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The Future of Patient Engagement in the Governance of Shared Data

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Abstract

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Opportunity for Improvement: Exploration of patient preferences about personal health data use for research and quality improvement is a fundamental element of the provider-patient relationship. Giving patients an explicit opportunity to discuss their options about use of their data and implementing a process that allows patients to receive desired communications about how their information is used can help build patient trust, a requirement for successful care partnerships.

Practice Advancement: Working to change organizational cultures that exclude patients from participation in important decisions related to personal health information use promotes a strong patient-provider relationship and, ultimately, lays the foundation for improved health care through expanded use of patient data.

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None

Keywords

patient engagement, decision making, patient-centered outcomes research, patient-centered care, data collection, organizational innovation

Disciplines

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Introduction

In the rapidly evolving age of precision medicine, there is much excitement about the use of patient data for research. Genomic medicine offers new opportunities to identify beneficial treatments previously not known or not recognized as appropriate for a patient. The growing shift to the patient-centered medical home model of care delivery facilitates increased practice of personalized medicine,[1] as well as expanded opportunities to bring genomic medicine into broader, primary care-based practice.[2] The National Institutes of Health's Precision Medicine Initiative Cohort Program[3] will enable a more thorough understanding of the biological, environmental, and behavioral influences on disease development and will position investigators to discover and develop treatments targeted to specific individuals. These new advances in treatment will bring with them greater quantities of personal health information (PHI) and clinical data than ever before seen in medicine.

The emergence of precision medicine and the technologies that make it possible bring new challenges in clinical care; research innovation; and ethical, legal, and social issues. Policies that govern data sharing and use will evolve too as the foremost concerns of patients and health care professionals come to light. As these technological advances become integrated into the cycle of practice innovation, implementation, evaluation, and improvement, patients and providers will need to forge new relationships based on mutual trust and shared decision-making. Nowhere will that requirement become more pressing than with regard to data use and sharing.

This commentary considers the evolving use of PHI in clinical care; explores key issues in provider-patient relationships that underlie data sharing; and describes an approach to PHI sharing that facilitates patient engagement, relationship building, and shared decision-making.

Uses of Personal Health Information (PHI) to Improve Care

To date, patients' opportunities to choose how their PHI is used outside of clinical encounters have often been limited, and in some cases providers too have had little to say about secondary uses. For example, health care institutions frequently review electronic health records to identify opportunities to improve quality of care, an activity that can benefit both patients and providers and that may be disclosed in general terms in facility registration forms.

Similarly, during hospital admission or clinic sign-in, patients sign an agreement permitting details of their visit to be shared with payers or perhaps to forego care. Research involving biospecimens may not entail patient consent at all, a situation that affords efficient tissue processing but can leave patients feeling marginalized and mistrustful of clinicians' motivation when ordering tests. Patients do not always understand information about genomic sequencing and, even when presented with information about what is involved, a significant number consider the benefits unclear.[4] Psychosocial distress occurs in some individuals who undergo testing,[5] and oncology nursing best practice includes patient education and support before, during, and after biospecimen collection and testing.[6,7]

The use of PHI in initiatives such as comparative effectiveness research and decades-long monitoring and reporting offers significant opportunities to improve care. Use of PHI is also critical in identifying unmet needs, such as the lack of adequate housing, and in addressing health care inequities. For example, provisions of the Patient Protection and Affordable Care Act provide for standardized data

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collection related to disability, which will enable the health care system to identify barriers to care and improve the care received by people with disabilities.[8]

In addition, emerging technologies such as wearable devices and home sensors for remote monitoring, as well as more established technologies such as social media and mobile health (mHealth) applications, are expanding the opportunities for patients to generate data about themselves. Patient-generated health data can help patients and their care teams facilitate health management and optimize quality of life.[9] As use of these new technologies becomes routine, clinical practices and researchers will find secondary uses for such data and will need processes for managing it.

At the same time, use of PHI in such data-driven efforts raises multiple challenges, including privacy-related concerns, issues associated with obtaining informed consent for current and future data uses, difficulties related to patient participation in precision medicine-focused initiatives, and matters of equity in who receives care and how data are used with regard to varying ethnic and socioeconomic groups.[10] More broadly, the issue of equity is also of concern in low- and middle-income countries, which frequently lack not only the resources for precision medicine but also the resources for routine procedures and medications under patent.[11] This list is likely to grow as greater uses for data are developed and embedded within clinical practice and health care research.

The evolution of medicine to this more personalized, complex form brings with it the need for a richer and more nuanced relationship between patients and their care teams, and the need for new strategies that promote greater security, transparency, and appreciation of patient contribution and perspectives.

Building Trust, Ensuring Security, and Building Capacity

Reaping the benefits of precision medicine, however, will require greater patient engagement with the health care system than is the norm in many settings currently. Not only will patients be seen in clinical and online settings, as they are today, but also patient information will be reviewed and reused in clinical and research settings in which patients are not present. Growing pressure on health care institutions to track and publish outcomes is expanding data analysis performed routinely, much of which relies on retrospective record review. The ongoing scarcity of research funding has motivated researchers to find new uses for existing data, and current regulations do not require disclosure of all such uses to patients. Data on patient perspectives and priorities is integral to developing new therapies and practices that will result in improved outcomes. Achieving these goals relies in large measure on patients' confidence that what they are told about how their information will be used is true, and will be truly of benefit to them and other patients.

Numerous research and survey efforts indicate that patients are willing to share their health information for both therapeutic and research uses when data users and managers take adequate and appropriate actions such as encryption and data access auditing to protect patients' privacy.[12-15] Building trust related to the use of even de identified data is critical,[16] as is having the ability to control one's information. By gathering pertinent details about patient preferences related to permission seeking, de identification, notification of data use, and ongoing engagement at the time that patients establish a relationship with their primary provider, clinicians can begin building the relationship needed to support lifelong data use and sharing. Preferably this conversation would occur at an early visit (e.g., the patient's first or second clinical encounter with the provider), but

could occur later if the patient wished to develop a stronger relationship with the provider or care team before making decisions about data sharing. Ideally, the patient's decisions would be recorded in the electronic health record as well as given to the patient in hard copy or electronic form, as preferred.

This initial detail-gathering process also offers a nonthreatening way for providers to start a conversation about the value of shared decision-making if a patient does not wish to participate in making choices about the use of his or her data, an effort that may benefit both parties when difficult care decisions must be made in the future. Such difficult care decisions can take many forms. For example, patients who feel it is disrespectful to question a provider's advice may be reluctant to state any preference regarding use of personal data. Similarly, patients who are very ill may lack the energy or interest to read patient education materials about the benefits and risks of data sharing, preferring to leave this seemingly less important decision to the provider. Health literacy and numeracy skills also affect patients' willingness to make decisions about their care,[17-19] adding to the challenge of talking through care decisions with providers. Though patient engagement in decision-making is becoming a core value in health care, some patients prefer the more traditional provider-centric approach,[20] and their preferences need to be respected and accommodated.

Patients have varying degrees of sensitivity toward sharing their PHI, and willingness to provide that information may vary between demographic and financial data, anthropometric measurements, lifestyle and nutrition practices, diagnosis and treatment specifics, and genomic data. These types of data are associated with a varying desire for confidentiality, as well as a variable commercial value beyond their use in management of patients' health and mandated public health reporting. Some individuals fear the sharing of information that has resulted in, or that they believe will, result in stigmatization—such as about their obesity or their history of mental illness or having had an abortion. Others fear the revelation of information that could disrupt their lives or put them at financial peril, such as documentation of marital infidelity or substance abuse, or the discovery of a life-shortening condition. Information that may be predictive of an individual's future health status, such as genetic data or a history of life-threatening conditions, may by its nature spur confidentiality concerns.

The unintended sharing of different types of data may elicit varying degrees of concern among patients, e.g., sharing of general demographic data may be less distressing to patients than sharing of medication history. Thus, an approach that facilitates informed consent, management of data use permissions, and data sharing by data type will offer patients and their care team the greatest flexibility in managing health data for research. An application that provides opportunities for clinicians and researchers to identify data relevant to specific investigations and for patients to choose the types of data they wish to share and the purposes for which sharing may occur can be an effective bridge between the need for privacy and the desire to innovate. This application should facilitate mandated public health reporting as well as institutional and commercial purposes of specific value to the populations whose data are collected. For example, in a region with a high incidence of vehicular-related injuries and deaths, the application might include items about motorcycle and automobile ownership, seatbelt use, and frequency of driving after drinking alcohol.

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Strategies for Eliciting Patient Preferences on Data Sharing

Though implementing a data-sharing mechanism requires efforts not commonly included in current processes, implementing an approach that meets the data-sharing preferences of each patient with regard to privacy, security, and transparency need not be onerous, financially ruinous, or technically overtaxing. When a patient provides the personal demographic and historical information necessary to set up the electronic medical record initially, the patient can be asked a series of additional questions related to his or her understanding of how what data are collected and how they can be used, such as for retrospective analysis for quality improvement, for medication adverse effect identification and reporting, for identification of eligible clinical trial registrants, and others. For instance, patients can be asked if they wish to evaluate opportunities to participate in research involving only records review, research involving some additional data collection (e.g., blood tests beyond those they normally undergo), or other research that may help their care partners to better understand their health and, potentially, identify therapies or care that may help maintain their health. Explanation of data de identification methods can help alleviate patient concerns about data sharing. Patient education materials developed for this effort should encompass the principles used in creating other patient-directed materials, e.g., text that is readable by individuals with moderate levels of health literacy, accurate illustrations, use of multimedia to illustrate complex concepts, etc.

At the initial encounter, patients can also be offered the option of making decisions about use of their data at a future clinical encounter, after they have had time to think about their preferences and, if appropriate, develop a list of questions to ask their provider. This opportunity for reflection and consultation with family, friends, and trusted associates (e.g., culture brokers) is critical for two reasons. First, it provides patients with education and an opportunity to think through the many issues related to decisions about the use of their personal data. Second, it demonstrates the shared nature of the decision-making that will occur between patients and the members of their care teams. In this way clinicians, researchers, and patients can move forward together in a true spirit of "nothing about me without me."[21] This clear and present effort to *partner with* patients rather than *act unilaterally* on their behalf strengthens the dynamic of patient engagement that will underlie provider-patient relationship in years to come.

If a patient wishes to share his or her data, the clinician can then inquire as to whether the patient wishes to receive notifications when the data are used in clinical- or research-focused initiatives. If the patient does wish to receive such communications, he or she can provide an email address where notifications can be sent that contain a link to a secure patient portal or protected website where study information may be accessed. In this way patients' data, and even the fact that an individual's data have been used, remain in a protected environment. Including an additional field containing the patient's email address in the record is unlikely to place an undue burden on database administrators or system requirements. Annual requests to the patient to confirm the email address, as well as a simple procedure for updating the address outside the annual cycle, will help patients make more active decisions regarding their information and engage proactively with the health care system without adding substantially to the organization's workload.

Providing summaries of analyses to patients whose data were used, when desired by patients, will promote a positive view of data sharing and will strengthen relationships by helping patients to

understand the importance and safety of using PHI in research. Return of raw genomic data has already generated interest among potential research participants;[22] though such activity may not be immediately feasible, it points to patient desire for a greater role in health management. Given the highly publicized possible drawbacks to sharing genomic information—discrimination in employment and insurance procurement, disruption of family relationships when individuals are made aware of health information they wished not to know, and anxiety over predisposition to health conditions for which there is yet no cure, among others—the fact that individuals still seek to obtain genetic information about themselves reflects a more proactive to personal health. Such a system could also offer patients the option to share their data without receiving notifications of data use and to change their notification preference at a future time.

In addition, a process like the one described here can facilitate data access management at multiple levels based on purpose and personnel. For some data uses, such as public health surveillance, federal and state laws will determine the type and degree of data sharing required without explicit decision-making by patients and their care team. For other uses, such as clinical trial recruitment and health goal tracking, patients are well placed to identify who—providers, researchers, family members, durable powers of attorney for health care, etc.—should be able to access each data type. In an environment of shared decision-making, a process that manages patient preferences and permissions can flexibly support the needs of patient, care teams, and researchers.

Conclusion

New approaches that require changes to existing workflows may be among the most difficult to implement. Nonetheless, retaining the status quo carries its own risks. Although technical issues are real, the primary challenges to change may be attitudinal and cultural, as in the case of the sharing of genomic information with patients.[23] Processes such as the one previously described in this paper could facilitate shared decision-making and help health care providers address emerging concerns such as data use policy development and implementation, data management and protection, and compliance with federal and state regulations such as the Health Insurance Portability and Accountability Act. Applications that facilitate shared decision-making can help health care providers address emerging concerns such as the monitoring of patients receiving investigational therapies outside clinical trials;[24] growing use of telemedicine in the provision of routine care; and the shift to care management through patient portals, mobile health applications, and other digital tools. Systems that support greater patient decision-making will benefit not only patients, but also providers and health care organizations today and in the future.

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