Perspective

Potential and Challenges of Patient-Generated Health Data for High-Quality Cancer Care

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The recent proliferation of more affordable wearable devices, sensors, and technologies such as patient portals to capture and transmit patient-generated health data (PGHD) provides an unparalleled opportunity to monitor and track a patient's longitudinal cancer experience, to engage patients as partners in their care, and to make advancements toward a true learning health care system for cancer care. This vision for a learning cancer care system centers on data coming from individual patients and their cancer care teams.[1] With 90% of oncology practices reporting that they either already have or plan to have an electronic health record (EHR)[2] and advancements in EHR functionalities, the necessary technical infrastructure is now available to realize the potential for PGHD to enhance quality cancer care and build learning cancer care systems. Whereas much progress has been made in collecting data from clinical care teams via EHRs and cancer registries, there is still a critical gap in capture of information from patients/caregivers. PGHD integrated into EHRs could address this important gap and make this information available for clinical care, research, and quality improvement.

PGHD are defined as "health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and so on—created, recorded, gathered, or inferred by or from patients/caregivers to help address a health concern."[3(p2)] This is differentiated from data generated during clinical care, because *patients* (not providers) are the ones responsible for capturing these data and also have the ultimate control over how these data are shared. Examples of biometric PGHD that have promise for cancer care include heart rate, temperature, weight, blood pressure, pulse oximetry, physical activity and intensity, caloric expenditure, and sleep duration and quality. Another type of PGHD with potential is patient-entered data through patient portals, which could be used to keep medical histories updated; to share advance directives; to capture information about barriers to care such as transportation issues; and to collect information about symptoms, physical function, and quality of life through patient-reported outcomes (PROs). Although many types of PGHD are already used in clinical care (eg, paper logs of blood pressures), the collection and integration of the wide range of PGHD that now can be captured during patients' everyday lives has not been typically recorded as structured or discrete data elements in EHRs. Integrating PGHD into EHRs could help to accelerate not only understanding a patient's cancer experience but also increasing efficiency and productivity of clinical trials, improving prediction of addressable treatment toxicities, and ultimately improving quality of care and clinical outcomes.

Multiple forces are aligning toward systematically integrating the patient's voice and experience into EHRs through PGHD as part of routine clinical care. Key organizations such as the Institute of Medicine[4] and ASCO[5] have recently focused on the importance of information technology for making the vision of a learning health care system for cancer a reality. Patients are also increasingly engaged in their health and are willing and able to track and monitor health; 21% of Americans already track health using technology.[6] The personal health device market is expected to grow to more than 70 million devices sold by 2018,[7] which will improve the availability and affordability of wearable devices for health. In addition, upcoming federal stage 3 meaningful use will require that provider-requested PGHD, including PROs, be accepted electronically, with the goal of having patients contribute information to the EHR.[8]

The intermittent monitoring that typically takes place during clinical encounters provides only a snapshot of the patient's health, but with PGHD, this could be extended to continuous, longitudinal monitoring given that the majority of patients' lives are spent outside of the hospital/clinic setting. In this way, ubiquitously monitoring patients in real-world settings could transform the current model of cancer care and generate a more holistic view of the health of the patient. PGHD could also create efficiencies by moving data collection outside of encounters such the review of systems via patient portals,[9] and that time could then be used for shared decision making. It could also strengthen patient-provider communication and care coordination through continuously updated patient information. PROs, a type of PGHD, could help to improve the completeness and accuracy of data collection of symptoms and toxicities within the EHR.[10-13] Several use cases demonstrate the potential benefit of PGHD in improving patient satisfaction, symptom control and supportive measures, and health outcomes.[10,14-18]

There are several challenges to unlocking the potential for PGHD in cancer care that need to be addressed including provider concerns, workflow issues, standardization of PGHD and interoperability of devices/sensors, security and privacy issues, and lack of the necessary EHR functionalities and software innovations to harness PGHD to make these data useful to stakeholders.

For providers, PGHD brings up a multitude of concerns including information overload from the deluge of data, whether the data will be usable and of high enough quality for decision making, workload concerns, and liabilities that may

stem from lack of timely and appropriate review and action.[3,19] Providers also cite concerns about the financial impact of PGHD. The additional time and resources required for review and management of PGHD may outweigh the efficiencies gained from outsourcing data collection to the patient. However, reimbursement models are aligning for the use of PGHD for remote monitoring. Beginning January 1, 2015, the Centers for Medicare & Medicaid Services will cover remote chronic care management using a new current procedural terminology code (99490) to reimburse a monthly unadjusted, nonfacility fee of $42.60 per patient.[20]

Workflow issues are also a substantial hurdle for operationalizing PGHD. Who will be responsible for reviewing and responding to PGHD, within what timeframe, and through what modality (secure message versus telephone call)? What is the optimal frequency for both generating PGHD and submitting/transmitting these data to the EHR for review? Little is known about whether certain types of PGHD are better suited for continuous monitoring or for certain patient populations or conditions. And it is not clear which types of PGHD will be the most valuable for self-monitoring for patients or whether these will be concordant with those that providers feel are the most important. These are some of the questions that must be worked through and are actively being pursued through research. As experience grows in this area, best practices may guide providers who wish to adopt PGHD.

Lack of industry-wide standards for both PGHD and interoperability of devices is a growing concern within the information technology community. Although many device companies are using the consolidated care document standard that enables connectivity between sources, many devices (like the popular Fitbit device) still use proprietary architecture, making it more difficult for interoperability given that patients may have multiple devices. The Office of the National Coordinator and industry standards organizations such as HL7 are actively working on these issues. Additionally, the development of a recommended common core set of symptoms for patients with cancer[21,22] is gaining momentum; there are already validated questionnaires such as Patient Reported Outcomes Measurement Information System (PROMIS) available within many existing EHRs.

The privacy and security of PGHD is also a challenge and potential barrier to operationalizing PGHD. Patients, providers, and researchers all desire assurance that the data submitted are indeed authentic and from the patient or designated caregiver and that they are linked to the correct patient record within the EHR. The locus of control over the data should rest with the patient, such that he/she has the choice of who has authorization to view his/her data and how, if at all, it should be shared with other providers. Tracking the source of the data, or data provenance, will be important as it moves from the patient to EHRs, and secure transmission will be critical.[23]

EHRs are also beginning to enable integration of wearable device data and PROs into the clinical record, which also provides new sources of data that can be funneled into research databases. For example, several of the largest EHR vendors (Cerner, athenahealth, Allscripts Healthcare Solutions, Epic) either have existing or planned integration with Apple's Health Kit application, which aggregates multiple sources of PGHD into a unified dashboard for health and fitness data. It is clear that providers feel that the provenance of PGHD must be preserved given that these data are exchanged and stored in EHRs in a way that they are demarcated from data created within clinical encounters.[3] Many of the largest EHR vendors also provide the capability to send PRO questionnaires to patients via the patient portal. Another example of how PGHD in EHRs could improve quality would be to provide structured data fields for documenting review of PGHD and whether appropriate actions for managing symptoms or toxicities were taken. These structured data could then be used for performance and quality reporting. Quality and performance dashboards within the EHR could be used at the levels of individual provider, practice, and health care system to identify areas for improvement. Developing these types of features for model EHR systems could thus enhance reporting and quality improvement efforts.

However, the future of PGHD ultimately depends on advances in technologies that will enable the transformation of these data into meaningful, digestible, and actionable information to improve clinical outcomes. Wearables generate large volumes of asynchronous or continuous streams of data, which would be impossible to manage and review without intelligent filtering and summarization. Moreover, it will be critical to combine longitudinal symptom information collected via PROs, wearable/sensor device data, and clinical data into a single dashboard within the EHR that could be updated with real-time information at the point of care for decision making without having to review multiple screens. Innovations in advanced clinical decision support are needed and could provide mechanisms to algorithmically determine which patients need attention because of deteriorating clinical status or to predict which patients will have a higher risk for developing toxicities. EHRs and clinical decisions support systems will need to provide easily customizable alert systems that can be tailored for individuals without substantial software programming, given that manual review of PGHD is not feasible.

From a research perspective, there are still many questions—the field of PGHD is still nascent. We highlight some key questions that are being explored by our team and others on the value of PGHD and on measurement, workflow, and informatics issues. Because widespread collection of such a variety of PGHD is now possible on a population level, research is needed to identify which types of PGHD are the most useful for improving health outcomes and quality of care both on an individual and population level. Research is also needed to determine whether these are the same types of PGHD that patients find are the most helpful so they can manage chronic conditions and health. There are current gaps in knowledge about how PGHD are actually used by both patients and providers, how PGHD should optimally be used by patients and providers for both self-care and chronic disease management purposes, and which types of patients may benefit the most

from monitoring with PGHD. Randomized and pragmatic trials are needed to examine whether PGHD improves shared decision making and longitudinal health outcomes. Continuous monitoring, even at its best, will still have missed days or missing instances of device use or wear. How to handle missing data as well as determining how much missing data makes the PGHD unusable for research and clinical care are not yet clear. Research should focus on how frequently PGHD should be collected to provide meaningful trends and information (continuous *v* intermittent). Additionally, research is needed regarding optimal timing for when and how to incorporate submission of PGHD into clinical workflows and whether this will need to be tailored at provider, practice, or health care system levels. Creation and evaluation of user-centered data visualizations and intelligent filtering systems for PGHD are also necessary for optimizing use of PGHD in clinical care. Different methods of data display and aggregation are being explored by many researchers, primarily focused on PROs, but there is growing interest in expanding this work to other types of PGHD.

In the near future, one could envision that sensors embedded within our environments or appliances and worn on our bodies could create rich contextual data that could provide an ecosystem of information for health that improves not only the health of that individual but also the health of populations of patients like those individuals. A future in which a smart pill bottle senses that there are only few imatinib tablets remaining and generates a refill request before sending it electronically to the prescribing oncologist's EHR inbox, and then the pharmacy sends a text message to the patient to pick up the medication (and to the oncologist if the medication is not picked up).

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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