowledge to harness and integrate such disparate data streams as well as the methodological rigor to properly design studies to elucidate novel health connections between environment, behavior, and genes.

Challenges

Despite enthusiasm for the potential that PHRs, PCHRs, HSNs, and QST hold for research and health outcomes, many significant challenges remain. Although the HITECH Act makes patient access to data through PHRs one of the goals for 2012, there is less definition over what type of systems are applicable and how much control patients should have. Additionally, consumer demand for PCHRs is largely predicated by having a “life-changing” health event that creates a need to take an active role in self–health management. With obesity and diabetes exploding across the US, the prevention of such conditions, management of existing ones, and reduction of overall rates could be the impetus needed for consumer uptake.

Internet access, education, age (74), and even ethnicity (75) represent barriers to adoption of PHRs as well as general information of patient benefits. Some reports have shown a general lack of interest or knowledge of PHRs among the general population with concerns over privacy, cost, and access seen as chief concerns. These barriers could lead to selection bias and limit the generalizability of studies using PHRs, at least in the near term. However, among patients with chronic and life-threatening conditions, PHRs are seen as an instrumental tool to managing their care once they have been adopted. Additionally, HSNs provide patients with means to confirm their diagnosis and to become better adherent to medications and realistic about their expectations for improvement.

In terms of the HSN and QST communities, caution is warranted on the reliability of patients representing true symptoms, or even having the diseases at all. There are two ways this may be addressed. First, the patient communities themselves are often best at determining who truly has a disease and who is attempting to fraud the system (57). Individuals in a Munchausen Syndrome type situation could find themselves under scrutiny if they are too vocal. Thus, researchers could potentially screen based on activity level. Second, if QST Web sites become integrated into PHRs/PCHRs, then patients will have a

greater incentive to remain honest with themselves, since their physicians and healthcare providers would use the data to assess their status. While a certain level of misrepresentation and misclassification may be expected, the hope is that the size of the patient population properly reporting health information will overcome any introduced noise.

CONCLUSION

Demand for EHR adoption has largely been driven by the desire to reduce waste and foster better communication within the healthcare system as a whole. Because the benefits of EHRs are system-wide, but the costs are borne by individual providers, uptake has been slow and fragmented outside of large providers. With the introduction of the HITECH Act, it is now likely that system-wide adoption will take place. This should lead to a step forward in the use of EHRs for health outcomes research, with the ability to query unified records across multiple health systems in a radically inexpensive manner.

The drivers for PCHRs are distinctly different from those of EHRs, being driven by consumers/patients rather than by providers. Although the uptake of PCHR systems does not have direct incentives in HITECH, there are several social elements that are combining to make PCHRs a game-changing force in healthcare: the rise of social networking, the explosion of mobile technologies, the availability of powerful self-analytical tools, and the desire for patient autonomy and empowerment via personalized medicine (e.g., patients as decision-makers and the concordance model). The unification of these social forces through the PCHR appears inevitable, with a concomitant explosion in information available for future health researchers.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Research Funding: NIH National Center for Biomedical Computing (grant 5U54-LM-008748).

Role of Sponsor: The funding organizations played no role in the design of study, choice of enrolled patients, review and interpretation of data, or preparation or approval of manuscript.

Abbreviations:

ADE	adverse drug event
ALS	amyotrophic lateral sclerosis
FDA	U.S. Food and Drug Administration
HER	electronic health record
HITECH	Health Information Technology for Economic and Clinical Health
HMO	health maintenance organization
HSN	health social network

PCHR	personally controlled health record
PHR	personal health record
QST	quantified self-tracking
RCT	randomized controlled trial

REFERENCES

1. HealthIT.hhs.gov: Standards and Certification Fact Sheet. http://healthit.hhs.gov/portal/server.pt?CommunityID=3002&spaceID=48&parentname=&control=SetCommunity&parentid=&in_hi_userid=11673&PageID=0&space=CommunityPage (Accessed July 2010).
2. Blumenthal D, Tavenner M. The “meaningful use” regulation for electronic health records. N Engl J Med 2010:363:501–4. [PubMed: 20647183]
3. Jha AK, DesRoches CM, Campbell EG, Donelan K, Rao SR, Ferris TG et al. Use of electronic health records in U.S. hospitals. N Engl J Med 2009;360:1628–38. [PubMed: 19321858]
4. Marshall P. Keeping tabs: how personal health records are changing the face of healthcare. Mark Health Serv 2009;29:20–5. [PubMed: 20043413]
5. Mandl KD, Kohane IS. Tectonic shifts in the health information economy. N Engl J Med 2008;358:1732–7. [PubMed: 18420506]
6. Detmer D, Bloomrosen M, Raymond B, Tang P. Integrated personal health records: transformative tools for consumer-centric care. BMC Med Inform Decis Mak 2008;8:45. [PubMed: 18837999]
7. Brownstein CA, Brownstein JS, Williams DS, Wicks P, Heywood JA. The power of social networking in medicine. Nat Biotech 2009;27:888–90.
8. Härmark L, van Grootheest AC. Pharmacovigilance: methods, recent developments and future perspectives. Eur J Clin Pharmacol 2008;64:743–52. [PubMed: 18523760]
9. Avorn J. In defense of pharmacoepidemiology: embracing the yin and yang of drug research. N Engl J Med 2007;357:2219–21. [PubMed: 18046025]
10. Goettsch WG, Heintjes EM, Kastelein JJP, Rabelink TJ, Johansson S, Herings RMC. Results from a rosuvastatin historical cohort study in more than 45 000 Dutch statin users, a PHARMO study. Pharmacoepidemiol Drug Saf 2006;15:435–43. [PubMed: 16761304]
11. Aagaard L, Hansen EH. Information about ADRs explored by pharmacovigilance approaches: a qualitative review of studies on antibiotics, SSRIs and NSAIDs. BMC Clin Pharmacol 2009;9:4. [PubMed: 19254390]
12. Schneeweiss S. Developments in post-marketing comparative effectiveness research. Clin Pharmacol Ther 2007;82:143–56. [PubMed: 17554243]
13. Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP. Adverse drug events in hospitalized patients: excess length of stay, extra costs, and attributable mortality. JAMA 1997;277:301–6. [PubMed: 9002492]
14. Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T et al. Systems analysis of adverse drug events. JAMA 1995;274:35–43. [PubMed: 7791256]
15. Moore TJ, Cohen MR, Furberg CD. Serious adverse drug events reported to the Food and Drug Administration, 1998–2005. Arch Intern Med 2007;167:1752–9. [PubMed: 17846394]
16. Bourgeois FT, Mandl KD, Valim C, Shannon MW. Pediatric adverse drug events in the outpatient setting: an 11-year national analysis. Pediatrics 2009;124:e744–50. [PubMed: 19786435]
17. Dore DD, Seeger JD, Arnold Chan K. Use of a claims-based active drug safety surveillance system to assess the risk of acute pancreatitis with exenatide or sitagliptin compared to metformin or glyburide. Curr Med Res Opin 2009;25:1019–27. [PubMed: 19278373]
18. Classen DC, Pestotnik SL, Evans RS, Burke JP. Computerized surveillance of adverse drug events in hospital patients. Qual Saf Health Care 2005;14:221–6. [PubMed: 15933322]
19. Chan KA, Hauben M. Signal detection in pharmacovigilance: empirical evaluation of data mining tools. Pharmacoepidemiol Drug Saf 2005;14:597–9. [PubMed: 16134080]

20. Davis RL, Kolczak M, Lewis E, Nordin J, Goodman M, Shay DK et al. Active surveillance of vaccine safety: a system to detect early signs of adverse events. Epidemiology 2005;16:336–41. [PubMed: 15824549]
21. Brownstein JS, Sordo M, Kohane IS, Mandl KD. The tell-tale heart: population-based surveillance reveals an association of rofecoxib and celecoxib with myocardial infarction. PLoS One 2007;2;e840. [PubMed: 17786211]
22. Himes BE, Kohane IS, Ramoni MF, Weiss ST. Characterization of patients who suffer asthma exacerbations using data extracted from electronic medical records. AMIA Annu Symp Proc 2008;308–312. [PubMed: 18999057]
23. FDA's Sentinel Initiative. http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm (Accessed November 2010).
24. Stang PE, Ryan PB, Racoosin JA, Overhage JM, Hartzema AG, Reich C et al. Advancing the science for active surveillance: rationale and design for the observational medical outcomes partnership. Ann Intern Med 2010;153:600–6. [PubMed: 21041580]
25. Pablos-Mendez A, Barr RG, Shea S. Run-in periods in randomized trials: implications for the application of results in clinical practice. JAMA 1998;279:222. [PubMed: 9438743]
26. Clancy CM. Getting to 'smart' health care. Health Affairs 2006;25:w589. [PubMed: 17090557]
27. Wald JS, Grant RW, Schnipper JL, Gandhi TK, Poon EG, Businger AC et al. Survey analysis of patient experience using a practice-linked PHR for type 2 diabetes mellitus. AMIA Annu Symp Proc 2009;678–82. [PubMed: 20351940]
28. Johnson JA, Singal R. Impact of a Web-based diabetes program and personal health record on diabetes quality of care. J Manag Care Med 2006;9:13.
29. Evans JMM, Donnelly LA, Emslie-Smith AM, Alessi DR, Morris AD. Metformin and reduced risk of cancer in diabetic patients. BMJ 2005;330:1304–5. [PubMed: 15849206]
30. Bowker SL, Majumdar SR, Veugelers P, Johnson JA. Increased cancer-related mortality for patients with type 2 diabetes who use sulfonylureas or insulin. Diabetes Care 2006;29:254–8. [PubMed: 16443869]
31. Brownstein JS, Murphy SN, Goldfine AB, Grant RW, Sordo M, Gainer V et al. Rapid identification of myocardial infarction risk associated with diabetes medications using electronic medical records. Diabetes Care 2009;33:526–31. [PubMed: 20009093]
32. Graham DJ, Ouellet-Hellstrom R, MaCurdy TE, Ali F, Sholley C, Worrall C et al. Risk of acute myocardial infarction, stroke, heart failure, and death in elderly Medicare patients treated with rosiglitazone or pioglitazone. JAMA 2010;304:411–8. [PubMed: 20584880]
33. Center for Drug Evaluation and Research. Endocrinologic and Metabolic Drugs Advisory Committee: Briefing Information for the July 13–14, 2010, Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm218491.htm (Accessed November 2010).
34. Hivert M, Grant R, Shrader P, Meigs J. Identifying primary care patients at risk for future diabetes and cardiovascular disease using electronic health records. BMC Health Services Research 2009;9:170. [PubMed: 19772639]
35. Grodstein F, Stampfer MJ, Manson JAE, Colditz GA, Willett WC, Rosner B et al. Postmenopausal estrogen and progestin use and the risk of cardiovascular disease. N Engl J Med 1996;335:453. [PubMed: 8672166]
36. Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative Randomized Controlled Trial. JAMA 2002;288:321–33. [PubMed: 12117397]
37. D'Agostino RB Jr, D'Agostino RB Sr. Estimating treatment effects using observational data. JAMA 2007;297:314. [PubMed: 17227985]
38. Stukel TA, Fisher ES, Wennberg DE, Alter DA, Gottlieb DJ, Vermeulen MJ. Analysis of observational studies in the presence of treatment selection bias: effects of invasive cardiac management on AMI survival using propensity score and instrumental variable methods. JAMA 2007;297:278–85. [PubMed: 17227979]

39. Hennessy S. Use of health care databases in pharmacoepidemiology. Basic Clin Pharmacol Toxicol 2006;98:311–13. [PubMed: 16611207]
40. Dean BB, Lam J, Natoli JL, Butler Q, Aguilar D, Nordyke RJ. Review: Use of electronic medical records for health outcomes research: a literature review. Med Care Res Rev 2009;66:611. [PubMed: 19279318]
41. The Future of Drug Safety: Challenges for the FDA: Institute of Medicine. http://www.iom.edu/Activities/Research/DrugForum/2007-MAR-12.aspx (Accessed July 2010).
42. Waller PC, Evans SJW. A model for the future conduct of pharmacovigilance. Pharmacoepidemiol Drug Saf 2003;12:17–29. [PubMed: 12616844]
43. Goettsch WG, Yin DD, Alemao E, Klungel OH, Stalenhoef AF, Herings RM. Statins are less effective in common daily practice among patients with hypercholesterolemia: the REALITY-PHARMO study. Curr Med Res Opin 2004;20:1025–33. [PubMed: 15265247]
44. i2b2: Informatics for Integrating Biology and the Bedside. https://www.i2b2.org/about/intro.html (Accessed August 2010).
45. Halamka JD, Mandl KD, Tang PC. Early experiences with personal health records. J Am Med Inform Assoc 2008;15:1–7. [PubMed: 17947615]
46. myPHR. What is a PHR? http://www.myphr.com/index.php/start_a_phr/what_is_a_phr/ (Accessed July 2010).
47. 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. [PubMed: 16357345]
48. Mandl KD, Szolovits P, Kohane IS. Public standards and patients' control: how to keep electronic medical records accessible but private. BMJ 2001;322:283–7. [PubMed: 11157533]
49. Mandl K, Simons W, Crawford W, Abbett J. Indivo: a personally controlled health record for health information exchange and communication. BMC Med Inform Decis Mak 2007;7:25. [PubMed: 17850667]
50. Wuerdeman L, Volk L, Pizziferri L, Tsurikova R, Harris C, Feygin R et al. How accurate is information that patients contribute to their electronic health record? AMIA Annu Symp Proc 2005;2005:834–8.
51. Kaelber DC, Jha AK, Johnston D, Middleton B, Bates DW. A research agenda for personal health records (PHRs). J Am Med Inform Assoc 2008;15:729–36. [PubMed: 18756002]
52. Grant RW, Wald JS, Schnipper JL, Gandhi TK, Poon EG, Orav J et al. Practice-linked online personal health records for type 2 diabetes mellitus: a randomized controlled trial. Arch Intern Med 2008;168:1776–82. [PubMed: 18779465]
53. Kohane IS, Mandl KD, Taylor PL, Holm IA, Nigrin DJ, Kunkel LM. MEDICINE: Reestablishing the researcher-patient compact. Science 2007;316:836–7. [PubMed: 17495156]
54. Wicks P, Massagli M, Frost J, Brownstein C, Okun S, Vaughan T et al. Sharing health data for better outcomes on PatientsLikeMe. J Med Internet Res 2010;12;e19. http://www.jmir.org/2010/2/e19 (Accessed July 2010).
55. Weitzman ER, Kaci L, Mandl KD. Sharing medical data for health research: the early personal health record experience. J Med Internet Res 2010;12;e14 http://www.jmir.org/2010/2/e14/HTML (Accessed July 2010). [PubMed: 20501431]
56. Kohane IS, Altman RB. Health-information altruists: a potentially critical resource. N Engl J Med 2005;353:2074–7. [PubMed: 16282184]
57. Swan M. Emerging patient-driven health care models: an examination of health social networks, consumer personalized medicine and quantified self-tracking. Int J Environ Res Public Health 2009;6:492–525. [PubMed: 19440396]
58. PatientsLikeMe. Real-world treatment and symptom information from fibromyalgia, chronic fatigue syndrome, depression, anxiety, MS, Parkinsons, HIV/AIDS, and ALS patients like you http://www.patientslikeme.com/all/patients (Accessed July 2010).
59. Turner MR, Wicks P, Brownstein CA, Massagli MP, Toronjo M, Talbot K et al. Concordance between site of onset and limb dominance in amyotrophic lateral sclerosis. J Neurol Neurosurg Psychiatry 2010 http://jnnp.bmj.com/content/early/2010/06/18/jnnp.2010.208413.abstract (Accessed July 2010).

60. Wicks P, MacPhee GJA. Pathological gambling amongst Parkinson's disease and ALS patients in an online community (PatientsLikeMe.com). Mov Disord 2009;24:1085–8. [PubMed: 19353722]
61. PatientsLikeMe. Research. http://www.patientslikeme.com/research (Accessed November 2010).
62. The Collective Well, Open Source Health Research Plan. http://curetogether.com/blog/about/open-source-health-research-plan/ (Accessed July 2010).
63. CureTogether Stats, Vulvodynia Treatment Gap. http://curetogether.com/vulvodynia/ig/treatment-effectiveness-vs-popularity (Accessed July 2010).
64. Health and Wellness Tools, free online interactive tools from MedHelp. http://www.medhelp.org/health_tools (Accessed July 2010).
65. TuAnalyze. Track, share and compare your diabetes data. http://www.tuanalyze.org/ (Accessed July 2010).
66. Frost JH, Massagli MP, Wicks P, Heywood J. How the social web supports patient experimentation with a new therapy: the demand for patient-controlled and patient-centered informatics. AMIA Annu Symp Proc 2008;217–221. [PubMed: 18999176]
67. Aggarwal SP, Zinman L, Simpson E, McKinley J, Jackson KE, Pinto H et al. Safety and efficacy of lithium in combination with riluzole for treatment of amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. Autophagy 2010;1:2.
68. Bernard ML, Quin EM, Gold MR. Remote monitoring: the future of implantable cardioverter-defibrillator follow-up. Card Electrophysiol Clin 2009;1:193–200. [PubMed: 28770784]
69. Santini M, Ricci RP, Lunati M, Landolina M, Perego GB, Marzegalli M et al. Remote monitoring of patients with biventricular defibrillators through the CareLink system improves clinical management of arrhythmias and heart failure episodes. J Interv Card Electrophysiol 2008;24:53–61. [PubMed: 18975066]
70. Bexelius C, Löf M, Sandin S, Lagerros TY, Forsum E, Litton J. Measures of physical activity using cell phones: validation using criterion methods. J Med Internet Res 2010;12:e2 http://www.jmir.org/2010/1/e2/ (Accessed November 2010). [PubMed: 20118036]
71. 7 Diabetes Android Apps for Diabetic Patients: Goomedic.com. http://www.goomedic.com/7-diabetes-android-apps-for-diabetic-patients.html (Accessed August 2010).
72. Diabetes and the iPhone: Diabetes Health. http://www.diabeteshealth.com/read/2009/07/13/6274/diabetes-and-the-iphone/ (Accessed August 2010).
73. Pearson JF, Bachireddy C, Shyamprasad S, Goldfine AB, Brownstein JS. Association between fine particulate matter and diabetes prevalence in the United States. Diabetes Care 2010;33:2196–201. [PubMed: 20628090]
74. Kim E, Stolyar A, Lober WB, Herbaugh AL, Shinstrom SE, Zierler BK et al. Challenges to using an electronic personal health record by a low-income elderly population. J Med Internet Res 2009;11;e44. http://www.jmir.org/2009/4/e44/ (Accessed November 2010).
75. Roblin DW, Houston TK, Allison JJ, Joski PJ, Becker ER. Disparities in use of a personal health record in a managed care organization. J Am Med Inform Assoc 2009;16:683–9. [PubMed: 19567790]