



## **Issue Brief: Patient-Generated Health Data and Health IT**

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## What's the Issue?

Providers base their care decisions on information received from the patient, such as vital signs, symptoms, medical allergies, laboratory results, and a variety of other types of data.

Traditionally, the information is generated in a clinical setting: during a visit, in a lab, in a diagnostic screening office, etc. The data are often a one-time snapshot or are gathered infrequently. New technologies can enable patients to generate important data outside of these settings as often as needed and share it with their providers to expand the depth, breadth or continuity of information available to improve care and outcomes.

The increasing number of smart phones, mobile applications and remote monitoring devices, coupled with providers' deployment of electronic health records (EHRs), patient portals, and secure messaging, offers innovative ways to connect patients and providers and to strengthen people's engagement in their health and care.<sup>1</sup> Over 30% of Americans online are eager to use their smart phones or tablets for health management or services,<sup>2</sup> and over 60% say they would like to communicate with their providers electronically.<sup>3</sup> One expert has projected that "within 5 years, the majority of clinically relevant data...will be collected outside of clinical settings."<sup>4</sup>

Patient-generated health data (PGHD) are health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern. PGHD are distinct from data generated in clinical settings and through encounters with providers in two important ways. First, patients, not providers, are primarily responsible for capturing or recording these data. Second, patients direct the sharing or distributing of these data to health care providers and other stakeholders.<sup>5</sup>

Patient-generated health data are not new. Information such as patient-reported outcomes is already valued and incorporated into the physician's record. However, there are no widely established policies and practices to define the optimal use of PGHD, much less to support its growth as a viable health care tool. A framework of policies and good practices can help to successfully engage physicians and patients and ensure the privacy, security, and appropriate use of PGHD. The Office of the National Coordinator for Health IT (ONC) has initiated several activities to advance knowledge of the field and identify policies and promising practices to support PGHD. This brief will review the issues and progress to date, and will identify some of the remaining challenges.

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<sup>1</sup> Ninety-one percent of U.S. own a cell phone; 60% access the internet and 50% download apps.

<http://pewinternet.org/Reports/2013/Cell-Activities/Main-Findings.aspx>

<sup>2</sup><http://www.harrisinteractive.com/NewsRoom/PressReleases/tabid/446/mid/1506/articleId/1215/ctl/ReadCustom%20Default/Default.aspx>

<sup>3</sup> Optum. Meaningful Consumer Engagement: A Survey of Stakeholder Views. Optum Institute Issue Brief.

[http://institute.optum.com/technologies/~/\\_media/OptumInstitute/Page\\_Elements/Articles/Institute\\_HealthIT\\_FINAL.pdf](http://institute.optum.com/technologies/~/_media/OptumInstitute/Page_Elements/Articles/Institute_HealthIT_FINAL.pdf)

<sup>4</sup> Abowd G. Keynote address to American Medical Informatics Association Annual Conference on Biomedical and Health Informatics, October 24, 2011. Available at <http://www.amia.org/amia2011/keynotes>.

<sup>5</sup> Shapiro M, Johnston D, Wald J and Mon D. Patient-Generated Health Data: White Paper Prepared for the Office of the National Coordinator for Health IT by RTI International. April 2012. Available at <http://www.rti.org/pubs/patientgeneratedhealthdata.pdf>.

## What Has Happened So Far?

### Patient-Generated Health Data in Clinical Settings

Health care organizations have started accepting some PGHD in recent years. The specific purposes and approaches vary, and are driven by clinical priorities. Here are a few documented examples.<sup>6</sup>

- [Kaiser Permanente](#)<sup>7</sup> Kaiser uses secure messaging to enable patients to ask questions, seek clarification, report on adverse effects, inquire about test results, or communicate a variety of concerns. Kaiser follows guidelines for electronic communication with patients developed by the American Medical Association and by the American Medical Informatics Association, which advise that physicians have a patient-clinician agreement and consent form that is discussed with and signed by each patient before engaging in electronic communication. Physicians review the communications. HIPAA-compliant software incorporates the messages and physician replies into the patient's electronic record.

Kaiser found that secure messaging with physician review has been associated with a decrease in office visits, an increase in measurable quality outcomes (at least in primary care), and excellent patient satisfaction. Secure messaging allows health issues to be closely monitored without the inconveniences of traffic, parking, insurance copayments, or lost days at work. It provides patients with written advice that might be forgotten or misunderstood if communicated verbally and avoids the annoyance of telephone tag.

- [Group Health](#)<sup>8</sup> Group Health created an electronic Health Risk Assessment (e-HRA) on its MyGroupHealth portal to gather health risk and health history information from patients. The Health Profile feature of the portal includes questionnaires and a patient summary form that is available to be updated whenever the patient wants. Patients also can enter other personal health information directly into their medical record, including demographics, medical history, self-reported health, functional health status, and social circumstances. A member of the clinical team reviews the data submitted, and because the information was collected as structured data, it can be integrated into the EHR.

In one study, Health Profile functions were used as a decision support tool to systematically identify prevention and chronic-care needs. Integrated with an EHR, the profile functions delivered immediate prompts to clinicians and the care teams. This actionable information allowed for future disease risk assessment and identified issues requiring urgent attention. The Health Profile strengthened patient-provider relationships by promoting mutual knowledge and understanding.

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<sup>6</sup> See also Patient-Generated Health Data White Paper, April 2012, references; Patient-Generated Health Data Technical Expert Panel, Final Report, December 2013, Appendix; and Using Patient-Reported Information to Improve Health Outcomes and Health Care Value: Case Studies from Dartmouth, Karolinska and Group Health, Peer Reviewed Technical Report published by The Dartmouth Institute for Health Policy and Practice, available at <http://ki.se/content/1/c6/14/03/06/Using%20patientreported%20information%20to%20improve%20health%20outcomes%20and%20health%20care%20value.pdf>

<sup>7</sup> Zhou YY, Kanter MH, Wang JJ, Garrido T. Improved quality at Kaiser Permanente through e-mail between physicians and patients. *Health Aff (Millwood)*. 2010 Jul;29(7):1370-5

<sup>8</sup> Using Patient-Reported Information op. cit.

- Dartmouth Hitchcock Spine Center<sup>9</sup> The Spine Center collects information from patients in a structured format before each visit to measure their health status in real time as well as their expectations for quality treatment results. Providers use the data to plan care for the patient, to address the patient's needs and preferences, and for shared decision-making between the provider and the patient. The data are aggregated longitudinally to assess the impact of treatments on the patient over time, as well as to gather valuable information for population health and quality activities.

Findings from an assessment of the Spine Center's system showed that both clinicians and providers rated the system highly. Patients felt it improved their visits. Providers found that it was extremely important for both follow-up and feedback.

### Patient-Generated Health Data in Research and Development

In addition to studies of established PGHD activities, ONC and other funders have supported research on specific approaches to capturing and using data directly from patients. Here are two examples.

- Geisinger Health System<sup>10</sup> Geisinger conducted an ONC-funded pilot project where patients accessed their medication lists and provided feedback to their providers online through the patient portal prior to an upcoming visit. They submitted changes in frequency and dosage, new or discontinued medications, and any questions about their medications. A Geisinger pharmacist reviewed the input and followed up with the patient by phone or through secure messaging if needed. The pharmacist subsequently updated the medication record and notified the patient's provider, as well as added a note in the EHR about the source of the change.

Geisinger found that patients were eager to provide feedback on their medication data and felt that it enabled them to track their medications in a more effective manner. Patients also appreciated the improved communication with their providers during office visits. Geisinger found that information provided by patients was useful and accurate. Pharmacists made patient-suggested changes in 80% of the cases. Providers found that medication reconciliation was more efficient, with significant time savings.

- Project HealthDesign<sup>11</sup> Project Health Design, supported by the Robert Wood Johnson Foundation, funded project teams to demonstrate how to improve participants' health and well-being by helping them capture, understand, interpret, and act upon data about observations of daily living (ODL). Each project team worked with clinical partners and patients to identify, capture, and store several types of ODLs for their target patient population; analyze and interpret ODL data to extract clinically useful information; use this information to provide feedback to patients so they could better manage their conditions and improve their health; and enable patients to share this information with members of their clinical care team in ways that easily integrated into their clinical workflow.

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<sup>9</sup> Using Patient-Reported Information.

<sup>10</sup> Dullabh P et al, NORC. Demonstrating the Effectiveness of Patient Feedback in Improving the Accuracy of Medical Records. Report presented to ONC. August 2012.

<sup>11</sup> Project HealthDesign. Available at <http://www.projecthealthdesign.org/projects/round-2-projects>.

Two projects are especially pertinent:

- The **BreathEasy** app was developed by RTI International and Virginia Commonwealth University for patients with asthma. The app provides a clearer picture of their health in everyday life for treatment and self-monitoring. Both patients and clinicians used ODL data to make lifestyle and treatment adjustments and better manage asthma symptoms.
- **Estrellita** was developed by the University of California, Irvine, to collect ODL information about high-risk infants from their primary caregivers. The app allowed the caregivers using Estrellita to easily interface with their health care providers to improve care and communication. The app also allowed caregivers to easily interface with clinicians and resulted in improved care and communication. In addition, caregivers were able to track clinical appointments and providers were encouraged to review the ODL data and ask questions during appointments.
- [NoMoreClipboard](#)<sup>12</sup> NoMoreClipboard (NMC) is a commercial electronic personal health record (PHR) that allows patients to share demographic and clinical information, and send and receive secure messages. As part of an ONC Challenge Grant, NMC partnered with a 24-physician cardiology practice to offer an interoperable PHR to 200 cardiology patients. The PHR included a Health Diary in which patients entered and transmitted key health data such as blood pressure and heart rate to the practice.

NMC found that scores increased for the Patient Activation Measure,<sup>13</sup> which assesses patient knowledge, skill, and confidence for self-management. Patients took a bigger role in managing their health, in building knowledge and confidence, and in maintaining desired behaviors. NMC also enabled patients to take an active role in identifying errors in their data records and notifying providers to make corrections.

### Patient-Generated Health Data in Policy

In 2011, ONC identified PGHD as an important issue for advancing patient engagement and initiated a series of activities to gain more information about its value and approaches to implementing it.

ONC commissioned a report to establish baseline understanding of PGHD uses, challenges and opportunities. The Patient-Generated Health Data White Paper was delivered in April 2012.<sup>14</sup> ONC's Federal Advisory Committees (the Health IT Policy Committee (HITPC) and the Health IT Standards Committee (HITSC)) built on this foundation by convening a public hearing in July 2012 to gather additional input on policies and standards needed to support PGHD. The Committees are now exploring ways to include PGHD in Stage 3 of the EHR Incentive Programs (commonly referred to as the Meaningful use Program), which supports the adoption and use of EHRs.

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<sup>12</sup> See Parkview COPE Case Study available at [https://www.nomoreclipboard.com/wiki/images/9/95/NMC\\_Case\\_Study\\_COPE.pdf](https://www.nomoreclipboard.com/wiki/images/9/95/NMC_Case_Study_COPE.pdf).

<sup>13</sup> See Patient Activation Measure available at <http://www.insigniahealth.com/solutions/patient-activation-measure/>.

<sup>14</sup> Patient-Generated Health Data: White Paper. April 2012.

In 2013, ONC convened a Technical Expert Panel on Patient-Generated Health Data to identify good practices that can reduce concerns and risks and to encourage providers to implement PGHD through Meaningful Use and for purposes outside Meaningful Use. ONC also funded a study on data provenance, i.e., methods of recording and conveying the source of data. The results of these two studies were delivered in June 2013, and December 2013 respectively.

- Patient-Generated Health Data White Paper<sup>15</sup> The White Paper prepared by RTI, International established a definition of PGHD that is now widely accepted: health-related data created, recorded, gathered, or inferred by or from patients or their designees to help address a health concern. The paper distinguishes between data capture, data transfer and data review, and identifies barriers such as limited processing power and the fact that not all PGHD is of equal value to everyone. The White Paper identifies four potential policy levers that ONC may consider going forward:
  - Consider Stage 3 Meaningful Use criteria to enable and support the use of PGHD by providers;
  - Convene stakeholders to identify PGHD opportunities, barriers, and value;
  - Support development and use of PGHD-related standards; and
  - Conduct additional PGHD research to collect lessons learned, support adoption, and inform policy.
- Health IT Policy Committee and Health IT Standards Committee Joint Hearing on Patient-Generated Health Data<sup>16</sup> Several key themes emerged from the hearing:
  - PGHD is cross-cutting and has applications in each Meaningful Use Policy Objective;
  - Specifying a plan for collection and use of PGHD, along with clear objectives and goals, is a key component of successful efforts;
  - Information must be meaningful and useful for both patients and providers;
  - Attribution of source is critical; but this is true for all information as we move toward integrating data from multiple data sources;
  - Standards are important, but sharing of information is paramount;
  - Much PGHD is accommodated by current standards; and
  - PGHD should follow the same standards as all other information.
- Patient-Generated Health Data Technical Expert Panel (TEP)<sup>17</sup> The TEP identified many examples of valued PGHD. Examples of the TEP's findings are:
  - Information about allergies and a patient's medication list is important for safety.
  - Valued information related to a treatment plan includes information the provider has requested, or information that could trigger a change in the plan, such as biometric data or behavioral health data (e.g., depression).
  - Providers want to know important patient concerns, such as new or worsening symptoms, and other important items of potentially high impact on care such as changes to contact information or insurance.

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<sup>15</sup> Patient-Generated Health Data: White Paper. April 2012.

<sup>16</sup> PGHD Hearing Summary (.ppt) available at <http://www.healthit.gov/archive?dir=HIT%20Policy%20Committee/2012/2012-07-10>

<sup>17</sup> Patient-Generated Health Data Technical Expert Panel, Final Report and Appendix. December 2013.

In addition, the TEP stressed the importance of policies and procedures regarding what information will be received and through what channel(s); who will review it and when; what response will be given to the patient and when; if/when/how the information might be entered into the patient's medical record; and how privacy and security will be ensured. The panel also emphasized strong and ongoing communication with patients and with providers and staff to establish a sound foundation for PGHD implementation and to reinforce good practices. If properly implemented, these policies and procedures will set mutual expectations among patients, providers and staff. Most importantly, these policies and procedures would reduce risks.

The TEP also concluded that many factors will impact the use of PGHD, which has multiple contexts of use in self-management, care delivery by providers, screening and prevention, and wellness. These factors are grouped into four areas: a) consumerism and the growing empowerment of the patient, b) medical practice changes, c) societal trends, and d) technology advances. The factors may impact multiple areas and collectively are anticipated to drive significant PGHD advances.

- Data Provenance: Environmental Scan<sup>18</sup> ONC sponsored an environmental scan of the issues and approaches related to data provenance. Provenance refers to the origin of clinical information when first created, including information about the source of the data and about processing/transitions the data has undergone. Provenance metadata, or data that identifies the source of clinical information, could allow a system that aggregates patient information (EHR, personal health record (PHR) or health information exchange (HIE)) to understand where particular medications and diagnoses in a patient's record came from. Being able to identify provenance is critical to provider trust in data received from patients or from patients' PHRs. Some HIEs have improved provenance tracking by marking and retaining provenance as they aggregate data from multiple sources and exchange records. This is different from the provenance that would be associated with a direct transmission from a patient or a patient's PHR. The environmental scan found:
  - Most systems do not capture origin with sufficient granularity to meet providers' needs related to PGHD;
  - Currently no dominant provenance model exists within the HIT community;
  - No uniform way of handling data provenance when data is originally created and/or when shared and integrated, including reconciliation;
  - No harmonized standard currently in place; and
  - Upcoming work includes HL7 data provenance and privacy support in C-CDA initiative.

## What Are the Opportunities?

PGHD offers an opportunity to capture needed information for use during care, with potential cost savings and improvements in quality, care coordination, and patient safety.

The timely receipt of additional data from the patient, the patient's family and other caregivers outside the clinical visit can reduce critical information gaps, such as recent changes in the patient's condition or symptoms that might prompt a change or reconsideration of the care plan. Knowing that a patient had a procedure or test from another provider can reduce duplicative

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<sup>18</sup> <http://www.healthit.gov/FACAS/calendar/2013/07/18/policy-consumer-empowerment-workgroup> .

services. Having an up to date list of medications from all providers, including what is being taken as compared to what has been prescribed, is important for care coordination and may be able to reduce time spent on medication reconciliation. Data about medications, allergies, intolerances, and outcomes can help mitigate safety risks.

Policies and practices for the safe and effective collection and use of data generated by patients outside the clinical setting will help support delivery and payment reform goals. Developments in health care delivery, such as patient-centered care, the patient-centered medical home, and payment reform programs such as pioneer Accountable Care Organizations (ACOs) seek to strengthen patient engagement and care team coordination as contributors to better outcomes and efficiencies. These developments reflect increasing recognition that what happens outside the clinical visit contributes to improved health outcomes in the same way that what happens during the visit can lead to improved health outcomes. It therefore becomes more critical to value the patient as a source of vital information.

Additionally, the use of PGHD can foster patient engagement, learning, self-monitoring, and self-management, enabling some activities to shift from being provider-driven to patient-led. Patients who feel that information about their health status or response to treatment is important to their health and care, and valued by their providers, are shown in several examples cited above to be more engaged and active in managing their health.

## **What Are the Concerns?**

Discussion about the potential for receiving data from patients outside the clinical visit raises concerns among both providers and patients that have not been systematically addressed. In addition, there are technical issues related to the capture, transmission and integration of the data. Overarching privacy and security issues also exist.

### **Provider Concerns**

Providers may be hesitant to accept PGHD because they fear an influx of information that might interfere with their ability to deliver quality care. Such providers may be concerned that they will have the burden of reviewing large amounts of data, leading to increased liability and unrealistic patient expectations. Specifically, there are concerns about providers being held accountable for information that was not received or reviewed in a timely manner and information that may require an urgent response. Additionally, some providers have expressed concern about the financial impact of PGHD including the use of staff and physician time for reviewing, processing and analyzing the data and potentially integrating it into the EHR.<sup>19</sup>

### **Patient Concerns**

Patients may be concerned about their providers failing to use PGHD to meet their health care expectations. Concerns may include whether their doctor or her staff has received or seen the data the patient sent and if they will confirm receipt; whether the information sent was saved in the patient's chart; whether the information was shared with his or her provider or family members as appropriate; whether the information was securely received and stored; and whether the patient generated data is valued and well-received by their doctor.<sup>20</sup>

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<sup>19</sup> Patient-Generated Health Data Technical Expert Panel Final Report. December 2013.

<sup>20</sup> Patient-Generated Health Data Technical Expert Panel Final Report. December 2013.

## Technical Issues

Technical and data standards are vital to the effective use of PGHD. The information must be collected and submitted in standardized ways that ensure that the information cannot only be received but also understood and integrated into the EHR if desired. Consumer-friendly vocabularies will need to be identified and integrated into patient portals and eHealth tools to help patients submit useful information. In a dynamic consumer eHealth environment, it will be critical to balance the need for initial standards to jump start PGHD activity and the need to enable innovation, which requires allowing standards to evolve. Also, given the importance of provenance in PGHD, the technical shortcomings identified in the environmental scan mentioned above will need to be addressed.

## Privacy and Security Issues

All stakeholders need to be assured that PGHD is private and secure. Authentication of the patient (or caregiver if that person is submitting information) is critical to ensure that information can be attributed to him or her with confidence. The issues identified in the provenance report, mentioned above, will need to be addressed. A method of linking specific information to its source will be important in tracking data as it moves from system to system, particularly from patient-controlled sources to provider EHRs, so that the integrity of the data can be ensured.<sup>21</sup> There could be a need to address patient authorization for secondary sharing of PGHD, if the patient prefers that the data not be shared with other providers or for other purposes. The identity of and authorization for providers and staff receiving or accessing the information needs to be established. Transmission must be secure; encryption may be desired.<sup>22</sup>

## What's Next?

Many developments in the broader field of patient engagement will have an impact on PGHD. Policy activities to promote patients' access to their data may trigger more patient requests for corrections and additions to their records. The growth and diversity of consumer technologies is raising greater interest in consumer tracking data. As genetic information becomes more readily available from patient-initiated analyses, new policies and approaches for extracting and incorporating valued genetic data from huge data files will be needed.

The HITPC adopted recommendations on PGHD from its Consumer Empowerment Workgroup at the HITPC meeting on December 4, 2013.<sup>23</sup> The committee reaffirmed that an objective stating that "Patients have the ability to electronically submit patient-generated health information" should be part of Meaningful Use Stage 3. It suggested that PGHD could be submitted through structured or semi-structured questionnaires and secure messaging and, depending on input from the HITSC, possibly through devices. The HITPC will be finalizing its complete Stage 3 recommendations in February 2014.

The HITSC's Consumer Technology Workgroup is identifying standards to support this objective, as well as to support the collection of PGHD from devices.<sup>24</sup> If standards for device PGHD are judged to be sufficiently mature, the HITPC could consider including devices as submission channels in its Stage 3 recommendations. Final recommendations are expected in February 2014.

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<sup>21</sup> Patient-Generated Health Data Technical Expert Panel Final Report. December 2013.

<sup>22</sup> Patient-Generated Health Data Technical Expert Panel Final Report. December 2013.

<sup>23</sup> The recommendations will be posted on [healthit.gov](http://healthit.gov) in January 2014.

<sup>24</sup> HIT Standards Committee, Consumer Technology Workgroup. Presentation to HITSC. December 18, 2013.

ONC currently is exploring a Standards and Interoperability (S&I) Framework initiative to identify existing standards used to indicate the provenance of clinical information, to examine the inconsistencies in the way these standards are currently used, and to develop implementation guidance to improve the quality and standard usage of this metadata. More consistency in the standards for data provenance could facilitate consumer-mediated exchange by allowing systems to indicate which aspects of a personal health record are authored by a patient versus by a health provider. As a result, receiving health IT systems could better track where information in a patient's record came from.

ONC will consider these recommendations and other input to help shape policy and standards work in 2014 and beyond. ONC will prepare documents that help providers understand the value and feasibility of accepting PGHD in ways that can address their concerns and those of their patients. ONC is working to advance a vision of the person at the center of their health and health care, empowered by health IT to self-manage health and care when appropriate and partner in their care when necessary. Patient-generated health data is a critical component of the vision, and ONC will be identifying additional opportunities to expand its use.