

Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024

Draft White Paper for a PGHD Policy Framework

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Executive Summary

The Office of the National Coordinator for Health Information Technology (ONC) defines patient-generated health data (PGHD) as health-related data created and recorded by or from patients outside of the clinical setting to help address a health concern.¹ To date, patient health information, such as activity level, vital signs, symptoms, and medication effects, has been predominantly collected by members of the care team in a clinical setting or through clinical in-home devices for remote monitoring. The recent proliferation of consumer health technologies, such as online questionnaires, mobile applications (apps), and wearable devices, has increased the frequency, amount, and types of PGHD available. These advances can enable patients and their caregivers to independently and seamlessly capture and share their health data electronically with clinicians and researchers from any location. To contribute to the development of an overall PGHD policy framework, this white paper describes key opportunities and challenges for realizing the potential of PGHD use and offers relevant enabling actions that could further enhance PGHD capture, use, and sharing for health care delivery and research in the United States.

Opportunities

Consumer technologies can empower patients to capture, use, and share PGHD to better manage their health and participate in their health care.² When used by clinicians and researchers, PGHD can provide a more holistic view of a patient's health over time, increase visibility into a patient's adherence to a treatment plan or study protocol, and enable timely intervention before a costly care episode. Clinicians can strengthen their relationships with, and improve the experience of, their patients by using PGHD to develop a personalized care plan and to engage in joint decision-making to foster better outcomes.³ The availability of PGHD provides researchers with access to a larger pool of participants and research data. The ability to remotely capture and share PGHD reduces the time, effort, and costs of patients visiting a clinical setting or research site and can improve workflow efficiencies.

Challenges







While the use of PGHD holds great promise to benefit patients, challenges must be overcome to realize that potential. Many health care systems and research institutions lack the technical infrastructure, functional workflows, workforce capacity, and training to support PGHD intake. They also struggle to draw actionable insights from the data due to the large volume of data being collected and lack of demonstrated value. The lack of guidance and best practices for incorporating PGHD into clinical and research workflows inhibits the implementation of PGHD initiatives. In addition, because the use of PGHD in care delivery and research is nascent, evidence of the benefits of PGHD is still inconclusive, which has slowed funding for its implementation.⁴

Data- and device-related concerns pose additional challenges for the capture, use, and sharing of PGHD. Device abandonment of consumer health technologies, such as wearable activity trackers, can be high.⁵ Once patients have generated and shared data, clinicians and researchers face several challenges, such as confirming the accuracy and validity of PGHD from consumer health devices that do not operate within the U.S. Food and Drug Administration (FDA) data reliability specifications, and standardizing data from multiple devices. Some stakeholders have noted that the use of PGHD may present liability concerns if inaccurate PGHD are used in clinical decisions or if the clinician chooses not to take action based on the PGHD received. Furthermore, clinicians may have concerns about whether accepting PGHD that are delivered to the clinician's electronic health record (EHR) poses a security risk to the EHR systems. However, clinicians and EHR vendors have obligations under the Health Insurance Portability

and Accountability Act of 1996 (HIPAA) to protect against inbound security risks from all sources, not just PGHD.

Enabling Actions

Advancing the use of PGHD will require action and collaboration across the health care ecosystem. The strategies outlined below would inform the development of a policy framework that should suggest enabling actions for each stakeholder group:

Stakeholders	Enabling Action to Consider for the Policy Framework
 <p>Patients & Caregivers</p>	<ul style="list-style-type: none"> Encourage patients and caregivers to collaborate with clinicians and researchers to determine how capturing, using, and sharing PGHD can be valuable for managing their health. Support active patient participation in testing the functionality and usability of devices and in reporting feedback directly to manufacturers.
 <p>Clinicians</p>	<ul style="list-style-type: none"> Support clinicians who work within and across organizations to incorporate prioritized PGHD use cases into their workflows. Foster collaboration between clinicians and developers to advance technologies supporting PGHD use. Identify and communicate benefits, challenges, and best practices of PGHD use to help strengthen the evidence for clinical value and business case. Encourage clinicians to use PGHD to support patient data donation in research.
 <p>Researchers</p>	<ul style="list-style-type: none"> Call for increased funding for studies that investigate the benefits, challenges, and best practices of using PGHD in care delivery and research. Motivate researchers to design and develop studies that incorporate PGHD. Expand methods for data donation to research studies. Strengthen patients' understanding of consent and data use.
 <p>Policymakers</p>	<ul style="list-style-type: none"> Prompt collaboration with industry to strengthen model practices, consumer education, and outreach that support the private and secure capture, use, and sharing of PGHD. Call for increased funding for programs that aim to further understand the impact of PGHD use as part of delivery system reform and advanced health care models. Suggest review of medical malpractice and liability laws at the state level and how they intersect with legal cases involving use of PGHD.
 <p>Developers & Standards Bodies</p>	<ul style="list-style-type: none"> Suggest developers improve usability and accessibility and implement user-centered design principles into products that capture PGHD. Increase adoption of strong privacy and security practices regarding PGHD capture, use, and sharing by developers and support transparency with consumers about these policies. Challenge standards bodies to address the needs of the PGHD ecosystem and to increase the pace of standards development for capturing and integrating PGHD.
 <p>Payers & Employers</p>	<ul style="list-style-type: none"> Continue to motivate clinicians to capture and use PGHD through reimbursement programs. Continue to incorporate incentives to use PGHD into their insurance plans and wellness programs.

Introduction

The rise of innovative digital health technologies has increased the ease of generating and collecting PGHD. Such technologies provide a unique opportunity for patients to share their health data in day-to-day settings and in real time with clinicians and researchers. Although patients are creating an abundance of PGHD, a number of technical and cultural barriers currently exist that have slowed the movement of that PGHD into care delivery for patients. Capitalizing on the increase of the technologies and mitigating the barriers to using the data captured requires industry guidance and best practices for integrating PGHD into clinical and research settings. This white paper envisions a health IT ecosystem that optimizes PGHD for care delivery and research. It identifies many, but not all, opportunities and challenges related to widespread capture, use, and sharing of PGHD. Finally, it offers suggestions for a policy framework that calls for enabling actions by stakeholders to address the challenges identified.

Purpose

ONC contracted with Accenture to develop a white paper on the capture, use, and sharing of PGHD in care delivery and research settings through 2024 for ONC to leverage in creating a PGHD policy framework. This project aligns with several calls to action referencing PGHD in ONC's 10-year vision to achieve an interoperable health IT infrastructure by 2024 as defined in the *2015 Shared Nationwide Interoperability Roadmap*, including the development of a PGHD policy framework.⁶ The white paper has been structured to describe considerations for the future PGHD policy framework to be developed by ONC. It discusses challenges and opportunities for the capture, use, and sharing of PGHD that can be addressed by several stakeholder groups.

This project is funded by the Patient-Centered Outcomes Research (PCOR) Trust Fund that is administered by the HHS Assistant Secretary for Planning and Evaluation. This project is part of a suite of PCOR projects at ONC that contributes to building a data infrastructure to support patient-centered outcomes in research and to integrate them into clinical care delivery.⁷ PCOR efforts, and specifically this PGHD project, aim to expand data sharing and to complete feedback loops between patients, clinicians, and researchers as part of a learning health system to engage patients in improving health outcomes and advancing research.

This white paper focuses on the perspectives of patients, clinicians, and researchers as key stakeholders in the use of PGHD. It also calls on policymakers, technology developers and standards bodies, and payers and employers, whose actions support the capture, use, and sharing of PGHD for use in care delivery and research. For the purposes of this white paper, caregivers are included whenever patients are referenced but may in some cases have different needs.

Methodology

Beginning in October 2015, the Accenture team researched seven PGHD policy topic areas to help inform this white paper:

1. **Collection and Validation of Data and Tools** focuses on the existing and emerging tools for capturing PGHD. The topic also considers the types of PGHD that clinicians and researchers collect and how they validate the data and tools.
2. **Data Donation** explores patient expectations for sharing data with clinicians and researchers. The topic also examines existing and emerging methods of data donation for research.

3. **Regulatory Overview** discusses the current federal statutory and regulatory paradigms relevant to PGHD, including the tools and technologies used to capture PGHD.
4. **Ability to Combine PGHD with Medical Record Data in Multiple Ways** examines the opportunities for combining PGHD with clinical data for analysis and patient care. The topic also includes methods for combining data from multiple sources, as well as the standards and technology needed to support this practice.
5. **Patient Recruitment for Research Studies and Trials** focuses on the ways PGHD could be used to identify patients for research studies and trials and to connect patients directly with researchers.
6. **Data Interoperability** examines the benefits of, and barriers to, increased interoperability between the health IT system and devices used to capture PGHD. The topic also explores technical barriers such as standards, as well as cultural and workflow barriers.
7. **Big Data Analysis** assesses the technical and cultural challenges to using PGHD in big data analysis. These challenges include patient concerns about data privacy, storing and transmitting potentially large volumes of data, and providing clinically useful presentations of PGHD.



This draft white paper synthesizes our findings from research on the seven topic areas conducted from October 2015 to October 2016. The findings provide an integrated view of the issues and opportunities for the capture, use, and sharing of PGHD across stakeholder groups. Also in this white paper are several appendices, including a glossary of terms used.

To further validate and expand the findings of this draft white paper, two digital health technology organizations will conduct pilot testing with care delivery partners. Validic and its partner, Sutter Health, are using PGHD collected from a multitude of devices to inform diabetes care while assessing the infrastructure and workflows needed to implement and scale such initiatives. TapCloud and its partner, AMITA Health, are gathering PGHD across several medical areas such as orthopedic surgery, stroke, behavioral health, and kidney transplantation to identify and collect information that includes how patients feel, incorporating this information into a dashboard that can be reviewed by clinical staff. The findings from these pilots will provide actionable insights for multiple industry stakeholders and, along with public comments, will inform the final version of this white paper.

Background

PGHD are not new. Patients have long kept paper logs of data about their health such as weight, symptoms, blood sugar readings, and medication effects. Patients have then brought these paper logs to doctor's visits to assist them in discussing their health status, at-home treatments, and overall care. The increase of social networking, cloud-based platforms, connected devices, and smartphone apps that support data collection has provided patients with simplified means to collect data outside of the traditional clinical environment. In addition, advances in cloud computing simplify and reduce the cost of capturing large data sets and enable seamless connections across the devices and apps. These

advances have led to the proliferation of PGHD and the opportunity for clinicians and researchers to gain insight into patient health outside of clinical settings in real time.

Consumer interest in PGHD has grown considerably in recent years with the increase in wearable fitness trackers and mobile health apps. A report by the IMS Institute published in September 2015 found that there are over 165,000 mobile health apps for download from the U.S. Apple iTunes store and Google Play, with two-thirds of them focused on general wellness, including fitness, diet, and stress.⁸ A recent Gartner forecast predicted that the overall wearable market will expand from 275 million devices in 2016 to 477 million devices in 2020.⁹ Clinicians and researchers are looking for ways to capitalize on the pervasiveness of these devices and the abundance of data that patients are generating.



A recent Gartner forecast predicted that the wearable market will expand from

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Recent payment reforms and regulatory measures that incentivize the capture and use of data from nonclinical settings have supported the provider interest and use of PGHD. Within the Medicare and Medicaid Electronic Health Record Incentive Programs - Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 (MU3) (Centers for Medicare and Medicaid Services, 2015) regulation, an optional measure allows a covered provider to receive credit in the program when PGHD or data from a nonclinical setting are incorporated into the certified EHR technology for more than five percent of all unique patients seen by the eligible provider or discharged from the eligible hospital or critical access hospital inpatient or emergency department during the EHR reporting period.¹⁰ With the increasing adoption of certified EHRs and the rapid pace of innovation in health IT, ONC established new requirements within its 2015 Edition Health IT Certification Criteria final rule that would further enhance the safety, reliability, transparency, and accountability of certified health IT for users.¹¹ Since 2015, the Centers for Medicare & Medicaid Services (CMS) has also offered reimbursement for non-face-to-face care coordination for Medicare beneficiaries with multiple chronic conditions and for transitional care programs, which can both be supported through the use of PGHD.^{12,13} Looking toward the future, the Merit-Based Incentive Payment System (MIPS) as part of CMS's regulation for the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA) also includes an optional measure for using PGHD to support the goal of coordinating care through patient engagement.¹⁴

All of these factors create an environment that is ripe for the capture, use, and sharing of PGHD. However, relatively few health care and research organizations are capitalizing on the opportunity to use PGHD to advance medical knowledge and support care delivery. Recognizing the current limited use of PGHD, ONC has led several efforts to better understand PGHD, their value in clinical and research settings, and challenges related to their capture and use. These efforts include commissioning the Research Triangle Institute (RTI) International *PGHD White Paper* (2012), which defines PGHD and analyzes the technical, operational, legal, and cultural issues related to PGHD;¹⁵ convening consumer workgroups for the Federal Advisory Committees (2012) to provide policy recommendations and feedback on the MU3 recommended measures for PGHD;¹⁶ convening a technical expert panel (2013) to identify best practices for using technology to enhance patient engagement and to support MU3 requirements;¹⁷ and publishing an issue brief on PGHD and health IT (2013) describing the policy challenges and opportunities related to the capture and use of PGHD in clinical care and research.¹⁸ This white paper builds on these past efforts to address advances in health information technology and

changes in the ecosystem in the intervening years, for example, the rapid evolution of health-oriented consumer technology and an increased interest in measuring patient outcomes.

Several of ONC's published documents envision a future health IT ecosystem that supports the capture, use, and sharing of PGHD to improve care delivery and research. The *Federal Health IT Strategic Plan* (2015) describes the federal government's plan for achieving a learning health system that includes "high-quality care, lower costs, a healthy population, and engaged individuals."¹⁹ *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap* (2015) highlights the need for ONC to develop a PGHD policy framework by 2017 to support the transmission of data, promote interoperability, and achieve a learning health system.²⁰ ONC's report *Examining Oversight of the Privacy and Security of Health Data Collected by Entities Not Regulated by HIPAA* (NCE Report), submitted to Congress in July 2016, describes the privacy and security regulatory landscape for products that are used to capture PGHD that are not covered by HIPAA and identifies areas for action to strengthen privacy and security.

Findings

Realizing the significant potential of PGHD use requires that numerous challenges be addressed by a broad range of stakeholders. An examination of the current state and projection of the future state of PGHD reveals the opportunities, challenges, and calls to action for the main health care stakeholders, as well as supporting stakeholders. Progress in all of these areas is essential to achieving the envisioned future for PGHD.

Current State

In today's health care environment, clinicians typically make decisions based on data they collect in clinical care settings that create a snapshot of the patient's health at single points in time, rather than continuous measurements outside of clinical settings.²¹ Rarely do clinicians and researchers have access to data collected in real time about their patients' lives outside of the clinical setting, thereby reducing the holistic perspective of their patients' health.

PGHD captured using digital health tools such as online questionnaires, mobile apps, wearables, and connected medical devices could help patients become more engaged in health care. The recent popularity of these devices for PGHD collection is easy to understand. First, the use of the smartphone makes the collection and exchange of PGHD easy and convenient. A device that 64% of American adults own and often carry with them everywhere, the smartphone has become a central hub for capturing measurements or storing and sharing data.²² Second, many consumer technologies can passively collect health data, and so generate large volumes of data. For example, a device can passively collect data such as step count, location, and heart rate without actively notifying the user. Finally, many of the apps and devices that capture PGHD allow data visualization, so patients can receive valuable feedback, quickly understand their data in real time, and proactively choose to modify behavior. For example, some wearable fitness trackers have features that allow users to track hourly activity and sedentary time. Knowing how many hours one spends a day being stationary can drive healthier behavior change by providing users with insight into their behavior and reminders to be active.²³

Technical Challenges

While patients purchase and use digital health devices to generate PGHD, the capture, use, and sharing of PGHD for clinical care and research are not yet in widespread practice, in part, due to technical barriers affecting multiple stakeholders. These barriers include concerns about managing large volumes of PGHD, questions about the accuracy of measurements from devices that collect PGHD, user

authentication risks, lack of PGHD interoperability standards, data provenance issues, and gaps in privacy and security protections.

The potential volume of the data from devices collecting PGHD requires stakeholders to determine and invest in the data storage and technical architecture needed to support PGHD use. In the absence of tools that can quickly analyze data and offer actionable insights, large amounts of PGHD may add inefficiencies to clinical and research workflows and noise to the clinical data.

Technical challenges also lead to questions about the accuracy of devices that collect PGHD. Patients, researchers, and clinicians alike have also called into question the accuracy and validity of PGHD currently collected from consumer health devices. The quality of data captured using FDA-approved home health monitoring devices meets specified levels of accuracy, but studies have indicated that some PGHD captured by consumer health devices not subject to FDA approval, such as wearable activity trackers, may vary significantly from clinical-grade devices and methods. A recent study reported that some popular wearables are consistently inaccurate at measuring energy expenditure, such as calories burned, when compared to gold-standard measurements, such as metabolic chambers, which are control rooms where a person can reside for a period of time, while metabolic rate is measured during meals, sleep, and light activities.²⁴ Given these variations in accuracy, some PGHD may not yet be fit for clinical and research use cases where data accuracy is paramount. When monitoring general wellness, leveraging data collected by a consumer health device may be sufficient. However, a clinical-grade device with a low margin of error and high data accuracy may be required when a clinician or researcher manages or treats a health condition.

User authentication also introduces data accuracy concerns. In the case of remote patient monitoring, clinicians and researchers must have the ability to trust that the data received are recorded solely for one person.²⁵ Currently, many devices require a user to present credentials only during initial authentication, which may not be adequate. The lack of continuous user verification introduces two risks, both of which can threaten data integrity.²⁶ One is the risk of a stolen device, and therefore, a stolen identity. The other is the risk of wearable, a mobile phone, or other digital health device being passed among several people. However, continuous user verification may be disruptive to the user and create a poor user experience.

Merging data from disparate sources introduces a number of data curation challenges, particularly in standardizing PGHD and capturing data provenance. To create more robust datasets for analysis, clinicians and researchers may combine PGHD with data from multiple sources such as an EHR, claims databases, other PGHD technologies, or non-health information such as geolocation and shopping data. Without standards that fully address PGHD use cases and consensus on which interoperability standards to use, variations in data representation and coding limit the exchange of data, data normalization and completeness, and the ability to draw valuable insights. The absence of a standard protocol for tracking data provenance issues prevents clinicians and researchers from tracing the origins of PGHD as they are transmitted. Knowing where the PGHD originated and if they have been altered helps the clinician or researcher to establish trust in the data.



Technical Challenges

- Concerns about managing large volume of PGHD
- Questions about accuracy of measurements from devices that collect PGHD
- Use authentication risks
- Lack of PGHD interoperability standards inhibit data exchange and merging
- Data provenance issues
- Gaps in privacy and security protections

Finally, ensuring the security and privacy of PGHD is a challenge to clinicians and researchers. As HHS's recent NCE Report demonstrates, the privacy and security protections that apply to PGHD are uneven and may not be subject to a consistent legal and regulatory framework.²⁷ These privacy and security gaps can reduce patient, clinician, and researcher trust. Data captured in settings that fall outside of HIPAA regulations may be at higher risk of security breaches that could affect the integrity of the data and expose the data to access for malicious purposes. Concerns include insecure points of data collection and insecure data that potentially expose the clinician's system to pollutants, such as malware. Privacy concerns include how clinicians and researchers use the data and whether those uses are transparently and understandably described to the patient whose data are collected. Even if clinicians and researchers adhere to the requirements outlined in the HIPAA Privacy and Security Rules, such as de-identifying data in accordance with HIPAA standards and instituting physical safeguards, data breaches can still occur.²⁸ While not unique to PGHD, there is growing potential for cyber threats, with criminal attacks in health care up 125 percent between 2010 and 2015.²⁹ Integration of properly de-identified data across data sets from different sources can open the risk to re-identification as the information is linked across these sources. As one National Institute of Standards and Technology (NIST) report notes, "the risk of re-identification will increase over time as techniques improve and more contextual information become available."³⁰

Several initiatives currently advance solutions that address these technical challenges. For example, emerging biometric authentication technologies, such as gait recognition algorithms that analyze body movements to identify individuals, are targeted to address user authentication issues. Big data companies enable the use of analytics, such as natural language processing and machine learning on unstructured data, to help doctors and hospitals make their data more usable.³¹ Furthermore, to prevent the duplication of records when integrating PGHD with data from different systems, clinicians and researchers employ patient-matching techniques. Current procedures that use statistical algorithms to match data in local systems, such as demographic data, with PGHD are showing increasing levels of reliability.

Future State – A Look Toward 2024

As shown in Figure 1, PGHD use for clinical care and research is currently in the early adoption stage. Cutting-edge organizations are piloting and beginning to understand the value of PGHD. Initiatives like these will likely grow and scale to maturity over the next eight years. In the future, a fully functional health ecosystem will have digital capabilities to seamlessly and electronically capture and share PGHD among patients, clinicians, and researchers, as well as across communities and non-clinical settings. This ecosystem focuses on patient preferences and goals and keeps patients at the center of care delivery and research. To better illustrate the potential impact of the use of PGHD, the following scenario describes how a patient's experience could look in 2024.

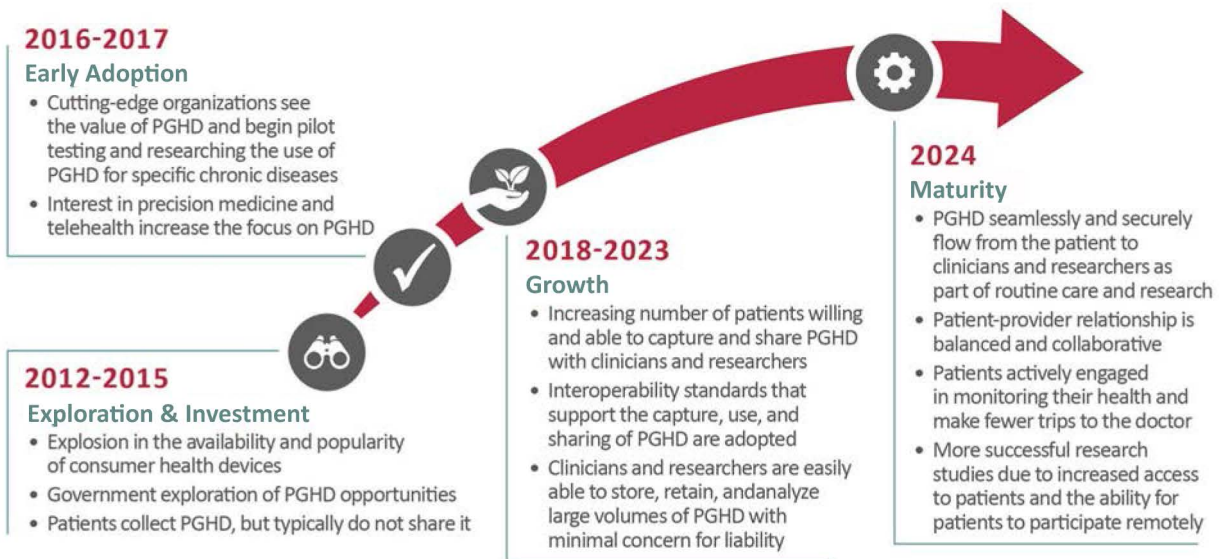


Figure 1: PGHD Adoption Curve

Christie is a 39-year-old female with a history of high blood pressure. She completes her annual physical exam each year. Between clinical visits, Christie manages her health by tracking her weight using a Bluetooth scale that syncs with her smartphone and by keeping food and mood journals recorded in a mobile app. She also measures her steps, energy expenditure, sleep, blood pressure, stress, and heart rate with a wearable activity tracker provided by her insurer. She also takes medication, including ingestible sensors, to manage her high blood pressure and to monitor the effectiveness of and adherence to her treatment plan through a mobile device.

Christie previously authenticated her apps and devices so that her PGHD could be fully integrated into her medical record in her local health system's EHR. As a result, PGHD from her weight scale, food and mood apps, activity tracker, and ingestible sensor are automatically uploaded to her care team's record system without Christie's action. Her information from other health systems, such as the flu shot she received at her retail pharmacy and the cold medicine purchased at the community health clinic, are also integrated into her medical record. Within her PGHD apps and devices and before the PGHD are sent to her clinician, Christie controls who can see and use her information by authorizing and revoking access using an app linked to her health record on her mobile device. Once the clinician has the data in her EHR, under HIPAA, Christie's clinician can share that data seamlessly with other clinicians for Christie's treatment. In fact, that type of sharing is expected by patients, so Christie's clinician does so, making sure that all other clinicians who are caring for Christie have the data they need for a complete picture of her health.³²

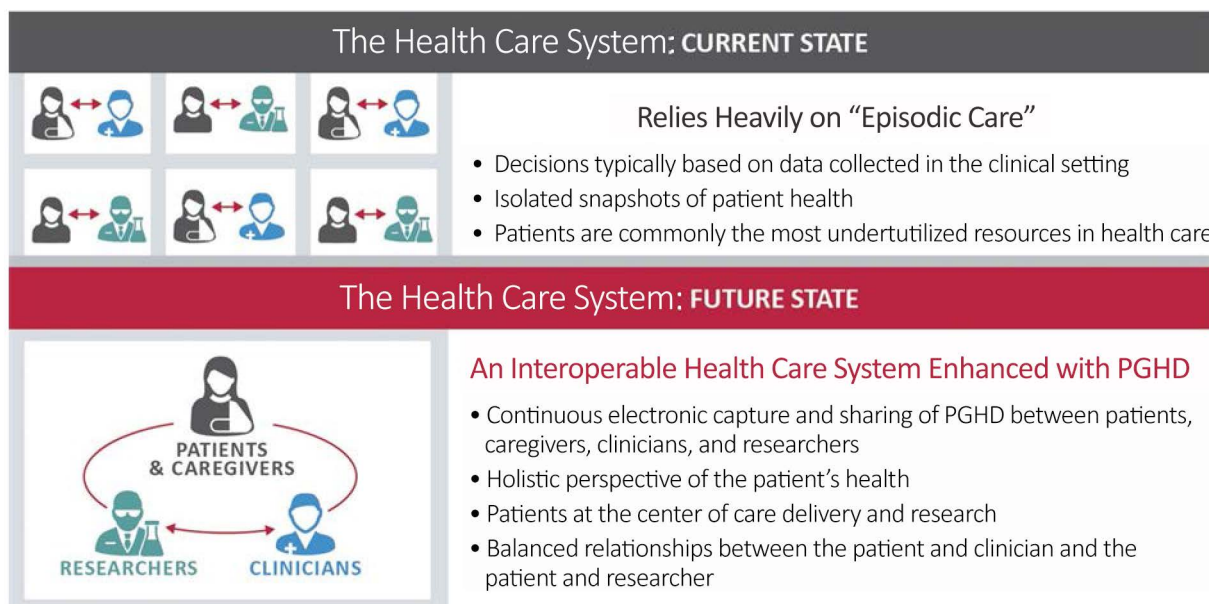
Within the clinician's EHR privacy and security mechanisms defined by HIPAA are in place to ensure that all patient health data are transmitted securely to the intended recipients. Clinicians will accept these PGHD into the EHR without concern for data accuracy and validity because all of her PGHD technologies have been calibrated, the data collected are standardized, and the provenance is clear. The EHR automatically screens the data for any concerning values or trends, and notifies Christie and her care team about these concerns via appropriately secure messages and secure log-in access. These best practices have been reviewed and endorsed by clinical societies.

A few months later, the care team receives an urgent alert that Christie had not taken her medication in over two days and experienced a rise in her blood pressure, as well as changes in mood and sleep. A

care team member contacts Christie via phone, her preferred method of communication for urgent matters. Christie explains that she recently experienced a death in the family. The care team member provides initial guidance to get Christie back on her routine and adds a behavioral medicine clinician to the team, sharing Christie’s relevant data. The EHR system then initiates a request to schedule a telehealth consultation for Christie with the behavioral medicine clinician. In this way, the capture, use, and sharing of PGHD enables preventive care, monitoring the data, and proactively identifying changes.

Meanwhile, the EHR system not only automatically reviews Christie’s PGHD for clinical care purposes; it also automatically compares them to a database of clinical trials and studies currently recruiting and enrolling patients because Christie has indicated through an online research registry tool that she wants to be notified of opportunities to contribute to research. Using artificial intelligence, the system identifies research studies and clinical trials for which Christie is eligible to participate and provides her with details about those studies. Christie fills out an online intake form to be considered for a sleep disorders study. Once accepted, she consents to participate in the study through an electronic consent process that also authenticates her identity, validates her devices including her connected mattress in her smart home, and allows her to sign up to securely donate her data to the researcher. Her health data will be automatically transmitted from the device to researchers through the research study database.

Achieving this future vision will require collaboration across the health ecosystem including not only the key health care stakeholders of patients, clinicians, and researchers, but also federal government agencies, technology developers, payers, and employers. Challenges that a specific group faces may affect and require action on the part of multiple stakeholders. To that end, enabling actions for one stakeholder may resolve the challenges of another stakeholder.



Opportunities, Challenges, and Enabling Actions for Key Stakeholders

Patients and Caregivers

Opportunities

The use of PGHD can empower patients and caregivers to manage their health and to collaborate with clinicians and researchers via shared decision-making that considers patients' preferences. Clinicians and researchers can gain a better understanding of the patient's health over time and reduce office visits and hospital readmissions, resulting in better outcomes and less burden for the patient.

Through the use of PGHD, patients can become more engaged and knowledgeable as partners in their care and in research. PGHD technologies engage patients in the data collection process, which allows them to observe how their health may fluctuate over time to understand how certain actions and behaviors may influence their health outcomes.³³ For example, a survey of patients enrolled in the Connected Cardiac Care Program at Partners HealthCare, which allows heart failure patients to capture and share weight, heart rate, pulse, and blood pressure data to support telemonitoring and patient education, found that 98% of participants reported learning more information about heart failure because they were enrolled in the program, and 85% reported that they felt in control of their health because of the program.³⁴ The ability for patients to monitor their data outside of clinical settings may increase treatment compliance by demonstrating the tangible effects of adhering to treatment protocols.³⁵ Patient and clinician access to PGHD may improve health outcomes when used to manage a specific condition as proven by studies that have shown efficacy of the use of relevant PGHD to monitor specific chronic conditions.³⁶

PGHD may help to create more balanced relationships between the patient and clinicians and researchers. Patients can express their health status and generate and view data that support their understanding of their health. The sharing of PGHD also allows patients to share their habits and preferences so that care can be personalized to their needs and lifestyles. As a result, shared decision-making becomes an ongoing collaboration between patients and clinicians, and patient understanding of and adherence to treatment plans rises.³⁷

PGHD use can reduce the time, effort, and costs of visiting a clinician or researcher and optimize the value of these encounters. When clinicians receive and review PGHD between clinical encounters, they may gain a better understanding of the patient's health. Periodic review of data by clinicians can make it less necessary for healthy patients to spend time in the clinician's office for routine, in-person visits. By having access to these data, clinicians could intervene sooner, ideally when potentially negative indicators are first observed, and can make changes to a patient's treatment protocol or instruct the patient to visit the clinician.³⁸ Visiting a clinician requires not only time for the appointment, but also travel time to and from the clinic. For patients who live far from their clinics or may have disabilities or other serious conditions that impede travel, these burdens may be even greater.³⁹ The availability of these data also enables telehealth options, such as virtual visits, to become an alternative to in-person visits by using remote monitoring to minimize the need for clinician capture of vital signs and status updates. Traditionally, a patient's geographic location may limit ability to participate in research studies, as research protocols often require patients to visit a research center

Patients and Caregivers Opportunities



PGHD use can...

- Empower patients and caregivers to better manage their health
- Support shared decision-making that considers patients' preferences
- Provide clinicians with a better understanding of the patient's health over times
- Reduce the time, effort, and cost associated with visiting a clinician or research site

to capture their data. By using tools that generate, collect, and share PGHD, patients have increased opportunities to remotely participate in clinical trials and studies.⁴⁰

Use of PGHD between encounters can help to ensure that patients remain in good health and avoid costly escalations in care, such as emergency room visits. For example, in a 2014 study at Brockton Hospital of Massachusetts, researchers observed an immediate overall savings of \$216,000 from avoided hospital readmissions among 31 patients with heart failure and chronic obstructive pulmonary disease (COPD) by monitoring patient weight and blood pressure after their initial hospitalizations. Brockton Hospital typically sees a 28 percent readmission rate at a cost of \$27,000 per readmission, but no patients were readmitted in this study.⁴¹

Challenges

While there are many potential benefits to patients from the capture and use of PGHD, there are challenges that may delay or minimize these benefits, such as lack of access to technology, high device abandonment rates, perceived lack of value by healthy patients, concerns about data privacy and security, and issues of health and technology literacy.

Patients will not be able to remotely share the PGHD they collect without access to technologies that capture and share PGHD or a reliable internet connection. According to the most recent *Broadband Progress Report*, 34 million Americans still lack access to broadband benchmark speeds.⁴² Moreover, a Pew Research Center study indicates that 36% of Americans do not own a smartphone.⁴³

Once patients own or have access to a consumer health device, these devices may lack staying power with their users. While analysts have observed an increase in sales of wearable fitness trackers, they have also observed high abandonment rates for these devices.⁴⁴ A 2014 report estimated that one-third of fitness trackers are abandoned after only six months of use. This may in part be due to designs requiring patient action to charge and sync devices and lacking impactful data and motivational elements that encourage behavior change and longer-term engagement.⁴⁵ Both clinical-grade and consumer-oriented devices may still require some patient effort to ensure that the devices are charged and worn or carried to capture and synchronize data.

Patients who use these devices to manage a specific health condition may be motivated to perform these tasks regularly, but healthy patients not already tracking their health data or interested in changing their health behaviors may be less motivated to do so without tangible benefits or incentives.⁴⁶ Current mobile health devices often lack the feedback mechanisms, such as personalized coaching, that could provide immediate value to patients and keep them engaged with the device over a longer period and for other, non-health-related benefits. Even if patients are motivated to capture and share PGHD, clinicians do not always allow or positively reinforce it. With no indication that these data are useful to clinicians, patients may be discouraged from capturing and sharing their data.

Patients' concerns about data privacy and security and about how researchers and companies use their data may also prevent patients from sharing their PGHD or from using technologies that could help them manage their health. While patients have expressed a willingness to share their data to improve care delivery and advance knowledge about their medical conditions, these same patients have

Patients and Caregivers Challenges



- Lack of ubiquitous access to the Internet or a smartphone
- High abandonment rates
- Patients are not always encouraged to capture or share their PGHD with their clinicians
- Concerns about data privacy and security
- Lack of health, technology, and language literacy to accurately use PGHD technologies and interpret instructions

expressed concerns about data privacy and security and the potential for discrimination by payers and employers.⁴⁷ One PatientsLikeMe survey found that of patients with a medical condition, 72% and 68% respectively believed that data from their personal health records could be used to deny them health care benefits or job opportunities.⁴⁸ Recent headlines about health data breaches have also brought health data privacy and security issues to the forefront of patients' minds. **A key finding of ONC's NCE Report is that consumers are confused about which privacy and security rules apply in which contexts, and they may think that HIPAA applies when it does not.**⁴⁹

Health, technology, and language literacy may influence a patient's ability to access and use PGHD technologies to complete a number of health-related activities, including accurately completing a questionnaire on a mobile app, consenting to authenticate and authorize the use of PGHD, or interpreting coaching and instructions received through new technologies and devices.⁵⁰



Patients and Caregivers: Enabling Actions

The future PGHD policy framework should consider the following enabling actions:

Encourage patients and caregivers to collaborate with clinicians and researchers to determine how capturing, using, and sharing PGHD can be valuable for managing their health. Patient collaboration with clinicians and researchers can determine if broadening the collection and sharing of PGHD will be valuable for better patient health management. The framework should also provide educational opportunities for patients to learn more about the value, limitations, and appropriate use of PGHD and whether doing so will improve their own care outcomes. These educational opportunities should ensure that patients understand the privacy and security of devices that they choose for themselves.

Support active patient participation in testing the functionality and usability of devices and in reporting feedback to device manufacturers. Patients can attest to the functionality and usability of the devices in managing their health and helping them to meet their health goals. The framework should outline ways in which patients can provide feedback to device manufacturers about features that they like and those that fall short of their needs, including accessibility features, **by writing product reviews directly to the manufacturer.** Without patient input in the development of mobile health devices, these tools will fail to meet patient needs and to keep patients motivated to continue to capture and share PGHD with clinicians and researchers.

Clinicians

Opportunities

The use of PGHD can support clinical care delivery by enabling clinicians and care teams to make timelier, better-informed decisions and to create personalized treatment plans with patients. **The use of PGHD also offers the potential to increase workflow efficiency, to reduce health care costs,** and to attract and retain patients.

By leveraging PGHD, clinicians can obtain insight into their patients' health in real-life settings and over time. Emerging consumer technologies also provide clinicians with access to new types of data that historically have been difficult to collect,

Clinicians Opportunities



PGHD use can...

- Enable clinicians and care teams to make timelier, better-informed decisions
- Improve collaboration with patients to create personalized treatment plans
- Redistribute workload and increase efficiency
- Reduce health care costs
- Better attract and retain patients

such as medication adherence data. This helps clinicians and care teams gain a more holistic view of their patients' health and understand how contributing factors may influence health outcomes. With this increased knowledge, clinicians can work with patients to develop care plans that align with patients' health needs and goals. Clinicians can also use PGHD to track patients' progress with treatment plans and to make necessary alterations to the plans based on the data without requiring patients to visit the clinical care setting.

The use of PGHD has the potential to allow clinicians to improve efficiency and to use patient-facing time more effectively. Patients may be more prepared for clinical visits because they have captured and reviewed their data and may have identified their own concerns and discussion points before the visit.⁵¹ As a result, the care team can distribute their workloads and use their time more efficiently, potentially allowing them to see more patients in the same amount of time.⁵² This efficiency is especially important in settings where patient populations are growing, the clinical workforce is diminishing, and demands on the health care system are mounting.^{53,54}

PGHD use may also provide clinicians the opportunity to reduce health care costs. Monitoring patient data between clinical visits allows clinicians to intervene to prevent hospital visits or other costly care encounters. For example, a Geneia, LLC, study found that remote monitoring of patients with heart failure who had been admitted to the hospital or visited the emergency room yielded a savings of \$8,375 per patient monitored.⁵⁵ Most of these savings came from a reduction in hospitalizations for heart failure or other reasons.

Finally, health care systems using consumer technologies have an opportunity to attract and retain patients based on their use of tools that may improve care and enhance patient engagement to meet patients' expectations. In a recent Salesforce survey, 62% of respondents indicated that they would choose a clinician who uses their wearable device data over one who does not.⁵⁶

Challenges

Clinicians may encounter several challenges in using and sharing PGHD, such as the impact on clinical workflows, the management of patient expectations, the potential for increased liability, and the limited body of evidence for the clinical value of and the business case for use of PGHD.

Currently, clinical workflows do not support the optimal capture, use, and sharing of PGHD. Today, clinicians predominantly rely on data that are collected during a care encounter. The use of PGHD enables the patient to capture data before and after a care encounter so that the care team can review the data before, during, or in between patient visits. Given the potentially large volumes of PGHD generated and shared via consumer health technologies, care teams may have difficulty accepting and interpreting PGHD without altering their workflows.⁵⁷ Resources must be allocated to review the data. However, members of the care team may not have the time, expertise, or tools to analyze and interpret PGHD from multiple sources. Incorporating PGHD into clinical care requires upfront investments in the workforce and technical infrastructure. Attempting to use PGHD without making corresponding revisions to the workflow may increase the potential for inaccurate or duplicate records or for data to be overlooked.⁵⁸

As a result, some clinicians may decline to receive unsolicited PGHD. Unsolicited PGHD, which are data received by a clinician or care team without a prior request from the clinician or agreement with the patient for use for a targeted health outcome, may have little context for interpretation in clinical



- Impact on clinical workflows
- Management of patient expectations
- Potential for increased liability
- Limited body of evidence for the clinical value of and the business case for use of PGHD

settings and may introduce inefficiency to clinical workflows. Absent guidance and best practices on how to accept, review, and retain **large volumes of data**, many clinicians hesitate to accept PGHD for fear that they will receive more data than are clinically useful.⁵⁹ Patients and clinicians therefore lack alignment on expectations around the use of PGHD for care delivery. Clinicians have questions about how to best acknowledge receipt of PGHD, how to provide an adequate and timely response to patients, and how long they should retain the data.⁶⁰

Clinicians are concerned about the liability issues that arise around the reliability and quality of PGHD for clinical decision-making, especially when unsolicited. The potentially large amounts of PGHD a patient could share leaves clinicians wondering how they will keep up with and appropriately respond to important clinical issues that may be presented by the data.⁶¹ Some stakeholders have noted that the use of PGHD may present liability concerns if inaccurate PGHD are used in clinical decisions or if the clinician chooses not to take action based on the PGHD received.⁶² **Standards of care for the use of PGHD are still forming, leaving clinicians with little guidance on how to address these concerns.**

Despite the potential of consumer technologies to improve care delivery, the few findings on the impact of these tools on health outcomes and costs are inconsistent across studies. While some studies have demonstrated improved health outcomes and cost savings, others have shown less promising results. As the proliferation of consumer technologies is fairly recent, it may be some time before a reliable body of research emerges on the best practices for using PGHD.



Clinicians: Enabling Actions

The future PGHD policy framework should consider the following enabling actions:

Support clinicians to work within and across organizations to incorporate prioritized PGHD use cases into their workflows. The framework should consider opportunities to help clinicians and care teams to identify priority use cases and relevant PGHD data types that would be valuable to improving care delivery for patient populations. It should encourage them to develop standard practices for the use of PGHD, incorporate PGHD into their workflows, and use tools to analyze the data. To deal with potentially large volumes of PGHD, the framework should assist care delivery systems when considering investments in data acquisition, storage, and analysis technologies and exploring solutions to assess and manage data provenance and accuracy.

Innovative health care organizations have incorporated the use of PGHD into their current workflows in ways that prevent burdening the care team with extra work or overwhelming them with extraneous data. The care team needs to share responsibilities among team members to reduce the burden of collecting, verifying the quality and provenance, and analyzing PGHD.⁶³ Some organizations have assigned specific members of the care team to review PGHD, determine where to store the data, notify providers of abnormal values, and respond to the patient. In the future, the EHR will be able to facilitate PGHD review, helping to simplify the clinician workflow.

Foster collaboration between clinicians and developers to advance technologies supporting PGHD use. The framework should encourage clinicians to request that developers of core clinical systems and technologies that capture PGHD offer functionalities that allow analysis of PGHD in line with their workflows and offer views that highlight data of clinical importance. To do this, the framework should establish a mechanism for clinicians to communicate prioritized use cases with developers and provide feedback on features that support the secure capture, use, and sharing of PGHD.

Identify and communicate benefits, challenges, and best practices of PGHD use to help strengthen the determination of its clinical value and business case. To increase the evidence base about benefits, challenges, and best practices of PGHD use, the framework should encourage early adopters to share their successes and lessons learned through channels such as publications in peer-reviewed journals or presentations at industry conferences. Early-adopter organizations can also share this information with other organizations, such as clinical societies, to help define the standard of care for PGHD use. Sharing this information will help other organizations to understand the value of and to invest in the use of PGHD. The framework should encourage clinicians and health care systems to proactively launch and support research studies examining the risks and benefits of using PGHD in care delivery among both healthy patients and those with acute or chronic health conditions.

Encourage clinicians to use PGHD to support patient data donation in research. Clinicians and health care systems can play a significant role in bridging the data silos among clinicians and researchers by encouraging patients to donate PGHD to researchers. Patients may not initially think or know how to share their PGHD with researchers, perhaps because the clinician solicited these data and the patient sees their data as essential only for managing their health, rather than contributing to research. The framework should motivate clinicians to raise awareness of studies and trials seeking PGHD and encourage their patients to participate in relevant studies, and should explore mechanisms for transmitting the PGHD that the clinicians accept to researchers.

Researchers

Opportunities

Through the use of digital tools to collect PGHD, researchers may be able to gain wider and more direct access to potential study participants, to collect a larger quantity of data, and to improve their workflow. Specific techniques include the use of research data platforms and remote monitoring.

Researchers may be able to expand recruitment and enrollment in their studies by incorporating digital tools that collect PGHD into their study design and protocols, such as mobile health devices, online discussion boards, and health-data sharing platforms. Researchers need not rely as heavily on relationships with clinicians or health care systems that might identify potential study participants. Instead, they can provide recruitment information about their studies more directly to a wider and potentially more diverse population of patients through online posts on social media sites or email listservs.⁶⁴

Through the use of research-oriented platforms such as Apple Research Kit, patients are enabled to sign up directly for studies of their choosing, offering new channels to recruit patients. These new recruitment methods may speed up research studies by increasing the rate of enrollment and the time required to build a cohort or dataset sufficient for analysis. In a recent experiment at Stanford University, researchers using Stanford's MyHeartCounts app, promoted through social media, were able to recruit about 10,000 participants globally within the first 24 hours.⁶⁵ Traditional methods for recruiting study volunteers would have taken well over a year to enroll this number of participants.⁶⁶

Allowing patients to remotely capture and share data in lieu of in-clinic visits reduces travel burdens for patients, which may help researchers to increase study or clinical trial subject retention rates.⁶⁷ Patient

Researchers Opportunities



PGHD use can...

- Expand recruitment and enrollment in studies
- Increase study or clinical trial subject retention rates
- Offer new insights into patient health
- Simplify research workflow

drop-out rates are as high as 30 percent in some studies.⁶⁸ While many factors contribute to patient drop-out rates, a contributing factor is the inconvenient location of study sites.⁶⁹ Some mobile health devices also include prompts and feedback for the patient that encourage continued participation.⁷⁰

Some websites and online platforms allow patients to donate data broadly for research so that researchers can download large datasets of PGHD for analysis. PatientsLikeMe is an example of a platform using PGHD not only to improve the way patients manage their conditions, but also to help researchers obtain data sources to conduct research. Mobile apps built on Apple's ResearchKit open-source platform allow patients to capture and share PGHD with researchers using mobile devices, such as smartphones and tablets. The National Institutes of Health's (NIH) *All of Us*SM Research Program, which is part of the Precision Medicine Initiative (PMI), is collecting data, which could include PGHD, to develop more precise treatments and therapies for a number of health conditions.⁷¹ In support of the PMI, NIH, in collaboration with ONC, also funded the Sync for Science pilot program, which is developing and testing the technology to allow patients to share data from their providers' EHRs with researchers.⁷² Through the use of these data sources, researchers can supplement study data with PGHD from multiple sources and access data reflecting patient health outside of clinical care and research settings.

The use of PGHD allows researchers to gain new and deeper insights into patient health through increased volume and frequency of patient data capture. In the past, researchers were often limited to the data that they collected at the study site at regular intervals, or only had access to logs of data that patients captured and brought with them to the study site. Now, many mobile health devices, such as connected glucose monitors, capture data at frequent intervals or continuously, and can transmit data directly and electronically to clinicians and researchers.

The use of PGHD technologies to capture and transmit data electronically helps to simplify the research workflow as well. Instead of patient data being manually entered, data can flow electronically into a research database. Tools capable of cleaning the data can also simplify the process of ensuring data are complete and prepared for analysis. These electronic processes reduce the amount of effort required by researchers and reduce the potential for human error during data entry.

Challenges

When using PGHD in studies and trials, researchers face challenges in determining participant eligibility, managing the consent process, and obtaining high quality data from the care delivery process.

Although digital health tools allow patients to collect PGHD and participate remotely in research studies and trials, researchers may encounter issues with confirming the eligibility of remote participants. Absent in-person enrollment, verifying that a patient is eligible to participate in a study can be difficult, especially because patients may be able to more easily alter their information to meet the eligibility criteria of a study.⁷³

In 2015, the U.S. Department of Health and Human Services (HHS) announced proposed revisions to the Common Rule that detail protections for individuals who participate in most health research.⁷⁴ Advances in science and technology prompted the need to update the regulatory framework, and research institutions will be responsible for complying with any reforms once they are finalized. One proposed significant change for researchers is the strengthening of informed consent processes to ensure participants' understanding of the study's scope, including its risks and benefits. Through new data donation opportunities using PGHD, such as mobile apps, patients can give consent in new ways that



- Determining participant eligibility
- Managing patient consent process for studies and clinical trials
- Limited flow of high quality PGHD between clinicians and researchers

may be unfamiliar to them and challenging for researchers to manage. Under proposed consent mechanisms, patients may give broad consent for research on their health condition, or they may consent to share only certain types of data with specific organizations.⁷⁵

PGHD combined with other health data provide an opportunity to inform clinical care and research; however, the flow of PGHD between clinicians and researchers is currently limited, and so restricts the potential benefits to patients. Even when researchers are able to establish an exchange of PGHD with clinicians, the data patients collect for their health care may not meet more stringent data requirements for research.



Researchers: Enabling Actions

The future PGHD policy framework should consider the following enabling actions:

Call for increased funding for studies that investigate the benefits, challenges, and best practices of PGHD and the business case for using PGHD in care delivery and research. The framework should encourage organizations that fund or conduct research to consider increasing funding to incorporate the capture, use, and sharing of PGHD into research. It should increase the development of applications to support these practices. Part of this process requires that researchers seek to understand the effectiveness of the use of PGHD in improving trial participation, reducing costs, and expediting the completion of research. The framework should prompt universities and research institutes to consider requesting additional funding to conduct studies on both the use of PGHD in study protocols and the effectiveness of the use of PGHD in improving health outcomes, engaging patients, and lowering costs. It should push for funding educational programs on the use of PGHD in research for individuals entering into health care delivery, research, and technology development fields. More evidence for and training on the uses of PGHD could support the development of best practices, show the value of using PGHD in care delivery and research, and encourage innovation with developing new tools and methods.

Motivate researchers to design and develop studies that incorporate PGHD. Given the opportunities for improving research studies through the use of PGHD, the framework should advise researchers to incorporate PGHD into their study designs and implement analytical tools to interpret and summarize the findings. The framework should define different types of PGHD and help researchers determine which types of data, and from which sources, can improve health outcomes. It should support researchers as they strive to engage patients in data capture and donation to gain access to broader, more diverse patient populations. The increased use and success of using PGHD in research studies can also help to establish the business case for capturing and using PGHD in both care delivery and research.

Expand methods for data donation to research studies. The framework should support researchers to continue exploring possible PGHD sources and methods of data donation for their research, and increasing patient awareness of platforms, such as Apple's ResearchKit, and other digital tools that capture PGHD.

Strengthen patients' understanding of consent and data use. To protect patient security and privacy, the framework should address the importance of researchers using the data for the purposes that the data donor intended when they provided the PGHD. The framework should also encourage researchers to validate that participants understand the study protocol, including how their data are used, and any risks and benefits of participating.⁷⁶ To further encourage individuals to participate, researchers can also consider using multimedia tools to explain consent to patients with different levels of health literacy.

Opportunities, Challenges, and Enabling Actions for Other Stakeholders

Optimal capture, use, and sharing of PGHD requires collaboration and support from the full health IT ecosystem to enable patients, clinicians, and researchers to effectively use PGHD. Policymakers, technology stakeholders, payers, and employers all play supporting roles, and their actions have the potential to help build an infrastructure that will enable the advancement of the capture, use, and sharing of PGHD and realize the benefits.



Policymakers

Opportunities

The federal government has the ability to encourage the use of PGHD in clinical care and research, for example, by strengthening privacy and security measures and by encouraging innovative uses of PGHD.

US has addressed privacy and security concerns for non-covered entities that could collect PGHD in its NCE Report. The report provides an overview of the federal legal landscape as it relates to health data captured and collected using mobile health technologies and health social media. For example, PGHD held by non-covered entities may be subject to the Federal Trade Commission's (FTC's) Section 5 authority, which enforces the prohibition against unfair or deceptive practices by both HIPAA-covered and non-HIPAA covered entities.⁷⁷ The NCE Report also provides an analysis of how certain protections differ between HIPAA-covered entities and non-covered entities, including individuals' rights to access their data and reuse of the data by third parties.

The federal government also has an opportunity to encourage innovative uses of PGHD through delivery system reform and health IT incentives. New reimbursement models, such as Alternative Payment Models, are shifting from payment for individual services to payment for episodes of care or for overall management of a patient's care. These new payment models give clinicians the flexibility and incentives to monitor a patient's health status outside of an office visit to reduce the need for face-to-face encounters and to reduce patient use of emergency and inpatient care. Use of PGHD including remote monitoring is one possible area to help clinicians improve their composite scores under MIPS.⁷⁸ Other federal government initiatives also encourage the use of PGHD. For example, the *All of Us*SM Research Program, which is part of the PMI, aims to create a cohort of "one million or more U.S. research participants, who will share biological samples, genetic data, and diet/lifestyle information,"⁷⁹ which could include PGHD.

Challenges

Several federal government agencies play a role in providing guidance on the use and protection of PGHD and on the technologies that capture PGHD, which will require cross-agency collaboration and increased speed to encourage innovation.

Agencies will need to collaborate on areas of overlap in guidance affecting the capture, use, and sharing of PGHD in order to add clarity for stakeholders and to support effective regulations that protect patients and their data. A result of a successful collaboration between several agencies can be seen in

recent FDA guidance to device developers and manufacturers on best practices for incorporating safety and security into the design and testing of certain types of health devices.⁸⁰

The fast pace at which technology evolves can be an important consideration in the development of regulations that are designed to encourage innovation and to remain relevant as technology changes. As a result, by the time regulations are ready to be introduced, newer, more innovative technologies may already be on the market. For example, to address this challenge and encourage innovation in the marketplace, the FDA has clarified that it will not regulate general wellness devices at this time.⁸¹ Instead, the FDA has issued guidance for these devices, which can be adjusted more rapidly to provide clarifications and to reflect changes in current thinking.^{82,83}



Policymakers: Enabling Actions

The future PGHD policy framework should consider the following enabling actions:

Prompt collaboration with industry to strengthen model practices, consumer education, and outreach to support the private and secure capture, use, and sharing of PGHD. To keep pace with the rapidly evolving consumer health technology marketplace, the framework should prompt policymakers to engage with industry leaders to create consensus on policies and practices. Industry guidance can build on the work of industry associations, such as the **Consumer Electronics Association (CEA) Guiding Principles on the Privacy and Security of Personal Wellness Data**, along with the work of federal agencies.⁸⁴ Through this collaboration, both federal and industry guidance can be developed using an agile and rapid approach and can be revised more easily over time to reflect changes in technology or the legislative domain. This should allow for innovation but also ensure that PGHD are captured, used, and shared safely and securely.

Call for increased funding for programs that aim to understand the outcomes of PGHD use as part of delivery system reform and advanced health care models. Federal policymakers can advance understanding of PGHD use by funding projects and initiatives that include or support the use of PGHD and assess the outcomes in clinical care and research. For clinicians and researchers to be able to justify the clinical value and business case for use of PGHD, they need evidence of desirable outcomes and knowledge of risks. The federal government could provide funding to researchers to conduct studies on both the use of PGHD in study protocols and the effectiveness of PGHD use in improving health outcomes, engaging patients, and lowering costs. Additional potential initiatives for federal government funding could include programs or pilots to develop and test solutions that expand upon current infrastructure, such as data privacy best practices for mobile health technologies, or testing the application of technologies, such as application programming interfaces (APIs), to support more secure and seamless exchange of PGHD.

Suggest review of medical malpractice and liability laws at the state level and how they intersect with legal cases involving use of PGHD. The capture, use, and sharing of PGHD brings another layer of complexity to clinicians' medical liability. Because use of PGHD in clinical decision-making is still an emerging practice, there are few cases in which a standard of care for the use of PGHD is established and can be argued. As the capture, use, and sharing of PGHD become more common and the standard of care is established, the framework should guide policymakers to ensure that state laws, where medical malpractice and liability laws are established, align with these practices and protect patient health and data.⁸⁵

Technology Stakeholders: Developers and Standards Bodies

Opportunities

Developers, including health IT vendors and app and device developers, have the opportunity to provide the technical infrastructure and tools required to enable the capture, use, and sharing of PGHD. Measurements and data elements across devices may vary significantly, and the structure and format of PGHD may not be compatible across devices, posing a challenge for combining or comparing PGHD from disparate sources. In an attempt to bring some standardization to the consumer technology field, professional associations are working to advance and increase adoption of device standards that further support consumer technologies. For example, the Consumer Technology Association recently convened a workgroup aimed at defining performance standards for wearable activity trackers⁸⁶ and earlier developed *Guiding Principles on the Privacy and Security of Personal Wellness Data*.⁸⁷ These standards and principles help to ensure the functionality of these devices and apps, as well as the accuracy and validity of data captured by these tools.

In addition to device standards, interoperability standards provide the technical infrastructure to support the sharing of PGHD between devices and their various users, including the key health care stakeholders. Variations in data representation and coding limit the exchange of PGHD among patients, clinicians, and researchers and the ability to draw valuable insights. Standards development organizations (SDOs) have the responsibility and mission to convene industry stakeholders to develop and test interoperability standards to break down these barriers in electronic data sharing. Several organizations, including the Health Level Seven International (HL7) and Continua Health Alliance, are working to develop device interoperability standards. The Fast Healthcare Interoperability Resources (FHIR) specification, created by HL7, is a standard for exchanging health care information electronically. The use of the FHIR specification helps to build a common way to define and represent resources satisfying the majority of common use cases and simplifies implementation without sacrificing information integrity or traceability.⁸⁸ Continua develops standards to enable end-to-end interoperability of personal connected health devices and systems for health management and health care delivery, and is working toward establishing design guidelines and certification criteria to support interoperable devices across the fitness, chronic disease management, and aging market categories.⁸⁹

By creating devices that support the standardized capture, use, and sharing of PGHD, developers may build the business case for their devices. For example, devices that allow patients to easily capture and view PGHD and enable clinicians and researchers to easily integrate the data into their systems in a standardized manner may be particularly attractive to users. These features may also allow developers to partner with health care systems and researchers to use their specific devices in care delivery and research protocols.⁹⁰ In addition, developers may be able to analyze the data their devices collect to better understand the health needs of their users and improve their devices to meet these needs.

Challenges

The current process for developing these device and interoperability standards takes time and involves convening workgroups or committees that meet regularly to develop and vote on a standard. The standard may go through a series of approvals and ballot cycles over several years before being piloted and becoming normative. The tools and technologies for capturing, storing, and sharing PGHD, however, are often developed and go to market faster than the relevant standards can be developed because the standards bodies lack the resources and investment to formalize standards at the pace of the market. The delays and the limited engagement of practitioners in standards development are impediments to delivering timely and pragmatic standards. Because technologies for using PGHD are still in their infancy, standards and specifications are still being developed in this area.



Technology Stakeholders: Enabling Actions

The future PGHD policy framework should consider the following enabling actions:

Suggest developers improve usability and accessibility and implement user-centered design principles into products that use PGHD. Addressing a number of challenges related to PGHD use begins with the design and development of devices capturing PGHD. Given the high potential for user abandonment of consumer health devices and varying levels of technology literacy among users, the framework should recommend that developers continue to focus on improving usability and accessibility and implementing user-centered design principles. It should direct developers to continue increasing the accuracy and validity of the data their devices capture through user verification solutions such as biometric authentication and multi-step identity verification. Adoption of interoperability standards can potentially ensure that mobile health devices can integrate seamlessly and exchange data with fewer barriers around the structure and format of the data. To support this work, the framework should encourage developers to come together to establish an **industry-led voluntary certification and testing mechanism for digital health devices that capture PGHD.**

Increase adoption of strong privacy and security practices by developers and be transparent with consumers about these policies. The framework should charge developers to continuously strengthen their privacy and security practices in accordance with the latest industry best practices, such as the Future of Privacy Forum's *Best Practices for Consumer Wearables and Wellness Apps and Devices Guide*⁹¹, and federal guidance, such as the NCE Report⁹² or ONC's *Model Privacy Notice*.⁹³ It should prompt developers to evaluate and incorporate technologies as necessary to secure PGHD and manage a patient's medical record. All apps and health IT devices should have privacy policies that state what data will be collected, how often it will be collected, with whom it will be shared, how patient privacy will be protected, and the patient's rights regarding their data. The privacy policy should specifically call out how a patient can access and transmit the PGHD to a designated third party. These privacy policies should be easily available within the device itself, as well as on associated materials, such as instruction manuals or websites. In addition, privacy policies should be written in language that is easy for the average patient to understand. By creating these policies and making them available upfront, developers can help build patient trust and ensure that the data will not be used to discriminate against patients.

Challenge standards bodies to address the needs of health care ecosystem for PGHD use and increase the pace of standards development for capturing and integrating PGHD. The framework should push SDOs to accelerate the development of standards for capturing and integrating PGHD into EHRs and other health IT systems. The process for developing these standards should consider the input of practicing clinicians and researchers with diverse experiences and target prioritized use cases. Once these standards are developed and tested, SDOs and their workgroups should monitor the adoption of standards and obtain actionable feedback on the implementation of standards in the marketplace to ensure that the standards meet the needs of the individuals and organizations that use them. **The framework should encourage SDOs to consider formulating an industry certification resource for digital health devices to verify that they are capable of standards-based communication with a health care system or research institution.**

Payers and Employers

Opportunities

Payers, both private and public, reimburse clinicians for the care they provide. The movement toward alternative payment models, such as bundled payments that reimburse for the expected costs of an episode of care rather than for the volume of services rendered, introduces incentives for patients and clinicians that increase the capture and use of PGHD. These models reimburse clinicians for improved health outcomes that result from monitoring PGHD and other patient data from nonclinical settings between clinical encounters. Payers can also motivate interoperability and data sharing by reimbursing clinicians for transmitting PGHD and other data as part of a patient's transition of care. To increase access to consumer technologies for all patients, payers can provide their members with devices or subsidize devices as part of their care models to ensure that the benefits of PGHD use are not limited to those patients who can afford the devices.

Many employers are moving toward encouraging the capture and use of PGHD by providing employees with discounted or free wearable activity trackers, prizes for reaching certain health milestones, and discounts on health insurance premiums.⁹⁴ Employers can benefit from these programs because their employees may achieve better health outcomes from monitoring their data and engaging in healthier behaviors, and so may miss fewer work days for illness and incur lower health care costs. By offering these devices and monitoring programs to their employees, employers may also receive discounts and reductions in the cost of offering insurance to their employees from insurance companies.⁹⁵

Challenges

While having access to PGHD may give payers greater insight into the health of their members and help them to stratify risk among their patient pools, patients and clinicians may hesitate to share PGHD with them. Patients have expressed concern that their health data may be used to discriminate against them by both payers and employers.⁹⁶ One lawsuit also argues that these programs, in their essence, are obligatory because it can be costly to not participate and forego the associated discounts.⁹⁷ Clinicians may resist proactively sharing patient data with payers beyond the requirements for reporting claims data for billing, even though PGHD becomes protected health information (PHI) once they are received by a clinician. Under HIPAA, clinicians are permitted to share PHI with payers for appropriate payment and health care operations. These cultural barriers to sharing PGHD with payers and employers may hinder the increased capture, use, and sharing of PGHD for payment purposes.



Payers and Employers: Enabling Actions


The future PGHD policy framework should consider the following enabling actions:

Urge payers to continue to motivate clinicians to capture and use PGHD through reimbursement programs. The framework should urge payers to alter their reimbursement programs to compensate clinicians for improving health outcomes by receiving, reviewing, and sharing PGHD. These reimbursement programs and quality of care measurements will increase the business value for clinicians to capture, use, and share PGHD in a standardized way that improves health outcomes and patient engagement. The framework should guide payers to continue shifting toward coordinated care models that increase collaboration, connectivity, and data sharing (including PGHD) between payers and clinicians to help reduce costs and improve the quality of care. The framework should also provide guidance to payers on how to overcome or eliminate the potential for discrimination based on PGHD.⁹⁸

Advise payers and employers to continue to incorporate feedback mechanisms and incentives into their insurance plans and wellness programs. Giving patients access to mobile health devices and the opportunity to share their PGHD with clinicians may not be enough to encourage them to regularly use the devices to capture and share data. In some cases, feedback may come in the form of a portal or mobile app that allows patients to view their data and compare them to healthy levels and to other patients' data. These portals and mobile apps may also provide coaching, action plans, and gamification to patients to encourage them to engage in healthier behaviors. Some patients may respond better to rewards programs that offer discounts on insurance plans or prizes for completing specific activities or reaching predefined goals.

Conclusion

A look toward 2024 anticipates that digital health technologies will become even more pervasive, offering ever more opportunities for patients to capture, use, and share their PGHD in support of health care delivery and research. However, the capture of PGHD alone is not sufficient to cause change within the health IT ecosystem. To progress toward the future bold vision of PGHD use in care delivery and research, cultural, technical, and regulatory barriers must be overcome through joint action.

 This bold vision starts by **demonstrating the value of PGHD use and the business case to justify investment.** Patients, clinicians, researchers, and payers can work together to highlight health conditions where the use of PGHD can have the most impact. Clinicians and researchers should prioritize those areas and develop an approach to integrate PGHD into the clinical workflows and research designs where it is most valuable. Payers should incentivize patients and clinicians to participate and maximize patient benefits through reimbursement plans.

As the business case for PGHD use continues to be determined and the value to care advancement continues to be documented, health care systems and research institutions should collaborate with technology stakeholders to drive the advancement of the technology infrastructure that is paramount in making the use of PGHD work for all patients. **Technology organizations should understand the opportunities and work in partnership with the health IT ecosystem in their efforts to improve existing tools and technical standards in support of PGHD use. Broad stakeholder participation within standards organizations is needed to ensure consensus on how to make PGHD available to clinicians and researchers in a way that all can adopt and understand.**

Policymakers should strengthen coordination with industry leaders to create a consensus on policies and practices that address newer consumer technology and support the private and secure capture, use, and sharing of PGHD. Federal government agencies should focus on developing the educational resources that help patients, clinicians, and researchers understand the benefits of PGHD use and establish guidance and best practices to aid the incorporation of PGHD into clinical and research workflows and cultures. Clear policy guidance that is developed in coordination with patients, clinicians, and researchers will help the broader patient community understand the ongoing impact of PGHD use and where it can best influence care delivery and research. The future vision is a health care ecosystem of partners working to seamlessly capture, use, and share PGHD electronically to enhance care delivery and research efforts. Through stakeholders working together, we can truly make this vision of increased capture, use, and sharing of PGHD as part of a learning health system a reality.

Appendix A: Glossary

Active Data Collection

Requires a user to spend time entering information and requires that a user feel comfortable with providing information over the internet. <http://web.mit.edu/ecom/www/Project98/G2/data.htm>

Adherence

The extent to which a person's behavior—including taking medication, following a diet, or making healthy lifestyle changes—corresponds with agreed-upon recommendations from a health care provider. <http://apps.who.int/medicinedocs/en/d/Js4883e/8.9.1.html>

Adverse Event/Outcome

An undesirable experience associated with the use of a medical product in a patient. Adverse events/outcomes are serious and appropriate documentation should be submitted to the FDA when resulting in death, life-threatening illness, hospitalization, disability or permanent damage, birth defects, or other impairments of body function.

http://www.fda.gov/Safety/MedWatch/HowToWhite_paper/ucm053087.htm

Apple iTunes Store

A software-based online digital media store operated by Apple Inc. allowing for users to download music, videos, and iOS applications (apps) for iPhone and iPad. <http://www.apple.com/itunes/>

Apple ResearchKit

A software framework developed by Apple Inc. that allows medical researchers to gather robust and meaningful data from iOS apps installed on an iPhone or iPad. <http://www.apple.com/researchkit/>

Application Program Interface (API)

A software application function that can be invoked or controlled through interactions with other software applications. APIs allow the user experience to be seamless between two or more software applications since the APIs are working behind the actual user interface.

Architecture

Refers to the collective components of a software system that interact in specified ways and across specified interfaces to ensure specified functionality.

https://www.healthit.gov/sites/default/files/ptp13-700hhs_white.pdf

Authentication

Authentication and access control measures should ensure appropriate access to information and information processing facilities – including mainframes, servers, desktop and laptop clients, mobile devices, apps, operating systems and network services – and prevent inappropriate access to such resources.

Big Data

High-volume, high-velocity, and/or high-variety information assets that allow for innovative forms of information processing resulting in enhanced insight, decision making, and process automation.

<http://www.gartner.com/it-glossary/big-data/>

Bluetooth

A global wireless communication standard that connects devices over a certain distance. Bluetooth is built into billions of devices and connects to the Internet of Things.

<https://www.bluetooth.com/what-is-bluetooth-technology/bluetooth-technology-basics>

Broadband Internet

Allows users to access the internet and internet-related services at significantly higher speeds than those available through “dial-up” services. Broadband allows user to access information via the internet using one of several high-speed transmission technologies, such as digital subscriber line (DSL), cable modem, optical fiber, wireless, and satellite. <https://www.fcc.gov/consumers/guides/getting-broadband>

Broadband Internet Access Service (BIAS)

A mass-market retail service by wire or radio that provides the capability to transmit data to and receive data from all or substantially all internet endpoints, including any capabilities that are incidental to and enable the operation of the communications service, but excluding dial-up internet access service. The FCC issued an NPRM regarding BIAS in April 2016. https://apps.fcc.gov/edocs_public/attachmatch/FCC-16-39A1_Rcd.pdf

Business Case

The rationale for initiating a project, task, or investment, often presented in a well-structured written document. A business case is part of the due diligence, measuring benefits, costs, and risks associated with the investment. The business case assesses and evaluates the available options to solve the business issue. The business case provides an opportunity for the business to determine if a project is needed and if the solution options are beneficial to the organization.

<http://www.iiba.org/ba-connect/2013/march/how-to-define-business-case-babok-guide.aspx>



Health Care Team

Consists of the health professionals, including physicians, registered nurses, physician assistants, clinical pharmacists, and other health care professionals with the training and skills needed to provide high-quality, coordinated care specific to the patient’s clinical needs and circumstances.

<http://annals.org/article.aspx?articleid=1737233>

Caregiver

A person who most often helps a patient with a particular illness, and is usually not paid to do so. In most cases, the primary caregiver is a spouse, partner, parent, or adult child. For the purposes of this white paper, caregivers are included whenever patients are referenced but may in some cases have different needs. <http://www.cancer.org/acs/groups/cid/documents/webcontent/003199-pdf.pdf>

Centers for Medicare and Medicaid Services (CMS)

An agency within the United States Department of Health and Human Services (HHS) responsible for administration of several key federal health care programs. In addition to Medicare (the federal health insurance program for seniors) and Medicaid (the federal needs-based program), CMS oversees the Children’s Health Insurance Program (CHIP) provisions in the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations that pertain to national standards for electronic health care transactions and national identifiers for providers, health plans and employers, and the Clinical Laboratory Improvement Amendments (CLIA), among other services.

<http://www.cms.gov>

Certified EHR Technology

Gives assurance to purchasers and other users that an EHR system or module offers the necessary technological capability, functionality, and security to help them meet the meaningful use criteria.

<http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification.html>

Clinical Data

Data created in a clinical setting and controlled by a clinician (as opposed to a patient or caregiver).

Clinical In-Home Device

A medical device intended for users in any environment outside of a professional health care facility, such as in the patient's home.

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/default.htm>

Clinical Research Trials and Studies

Research studies in which people participate as patients or volunteers, in order to develop a new treatment or medication, identify the causes of illness, study trends, or evaluate ways in which genetics may be related to an illness. Strict rules for clinical studies and trials have been put in place by the U.S. National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA).

<http://www.fda.gov/ForPatients/ClinicalTrials/ClinicalvsMedical/ucm20041761.htm>

Clinical Workflow

An established process comprised of a series of tasks that accomplish a defined step pertaining to the clinical care of patients. <https://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/workflow>.

Clinician

A person qualified in the clinical practice of medicine, psychiatry, or psychology as distinguished from one specializing in laboratory or research techniques or in theory.

<http://www.merriam-webster.com/dictionary/clinician>

Cloud-Based Platform

A platform hosted in a cloud environment, where the consumer does not manage or control the underlying infrastructure including network, servers, operating system, or storage, but rather has control over the deployed apps and configuration settings. In the Platform as a Service model, the consumer has the ability to deploy apps onto the cloud infrastructure, customizable to meet the consumer's needs. <http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-145.pdf>

Consent

Agreement to an action based on knowledge of what the action involves and its likely consequences.

<http://medical-dictionary.thefreedictionary.com/consent>

Continua Health Alliance

A membership association that seeks to transform health care through personalized, interoperable connected health solutions. The organization provides technical leadership, releases educational materials, and advocates for connected health and standardization around the world.

<http://www.continuaalliance.org/about-continua>

Data Analytics Tools

Tools that allow for raw data to be examined, with the purpose of drawing conclusions about that information. These tools can uncover hidden patterns, correlations, and other insights.

http://www.sas.com/en_us/insights/analytics/big-data-analytics.html

Data Capture Protocol

The process by which pieces of information (data) are collected and stored for future use, either by active or passive data collection.

Data Normalization

The process by which data within a database are organized to reduce redundancy in data and improve integrity and accuracy of the data.

Data Provenance

The process of tracing and recording the origins of data and its movement between databases, central to the validation of data. There is a Standards and Interoperability (S&I) Framework initiative working to define standards that support data provenance.

<https://oncprojecttracking.healthit.gov/wiki/display/TechLabSC/DPROV+Home>

Data Transfer Protocol

The process by which data from a device, smartphone app, or computer is electronically packaged, transported, and stored on a different device, smartphone app, or computer through the use of internet standards for data transmission.

Device Abandonment

The phenomenon in which an individual ceases use of a device, such as a fitness tracker, wearable device, smartphone app, or other medical device, due to various factors. Devices may be abandoned by individuals due to a lack of user-centered design, not understanding the value that the device provides, or for other technical or personal reasons.

Electronic Health Record (EHR)

A computer system that stores real-time, patient-centered, electronic medical records. Its use can make information available instantly and securely to authorized users. While an EHR typically does contain the medical and treatment histories of patients, an EHR can be built to go beyond clinical data traditionally collected in a provider's office to be inclusive of a broader view of a patient's care.

<http://www.healthit.gov/providers-professionals/faqs/what-electronic-health-record-ehr>

Email Listserv

An electronic mailing list to which email messages can be sent.

<http://www.isoftware.com/products/listserv.asp>

Episode of Care

The set of services provided to treat a clinical condition or procedure.

<https://www.mc.vanderbilt.edu/root/vumc.php?site=eoc&doc=46938>

Healthcare Interoperability Resources (FHIR)

Defines a set of "Resources" that represent granular clinical concepts. The resources can be managed in isolation, or aggregated into complex documents. <http://wiki.hl7.org/index.php?title=FHIR>

Federal Advisory Committee

Authorized by the American Recovery and Reinvestment Act of 2009 (ARRA), two Federal Advisory Committees, the Health IT Policy Committee (HITPC) and Health IT Standards Committee (HITSC), provide recommendations to the Office of the National Coordinator for Health IT (ONC) on a variety of topics related to health IT. <https://www.healthit.gov/facas/>

Federal Communications Commission (FCC)

An independent agency of the U.S. federal government that regulates interstate and international communications by radio, television, wire, satellite, and cable. It serves as the U.S. primary authority for communications laws, regulation, and technological innovation. <https://www.fcc.gov/about/overview>

Federal Trade Commission (FTC)

An independent agency of the U.S. federal government that prevents anticompetitive or deceptive business practices and enhances informed consumer choice and public understanding of the competitive process. <https://www.ftc.gov/about-ftc>

Feedback Mechanisms

The method by which a person receives feedback on a particular data point, series of data points, or activity through communication from a clinician or other health professional. A clinician will analyze the data point and provide a basis as to whether or not the person should continue with a specific treatment, medication, or lifestyle modification.

Gamification

The application of game elements and digital game design techniques to everyday problems such as business dilemmas and social challenges. <http://www.wexhealthinc.com/healthcare-trends-institute/the-gamification-of-healthcare/>

Geolocation Data

Data that shows the user's precise geographic location when using the internet or a mobile phone. Geolocation data can be pulled using global positioning system (GPS) coordinates, internet protocol (IP) address, media access control (MAC) address, radio-frequency identification (RFID), or device fingerprint. <http://www.pcworld.com/article/192803/geolo.html>

Gold Standard Measurement

A benchmark that is the best available under reasonable conditions. It is not the perfect test, but merely the best available one that has a standard with known results. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4296658/>

Google Play Store

A digital distribution service operated and developed by Google that serves as the official app store for the Android operating system. It allows users to browse and download apps developed with the Android software development kit (SDK) and published through Google. <https://googleblog.blogspot.com/2012/03/introducing-google-play-all-your.html>

Health Data Breach

An impermissible use or disclosure under the HIPAA Privacy Rule that compromises the security or privacy of protected health information. <http://www.hhs.gov/hipaa/for-professionals/breach-notification/>

Health Information Exchange (HIE)

Allows doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically—improving the speed, quality, safety, and cost of patient care. <http://www.healthit.gov/providers-professionals/health-information-exchange/what-hie>

Health Insurance Portability and Accountability Act of 1996 (HIPAA) Regulations

HIPAA was enacted by the U.S. Congress in 1996 to provide the ability to transfer and continue health insurance coverage for millions of American workers and their families when they change or lose their

jobs. It also reduces health care fraud and abuse, mandates industry-wide standards for health care information on electronic billing and other processes, and requires the protection and confidential handling of protected health information.

The Office for Civil Rights (OCR) enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information. The HIPAA Security Rule sets national standards for the security of electronic protected health information. The HIPAA Breach Notification Rule requires covered entities and business associates to provide notification following a breach of unsecured protected health information. The confidentiality provisions of the HIPAA Patient Safety Rule protect identifiable information being used to analyze patient safety events and improve patient safety.

<http://www.dhcs.ca.gov/formsandpubs/laws/hipaa/Pages/1.00WhatIsHIPAA.aspx>

<http://www.hhs.gov/ocr/privacy/>

Health IT Certification Program

The ONC Certification Program helps to ensure that EHR technologies meet the standards and certification criteria adopted by the Secretary of HHS to allow providers and hospitals to achieve meaningful use and participate in the CMS EHR Incentive Programs. <http://www.healthit.gov/policy-researchers-implementers/about-onc-hit-certification-program>

Health Level Seven International (HL7)

Founded in 1987, a not-for-profit, American National Standards Institute (ANSI)-accredited standards-developing organization. HL7 develops and maintains a framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information, defining how information is packaged and communicated from one party to another and setting the language, structure and data types required for seamless integration between systems. <http://www.hl7.org/about/index.cfm?ref=nav>

Health Literacy

The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.

<https://health.gov/communication/literacy/quickguide/factsbasic.htm>

Internet of Things

A network of physical objects that contain embedded technology, such as Bluetooth, to communicate and sense or interact with their internal states or the external environment. <http://www.gartner.com/it-glossary/internet-of-things/>

Interoperability

The ability of a system to exchange electronic health information with and use electronic health information from other systems without special effort on the part of the user. Interoperability is made possible by the implementation of standards.

http://www.ieee.org/education_careers/education/standards/standards_glossary.html

Learning Health System

This concept, first expressed by the Institute of Medicine in 2007, is now being rapidly adopted across the country and around the world. The Learning Health System is based on cycles that include data and analytics to generate knowledge, leading feedback of that knowledge to stakeholders, with the goal to change behavior to improve health and to transform organizational practice.

<https://www.healthit.gov/sites/default/files/hie-interoperability/Interoperability-Road-Map-Supplemental.pdf>

Machine Learning

A method of data analysis that uses algorithms that iteratively learn from data, allowing computers to find hidden insights without being explicitly programmed where to look.

http://www.sas.com/en_us/insights/analytics/machine-learning.html

Meaningful Use

Describes the use of certified EHR technology to improve quality, safety, efficiency and reduce health disparities; engage patients and family; and improve care coordination and population and public health. <http://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives>

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Rule

A regulation that will repeal the Medicare sustainable growth rate methodology for updates to the physician fee schedule and replace it with a new merit-based incentive payment system (MIPS). The proposed rule would establish MIPS in addition to other alternative payment methods to link fee-for-service payments to quality and value.


<https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-10032.pdf>

Merit-Based Incentive Program (MIPS)

A new program under MACRA that allows providers to be measured on quality, resource use, clinical practice improvement, and meaningful use of certified EHR technology.

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html>

Multi-Step Identity Verification

A method of computer access control in which a user is only granted access after presenting  eral separate pieces of identity-related evidence to an authentication mechanism. These pieces of evidence can be knowledge-based, possession-based, and inference-based. If one of the pieces of evidence is missing or incorrect, access is blocked.

[http://web.archive.org/web/20120112172841/http://www.insight.co.uk/files/whitepapers/Two-factor%20authentication%20\(White%20paper\).pdf](http://web.archive.org/web/20120112172841/http://www.insight.co.uk/files/whitepapers/Two-factor%20authentication%20(White%20paper).pdf)

National Institutes of Health (NIH)

A division of the HHS that serves as the nation's medical research agency.

<https://www.nih.gov/about-nih/who-we-are>

Natural Language Processing

Computer software that has the ability to analyze, understand, and generate language that humans use naturally. It can also be used to extract key terms or phrases from bodies of unstructured text, proving insights faster than a human could.

<https://www.microsoft.com/en-us/research/group/natural-language-processing/>

Office of the National Coordinator for Health Information Technology (ONC)

A federal government office that is at the forefront of the Administration's health IT efforts and is a resource to the entire health system to support the adoption of health IT and the promotion of nationwide health information exchange to improve health care. ONC is organizationally located within the Office of the Secretary of the HHS. <http://www.healthit.gov/newsroom/about-onc>

Paper Log

A method of data capture in which a patient records a health measurement, such as a weight, symptom, blood sugar reading, or medication effects on paper rather than electronically. Patients can then bring a notebook or journal of data points to a clinician visit for analysis.

Passive Data Collection

Data collection that occurs without patient interaction, usually from wearable devices and mobile devices. The most common types of passive data collected are usage behavior through the device's accelerometer and gyroscope, and location data from geolocation sensors.

<http://web.mit.edu/ecom/www/Project98/G2/data.htm>

Patient

An individual who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward maintenance, improvement, or protection of health or lessening of illness, disability or pain. For the purposes of this white paper, caregivers are included whenever patients are referenced but may in some cases have different needs. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/downloads/ICFMR_Glossary.pdf

Patient Portal

Secure online website that allows patients to access personal health information, review current medications, and schedule appointments, among other functions, from anywhere with an internet connection, using a secure user name and password.

<https://www.healthit.gov/providers-professionals/faqs/what-patient-portal>

Patient-Centered Outcomes Research (PCOR) Trust Fund

Created under the Patient Protection and Affordable Care Act to help build the national capacity and infrastructure needed to conduct patient-centered outcomes research and to enable PCOR findings to be integrated into clinical practice, the PCOR Trust Fund operates under the HHS.

<https://aspe.hhs.gov/meeting-aca-mandate-build-data-capacity>

Patient-Generated Health Data (PGHD)

Health-related data created, recorded, or gathered by or for patients (or family members or other caregivers) to help address a health concern. PGHD include, but are not limited to, health history, treatment history, biometric data, symptoms, and lifestyle choices. PGHD are distinct from data generated in clinical settings and through encounters with clinicians, as patients are primarily responsible for capturing and recording these data and patients decide how to share or distribute these data to health care providers.

<https://www.healthit.gov/policy-researchers-implementers/patient-generated-health-data>

Patient Matching

The process of comparing data from multiple sources to identify records that represent the same patient. It involves matching varied demographic fields from different health provider databases to create a unified view of a patient's health history.

<http://www.himssconference.org/sites/himssconference/files/pdf/IS30.pdf>

Personal Health Record

An electronic app used by patients to maintain and manage their health information in a private, secure and confidential environment.

<http://www.healthit.gov/providers-professionals/faqs/what-personal-health-record>

Pilot

A feasibility study or experimental trial launched on a small scale to help an organization learn how a larger-scale project might work in practice. Pilots are typically driven by requirements that help to prove a particular concept.

Population Health

The health outcomes of a group of individuals, including the distribution of such outcomes within the group. <http://www.improvingpopulationhealth.org/blog/what-is-population-health.html>

Precision Medicine Initiative

Announced by President Barack Obama in 2016, its objective is to enable a new era of medicine through research, technology, and policies that empowers patients, researchers, and providers to work together toward the development of highly individualized health care.

<https://www.whitehouse.gov/precision-medicine>

Preventative Care Services

Help patients to avoid illness and improve overall health and well-being. These services are almost always offered at no additional cost to the patient and, depending on the patient's age, can include blood pressure, diabetes, and cholesterol tests; cancer screenings, including mammograms and colonoscopies; depression and other health screenings; well-baby and well-child visits; and vaccines.

<http://www.hhs.gov/healthcare/about-the-law/preventive-care/index.html>

Privacy Policy

A statement or legal document that describes the ways in which a specific party gathers, uses, discloses, and manages a person's data.

Protocol

A set of rules governing the exchange or transmission of data between devices.

Randomized Control Study

A research study that randomly assigns participants into an experimental group who receives the treatment or drug, and a control group who does not receive the treatment or drug. The only expected difference between the experimental and control groups is the outcome variable that is being observed in the study. <https://himmelfarb.gwu.edu/tutorials/studydesign101/rcts.html>

Remote Monitoring/Telemonitoring

Use digital technologies to collect medical and other forms of health data from individuals and electronically transmit that information securely to health care providers in a different location for assessment and recommendations. Remote monitoring programs can collect many types of health data at the point of care, including vital signs, weight, blood pressure, blood sugar, and heart rate. Once the data are collected, health care professionals can monitor the daily changes and act on the information as part of the prescribed treatment plan. <http://cchpca.org/remote-patient-monitoring>

Research Workflow

The processes involved throughout a research study, which researchers and associated staff members use to create the study hypothesis, identify and recruit subjects, collect and analyze data, and publish research results.

Smartphone App

A software app designed to run on a smartphone, leveraging the phone's internal hardware to perform a specific function.

Social Networking

The process of connecting and sharing thoughts and ideas with individuals, using internet web sites such as Facebook and Twitter.

Standard

Common and repeated use of rules, conditions, guidelines, or characteristics for products or related processes and production methods and related management systems practices. For types of standards see reference. <http://www.nist.gov/standardsgov/definestandards.cfm>

Standards Development Organization (SDO)

A member-based organization whose members set the priorities for which standards will be developed and refined. Each SDO has a very refined process for developing, balloting, piloting, finalizing, and maintaining standards within its domain.

Technology Literacy

The ability to appropriately select and responsibly use technology to communicate, problem-solve, and function in society. <http://online.cune.edu/defining-technology-literacy/>

Telehealth/Telemedicine

A broad variety of technologies and tactics to deliver virtual medical, health, and education services. Telehealth services can be applied to home health, physical and occupational therapy, and chronic disease monitoring. <http://cchpca.org/what-is-telehealth>

Token

A virtual object that includes the identity and privileges of a user account, which a system verifies, or authenticates, to allow for access to a system.

[https://msdn.microsoft.com/en-us/library/windows/desktop/aa374909\(v=vs.85\).aspx](https://msdn.microsoft.com/en-us/library/windows/desktop/aa374909(v=vs.85).aspx)

Transition of Care

The movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another.

http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/8_Transition_of_Care_Summary.pdf

Unsolicited PGHD

Data received by a health care provider who has taken no active steps to ask for or collect that information. In some instances, this information is provided in the absence of an existing patient-clinician relationship. <http://library.ahima.org/doc?oid=106998#.V-UgICErLIU>

U.S. Food and Drug Administration (FDA)

A federal agency of the HHS responsible for protecting the public health of the nation by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, and products that emit radiation.

<http://www.fda.gov/AboutFDA/WhatWeDo/default.htm>

Usability Testing

The process of evaluating a product or service by testing it with representative users to understand and identify problems before they are coded. Usability testing can improve user performance satisfaction, and analyze the performance of a device or app to ensure it meets all business objectives.

<https://www.usability.gov/how-to-and-tools/methods/usability-testing.html>

User Authentication

Any process by which a system verifies the identity of a user who wishes to access it.

Visualization Tools

Tools that allow for large data sets to be understood by displaying visual representations of patterns, trends, and correlations, that may have gone undetected.

Wearable Device

An electronic device worn by an individual used to observe, capture, and share various pieces of biometric information, such as activity level, heart rate, and blood sugar measurements.

Appendix B: Subject Matter Experts

From February 2016 to May 2016, the Accenture team conducted informational meetings with industry subject matter experts (SMEs) to gain their insight into the best practices, gaps, and opportunities for capturing, using, and sharing PGHD in research and care-delivery settings. They represent a number of industry sectors, including care delivery, research, patient advocacy, technology development, and health law.

Collection and Validation of Data and Tools
Alexis Normand, MSc, MPA – Withings
Andrew York, JD, Pharm. D. – Centers for Medicare and Medicaid Services (CMS), Center for Medicare and Medicaid Innovation (CMMI)
Ashwini Davison, MD – Informatics Advantage, LLC
Lara Strawbridge, MPH – CMS, CMMI
Nicolas Schmidt, MSc – Withings
Rajiv Mehta, MBA, MS – Bhageera, Inc.
Sandeep Pulim – @Point of Care, LLC
Steven Steinhubl, MD, MSc – Scripps Translational Science Institute

Data Donation
Jaye Bea Smalley, MPA – Patient-Centered Outcomes Research Institute (PCORI)
Ethan Basch, MD, MSc – University of North Carolina, Chapel Hill
Hilary Wall, MPH – CMS Innovations Center/Centers for Disease Control and Prevention (CDC), Million Hearts Initiative
Janet Wright, MD, FACC – CMS Innovations Center/CDC, Million Hearts Initiative
Kevin Fowler – The Voice of the Patient, Inc.

Regulatory Overview
Erin Mackey, MPH – National Partnership for Women and Families
Jodi Daniel, JD, MPH – Crowell & Mooring, LLP
Jeff Coughlin, MPP – Health Information and Management Systems Society (HIMSS)
Mark Savage, JD – National Partnership for Women and Families
Robert Jarrin, JD – Qualcomm Incorporated
Thomas Martin, PhD, MBA – HIMSS

Ability to Combine PGHD with Medical Record Data in Multiple Ways
Andrea Hartzler, PhD – Group Health Research Institute
Jenna Marquard, PhD – University of Massachusetts, Amherst
Jim Walker, MD – Cerner Corporation
MaryAnne Sterling – Sterling Health IT Consulting, LLC, and Connected Health Resources
Patricia Flatley Brennan, PhD, MSN – University of Wisconsin, Madison, and Project HealthDesign
Thomas Agresta, MD – University of Connecticut School of Medicine

Patient Recruitment for Research Studies and Trials

Cynthia Baur, PhD – CDC, Office of the Associate Director for Communication

Paul Tarini, MA – Robert Wood Johnson Foundation

Data Interoperability

Chris Bradley, MS – Mana Health

Holly Miller, MD, MBA – MedAllies

John Sharp, MSSA – Continua/HIMSS' Personal Connected Health Alliance

Leslie Kelly Hall – Healthwise, Inc.

Paul White, MBA – AsthmaBrain Corporation

Robert Havasy, MS – Continua/HIMSS' Personal Connected Health Alliance

Big Data Analysis

Amy Abernethy, MD, PhD – Flatiron Health, Inc.

Bradford Hesse, PhD – NIH, National Cancer Institute, Health Communications and Research Branch

Jonathan Wald, MD, MPH – RTI International

Additionally, the Accenture team spoke with a number of health care delivery organizations and Patient-Powered Research Networks (PPRNs) about their experiences with and capability for conducting pilot demonstrations using PGHD.

Large Hospitals / Health Care Systems

Carolinas Healthcare Center

Geisinger Medical Center

Kaiser Permanente

Ochsner Health System

Partners HealthCare, Center for Connected Health

Academic Medical Centers / Research Institutions

Cedars-Sinai Medical Center

Dartmouth-Hitchcock Medical Center

Duke University School of Medicine

Kaiser Permanente CHARN Network

Mount Sinai Icahn School of Medicine

University of California, San Francisco

Stanford University Children's Hospital

Vanderbilt Health System

Community-Based Clinics / Rural Hospitals

Anne Arundel Medical Center

Fenway Health

PCORnet Patient-Powered Research Networks (PPRNs)
CCFA Partners PPRN
The COPD PPRN
MoodNetwork PPRN
PARTNERS PPRN
Phelan-McDermid Syndrome Data Network (PMS_DN)
PRIDEnet PPRN

Federal Organizations / Partnerships
U.S. Department of Veterans Affairs
PatientsLikeMe (FDA Partnership)

Developers
Hexcare
Sage Bionetworks
St. Andrew Development, Inc.
Validic

Appendix C: References

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