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Patient-Generated Health Data

White Paper

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Patient-Generated Health Data

("There's a difference between sensing data and making sense out of the data." Charles Safran[1])

INTRODUCTION

In his provocative keynote address at the American Medical Informatics Association (AMIA) 2011 Annual Symposium, Gregory Abowd predicted "within 5 years, the majority of clinically relevant data…will be collected outside of clinical settings."[2] The ability of a patient to record and share health data electronically, especially data from remote monitors, has placed patient-generated health data in the spotlight, and Professor Abowd's comments are hardly the only acknowledgment of the phenomena he described. Two recent news stories in the business media—"Diabetic Tester That Talks to iPhones and Doctors," in the *Wall Street Journal*[3] and "As Smartphones Get Smarter, You May Get Healthier: How mHealth Can Bring Cheaper Health Care to All," in *Fast Company*[4]—suggest that clinicians, suppliers, and patients are thinking seriously about this subject. While these stories may be speculative and focused on the business opportunities, the article, "The Quiet Health-Care Revolution," in *The Atlantic*[5] reported on a patient with chronic heart failure (CHF) whose life was likely saved when clinical staff responded immediately to data from an electronic scale in the patient's home alerting them to her potentially dangerous overnight weight increase. Beyond such anecdotal reports, initial pilot studies have already been published that show promising outcomes for the use of remote monitoring in the treatment of diabetes[6,7] and heart failure.[8,9] The potential of clinically relevant data captured outside traditional care settings, also known as patient-generated health data (PGHD), to improve outcomes and enhance patient-provider communication is likely very substantial. Assessing this potential, however, should consider how existing health care practices and systems may be affected by PGHD, and how these may need to change, in order to realize these benefits.

The Office of the National Coordinator for Health Information Technology's (ONC) Office of Policy and Planning (OPP) contracted with RTI International to analyze issues surrounding PGHD to inform ONC's thinking about this emerging trend. RTI conducted a rapid exploratory analysis of PGHD to assist the OPP in understanding and responding to the expanding PGHD landscape, and to help identify and assess options for addressing issues and alternatives related to the creation, sharing, and use of PGHD. Accordingly, a key aspect of our

analysis focuses on describing the various means PGHD are shared with providers and incorporated into electronic health record (EHR) technologies.

METHODS

RTI held informal conversations with 19 experts, including clinicians, health informatics researchers, patient advocates, health system leaders, and a health law specialist to discuss the definition of PGHD, key issues, and their views on possible approaches to resolving them—including the role of federal agencies (see **Appendix A**). RTI conducted a focused search of the literature and asked experts for suggestions on additional articles and resources about this subject. We also scanned health blogs that covered such topics as patient engagement and patient empowerment.

All these approaches to gathering information about PGHD focused on answering a range of research questions about PGHD, including its definition, issues, approaches to resolving issues, and the role of the federal government. Below we discuss the environmental scan results relative to our research questions. For each question, we present a synthesis of what we learned, what we heard or read that helped us answer these questions, and what questions require more research.

RESULTS

A. How should PGHD be defined, and which concepts are central in this definition? How have health care providers and patients defined and treated PGHD up to now?

A working definition evolved over the course of the environmental scan, as follows:

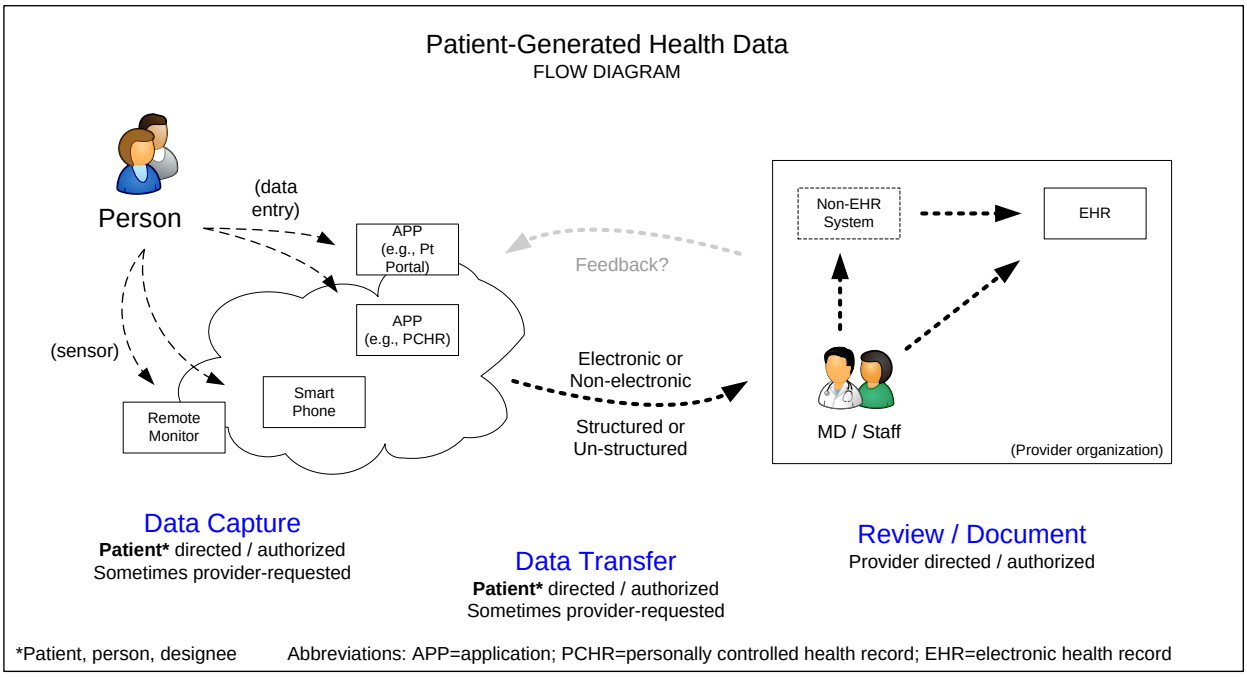
PGHD are health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern. 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. In these ways, PGHD complement provider-directed capture and flow of health-related data across the health care system.

PGHD are not new phenomena; many patients record and share information on their health and wellness with care providers. However, the proliferation of Smart phones, remote monitoring devices, application development platforms (e.g., iPhone and iPad apps) and ubiquitous networks are enabling massive growth of PGHD. Increasingly, PGHD will be created, recorded, and shared electronically.

B. What is the current and emerging state of electronic health data flows (i.e. health information exchange) today, and how will PGHD impact these flows in the next 3-5 years?

To assist our analysis—the identification of issues and possible approaches to working with PGHD—we developed a framework that helps describe the context and use of PGHD by providers. Depicted in **Figure 1**, we see three steps in PGHD flow: capture, transfer, and review.

Figure 1. Patient-Generated Health Data Flow



- **Data capture** refers to the creation and storing of health data by the patient or designee, which may include:
  - written data entered via a keyboard or other input device,
  - verbal data entered via a microphone, and/or
  - physiological and/or environmental data recorded on a monitoring device.

- **Different types of PGHD**
  - Patient (or patient proxy) measured vital signs by means of a device and recorded by patient (or proxy)—e.g., temperature, blood pressure, blood glucose, weight. These data might be captured manually, by reading a mechanical or electronic device, or automatically captured via a monitoring device.
  - Self-reported (recorded by patient or family member) lifestyle data—e.g., caloric intake, diet, exercise, hydration, medication adherence, ability to perform activities of daily living. The patient or a patient proxy would typically manually capture these data.
  - Self-reported as perceived quality of life data—e.g., mood, sleep quality, level of pain, social contacts. The patient or a patient proxy would typically manually capture these data.
  - Data, other than health-related that enable the patient to be known to the provider on a personalized individual basis.

Captured data may be structured or unstructured, machine-readable or not, numeric, text, image, waveform, etc. Data capture can include multiple methods and steps. For example, a patient could measure blood glucose using a glucometer, then copy that result into a spreadsheet for personal use, keeping a paper logbook for their next primary care physician (PCP) visit, and use secure e-mail to share the data with a nurse (see PGHD scenarios below). The variety of data, the proliferation of devices and growth in number of patients participating or wanting to participate in sharing data with their clinicians all contribute to perceptions of rapid PGHD growth in the coming years.

- **Data transfer** refers to the communication of the captured data to a member of the health team by the patient or designee. Data may be transferred electronically via secure e-mail or other Internet-enabled methods, or might be communicated via telephone, in-person meeting, etc.
- **Data review** refers to the process of a provider or staff member receiving the data/information and deciding what to do with it. Based on the source, quality, and utility of that data for clinical decision-making, data may be discarded, documented in the medical record, or shared but not documented in the record. Whether PGHD are

copied/entered into an EHR, discussed among care team members, or stored/maintained in a separate system or location (other than the EHR) is determined during the review process. Importantly, in our conversations, review of studies and scan of relevant social media, we did *not* find examples of PGHD flowing directly into the EHR *without* a review process or review policies in place. This makes sense since provider organizations have well-defined policies and practices for what can/should be documented in an EHR, by whom, with what approvals and notification policies, etc. Also, since many providers *already* place limited kinds of PGHD into EHRs, there is an opportunity to learn from those experiences to anticipate the possible impact of greater PGHD flow.

To illustrate the capture, transfer, and review of PGHD, **Figure 1** provides a flow diagram. The left side of the drawing depicts a varied and growing array of potential patient inputs, from data recorded manually by patients and/or their designees to data captured automatically by a device. Use of mobile health applications, Internet-connected monitoring equipment, end-user applications under complete patient control (such as a personally controlled health record, or PCHR), or end-user applications under mixed patient-and-provider control (such as an EHR-connected patient portal), is accelerating. Multiple factors could intensify PGHD capture and use, including more engaged patients, new technologies, incentives for patients and/or providers, provider and/or patient requests to collect and share data, or research that shows how PGHD satisfies the three-part aim of better care for individuals, better health for populations, and reduced expenditures through improvement in care delivery processes.

RTI developed several scenarios to illustrate variations in PGHD flow. These examples suggest how data capture, transfer, and review may function related to the care of chronic illnesses and patient attempts to correct data in their provider's record (**Figure 2**–**Figure 5**).

Figure 2. Hypertension Scenario

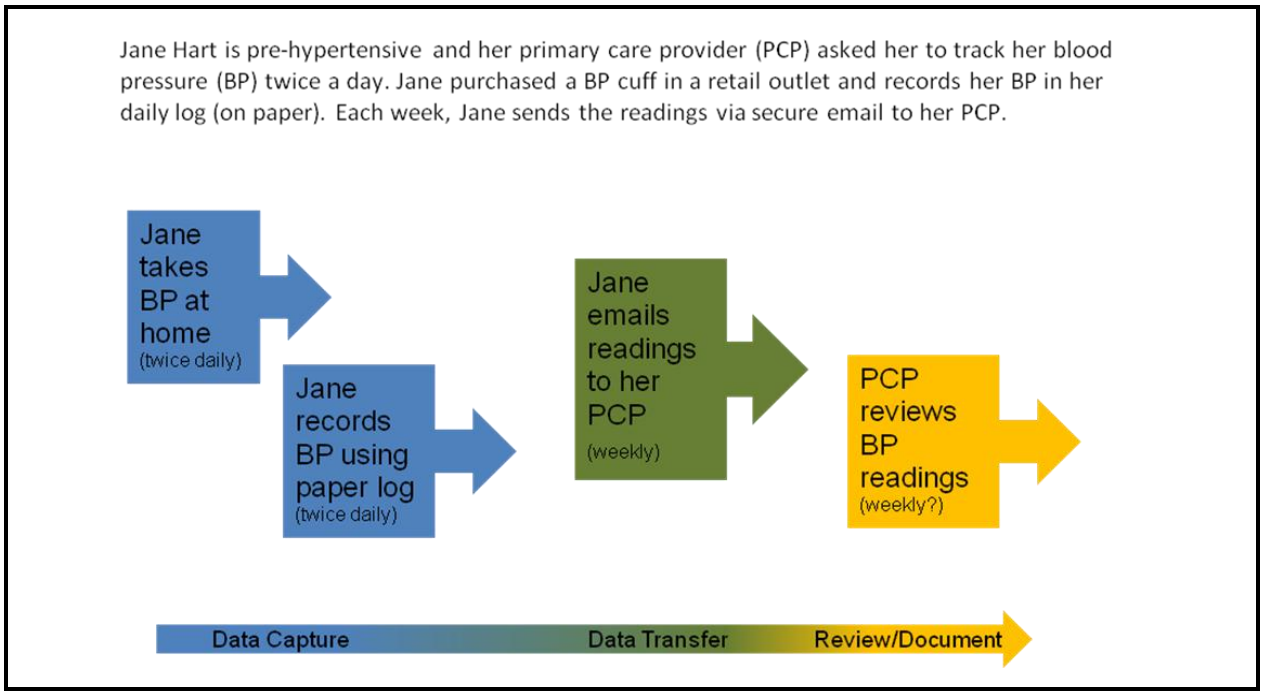


Figure 3. Diabetes Scenario

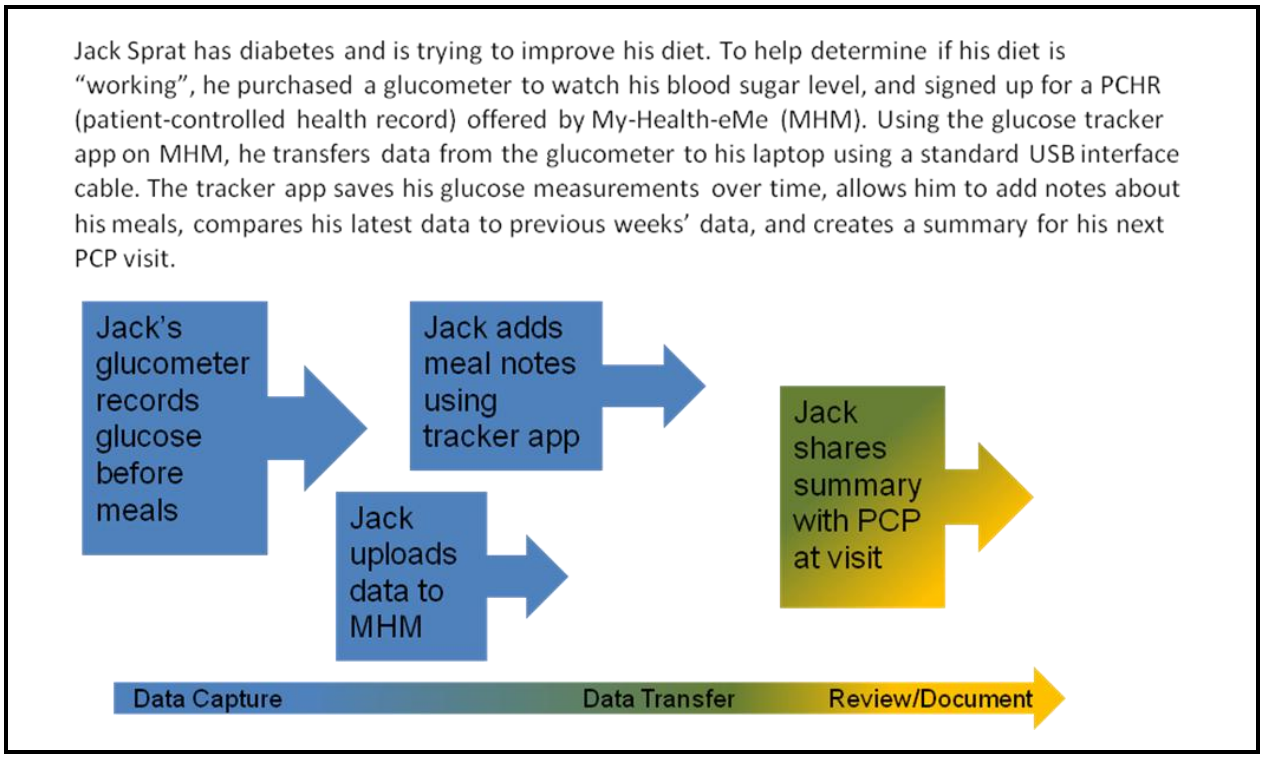


Figure 4. Asthma Scenario

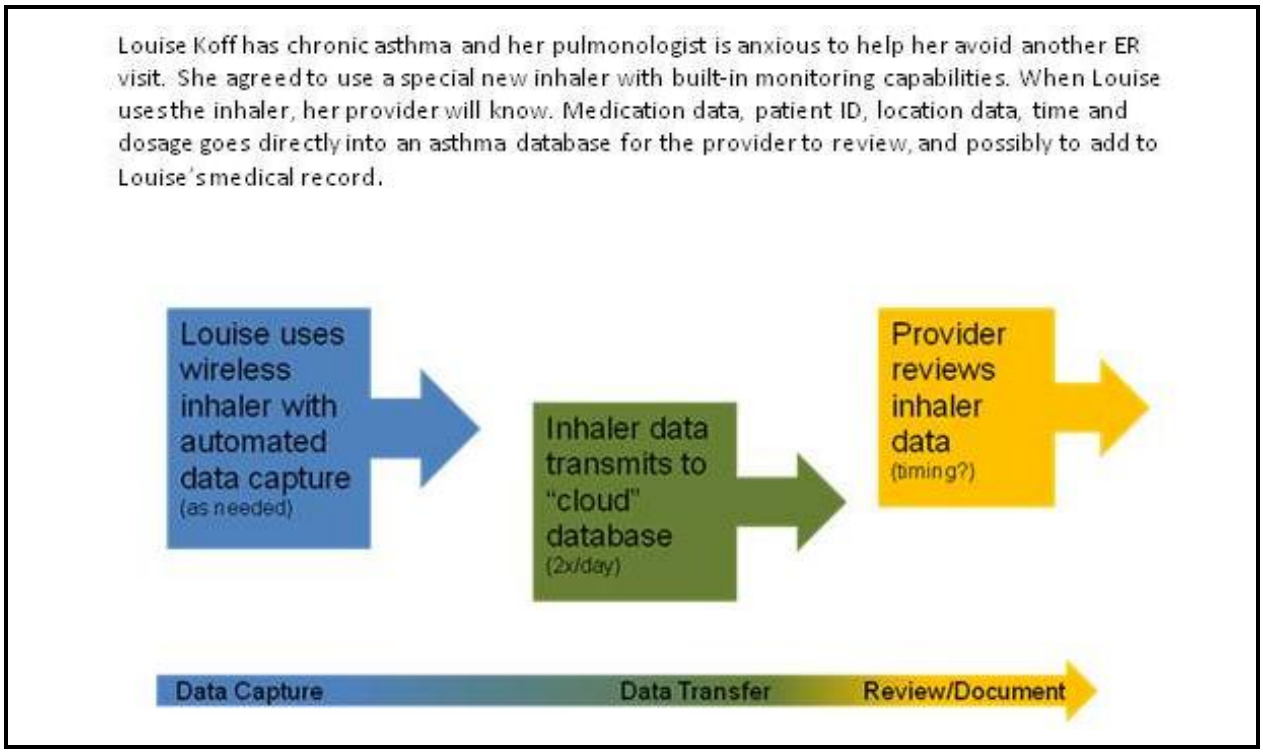
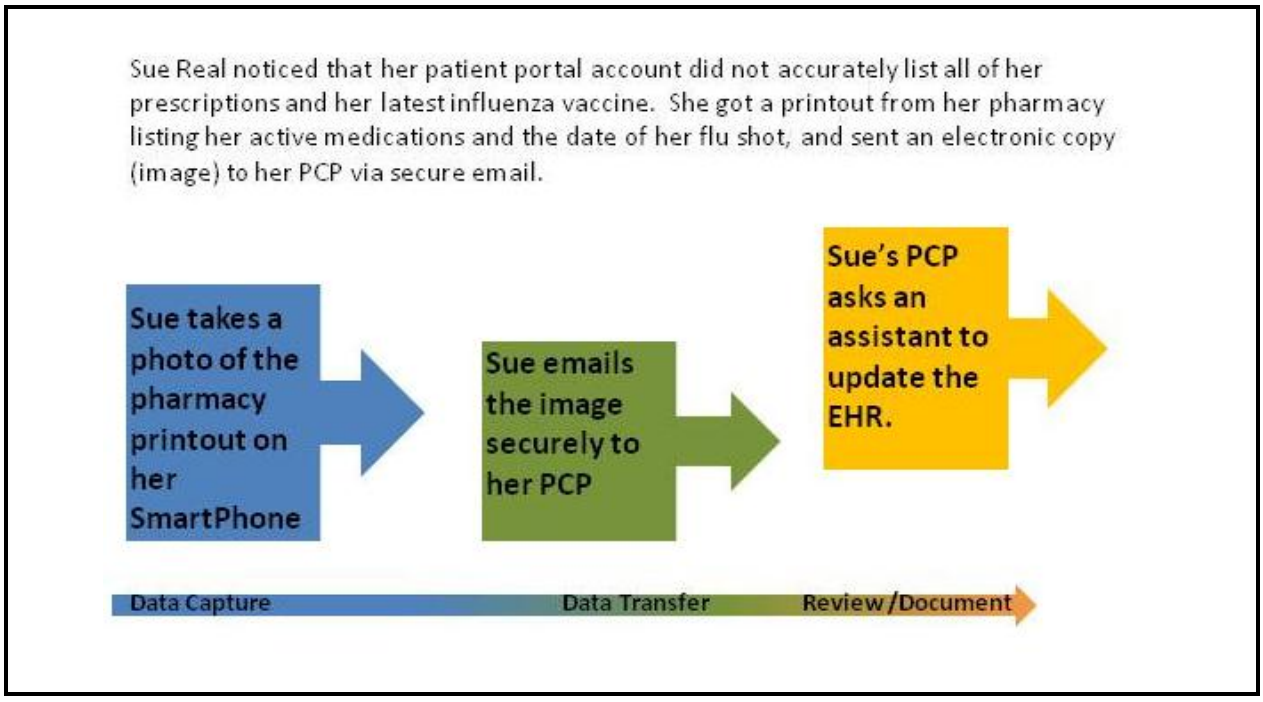


Figure 5. Correcting Patient Information Scenario



Patient-generated health data are not new; for decades, researchers and others have examined the use of various health information technologies by patients (see Appendix B). However, the context in which the volume and sources of PGHD are rapidly increasing is recent and dynamic. Advances in data-driven medical science, EHRs, sensors, and mobile technology are enabling rapid and substantial growth of PGHD. For example, researchers recently demonstrated the feasibility of a skin-like patch, applied like a tattoo, with sensors and wireless transmission capability built in (*Science*, 12 August 2011).[10] Uptake of mobile health technology is another driver—87% of adults in the United States now own a mobile device,[11] and an estimated 1 in 10 of those have a health app running on that device.

Yet the means of data capture and the pathways that those data follow to get from patient to provider are not limited to all-technology methods and conduits; rather, it is equally feasible that data pathways could be a compilation of manual and semi-automatic means. For example, in the Hypertension Scenario, Jane manually records her blood pressure readings in a paper log, and then e-mails that information weekly to her PCP using a secure messaging system. The variety of new sensor technology facilitates development of monitoring devices, expanding the range of health conditions whose treatment could potentially be assisted by use of remote monitoring. Collectively, these developments could lead to new types of patient data and increased expectations on the part of patients and providers.

As with much new technology, participation and consistent use among patients cannot be assumed. Access, usability, technology, education, health literacy, economic disparities, and so forth can be barriers to PGHD use. Conversely, demographic factors, such as higher rates of mobile connectivity among young adults are likely to contribute to increased PGHD volume.

C. What are the primary technical, operational, legal, and other issues facing providers, patients, and health care stakeholders in using PGHD?

1. Technical Issues

What technical standards for interoperability are relevant or necessary to promote flow of PGHD?

In both informal conversations and in review of selected studies, providers and researchers raised issues and questions about standards. Standards in data definitions, communication protocols, data analytics, and other areas are critical for information exchange and interoperability, and they will be no less important as PGHD use becomes more routine,

Given that PGHD covers such a broad range of data elements, devices, communication methods, and workflows, it is likely that some existing health IT standards should be leveraged for PGHD scenarios—such as RxNorm for medication terminologies, or LOINC for lab results, if possible. In many areas, new standards will likely have to be developed, largely driven by needs of various PGHD stakeholders: patients, apps developers, EHR vendors, clinicians, and others. Our discussions and review of the literature found little agreement on precisely what standards would be needed to support PGHD, given the nascent and fragmented status of this area. Still, the project team determined that standards for tagging the source of PGHD, and for ensuring its meaning is unambiguous and consistent across systems (i.e., semantic interoperability), do not appear to be available.

What new or existing authentication methods are needed to promote flow of PGHD? (Applies to both sender and receiver authentication.)

When data sharing occurs in the context of an existing patient-provider relationship, several reliable methods can ensure that the PGHD sender and receiver are authenticated; these methods can also resolve any doubt about the source of PGHD or who will receive the data, once communicated by the patient. Technical standards that specify how a "sending" and "receiving" system will authenticate patient identity or provider identity are important, and should leverage existing approaches wherever possible.

What common data set or minimum data set for PGHD is needed? How should EHR architectures be modified to support the use of PGHD?

Since PGHD include a broad range of data types and data formats, it seems premature to imagine a "minimum data set" or "common data set," overall. In a focused area such as diabetes or hypertension management, one representative from a PCHR company suggested it would be very helpful to identify the most common and important information that patients can provide, establish common data definitions and data types, and promote their use. EHR readiness for incorporating PGHD should be assessed in terms of consistency of data definitions (i.e., being able to store PGHD accurately and without altering meaning), and in terms of supporting the workflow of reviewing and validating PGHD on the way into the EHR (i.e., being able to store "status" information such as "not reviewed" or "reviewed"). These are just examples—the actual statuses and workflows have yet to emerge consistently across different systems and use cases. Even EHR-connected patient portals (tethered PHRs) that permit patient-entered data do not

apply data definitions or statuses that consistently coordinate PGHD with EHR-sourced data.[12,13] It is likely that the vast majority of PGHD currently in EHRs are in the form of a note, an attachment such as a PDF document, an image, or some other nominally structured and uncoded type of data. It will be important to bring together specific stakeholder groups to create consensus in these areas for different types of PGHD.

Regarding the modification of EHR architectures to support the use of PGHD, we found that providers who were formalizing their approach to reviewing PGHD developed an additional or separate database or data layer—a staging area, of sorts, as noted previously—to receive and store PGHD before the review process. We further discuss a few examples of this approach in sections that follow.

Questions to be Answered—Technical

The discussion of standards has been ongoing for many years, and while clinical data exchange, clinical terminology, and administrative transaction standards clearly exist, it is possible that new standards will evolve as stakeholder needs dictate, technologies mature, and suppliers consolidate. The basic question is whether the existing technical standards for interoperability among clinical information systems and data exchanges will be adequate and adhered to by the developers and implementers of the PGHD tools (e.g., apps, devices, services). Though fully endorsed within the health care standards community, some Health 2.0 bloggers argue that "standards such as HL7…pose a barrier to small open source software developers."[14]

On that point, some existing standards may be immediately useful, even to small open-source developers, while new standards may need to be developed. For example, providers and researchers in this study stated that laboratory results are one set of data that could be exchanged between PHR and EHR systems. From a standards perspective, HL7 has existing data, functional, and interoperability standards that could be immediately implemented by software developers for health information exchange. HL7's "greenCDA" solution offers software developers a means to implement such standards more easily and quickly, which smaller developers may find more acceptable.

Further, the development of new standards to enable "plug-and-play" capability between medical devices and a range of electronic personal and clinical health records has been developing slowly for several years. A clear set of standards for medical device interoperability, widely accepted and used by system vendors, remains a goal. Though HL7 is already working on

standards for mobile health, there is still the need to identify what mobile health technical standards are needed and which existing standards can be modified and applied in a lightweight manner, before such standards can be developed or modified.

2. ***Operational Issues***

Clinician's use of PGHD to help address health concerns can raise a number of operational issues. Provider *requests for PGHD* imply that data are valued in the care process. For example, Jane in the Hypertension Scenario sends her blood pressure readings weekly via secure e-mail in response to her PCP's request. Not only are PGHD expected, but her provider may be concerned if Jane *does not* send the information.

Alternatively, PGHD sent to a provider outside of an office visit, a two-way phone conversation, or provider request raises questions for the provider. Why are these PGHD being sent? Is there a new patient concern to evaluate? Can this wait until the next visit, or should it be addressed immediately? Will time spent reviewing or responding to the PGHD be reimbursed (especially in a fee-for-service environment)? For patients not recently cared for, is there still a treatment relationship? Can I be sure who is contacting me? Is it safe to respond, without risking a HIPAA violation?

In practice, helping patients to understand how and when PGHD are used in the care process requires providers to anticipate and consider their workflow. How will a provider be notified that PGHD have "arrived" for their review? Does their process for checking messages from patients include electronic messaging and any other channels for receiving PGHD? How does a provider acknowledge that PGHD have been received? Is the confirmation explicit (e.g., a reply is sent) or implicit? Whether practices are interested in encouraging PGHD use or restricting it, the experts we spoke with noted that expectations and guidelines regarding PGHD needed to be communicated effectively with patients at every point of contact.

The impact of increasing volumes of PGHD on workflow and staffing was discussed in several conversations, but no clear trend emerged. Some noted provider concerns about new time burdens from receiving and reviewing long streams of PGHD. Some believed net workload would increase due to growing PGHD and even pondered whether new "data review" roles might emerge among practice staff. Others felt that any time spent reviewing PGHD would be offset by a reduction in time spent providing unnecessary care, and the net effect would be neutral or beneficial to staff workload. For example, if patients with chronic illness could be

effectively monitored using remote technology, office visits and perhaps even emergency hospitalizations could be reduced.

Experts felt that the potential benefits of PGHD would be greatest for those who practice in a capitated reimbursement environment since these data could help reduce communication barriers and the cost of services used by the patient (e.g., a phone or e-visit instead of an in-person visit). Some experts also mentioned how important they felt analytic tools would be in pre-processing voluminous PGHD to highlight important trends or key pieces of information. As a minimum, one of our experts suggested a review priority structure to alert providers as to whether the data were low, medium, or high priority.

Another operational question that was raised in several discussions concerned which patient subgroups would be most active in the use of PGHD. Although speculative, many believe that providers will play an important role in "marketing" the use of PGHD to their patients or responding enthusiastically if their patients suggest PGHD use. Current use of patient portals, for instance, is somewhat low—between 7% to 14% by some estimates[15,16]—and is inconsistent among registered users.[17] If use of these patient-centered technologies serves as a proxy measure for PGHD generally, then capture and sharing of PGHD is not extensive. Just as providers discuss and recommend medicines, lab tests, exercise, and other health-related activities, their impact on promoting patient use of PGHD is likely to be important. Therefore, providers will likely need to understand their patient populations, and to target communications accordingly to where a greater need—and potentially greater impact—for receiving and reviewing PGHD are likely.

What policies are needed to promote increased use of PGHD?

Factors that might influence patient behavior, such as financial incentives, costs, education, training, level of patient activation, or technologies that streamline the capture and sharing of PGHD, could improve the flow of PGHD in ways that help patients reach important health goals. However, PGHD are not equally helpful to every patient, provider, or situation, in generating improvements to health status. For example, a patient with well-managed diabetes may have little room for improvement despite new technologies or incentives that result in greater information flow of PGHD. Or the same patient might embrace new PGHD methods because even though their HbA1c levels remain excellent, the ease of communicating information with a provider improves significantly. If outcomes (e.g., HbA1c) but not "user

experience" are measured, the impact of PGHD might be missed. Similarly, a patient having limited health literacy or low "patient activation"[18] may not engage effectively in capturing and sharing PGHD that require their understanding and engagement. Perhaps more "automated" methods are indicated in these situations, when available.

Similar factors—financial incentives, cost, education, training, technologies, etc.—are likely to influence provider willingness to consider and to use PGHD, which is important for several reasons. First, providers and their organizations must ready themselves to receive, review, and document PGHD, for PGHD value to be realized. Second, provider attitudes, behavior, and PGHD capabilities can exert a strong positive influence on patient behavior, or serve as a strong deterrent.[15,19] This has been repeatedly observed when introducing patient portal technology: rates of patient adoption are much lower when there is weak promotion by providers, and much higher with vigorous endorsement.[20]

For PGHD shared electronically, a broad set of policy considerations can impact the capture, transfer, review, and documentation processes. Provider organizations would need to develop and communicate policies to clinicians and patients to set expectations and guide practices around the types of data that are important to share, the frequency of sharing, and the review and use of these data by providers. Knowing which policies apply at each step in the capture and transfer of information is important and, since there will likely be communication breakdowns, risks and responsibilities will have to be understood and addressed.

Provider judgment, organizational policies, state laws, federal law, and reimbursement requirements determine policies about what should and should not be documented in medical records. These policies may shift as the volume of PGHD grows, the electronic "breadcrumbs" of its existence propagate, and as new expectations between providers and patients are reached. An approach being planned for the VA's Tele-health program is that all PGHD will go into a separate (non-EHR) database that clinicians will be able to view. In the development of the eJournal for the Patient Gateway (PG) system at Partners Healthcare, Wald et al.[17] described how providers could elect (or not) to move data into the patient's EHR from an "air lock," or designated digital holding pen for PGHD.

The Markle Foundation's Connecting for Health Collaboration developed a series of documents, the Markle Common Framework.[21] This is a structured approach for sharing of personal health information between patient and provider, as well as between providers, and

addresses many of the issues raised in the discussions about PGHD including how information is exchanged and how it is protected. Standard approaches to medical device interfaces supported by the Continua Alliance (The Continua Version 2011 Design Guidelines)[22] are intended to address a number of interoperability and connectivity challenges during patient-directed capture and transfer of PGHD.

Setting patient expectations for provider response to PGHD has specific implications for patient use of PHRs. Policies governing patient access to PHR must be examined to ensure privacy and security, as well as to set reasonable expectations for response to secure messages and other kind of data. Osborn et al.[23] write about this in their review of policy for the Vanderbilt PHR system. That institution found it needed to create new processes and procedures to ensure that patient messages were opened and reviewed by some member of the clinical team, and backed that up with an internal audit mechanism.

Questions to be Answered—Operational

Our investigation came primarily from the provider perspective, and we have not undertaken a concerted search for the commercial developers of the devices likely to be in broad use if and when utilization of PGHD reaches its anticipated potential. Inputs from researchers in Project HealthDesign reflected their concerns with solving usability and other patient-facing aspects of monitoring, leaving data compatibility (with EHR) issues for later resolution. These researchers asked whether or not systems, devices, and tools for capturing PGHD are designed simply, and do they offer ease of use for the patient and their designee? Also, they asked who would support the patient who is having difficulty with capturing and sharing PGHD, especially remotely? Questions about the usability of and support for PGHD data capture systems, devices, tools and so forth were raised, but we did not receive any clear guidance on these issues.

3. Legal Issues

Liability concerns were raised in a number of conversations with experts about PGHD, and the issues raised seemed straightforward. First, providers wanted to know when they were responsible for reviewing PGHD, and in what time frame. Second, providers wanted their patients to have clear and reasonable expectations about when PGHD would be reviewed and what kinds of data the provider was interested in receiving and reviewing. At the present time, according to discussions with a health law expert, little (if any) case law provides guidance on

how risks could intensify with greater amounts of PGHD. Since there is already a large amount of remote (e.g., telephone-based) care already offered to patients, many practices and organizations have practices and policies already developed that can extend to additional kinds of PGHD.

Another risk area identified, but without a predictable legal impact, relates to information overload[24] or information gaps due to data whose flow is interrupted. Ensuring that information sent by the patient matches what the provider received can help to avoid communication breakdowns and errors, and is a prudent approach to managing potential liability and risk as the volume and complexity of PGHD ramps-up.

Some physicians might want to limit the amount of PGHD that flows to their practice, especially if they are not ready to receive and review that information. It is likely that practices could vary sharply in their receptivity to PGHD, which underscores the importance of communicating expectations bi-directionally among patients and providers about what kind of PGHD are requested or welcomed from patients, and when PGHD review will take place.

For the most part, standards of practice are not widespread. An American Medical Association (AMA) policy from 2010 on the use of PHRs and PHR data by physicians asserts that "The physician is responsible only for the use of PHR data that the physician has actively chosen to incorporate into the patient-physician relationship; conversely, the physician bears no responsibility for PHR data that the physician has not actively and specifically incorporated into the patient's active medical care."[25] Institutions and medical associations that have begun to actively embrace PHRs and PGHD, such as the VHA and Kaiser-Permanente, have developed or are developing policies to provide guidance to their members.

One aspect of PGHD and health information more generally that has arisen is the question—who owns the data? This topic has been broached by Waller and Alcantara[26] who first issued the warning—"If what is meant by ownership of patient information is the right to exercise complete sovereignty over information, it cannot be said that any one person or entity 'owns' the information." They further explain that the more important question to be asked is "Who can do what to which data under what circumstances?" "Vendors…may seek to obtain ownership rights in the data of their provider customers, whether such data can be linked to individual patients or not. They often seek such rights so that they can build comparative databases and other health data products, which can have substantial commercial value." To the

extent that suppliers of clinical information products for decision support or other data analysis may exert the contractual right to use patient data, providers will need to understand their own obligations to protect PGDH that is reviewed and entered into their EHR.

4. Other Issues

A number of issues surfaced consistently in discussions with experts, including cultural, educational, and human limitations that may present significant obstacles to capture, transmission, and review of PGHD:

- Health literacy (if low, is a big barrier)
- Time (if lacking, is a big barrier for providers, and patients)
- Human or machine processing power (to make sense of large amounts of data, or data that are not obvious)
- Knowledge (to know what PGHD can be collected, and what's worth collecting)
- Communication (to clearly understand what information is sought, by whom, so patients can be responsive and so providers can be supportive and directive, if needed)

While the topic of physician-patient communication, for example, is not a core issue either impeding or driving the use of PGHD, experts we spoke with had strongly held views on changes needed in health care based on cultural and educational issues—and these pervaded our conversations. The perspective that clinicians are not trained to listen to their patients, while patients want their doctors to listen better, seems to underlie much of the call for patient-engagement and empowerment. Wynia and Dunn noted "proponents…emphasize how a PHR can facilitate communication, including for scheduling appointments, receiving testing or treatment instructions, asking questions, and renewing prescriptions. Improving such communication may be of greatest value to people with chronic illness, or those caring for someone with a chronic illness."[24]

At the same time, clinicians who strongly endorse this view see the need for significant educational reform to raise citizens who grow up learning to be responsible health consumers. Tang et al.[27] put forth specific proposals of health IT-related education beginning at the primary level and continuing in high school. Complementing those ideas, in their review of early PCHR

systems, Weitzman and colleagues identified the belief that "low levels of health and technology literacy may impede technology uptake and use."[28]

Another concern was the observation that the focus of health IT has been on the clinician and not on the patient. Yet, even providers who were sympathetic to these criticisms felt strongly that clinicians want hard evidence that PGHD are helpful. Wynia and Dunn caution, "It is an open question whether having all the blood pressure, glucose, cholesterol, and weight readings for a patient, taken daily, would be useful for medical decision making. In fact, the line between empowering and overwhelming patients and doctors with information is blurry, and depends on many variables."[24]

D. Who has identified and attempted to address these issues? What have they done?

Appendix B provides an overview of health IT literature relevant to PGHD, and the issues discussed in this literature. A number of organizations are in the early stages of encouraging more systematic use of PGHD among patients and providers, such as the Veterans Health Administration (VHA), Kaiser Permanente (KP), Vanderbilt University Medical Center (VUMC), and on a smaller scale, many others. Their efforts provide some examples of how provider organizations are beginning to address these issues. Moving forward, it may be helpful to sponsor activities that promote transparency among these efforts to accelerate the learning that takes place around addressing technical, operational, and policy issues.

KP has implemented EHR systems, including a suite of online patient-services, in each of their eight regions. Despite patients' coolness toward and provider apprehension to the rollout of these systems, studies conducted in several regions show that a majority of patients have enrolled to use secure e-mail, and that physicians' fears have been largely assuaged. Zhou et al.[12] found that office visits among online users in KP NW declined by 10.3% from 2005 to 2007, compared to 3.7% for a control group. At the same time, telephone encounters increased by 29% for the control cohort, but only 16% for online users. Baer[29] saw similar results in Northern California, and concluded that a key ingredient in this success was that "secure messaging was promoted enthusiastically to both patients and physicians." Also, providers were given communication training specific to the secure messaging system and were supported with message templates and prewritten patient education handouts. Patient outcomes have been impacted, and quality

indicators for numerous chronic illness measures have been shown to correlate favorably with use of secure messaging in KP Southern California.

Faced with a rapidly expanding population of older veterans with chronic conditions, yet diminishing inpatient resources, the VHA in 2003 initiated a home care program projected to support more than 100,000 non-institutional care patients by 2011. The Care Coordination / Home Telehealth (CCHT) primary mission was to provide chronic care management for patients with diabetes, CHF, depression and other chronic conditions common to older veterans. As Darkins et al.[13] reported CCHT was based upon a foundation of health informatics, disease management, and home health technologies to "enhance and extend care…and improve health of designated individuals and populations…" Care coordinators, formal patient assessments, selection (by care coordinators) of patient-appropriate technologies, as well as training for patients and caregivers were all planned in the rollout of CCHT. Provider concerns about how to manage large amounts of patient-generated data was addressed by assigning review of monitored data to the care coordinators (nurses or social workers). Care-coordinators are able to use objective data transmitted by biometric monitors, complemented by messaging devices, which could identify knowledge deficits and negative health-related behaviors to determine if other interventions might be required. The results over 4 years were a 25% reduction in bed days of care, and a 19% reduction in hospital admissions—plus very high levels of patient satisfaction.

When VUMC launched MyHealthAtVanderbilt (MHAV) in 2005, they developed policies and procedures addressing many of the concerns related to authentication, privacy and security, and provider workload. Osborn et al.[23] examined some of the process that VUMC went through and the resulting MHAV adoption rate. There are two access levels in MHAV: to access secure messaging with an established provider, a patient may register by supplying name, date of birth and social security number, but to access EHR data, in-person authentication is required. In response to concerns about patients viewing EHR data beyond their full comprehension, laboratory data were segmented into three categories. The first group included vital signs data and was viewable without restriction. The second category imposed a 7-day hold so providers could assist patients with data interpretation. A final category, which included HIV test results and similarly sensitive data, was never viewable by patients. The study illustrates VUMC's struggle with provider reluctance to open the medical chart to patients and how that provider

culture was able to consider change. Thus the study may inform procedure and policy discussion that relate to PGHD.

To maximize provider productivity, secure messages go to the provider's clinical group, and a nurse, administrative personnel, or another member of the care team may respond to them. However, messages deemed "clinically relevant…are forwarded to the patient's physician or another provider within a closed loop system." An audit of this system in 2006 determined that thousands of "clinically relevant" messages had remained unopened; therefore, additional mechanisms were put in place to ensure timely and certain response to all secure messages. Now, after 5 years of operation, approximately 26% of all VUMC patients are registered to use the patient portal capabilities—an enrollment rate above the national average.

PHRs are generally seen as a means to facilitate patient-provider communications and information sharing. Patients who are seen at the Brigham and Women's Hospital and its affiliated practices have this access via the Patient Gateway patient portal. Wald et al.[17] investigated how patient completion of pre-visit electronic journals (eJournals) could improve both patient and provider experience. Patients who participated in the study were asked to use the eJournal to review clinical information and answer questions within specific modules (e.g., medications, allergies, health maintenance). To provide sufficient time for eJournal completion, patients were prompted 3 weeks prior to scheduled visits. In parallel, tools were developed to encourage providers to respond to eJournal submissions in advance of scheduled visits, and buttons were added to the EHR to support record updates consistent with patient's eJournal inputs. Results from this study indicated that a majority of patients felt that the eJournal process had made them better prepared, and given the provider better information in advance of the visits. Providers in turn endorsed this system and assessed it to be time-neutral with no adverse impact on workflow. The patient eJournal can be seen as a form of PGHD and this study may provide insight into what motivates patient engagement. Similarly, the provider experience here may help to address the operational issues and concerns as to how using PGHD may impact workload.

E. What is the ONC's role in defining and enabling the flow and appropriate use of PGHD in clinical care settings? What approaches to addressing PGHD issues should ONC consider?

Through discussions with experts, review of literature, and analysis by team members, RTI determined several options the ONC could consider pursuing as part of coordinating national PGHD efforts. We have organized these options into general areas of activity for ONC to consider, such as convening, research, standards, and certification activities. However, we note that not all of our experts saw a clear role for the ONC, and some felt that early in the evolution of PGHD it was most important to spur innovation and also to avoid regulations or activities that might slow innovation.

Option 1. Consider Stage 3 Meaningful Use criteria to enable and support PGHD

Much of what the RTI team learned in the process of the environmental scan and expert discussions confirmed the summary comments of Josh Seidman regarding the Meaningful Use Stage 2 public comments. His report of divergent opinions on the value of PGHD matched some of our findings, and motivated the options provided to the ONC that follow.

Regarding Stage 3 of Meaningful Use, any new criteria related to PGHD should encourage patient data sharing as part of patient engagement, align with patient expectations, and be informed by real-world examples of PGHD capture, transfer, and review. First, new Meaningful Use measures could focus on PGHD use *at the point of care* in clinical settings. One study team member suggested measures focused on provider use of patient data first shared electronically *prior to a visit* as potentially appropriate.[19] For instance, providing a menu item measure that requires use of a pre-visit agenda—a patient-generated list of things they want to cover during the upcoming visit—especially for high-risk, complex patients.

Second, new Meaningful Use measures could focus on operational needs to support PGHD review and use by providers. These measures could include attesting to having clear mechanisms for "receiving" patient health data, and having a policy for accepting and reviewing PGHD. These measures could be broad, assessing readiness and support for PGHD generally. Alternatively, these measures could focus on provider's abilities to receive, review, incorporate, and to use PGHD for certain chronic conditions. For instance, ONC could recommend a progression of measures that involve the capacity to receive data related to diabetes monitoring

(e.g., periodic glucose data) for patients with this condition and a second related measure to assess development of policies or guidelines for review of diabetes-related data, perhaps as part of a care management initiative. Other types of Meaningful Use measures, such as those focusing on actual rates of PGHD volume or use by eligible providers and hospitals may make sense if PGHD penetration is very high. Accordingly, eligible providers and hospitals might be able to attest to the capability of receiving PGHD, but metrics based on *actually receiving and processing PGHD* seem premature. The PGHD research options described below, in particular for assessing the current state of PGHD adoption and use, may help ONC determine the extent to which such measures are viable.

Developing Meaningful Use measures that assess patients' experiences with PGHD might also be a worthy goal. As part of Meaningful Use, measures that include what patients think of providers' PGHD use and processes would help assess and ensure truly meaningful use of this emerging data. However, under the current EHR Incentive programs registration and attestation framework, it would be difficult to specify and collect measures reported by patients seen by eligible providers and hospitals.

Finally, the convening, standards, and research options noted below support developing these new measures as PGHD adoption, use, value, and policies continue to evolve.

Option 2. Convene Stakeholders to Identify PGHD Opportunities, Barriers, and Value

ONC should consider bringing together, through a conference, expert panel, pledge activity, etc., stakeholders in PGHD including technology and services suppliers and potential (or actual) consumers to network with one another and discuss PGHD-related issues and opportunities. In addition to stakeholders listed above, disease management experts and primary care and specialty care experts might be included to identify high-value data capture areas and operational challenges to PGHD. Questions and issues concerning EHR readiness to accept and incorporate PGHD into EHRs could be addressed in this forum.

As part of these efforts, ONC could develop a white paper and invite comments from stakeholders to expand the understanding of PGHD opportunities and challenges, improve communication about PGHD, and help to broaden the discussion and involvement of these stakeholders. This work could also focus on creating value statements for PGHD use across several high priority areas, including improving chronic care quality, care transitions, new

delivery and financing models (ACOs), etc. These statements could summarize the value of PGHD to patients and providers, and inform the development of PGHD-specific use cases (discussed in greater detail below).

Option 3. Support Development and Use of PGHD-related Standards

The right kinds of PGHD elements and metadata are essential for certain kinds of clinical data important to providers. Just as laboratory results (e.g., cholesterol = 180 mg/dl) include data such as a reference range, date/time, sample type, sample collection time, etc., PGHD (e.g., blood pressure of 120 systolic and 80 diastolic) interpretation and flow into clinical systems will require appropriate information, such as the data source (e.g., iHealth BP3, model 2453), key metadata (e.g., right arm, sitting position), reliability data (e.g., calibration of the device), and data to verify the patient identity, device identity, and so forth.

From our discussions and review of selected resources, we determined a range of needs related to standards: from identifying what health IT standards are required to support PGHD, to which existing standards can be modified, or what new standards may be needed, to support these requirements. The ONC should consider performing this needs assessment, and facilitating the adaptation of existing standards or the development of new standards based on the results.

RTI believes that it would be very helpful to identify the most common and important information that patients can provide, establish common data definitions and data types, and promote their use. The data elements currently proposed as part of 2014 Edition certification criteria related to Transition of Care—Incorporate Summary Care Record and to View, Download, and Transmit to 3rd Party —may already serve this purpose. EHR readiness for incorporating PGHD should be assessed in terms of consistency of data definitions (i.e., being able to store PGHD accurately and without altering meaning), and in terms of supporting the workflow of reviewing and validating PGHD on the way into the EHR (i.e., being able to store "status" information such as "not reviewed" or "reviewed").

Without more information about the types of PGHD data being shared, the business and clinical drivers for that sharing, and the identification of high-value, high-importance areas of PGHD capture, transfer, and use, it is difficult to discuss options for certification requirements related to PGHD over and above those proposed requirements to receive and electronically incorporate structured patient data and to electronically download a file in human readable

format that includes key demographic, vital sign, medication, problem, lab, referral, hospital discharge, care plan and care team data.

Option 4. Conduct Additional PGHD Research to Collect Lessons Learned, Support Adoption, and Inform Policy

Our review suggested several areas of additional research in PGHD, including gathering additional examples of PGHD, assessing the current state of PGHD adoption and use, assessing patient and provider needs for PGHD tools, identifying and comparing organizational PGHD policies and practices, and developing a PGHD research agenda.

Gather and Showcase PGHD Examples

In our analysis, we provide a few sources as well as hypothetical examples of PGHD capture, transfer, and review. To better understand how PGHD are being used, and how the issues we identified in our analysis are being addressed, ONC should consider gathering PGHD examples. ONC could invite stakeholders (patients, family members, care team members, providers, businesses, researchers, etc.) to provide case examples of PGHD that describe the types of PGHD captured and shared by patients; how these data are reviewed and used by providers, care team members, family caregivers, and others; how expectations and policies around PGHD use are developed and communicated; the impact of PGHD on provider workflow; and the value of PGHD to these various stakeholders.

Perhaps examples could be gathered through participants in ONC's Consumer eHealth Pledge initiative. The PGHD data flow framework we describe in this paper may serve to help inform what ONC requests from Pledge members as well as to help organize these examples. ONC could then showcase these examples though use of social media and at conferences, meetings of professional societies, and health care-related events as part of existing media campaigns—*Putting the I in Health IT*—and as part of new promotional efforts.

By raising attention to and informing the discussion around PGHD, ONC will enable patients and other PGHD stakeholders to guide what issues are important to PGHD and to share lessons/best practices, for example, from providers on PGHD review/documentation. This role is consistent with ONCs efforts on provider health IT adoption, specifically those of the Health IT Research Center (HITRC). These examples could also begin to serve as the basis for PGHD use cases—especially when considered in the context of other consumer eHealth-related use cases

such as those developed under the American Health Information Community (AHIC) and the Healthcare Information Technology Standards Panel (HITSP)—and deliberations of current ONC Federal Advisory Committee work groups (e.g., Meaningful Use).

Assess the Current State of PGHD Use among Providers

ONC could survey the provider organizations using PGHD and related patient self-management tools, to identify and broaden awareness of how and where PGHD has greatest potential including:

- What models of PGHD are most extensively used, currently?
- What kind of PGHD makes a difference to cost, quality, and experience of care?
- What PGHD approaches are best matched to "high-barrier" situations, such as patients with limited resources, low patient activation, or limited health literacy?

The results of this assessment could be published and, similar to landmark studies of EHR adoption, serve as one important factor informing the development of PGHD-related criteria for Stage 3 Meaningful Use.

Determine Needs for PGHD Tools

Many of our experts suggested the need for tools or resources to support parsing and use of PGHD by providers. ONC should consider confirming whether or not, or in what ways, software tools or services could be developed to aid providers. This research area may be of particular interest to the Agency for Healthcare Research and Quality (AHRQ), whose work in the health IT portfolio has produced a number of tools to support various aspects of health IT adoption and evaluation.

Collect and Compare PGHD Data Policies among Provider Organizations

It is important to determine what policies are needed to support flow and use of PGHD by providers, including acceptance of PGHD, expectations of provider review, and copying of PGHD into existing EHR systems. ONC could sponsor research and analysis to identify and ask leading organizations about their policies across a range of PGHD issues, including setting expectations with patients about PGHD use, acknowledging and reviewing PGHD received from patients, and how reimbursement impacts their handling of PGHD. This last issue—if and how providers are paid for review and incorporation of PGHD during care—is particularly key. We

heard little from our experts about reimbursement; however, when considering provider's experiences with electronic visits (eVisits), we believe that financial incentives/barriers will be a potent factor in the use of PGHD.

ONC could then summarize these policies (both formal and informal), compare them, and determine any important variations or gaps. Sharing this analysis with stakeholders could assist them in developing and improving their own PGHD policies. It could also be used to develop model policies, similar to or building upon those from the Markle Foundation described previously, based on lessons learned and current practices.

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APPENDIX A: LIST OF INFORMAL CONVERSATIONS

We held informal conversations with the following researchers, care providers, patient advocates, industry representatives, and legal counsel currently working with PGHD (individuals listed in one category may fit in others as well):

- Researchers—
  - Patricia Brennan, PhD, MSN, Project HealthDesign and University of Wisconsin
  - Barbara Massoudi, PhD, MPH, Project HealthDesign and RTI International
  - David Bates, MD, MSc, Partners Healthcare and Harvard Medical School
  - Joe Kvedar, MD, Center for Connected Health, Partners Healthcare
  - Warner Slack, MD, Beth Israel Deaconess Medical Center and Harvard Medical School
  - Jonathan Wald, MD, MPH, RTI International
- Health 2.0 sites and organizations—
  - Dave Clifford, PatientsLikeMe
  - Matthew Holt, Health 2.0
- Patient advocates—
  - Dave deBronkart (ePatient Dave)
  - Regina Holliday, Medical Advocacy Blog
- System and apps vendors—
  - Allen Wenner, MD, Instant Medical History
  - Kenneth Mandl, MD, MPH, Children's Hospital Boston and Harvard Medical School
  - Harry Bailes, Family Health Network
- Provider organizations—
  - Ted Eytan, MD, MS, MPH, Kaiser Permanente
  - Daniel Sands, MD, MPH, Beth Israel Deaconess Medical Center and Harvard Medical School
  - Charles Safran, MD, MS, Harvard Medical School and Beth Israel Deaconess Medical Center

  - Susan Woods, MD, MPH, Portland Veterans Administration Medical Center, My HealtheVet
  - Kathleen Frisbee, MPH, Veterans Health Administration—Mobile Health Strategy initiative
- Legal counsel
  - Chad Broulliard, JD, Foster & Eldridge LLP

APPENDIX B: SUMMARY OF HISTORICAL HEALTH IT LITERATURE RELEVANT TO PGHD

While much of the technology enabling the projected expansion of PGHD is new, many underlying issues are not, and discussion of these has a long history in the literature. In his 1972 article, "Patient Power: A Patient-Oriented Value System,"[30] Slack foresaw the drastically changed environment in which, "the medical chart traditionally closed to the patient, will be declassified at last and become a document developed jointly by patient and doctor." Dr. Slack's editorial, "The Patient's Right to Decide"[31] advocated for the patient's involvement in health care decisions, and his paper—"A Computer-based Medical-history System"[32]—proposed having the patient interface directly with the computer, independent of the physician.

Sands and Halamka addressed secure electronic communication from patient to provider, an important step in PGHD flow, in a 2003 paper. The paper concerns numerous discussions in the late 1990s at the Boston Beth Israel Hospital, about how to "allow patients to see their records online and communicate securely with their healthcare providers."[33] This article covers the design and implementation of a patient portal system—in use at the hospital clinics—established to provide patients with secure online access to their medical information and communication with their doctor's office.

Several papers on PHRs have identified many opportunities for sharing PGHD, whether those PHRs are pre-populated with patient data by a provider or insurer organization, or only populated with health data as directed by the patient. Tang et al.[27] reported on a 2005 AMIA organized symposium; this white paper on PHRs covers the entire landscape of issues, including proposals of health IT-related education for consumers, beginning in primary grade levels and continuing through high school. The Mandl[34] article on the Indivo system explains the concept of a personally controlled health record (PCHR) and states "PCHRs are designed on the principle that patients have the right to own and manage copies of their own medical information. PCHRs are complements to, rather than replacements for existing health care information management systems. In exercising *control* of their records, individuals decide what data sources populate the record and who is allowed to access or annotate any of the documents contained within the record." In a paper tackling provider concerns, Halamka et al.[35] addressed the fear that inviting

e-mail communication from patients might lead to a deluge of messages that adversely impact provider workload and workflow.

There has been some study of the impact of introducing PGHD into the workflows of providers (Osborn et al.);[23] it can be seen as having a disruptive impact on provider's workflow and practice, and researchers have studied the attitudes of providers toward utilizing these new sources of data. A small study of family practice physicians by Witry et al.[36] found that these providers viewed PHRs as a back-up source for patient information when the primary source was unavailable, and were not cognizant of the patient-centered features supported by the PHR. In a much larger sample, Wynia et al.[37] found that though a majority of providers had never accessed data via a PHR, 42% were willing to try.

PHRs have long been viewed as a primary tool to engage and empower the patient, and the broad array of PGHD devices now emerging can enable a richness of patient-input complementing that supported in the PHRs. Detmer et al.[38] reflected upon the results of a roundtable held in 2006 to explore the potential for PHR to be a transformative tool for moving healthcare in a consumer-centric direction. In their comparison across the spectrum from stand-alone PHRs to highly integrated, the authors concluded that only the integrated model had the potential to enable patients to manage their own health care. Ball and her colleagues[39] covered similar ground and laid out a course of action for moving forward, though the issues they listed 5 years ago are still current. Poon et al.[40]discussed implementation of a health maintenance module within their PHR directed toward routine preventive care. The module enabled the patient and the provider to share access to the patient's health record as well as decision support capabilities. Pilot studies reporting on the successful engagement of patients using PGHD for preventive care related to chronic illness are beginning to be published.[6-9]

Collectively, this literature from the past 40 years addresses the topics of patient engagement, sharing of information between provider and patient, and how providers manage and use patient-supplied information. These articles address the various issues we have covered and include concerns about the integrity of the data being input, and worries about patients seeing information via a patient portal that they would not be prepared for. Some of the papers detailed studies to learn which segments of the provider population were more accepting of the use of PHR systems. Though these articles focused on PHR or PCHR, not on PGHD as defined here, the issues are still applicable.