The Office of the National Coordinator for
Health Information Technology

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

WHITE PAPER

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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, biometric data, symptoms, medication effects, and patient preferences, has been predominantly collected by members of the care team in a clinical setting or through clinical in-home devices for remote monitoring. The 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. This white paper describes key opportunities and challenges and offers enabling actions that can further enhance PGHD capture, use, and sharing for health care delivery and research in the United States. The white paper could contribute to the development of a PGHD policy framework.

Opportunities

Consumer technologies can empower patients to capture, use, and share PGHD to better manage their health and to participate in their health care.[2] When used by clinicians and researchers, PGHD can provide a more holistic view of a patient's health and quality of life 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 experiences of, their patients by using PGHD to develop a personalized care plan and to engage in shared 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 cost of patients visiting a clinical setting or research site and can improve workflow efficiencies.

Challenges

While the use of PGHD promises to benefit patients, challenges must be overcome to realize that potential. Patients may not understand the advantages of capturing and sharing PGHD with clinicians and researchers. Lack of access to PGHD technologies, varying levels of health and technology literacy, and patient concerns about data privacy and security may prevent them from participating.

Many health care systems, clinical practices of varying sizes, and research institutions lack the technical infrastructure, functional workflows, workforce capacity, and training to support PGHD intake. Methodological or technological limitations and the large volume of data being collected means they struggle to pull actionable insights from the voluminous data. Without sufficient guidance and best practices for incorporating PGHD into clinical and research workflows, they worry that receiving PGHD from patients may add to their workloads and disrupt their workflows. While there is a growing body of clinical evidence demonstrating health and cost benefits of PGHD use, the evidence is still limited and inconclusive, which has hampered funding for implemented PGHD use.[4]

Data- and device-related concerns pose additional challenges for the capture, use, and sharing of PGHD. Device abandonment of consumer health technologies 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 wellness devices, managing the security risk, and standardizing the data collected from multiple devices. Some stakeholder groups note that the use of PGHD may present liability

concerns if inaccurate PGHD are used in clinical decisions or if the clinician chooses not to review or act based on the PGHD received.

Enabling Actions

Advancing the use of PGHD will require action and collaboration across the health care ecosystem. A policy framework could suggest that stakeholder groups consider taking the following enabling actions:

Stakeholder Group	Enabling Action
Patients & Caregivers	• 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 apps and in reporting feedback directly to manufacturers and app developers.
Clinicians	• 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 interpretation and use. • Identify and communicate benefits, challenges, and best practices of PGHD use to help strengthen the evidence for its clinical and economic value. • Encourage clinicians to use PGHD to support patient data donation in research. • Support clinicians in providing patient education to encourage PGHD capture and use in ways that maximize data quality.
Researchers	• Call for increased funding for studies that investigate the benefits, challenges, and best practices for 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.
Policymakers	• 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 understand the outcomes of PGHD use as part of advanced health care models. • Encourage review of medical malpractice and liability laws at the state level and how they intersect with legal issues related to the use of PGHD.
Developers & Standards Bodies	• Improve usability and accessibility of and implement user-centered design principles into products that capture PGHD. • Consistently adopt strong privacy and security practices for PGHD capture, use, and sharing and support transparency with consumers about these policies. • Challenge standards bodies to address the needs of the health care ecosystem for PGHD use and increase the pace of standards development for capturing and integrating PGHD.
Payers & Employers	• Continue to motivate clinicians to use PGHD as part of clinical care through supportive policies in reimbursement programs. • Continue to incorporate incentives to use PGHD into insurance plans and wellness programs.

Introduction

The rise of innovative digital health technologies has increased the ease of capturing, using, and sharing PGHD. Such technologies enable 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, several technical and cultural barriers currently exist that have slowed the adoption of PGHD in care delivery and research. Capitalizing on these technologies and mitigating the barriers to using the data captured require the development of guidance and best practices for integrating PGHD into clinical and research settings. This white paper envisions a health IT ecosystem that optimizes PGHD use 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 stakeholder action 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 that can be leveraged to create 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 describes considerations for a future PGHD policy framework. It discusses challenges and opportunities for the capture, use, and sharing of PGHD that several stakeholder groups can address. A PGHD policy framework can inform regulations and guidance to promote effective use of PGHD with the goals of providing care teams and researchers with timely, trustworthy, and relevant information to ultimately improve health outcomes and lower costs. Many types of guidance would be effective, from documents that further explain regulations to practical instructions for implementing PGHD in a clinician practice. Guidance can be developed by a variety of stakeholder groups across the industry.

This project is funded by the Patient-Centered Outcomes Research (PCOR) Trust Fund administered by the HHS Assistant Secretary for Planning and Evaluation. This project is part of a suite of PCOR projects at ONC that contribute to building a data infrastructure to support improving patient-centered outcomes clinical care delivery and research.[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 the key stakeholder groups in the use of PGHD. It also calls on policymakers, technology developers and standards bodies, and payers and employers to support the capture, use, and sharing of PGHD for use in care delivery and research.

Methodology

From October 2015 through October 2016, the Accenture team researched seven PGHD policy topic areas:

1. **Patient Recruitment for Research Studies and Trials** focuses on how PGHD can be used to identify patients for research studies and trials and to connect patients directly with researchers.

2. **Collection and Validation of Data and Tools** focuses on the existing and emerging tools for capturing PGHD. The topic considers the types of PGHD that clinicians and researchers collect and how they validate the data and tools.
3. **Data Donation** explores patient expectations for sharing data with clinicians and researchers. The topic examines existing and emerging methods of data donation for research.
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 includes methods for combining data from multiple sources, as well as the standards and technology needed to support this practice.
5. **Data Interoperability** examines the benefits of, and barriers to, increased interoperability between the health IT system and devices used to capture PGHD. The topic explores technical barriers such as standards, as well as cultural and workflow barriers.
6. **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.
7. **Regulatory Overview** discusses the current federal statutory and regulatory paradigms relevant to PGHD, including the tools and technologies used to capture PGHD.

7 PGHD Policy Topic Areas

1. Patient Recruitment for Research Studies and Trials
2. Collection and Validation of Data and Tools
3. Data Donation
4. Ability to Combine PGHD with Medical Record Data in Multiple Ways
5. Data Interoperability
6. Big Data Analysis
7. Regulatory Overview

This white paper synthesizes the findings from research on these seven topic areas, the results of two pilot demonstrations, and nearly 200 public comments from nine national organizations on the draft white paper published in January 2017. The findings provide an integrated view of the issues and opportunities for the capture, use, and sharing of PGHD across stakeholder groups. This white paper also includes several appendices, including a glossary of terms used.

Pilot Demonstrations

To further validate and expand the findings of the draft white paper, Accenture subcontracted with two digital health technology organizations to conduct pilot testing with care delivery partners. Validic and its partner, Sutter Health, used PGHD collected from a variety of glucometers to inform diabetes care while assessing the infrastructure and workflows needed to implement and scale such initiatives. TapCloud and its partner, AMITA Health, gathered PGHD across several medical areas, such as orthopedic surgery, behavioral health, and bariatric surgery, to identify and collect symptoms, pain ratings, activity levels, and self-assessments of how patients felt compared to the previous day. This information was incorporated into a dashboard that the clinical staff reviewed. The pilot findings provided real-world insights from industry stakeholders and informed the final version of this white paper. Further information about the two pilot demonstrations can be found in Appendix A.

Background

The collection of PGHD is not new. Patients have long kept paper logs of data about measures of their health, such as weight, symptoms, blood sugar readings, and medication effects. Patients often bring 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 and share data outside of the traditional clinical environment. Advances in cloud computing reduce the cost of capturing large datasets and enable seamless connections across the devices and apps. These advances led to the proliferation of PGHD and the opportunity for clinicians and researchers to gain real-time insight into patient health outside of clinical settings.

Consumer interest in PGHD has grown considerably in recent years with the increase in wearable fitness trackers and mobile health apps. A report by Research2Guidance in October 2016 found that there are more than 259,000 mobile health apps available for download from major app stores, including the Apple App Store and Google Play.[8] A 2017 Gartner forecast estimated that the overall wearable market will expand from 310 million devices in 2017 to more than 500 million devices in 2021.[9] In 2015, Gartner predicted that by 2019, 30 percent of hip and knee replacements will be monitored using wearable devices as part of the Internet of Things (IoT).[10] Clinicians and researchers are looking for ways to capitalize on the pervasiveness of these devices and the abundance of data patients are generating.

Gartner predicted that **by 2019, 30%** of hip and knee replacements will be monitored using wearable devices in combination with the Internet of Things.

Regulations that incent the capture and use of data from nonclinical settings have supported clinician interest in 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 & Medicaid Services, 2015) regulation, an optional measure allows an eligible 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.[11]
- 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 further enhance the safety, reliability, transparency, and accountability of certified health IT for users.[12]
- Since 2015, the Centers for Medicare & Medicaid Services (CMS) has offered reimbursement for non-face-to-face care coordination for Medicare beneficiaries with multiple chronic conditions and for transitional care programs, which can be supported through the use of PGHD.[13,14] 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) includes an optional measure for using PGHD to support the goal of coordinating care through patient engagement.[15]

These factors create an environment ripe for the capture, use, and sharing 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;[16] convening consumer workgroups for the Federal Advisory Committees (2012) to provide policy recommendations and feedback on the MU3 recommended measures for PGHD;[17] convening a technical expert panel (2013) to identify best practices for using technology to enhance patient engagement and to support MU3 requirements;[18] 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.[19] This white paper builds on these efforts to address advances in health IT and changes in the ecosystem in the intervening years, such as 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."[20] *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.[21] ONC's report *Examining Oversight of the Privacy and Security of Health Data Collected by Entities Not Regulated by HIPAA (*Non-Covered Entity report, hereafter referred to as the NCE report*),* submitted to Congress in July 2016, describes the privacy and security regulatory landscape for products used to capture PGHD that are not covered by HIPAA and identifies areas for action to strengthen privacy and security. In December 2016, ONC released a draft *Model Privacy Notice,* which provides a voluntary resource to help developers clearly convey the privacy and security policies of their apps and devices.[22]

Findings

Reaching the significant potential of the wider use of PGHD requires numerous challenges to 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 key stakeholder groups and supporting stakeholder groups. Progress in these areas is essential to achieving the envisioned future benefits of PGHD.

Current State

In today's health care environment, clinicians typically make decisions based on data they collect in clinical care settings. These data create a snapshot of the patient's health at single points in time, rather than continuous measurements outside of clinical settings.[23] Rarely do clinicians and researchers have access to data collected in real time about their patients' lives outside of the clinical setting, which limits the potential for a holistic perspective of their patients' health.

PGHD captured using digital health tools, such as online questionnaires, personal health records, mobile apps, wearables, and connected medical devices, can help patients become more engaged in health

care. The 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 percent of American adults own and often carry with them everywhere, the smartphone is a central hub for capturing measurements, storing, and sharing data.[24] Second, many consumer technologies can passively collect health data, and therefore generate large volumes of data over time. For example, some devices can passively collect data, such as step count, location, and heart rate, without actively notifying the user. Finally, many apps and devices that capture PGHD provide data visualization, so patients can receive valuable feedback, quickly understand their data in real time, and proactively modify their behavior. For example, some wearable fitness trackers have features that enable users to track hourly activity and sedentary time. Knowing how many hours a day one spends being stationary can drive healthier behavior changes by providing users with insights into their behaviors and reminders to be active.[25]

Technical Challenges

Although patients purchase and use digital health tools to generate PGHD, the use and sharing of PGHD for clinical care and research are not yet in widespread practice, in part, due to barriers affecting multiple stakeholder groups. These barriers include concerns about managing large volumes of PGHD, questions about the accuracy of measurements from devices that collect PGHD, user authentication risks, immature interoperability standards, data provenance issues, gaps in privacy and security protections, and differing views about who can access, use, and share PGHD.

Technical Challenges
- Concerns about managing large volumes of PGHD
- Questions about accuracy of measurements from devices that collect PGHD
- User authentication risks
- Immature PGHD interoperability standards
- Data provenance issues
- Gaps in privacy and security protections
- Differing views about rights to access, use, and share PGHD

Volume of PGHD

The potential volume of the data from tools collecting PGHD requires stakeholders to determine and invest in the data storage and technical architecture needed to support PGHD use. Without tools that can quickly analyze data and offer actionable insights, large amounts of PGHD may clutter views of the clinical data and create inefficiencies in the clinical and research workflows.

Accuracy of Devices

Technical challenges include questions about the accuracy of devices that collect PGHD. Patients, researchers, and clinicians 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. However, there is less clarity about the accuracy of general wellness devices that are not subject to FDA approval. A 2016 study reported 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.[26]

Given these variations in accuracy, some PGHD may not yet be fit for clinical and research use cases where data accuracy is paramount. As an example, when monitoring general wellness, the quality of the data collected by a consumer health device may be sufficient. However, a registered medical device, which is an instrument intended for medical use in the diagnosis of disease and regulated by the FDA, may be required when a clinician or researcher manages or treats a specific health condition. These

registered medical devices often have a low margin of error and high data accuracy. In other instances, data from registered medical and general wellness devices may complement one another. For example, trends from a consumer activity tracker can be used to validate and provide context to a blood pressure reading taken from a registered medical device. This holistic view can help a clinician determine an activity's effect on a patient's blood pressure reading and the existence of an episode that requires immediate follow-up.

User Authentication

User authentication introduces data accuracy concerns. In the case of remote patient monitoring, clinicians and researchers must trust that the data received can be attributed to a specific person.[27] Currently, many devices require a user to present credentials only during initial authentication, which may not be adequate. The lack of continuous user verification highlights two scenarios that can threaten data integrity.[28] One is the risk of a stolen device, and therefore, potentially a stolen identity as well. The other is the risk of an account accessed via a wearable, mobile phone, or other digital health device being shared among several people. However, continuous user verification may be disruptive to the user and create a poor user experience. Solutions must strike an acceptable balance between these competing requirements.

Data Provenance, Exchange, and Merging

Though not unique to PGHD, merging data from disparate sources introduces several data curation challenges, particularly in standardizing PGHD and capturing information about 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 without consensus on which interoperability standards to use, variations in data representation and coding limit the exchange, normalization, and completeness of the data. This limits the ability to draw valuable insights. The lack of standardized terminology and datasets for PGHD limits the secondary uses of the data in research studies and clinical trials. The absence of robust and widely adopted standards for associating and tracking data provenance prevents clinicians and researchers from being able to track the origins and transit route of PGHD they receive; knowing where the PGHD originates and if there are any alterations to it while in transit help the clinician or researcher to establish trust in the data.

Security and Privacy

Ensuring the security and privacy of PGHD is also a challenge to patients, clinicians, and researchers. As HHS's NCE report demonstrates, the security and privacy protections that apply to PGHD are uneven and do not establish a consistent legal and regulatory framework.[29] PGHD, like all data, may be at risk for security breaches that could affect the integrity of the data and expose the data to access for malicious purposes because they are not subject to the same security regulatory framework as HIPAA-regulated entities. Concerns include insecure points of data collection and insecure data movement that potentially expose the device or the clinician's information system to pollutants, such as malware. There is growing potential for risks related to unauthorized access, including cyber threats. Ponemon's 2016 *Study on Privacy and Security of Healthcare Data* found that nearly 90 percent of the health care organizations surveyed had suffered at least one data breach in the prior two years.[30] Ongoing security risk assessments and management can reduce these risks and make entities less susceptible to a security breach.

Privacy concerns include how clinicians, researchers, and others access and use the data, whether patients receive information about how their data are used, and if patients understand the protections that apply to their data. The HIPAA Privacy Rule establishes safeguards to protect patient health information and patient rights to understand how their data may be used and shared. 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, integration of de-identified data across datasets from different sources can open the risk of 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 becomes available."[31]

Rights to Access

Differing views exist about who can access, use, and share PGHD. PGHD may simultaneously be perceived to belong to the patient, the developers of the app or device used to capture and share the PGHD, the clinicians and researchers who receive the PGHD, and the developers of technologies used to store the PGHD. Stipulations around how data are used may be included in the terms and conditions for selected PGHD collection or storage technologies, organizational or program policies, or the consent and data use agreement for each research study or clinical trial. Without clear guidelines, it is less likely that the policies will align across all parties, introducing opportunities for disagreement around rights to access, use, and share PGHD.[32] However, individuals have the legal and enforceable right under HIPAA to access their health information when these data have been received and are managed by HIPAA covered entities. The HIPAA Privacy Rule requires covered entities to grant individuals access to their protected health information upon request.

Opportunities

Several initiatives and emerging technologies are advancing solutions that may address the technical challenges mentioned above. 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. To further advance patient matching, the Pew Charitable Trusts is researching policies and private sector actions to improve patient matching rates and mitigate problems.[33] ONC is leading a PCOR Trust Fund project on Patient Matching, Aggregating, and Linking that aims to use application programming interfaces (APIs) to enable linking of patient data, including PGHD, to other clinical and claims data.[34] Blockchain, an emerging technology that creates a distributed, digital ledger of cryptographically secure transactions, may provide solutions that support interoperability between EHRs and IoT devices, while enabling trust in the validity of the data and its source.[35]

Direct Secure Messaging, which was developed in 2010 under ONC's Direct Project, aims to achieve security, privacy, data integrity, and user authentication during the exchange of health information over the Internet.[36] 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 predictive analytics and artificial intelligence, such as natural language processing and machine learning on unstructured data, to help doctors and hospitals make their data more usable.[37]

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 such

as these will likely grow and scale to maturity during the next seven 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 will focus on patient preferences and goals and keep patients at the center of care delivery and research.
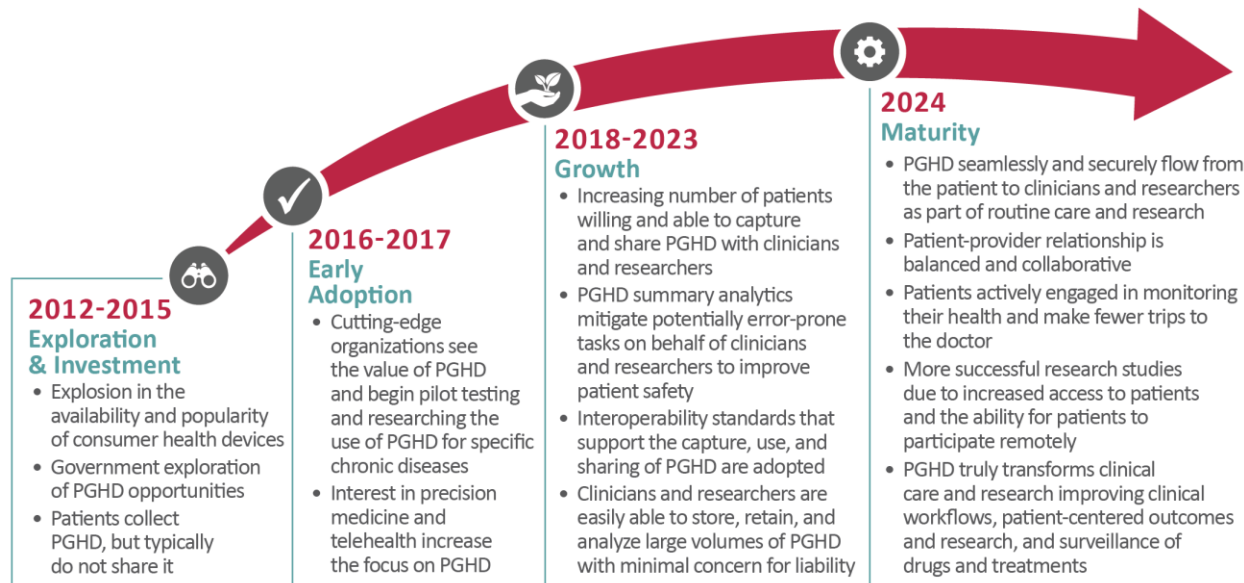

2012-2015
Exploration & Investment
- Explosion in the availability and popularity of consumer health devices
- Government exploration of PGHD opportunities
- Patients collect PGHD, but typically do not share it

2016-2017
Early Adoption
- Cutting-edge organizations see the value of PGHD and begin pilot testing and researching the use of PGHD for specific chronic diseases
- Interest in precision medicine and telehealth increase the focus on PGHD

2018-2023
Growth
- Increasing number of patients willing and able to capture and share PGHD with clinicians and researchers
- PGHD summary analytics mitigate potentially error-prone tasks on behalf of clinicians and researchers to improve patient safety
- Interoperability standards that support the capture, use, and sharing of PGHD are adopted
- Clinicians and researchers are easily able to store, retain, and analyze large volumes of PGHD with minimal concern for liability

2024
Maturity
- PGHD seamlessly and securely flow from the patient to clinicians and researchers as part of routine care and research
- Patient-provider relationship is balanced and collaborative
- Patients actively engaged in monitoring their health and make fewer trips to the doctor
- More successful research studies due to increased access to patients and the ability for patients to participate remotely
- PGHD truly transforms clinical care and research improving clinical workflows, patient-centered outcomes and research, and surveillance of drugs and treatments

Figure 1: PGHD Adoption Curve

To better illustrate the potential impact of the use of PGHD, the following scenario, one of many possible scenarios, describes how a patient's experience could look in 2024.

A Future State Scenario: Christie's Journey with the Use of PGHD

With heart disease being the No. 1 killer of men and women, Christie, a 39-year-old female with a history of high blood pressure, is taking no chances. Christie is diligent about completing her annual physical exam with her primary care clinician. Between clinical visits, Christie leverages a variety of technologies to monitor her health:

PATIENT: CHRISTIE
- 39-year-old female
- History of high blood pressure
- Managing her health using technology

- She tracks her weight with a Bluetooth scale and her blood pressure with a Bluetooth cuff monitor that both sync with an app on her smartphone.
- She measures her steps, energy expenditure, stress, and heart rate with a wearable activity tracker and her sleep data with an Internet-connected smart mattress, paid for by her insurer.
- She relies on ingestible sensor data to monitor adherence to medication regimen.
- She records side effects of her medications and tracks her activities against wellness goals in addition to food and mood journals on a mobile app.

So that she can share the results seamlessly and securely with her care team members, Christie authenticated her apps and devices. Christie's PGHD from her various digital technologies, i.e., weight

scale, food and mood apps, activity tracker, and ingestible sensor, are compiled on her mobile app and automatically transported to and integrated with her care team's health technology system. This seamless process saves time for Christie, so she can focus on her health.

Christie's information from other health information technology systems, such as a flu shot provided by her retail pharmacy, is also available for integration into her care team's technology system. A consent tool allows Christie to control who can see and use specific segments of her information. Christie can authorize and revoke access to her data using a mobile app linked to the data points.

Because Christie's PGHD capture technologies are calibrated, the data collected are standardized. The PGHD provenance information is clear and includes details about how and when third parties, such as data brokers, gateways, and aggregators, touch the data. Her clinician's health technology system automatically screens the data for any concerning values or trends and notifies Christie and her care team about these concerns via secure messages. Once Christie's data are integrated with the care team's system, Christie's clinician can share that data seamlessly with other clinicians across the continuum of care. Within the clinician's health technology system, HIPAA-compliant privacy and security mechanisms are in place to ensure that all patient health data are transmitted securely to the intended recipients.

Her care team is alerted via ingestible sensor data that Christie has not taken her medication in more than two days. They also can see Christie experienced a rise in her blood pressure readings, as well as changes in mood and sleep. A care team member contacts Christie via phone, her designated preferred method of communication. Christie explains she recently experienced a death in the family and was preoccupied by that event. The care team member provides support to Christie to help her return to her treatment plan and adds a behavioral health clinician to the care team, sharing Christie's relevant data as she had previously authorized. The care team's health technology system then requests to schedule a telehealth consultation for Christie with the behavioral health clinician. In this way, the capture, use, and sharing of PGHD enables preventive care, monitoring, and proactive identification of changes in Christie's health practices and status.

Christie has indicated through an online research registry tool that she wants to be notified of opportunities to contribute to research, so open-enrollment clinical trials and studies are reviewed against Christie's PGHD. Using artificial intelligence, the tool identifies research studies and clinical trials for which Christie is eligible to participate and provides her with details about those studies via secure messaging as she has indicated for this type of communication. As a result of this notification, Christie fills out an online intake form for a sleep disorder study. Once accepted, she agrees to participate in the study through an electronic consent process that authenticates her identity, and validates her devices, including her Internet-connected smart mattress. The consent process also encourages her to sign up to securely donate her data and to transmit it automatically to the researcher's study database and systems.

By capturing PGHD and integrating it with various care delivery and research technology systems, Christie is able to manage her health care more effectively. She has placed reliable health information at the fingertips of her care team members and researchers.

Achieving a future such as Christie's scenario described will require collaboration across the health ecosystem including the key stakeholder groups of patients, clinicians, and researchers, as well as other stakeholder groups including policymakers, technology developers and standards bodies, payers, and employers. Challenges a specific stakeholder group faces may affect and require action from multiple stakeholder groups. Similarly, enabling actions for one stakeholder group may resolve the challenges of another stakeholder group.

Opportunities, Challenges, and Enabling Actions for Key Stakeholder Groups

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 patient outcomes and experience.

Using PGHD, patients can become more engaged and knowledgeable partners in their care and in research. Patients can participate in the data collection process, observe how their health may fluctuate over time, and understand how certain actions and behaviors may influence their health outcomes.[38] For example, a survey of patients enrolled in the Connected Cardiac Care Program at Partners HealthCare, which required heart failure patients to capture and share weight, heart rate, pulse, and blood pressure data to support telemonitoring and patient education, found that 98 percent of participants reported learning more information about heart failure because they were enrolled in the program, and 85 percent reported that they felt in control of their health because of the program.[39] During the Validic/Sutter Health pilot demonstration, one clinician identified his patient's late-night snacking habits and the resultant increase in blood glucose levels before bed by reviewing trends in the patient's blood glucose levels over time. By reducing this late-night snacking, the patient made a clinically meaningful reduction in his HbA1c measurement in one month, representing a positive and significant improvement in blood glucose control.

Furthermore, 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.[40] Patient and clinician access to PGHD may improve health outcomes when used to manage a specific condition as proven by studies that show efficacy of the use of relevant PGHD to monitor specific chronic conditions.[41] For example, in the TapCloud/AMITA Health behavioral health pilot demonstration, clinicians encouraged their patients to use the TapCloud app daily to report their emotions and the corresponding coping strategies. Patients often used the app when they were experiencing an intense emotion or situation, which helped them be more mindful of their feelings and reminded them which coping strategies to use to manage their emotions.

The use of PGHD may help to create more balanced relationships between the patient and clinicians and researchers. Patients can express their health status on their own terms and over time, and generate data that support their understanding of their health. The sharing of PGHD also enables patients to share their health goals, habits, preferences, and priorities, such as those expressed in advance directives, so that care can be personalized to their needs and lifestyles. With the use of PGHD, shared decision-making between patients and clinicians is ongoing, and patient understanding of and adherence to treatment plans rises.[42]

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 time
- Reduce the time, effort, and cost associated with visiting a clinician or research site
- Benefit both sick and healthy patients

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 can 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.[43] For example, in the TapCloud/AMITA Health orthopedic surgery pilot demonstration, a lead monitoring nurse noted, "I monitor more than 100 patients a day with TapCloud. If I see they have calf pain, I have them speak to a doctor to check for a blood clot. I look at photos of the surgical site (uploaded by patients) to determine if everything is okay or if a patient needs attention. If I see pain increasing for a couple of days, I send a message asking if the patient is taking pain medication or over-exercising. Taken together, we have dramatically reduced readmissions."

Visiting a clinician requires time for the appointment and travel time to and from the clinic along with the associated travel costs. 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.[44] The availability of these data 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 his or her ability to participate in research studies, as research protocols often require patients to visit a research center to capture their data. By using tools that generate, collect, and share PGHD, increased opportunities exist to participate remotely in clinical trials and studies.[45]

Use of PGHD between visits 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.[46]

The benefits of PGHD use are not limited to patients with chronic conditions. A clinical trial among ambulatory patients undergoing breast reconstruction found that providing follow-up care via a mobile app during the first 30 days after the operation resulted in fewer in-person visits and improved patient-reported convenience scores, without affecting complication rates.[47] Regardless of patients' health status – whether they are healthy or have chronic conditions or acute injuries – there are mobile apps that increase convenience for patients by collecting PGHD, facilitating pre-visit check-in, and enrolling patients in studies. These steps eliminate wait times at a clinician's office, improve a patient's ability to communicate with the clinician's office staff, and enables efficient registration in multiple EHR systems. Furthermore, access to patient information, such as allergies or medications, through a mobile app can help save lives when first responders are authorized to access it in an emergency when a patient cannot communicate.

The use of PGHD by caregivers enables them to be more informed. Caregivers have the significant responsibility of managing the well-being of an individual, for example, the needs of a child or a person diagnosed with a chronic or debilitating medical condition.[48]

Having access to PGHD provides caregivers with insight into the patient's health status when the caregiver is not physically present, as is the case in long-distance caregiving. For patients with limited mental and communication capabilities, the use of PGHD enables them to record and share information about their health with their caregivers. The caregiver can use this PGHD to provide tailored support, advocate on behalf of the patient, and engage in discussions about care coordination and the patient's care plan.

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
- Caregivers lack access to the right data and have few tools to optimize patient care

Challenges

Although 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 and some clinicians, 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 support capture and transmission, including a reliable Internet connection. According to the 2016 *Broadband Progress Report*, 34 million Americans still lack access to broadband benchmark speeds.[49] Moreover, a Pew Research Center study indicated 36 percent of Americans do not own a smartphone.[50] Some patient populations, such as those with cognitive and physical impairments, low-income individuals, those with language barriers, and in some cases seniors may have higher barriers to accessing and using devices that capture PGHD than other patients. For example, in the TapCloud/AMITA Health stroke pilot demonstration, the care team made changes to the on-boarding process, the amount of data collected, and the data collection process to accommodate patients' compromised abilities, which enabled more stroke patients to use the app.

Once patients own or have access to a consumer health device, these devices may lack staying power with their users. Although analysts observe an increase in sales of wearable fitness trackers, they also observe high abandonment rates for these devices.[51] A 2016 Gartner survey found the abandonment rate for fitness trackers is 30 percent because users do not find them useful or the devices break.[52] Similar studies fault designs that require patient action to charge and sync devices and indicate the devices lack of impactful motivational elements to encourage behavior change and longer-term engagement for the high abandonment rates.[53] Both registered medical and general wellness devices may 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 tracking their health data or interested in changing their health behaviors may be less motivated to do so without tangible benefits or incentives.[54] Current mobile health devices often lack the feedback mechanisms, such as motivational messages, that can provide immediate value to patients and keep them engaged with the devices during a long period and for other, non-health-related benefits. Even if patients are motivated to capture and share PGHD, clinicians do not always positively reinforce this behavior. With little indication that attention is being

paid to these data or that they are of value to patients' clinical management, patients may be discouraged from capturing and sharing high-quality data on a prescribed basis.

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 can help them manage their health. While patients express a willingness to share their data to improve care delivery and advance knowledge about their medical conditions, these patients express concerns about data privacy and security and the potential for discrimination by payers and employers.[55] Willingness to share is impacted by the degree of trust in place between patients and the health care delivery or research organization and by patients' understanding of how their data may be used. A PatientsLikeMe survey found that of the patients with a medical condition, 72 percent believe data from their personal health records can be used to deny them health care benefits, and 68 percent feel they can be denied job opportunities based on these data.[56] Recent headlines about health data breaches bring health data privacy and security issues to the forefront of patients' minds. HHS' NCE report found that consumers are confused about which privacy, security, and right to data access requirements apply in various contexts, and they may think that HIPAA applies when it may not.[57] As a result, patients may use a HIPAA-covered app to track and record their data, which may be shared, sold, or used in ways not known to the patient.

Health, technology, and language literacy may influence patients' and caregivers' 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.[58]

Ensuring caregivers have access to the right data in a timely manner remains a challenge. For example, during a crisis, caregivers may need access to family health history, test results, and medication lists.[59] It is important that caregivers can quickly access these data and share them with the necessary parties. While helping to maintain patient health, caregivers must be able to regularly review PGHD and coordinate care within the context of their daily routines. Although laws and regulations address clinicians granting access to health data to caregivers, there is little discussion about patients granting access to their PGHD, which may or may not pass through a covered entity, to caregivers. Relatively few technologies are designed for the specific needs and capabilities of caregivers.[60]

Patients and Caregivers: Enabling Actions

A PGHD policy framework could suggest that patients and caregivers consider taking 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. To increase knowledge and awareness about the value of capturing, using, and sharing PGHD, a framework could encourage patients to play an increased role in care and research that uses PGHD. Patient collaboration with clinicians and researchers can determine if broadening the collection and sharing of PGHD will be valuable for patient health management. A framework could provide educational opportunities for patients to learn more about the value, limitations, and appropriate use of PGHD and whether capturing and sharing PGHD will improve their own care outcomes. These educational opportunities would ensure that patients understand the privacy and security of devices they choose.

Support active patient participation in testing the functionality and usability of devices and apps and in reporting feedback to device manufacturers and app developers. Patients can attest to the functionality and usability of the devices and apps in managing their health and helping to meet their health goals. A

framework could outline ways in which patients can provide feedback to device manufacturers about features they like and those that fall short of their needs, including accessibility features. Patients can participate in research focus groups and write 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, reduce health care costs, improve health data quality, and attract and retain patients.

The use of PGHD empowers clinicians to obtain insight into their patients' health in real-life settings and over time. Emerging consumer technologies provide clinicians with access to new types of data that historically have been difficult to collect, such as medication adherence or intolerance data, and with additional context when interpreting information. This helps clinicians and care teams gain a more holistic view of their patients' health and understand how contributing factors may influence health outcomes and quality of life. Using this information, clinicians can improve their interactions with their patients and work with patients to develop care plans that align with patients' health needs and goals, ultimately increasing patient engagement and adherence to care plans and improving care delivery. These care plans can include a prescription for the capture of specific types of PGHD for patients to share on a defined basis. Clinicians can use PGHD to track patients' progress with care 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 can help 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.[61] As a result, the care team does not have to capture this data during a patient encounter and can use their time more efficiently, potentially enabling them to see more patients in the same amount of time.[62] The pilot demonstration results indicated that the use of PGHD helped to prioritize, but not replace, human interaction. Through the use of PGHD, clinicians could quickly identify which patients needed specialized support or a quick check-in to see how they were feeling. 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.[63,64]

PGHD use may provide clinicians the opportunity to reduce health care costs. Monitoring patient data between clinical visits helps clinicians to intervene to prevent hospital visits or other costly care encounters. For example, in the TapCloud/AMITA Health Orthopedic surgery pilot demonstration, the readmission rate dropped from a baseline of 5.1 percent to 2 percent for TapCloud platform users. Similarly, 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 yields a savings of $8,375 per patient monitored.[65] Most savings come from a reduction in hospitalizations for heart failure or other reasons.

Finally, health care systems using consumer technologies can attract and retain patients based on their use of tools that may improve care and enhance patient engagement to meet patients' expectations. In a 2016 Salesforce survey, 62 percent of respondents indicated they would choose a clinician who uses their wearable device data over one who does not.[66] The pilot demonstrations found that patients notice clinician engagement and their use of PGHD, and that patients consider these factors when choosing health care organizations and clinicians. For example, one TapCloud/AMITA Health orthopedic surgery patient was pleasantly surprised when she received a personal note on her TapCloud app from a clinician who saw something concerning in the data. The patient was so impressed that she wrote back thanking "the kind nurse who is monitoring my progress." One Validic/Sutter Health pilot demonstration patient who participated in the Mpower program left his previous health care system because it did not offer the level of care and interaction the patient wanted. He noted Sutter Health's use of technology to guide decision-making and its personalized and engaging care influenced his decision to switch.

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 collected during a care encounter. The use of PGHD enables the patient to capture data before and after a care encounter, so the care team can review the data before, during, or between patient visits. Given the potentially large volumes of PGHD captured by apps and

Clinicians' Challenges

- 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

devices, care teams worry about the impact of PGHD use on their workflows.[67] Resources must be allocated to review the data and to make the system and tools more usable. 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.[68]

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 settings and may introduce inefficiencies to clinical workflows. Without guidance and best practices on how to receive, review, and retain large volumes of data, many clinicians hesitate to receive PGHD because they may receive more data than are clinically useful.[69] Patients and clinicians lack alignment on expectations around the use of PGHD for care delivery. Clinicians question 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.[70]

Many clinicians are concerned about the liability issues 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 these clinicians wondering how they will keep up with – and appropriately respond to

– important clinical issues that the data may present.[71] Some stakeholder groups note that the use of PGHD may present liability concerns if inaccurate PGHD are used in clinical decisions or if the clinician chooses not to act based on the PGHD received.[72] Standards of care for the use of PGHD are forming, leaving clinicians with little guidance on how to address concerns.

Despite the potential of consumer technologies to improve care delivery, the impact of these tools on health outcomes and costs are inconsistent across the few studies available. Although some studies demonstrate improved health outcomes and cost savings, others show less promising results. As the proliferation of consumer technologies continues and more research is conducted, a larger and more reliable body of research will emerge on the best practices for using PGHD.

Clinicians: Enabling Actions

A PGHD policy framework could suggest that clinicians consider taking the following enabling actions:

Support clinicians to work within and across organizations to incorporate prioritized PGHD use cases into their workflows. A framework could consider opportunities to help clinicians and care teams identify priority use cases and relevant PGHD types that would be valuable to improving care delivery for patient populations. It could encourage the development of standard practices for the use of PGHD, incorporating the use of PGHD into the clinicians' workflows, and promoting the use of data analysis tools. To deal with potentially large volumes of PGHD, a framework could assist care delivery systems in considering investments in data acquisition, storage, and analysis technologies and exploring solutions, such as employing data brokers, gateways, and aggregators, 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 heavy workloads or overwhelming them with extraneous data. The care team should share responsibilities among team members to manage the tasks of collecting, verifying the quality and provenance, and analyzing PGHD.[73] Some organizations have assigned specific members of the care team to review PGHD, determine where to store the data, notify clinicians of abnormal values, and respond to the patient. In the pilot demonstrations, establishing a workflow and "chain of command" helped to reduce organizational and clinician liability concerns by assigning accountability and responsibility through clearly defined procedures.

Foster collaboration between clinicians and developers to advance technologies supporting PGHD interpretation and use. A framework could encourage clinicians to request that developers of core clinical systems and technologies that capture, receive, and store PGHD offer certain functionalities. These functionalities should facilitate PGHD analysis in line with their workflows. They should offer views that highlight data of clinical importance. To accomplish this, a mechanism could be established for clinicians to communicate prioritized use cases with developers and provide feedback on features that support the secure capture, use, and sharing of PGHD.

The pilot demonstrations found this collaboration to be important for building tools and technologies that meet the users' needs. In the TapCloud/AMITA Health pilot demonstration, the implementation planning sessions let clinicians describe how PGHD could be most helpful to them. In the initial view, the clinicians wanted to see the data that mattered for clinical decision-making, and they wanted to be able to dig deeper quickly if they saw an issue. They preferred to view the PGHD graphically, rather than read lots of text. This input informed the design of a clinician-centric dashboard that fit into the clinical workflow. In the Validic/Sutter Health pilot demonstration, the dashboards evolved over time based on feedback and experience. Initial concepts were developed using ethnography and user-centered design methods to

identify user needs and preferences while considering tools and methods in place. Prototype dashboards for the various user groups of patients, clinicians, and care managers were developed and tested with these user groups. Refinements were made based on feedback that was actively sought.

Identify and communicate benefits, challenges, and best practices of PGHD use to help strengthen the evidence for its clinical and economic value. To increase the evidence base about the benefits, challenges, and best practices of PGHD use, a framework could encourage early adopters to share their successes and lessons learned through such channels as publications in peer-reviewed journals and presentations at industry conferences. Early-adopter organizations can 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 organizations to understand the value of and invest in the use of PGHD. A framework could 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 and chronic health conditions.

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

Support clinicians in providing patient education to encourage PGHD capture and use in ways that maximize data quality. A framework could support clinicians in educating patients and caregivers about capture, use, and sharing of PGHD, including the differences between solicited and unsolicited PGHD, how PGHD are relevant for the patient's care, and the benefits patients receive. Patient education should discuss the benefits for patients with chronic conditions, as well as for healthy patients, such as pre-visit questionnaires that may make the clinical encounter more effective and efficient. It should motivate patients to capture PGHD in a high-quality manner and share the PGHD in accordance with their care plans. Patient education should include a discussion about consent and data use in language that patients of all health literacy levels can understand.

Researchers

Opportunities

Using digital tools to collect PGHD, researchers may be able to gain wider and more direct access to potential study participants, enabling them to collect a larger quantity of data, and to improve their workflows. 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 would not need to rely as

Researchers' Opportunities

PGHD use can...
- Expand recruitment and enrollment in studies
- Increase study and clinical trial subject retention rates
- Offer new insights into patient and population health
- Simplify research workflow

heavily on relationships with clinicians or health care systems to identify potential study participants. Instead, they could provide recruitment information about their studies directly to a wider and potentially more diverse population of patients through online posts on social media sites and email listservs.[74]

Using research-oriented platforms, such as Apple Research Kit, a patient can sign up directly for studies of his or her choosing, offering new patient-recruitment channels. 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 2015 experiment at Stanford University, researchers using Stanford's MyHeartCounts app promoted through social media, and recruited about 10,000 participants globally within the first 24 hours.[75] Traditional methods for recruiting study volunteers would have taken more than a year to enroll this number of participants.[76]

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 retention rates.[77] Patient withdrawal rates are as high as 30 percent in some studies.[78] While many factors contribute to patient dropout, a contributing factor is the inconvenient location of study sites.[79] Some mobile health devices include prompts and feedback for the patient that encourage continued participation.[80]

Some websites and online platforms encourage patients to donate data broadly for research so researchers can download large datasets of PGHD for analysis. PatientsLikeMe is a platform using PGHD to improve the way patients manage their conditions and help researchers obtain research data sources. 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* Research Program, which is part of the Precision Medicine Initiative (PMI), is collecting data that can include PGHD to develop more precise treatments and therapies for a number of health conditions.[81] The program 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."[82] In support of the PMI, NIH and ONC are leading the Sync for Science pilot program, which is developing and testing the technology to enable patients to share data from their clinicians' EHRs with researchers.[83] Using 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 enables researchers to gain deeper insights into patient health through increased volume and frequency of patient data capture. In the past, researchers often were limited to the data they collected at the study site at regular intervals or 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 they can transmit data directly and electronically to clinicians and researchers.

At the population level, researchers can analyze large volumes of PGHD to monitor adverse events and predict and track the spread of infectious diseases.[84,85] Using artificial intelligence and other analytical tools, researchers can analyze free-text, unstructured PGHD and supplement them with claims data and other health-related data. Through this process, researchers can identify and confirm relationships between a drug and its associated side effects and adverse events. By combining PGHD with other data, researchers can predict influenza outbreaks earlier and with greater accuracy than traditional prediction methods.[86]

The use of PGHD technologies to capture and transmit data electronically helps to simplify the research workflow. Instead of manually entered patient data, data can flow electronically into a research

database. Tools capable of cleaning the data can 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 empower patients to collect PGHD and participate remotely in research studies and trials, researchers may encounter difficulties confirming the eligibility of remote participants. Without in-person enrollment, verifying a patient is eligible to participate in a study can be difficult because patients may alter their information to meet a study's eligibility criteria.[87]

Researchers' Challenges

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

In 2015, HHS announced proposed revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule) that detail protections for individuals who participate in most health research.[88] 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 final. One proposed change for researchers is the strengthening of informed consent processes to ensure that participants understand the study's scope, including its risks and benefits. For example, in the Validic/Sutter Health pilot demonstration, patients were generally willing to provide PGHD, but they were unfamiliar with programs that made use of these data. Therefore, they required explanation and reassurance about the program's structure and benefits before agreeing to participate. Patients may be uncertain of the commitment required or impact of participating in a research study. Through new data donation opportunities using PGHD, such as mobile apps, patients can consent in new ways that may be unfamiliar to them and challenging for researchers to manage. Under proposed consent mechanisms, patients may broadly consent to participate in research on their health conditions, or they may consent to share only certain types of data with specific organizations.[89]

Though not unique to PGHD, conducting responsible research requires researchers to consider all aspects of data management, including collection and storage. With respect to collection, 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 restricts the potential benefits to patients. Even when researchers establish an exchange of PGHD with clinicians, the data patients collect for their health care may not meet more stringent data requirements for research. Similarly, when researchers receive PGHD directly from patients, they need to ensure that the PGHD are collected in a high-quality manner and are valid and reliable. Given the variety and the potentially large volumes of PGHD from devices and apps, traditional data storage methods may not offer the technical capacity or capabilities to store PGHD in a way that facilitates sophisticated analytics.

 Researchers: Enabling Actions

A PGHD policy framework could suggest that researchers consider taking the following enabling actions:

Call for increased funding for studies that investigate the benefits, challenges, and best practices for using PGHD in care delivery and research. A framework could encourage organizations that fund or conduct research to consider increasing funding to incorporate the capture, use, and sharing of PGHD into research. It could increase the development of applications to support these practices. This process requires researchers to seek to understand the effectiveness of the use of PGHD in improving trial participation, reducing costs, and expediting the completion of research. A framework could prompt universities and research institutes to consider requesting funding to conduct studies on the use of PGHD in study protocols and the effectiveness of the use of PGHD in improving health outcomes, engaging patients, and lowering costs. A policy framework could push for funding educational programs on the use of PGHD in research for individuals entering 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 the development of 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, A framework could advise researchers to incorporate PGHD into their study designs. A framework could define different types of PGHD and help researchers determine which types of data, and from which sources, can be used in care delivery to improve health outcomes. It could 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 help to establish the business case for capturing and using PGHD in care delivery and research. Researchers could be encouraged to include an evaluation of patient willingness to donate PGHD so barriers to wider use are more broadly understood and addressed.

Expand methods for data donation to research studies. A framework could support researchers to continue exploring possible PGHD sources and methods of data donation for their research. It could call for increased patient awareness of digital health tools that capture PGHD and data donation platforms, such as Apple's ResearchKit and the Sync for Science pilot program.[90]

Strengthen patients' understanding of consent and data use. To protect patient security and privacy, a framework could address the importance of researchers using the data for the purposes that the data donor intended when patients provided the PGHD. A framework could encourage researchers to validate that participants understand the study protocol, including how their data are used and any participation risks and benefits.[91] Researchers could strive to demonstrate the value of PGHD collection and use and to provide study results to patients. To further encourage individuals to participate, researchers can use multimedia tools to explain consent to patients with different levels of health literacy.

Opportunities, Challenges, and Enabling Actions for Other Stakeholder Groups

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 play supporting roles, and their actions can 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 can encourage the use of PGHD in clinical care and research, for example, by ensuring consistent privacy and security measures, encouraging innovative uses of PGHD, and offering guidance and best practices.

Policymakers can reduce privacy and security concerns for patients, clinicians, and researchers by identifying and publishing relevant guidance and best practices for PGHD use. In its NCE report, HHS provides an overview of the federal legal landscape of health information privacy and security and analyzes areas where HIPAA's privacy and security protections differ from those of non-covered entities, including individuals' rights to access their data and reuse of the data by third parties.[92] For example, PGHD kept 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.[93] In some cases, states may also impose laws and regulations to further protect patients and their data.[94] Policymakers can encourage innovative uses of PGHD through regulatory measures, payment models, 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.[95] Federal government initiatives can encourage the use of PGHD for research, like in the NIH *All of Us* Research Program.

Finally, policymakers can work with clinical and research organizations as they select technologies for using PGHD. In an example from the pilot demonstrations, AMITA Health conducted an extensive selection process before ultimately choosing to use the TapCloud application. Administrators from AMITA Health and Sutter Health noted that more guidance and information about best practices for device selection would have been helpful. There are many app and device options to choose from but a limited body of knowledge about best practices for selecting a technology, including possible criteria to consider.

A conversation with Sutter Health administrators highlighted the need for an established standard of care for PGHD use. While these norms are being established, guidance documents that define and suggest best practices would help clinicians and health care organizations as they capture, use, and share 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 can collaborate on areas of overlap in guidance affecting the capture, use, and sharing of PGHD to add clarity for stakeholder groups and to support effective regulations that protect patients and their data. A result of existing coordination between several agencies can be seen in 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.[96] In its guidance, the FDA instructs readers to refer to the Centers for Disease Control and Prevention (CDC) and the Department of Homeland Security's (DHS) websites for additional information and procedures.

The fast pace at which technology evolves can be an important consideration in the development of regulations designed to encourage innovation and to remain relevant as technology changes. By the time regulations are ready to be introduced, more innovative technologies may 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.[97] 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.[98,99]

Policymakers: Enabling Actions

A PGHD policy framework could suggest that policymakers consider taking the following enabling actions:

Prompt collaboration with stakeholder groups 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, a framework could prompt policymakers to engage with stakeholder groups to create consensus on policies and practices. Guidance for the health care industry 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* and the Future of Privacy Forum's *Best Practices for Consumer Wearables and Wellness Apps and Devices Guide,* along with the work of federal agencies.[100,101] 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 and the legislative domain. This approach could encourage innovation while also ensuring that PGHD are captured, used, and shared safely and securely. A framework could promote policymaker coordination with industry leaders to develop consumer education materials for various stakeholder groups. This can help to raise awareness of the benefits and concerns about PGHD use, including consent, and close the gap in health and technology literacy.

Call for increased funding for programs that aim to understand the outcomes of PGHD use as part of 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 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 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 and pilots to develop and test solutions that expand upon current infrastructure, such as data privacy best practices for mobile health technologies, and testing the application of technologies, such as application programming interfaces (APIs), to support more secure and seamless exchange of PGHD.

Encourage 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, a framework could 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.[102]

Technology Stakeholders: Developers and Standards Bodies

Opportunities

Developers can 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 and comparing PGHD from disparate sources. To bring 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 convened a workgroup aimed at defining performance standards for wearable activity trackers[103] and earlier developed the *Guiding Principles on the Privacy and Security of Personal Wellness Data*.[104] 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 consistent computable methods to support sharing of PGHD between devices and their various users. 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) are responsible for convening 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 HL7® Fast Healthcare Interoperability Resource (FHIR®) standard for exchanging health care information electronically and its

use help 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.[105] Continua develops standards to enable end-to-end interoperability of personal connected health devices and systems for health management and health care delivery. It is working on establishing design guidelines and certification criteria to support interoperable devices across the fitness, chronic disease management, and aging market categories.[106] These emerging standards enable PGHD to flow between devices and systems.

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 enable 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 encourage developers to collaborate with health care systems and researchers to use their specific devices in care delivery and research protocols.[107] 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 process for developing these device and interoperability standards takes time and involves convening workgroups and 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, often are 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. Standards and specifications for newer technologies used to collect PGHD are maturing and have not achieved full adoption.

Similarly, the FDA device approval process requires time and resources before apps and devices can go to market. Regulatory bodies must carefully consider how to balance the priorities of patient safety and medical innovation. The FDA as recently as July 2017 took steps to review, modify, and improve its approval processes through programs such as the Pre-Cert for Software Pilot Program and Digital Health Innovation Action Plan.[108] These initiatives strive to encourage innovation and speed the pace of development for technology stakeholder group members.

Technology Stakeholders: Enabling Actions

A PGHD policy framework could suggest that the developers and standards bodies consider taking the following enabling actions:

Suggest developers improve usability and accessibility of 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 patient abandonment of general wellness devices and varying levels of accessibility and technology literacy among these users, including those with cognitive and physical impairments, a framework could recommend that developers focus on improving usability and accessibility and implementing user-centered design principles. These principles can be applied to patient-facing technologies and to those the clinicians and researchers use. For example, in the Validic/Sutter Health pilot demonstration, the dashboards evolved over time based on feedback and experience. The initial concepts were developed

using ethnography and user-centered design methods to identify user needs and preferences while considering tools and methods in place that are valuable. Prototype dashboards for the various user groups of patients, clinicians, and care managers were developed and tested with these user groups. Refinements were made based on user feedback.

A framework could 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, a framework could encourage developers to come together to establish an industry-led voluntary certification and testing mechanism for digital health devices and apps that capture PGHD. These resources should align with and build upon certification measures that are in place.

Consistently adopt strong privacy and security practices for PGHD capture, use, and sharing and support transparency with consumers about these policies.

A framework could 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*[109], and federal guidance, such as the NCE report[110] and ONC's *Model Privacy Notice*.[111] The 21st Century Cures Act , signed into law in December 2016, also requires new guidance to clarify and strengthen privacy and security protections for patient health data.[112] Technology stakeholders could align their work with this guidance.

A framework could prompt developers to evaluate and incorporate technologies as necessary to secure PGHD. 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 his or her data. The privacy policy should specifically include information about 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 and websites. 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.

Challenge standards bodies to address the needs of the health care ecosystem for PGHD use and increase the pace of standards development for capturing and integrating PGHD. A framework could 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. SDOs could work with various technology stakeholders to develop standards and an interoperability framework that support these 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. A framework could encourage the health IT industry to consider formulating an industry certification resource for digital health devices to verify that they are capable of standards-based communication, including semantic interoperability, with a health care system or research institution.

Payers and Employers

Opportunities

Private and public payers 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. This approach aligns incentives between clinicians and patients and promotes shared decision-making.

Payers can motivate interoperability and data sharing by reimbursing clinicians for using PGHD and other data during patients' transitions of care. To increase access to consumer technologies for all patients, payers can provide their members with devices. Payers can cover part of the cost of 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. Payers can provide their members with consumer-facing apps to collect treatment goals, preferences, and priorities. Where appropriate, payers can use reimbursement policies to align clinicians' objectives to these treatment goals, preferences, and priorities during the clinical decision-making process.

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.[113] Employers can benefit from these programs because their employees may achieve better health outcomes from monitoring their data and engaging in healthier behaviors. Employees may miss fewer workdays for illness and incur lower health care costs. By offering these devices and monitoring programs to employees, employers may also receive discounts and reductions in the cost of offering insurance to their employees from insurance companies.[114]

Challenges

Although 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. Patients express concern that their health data may be used to discriminate against them by payers and employers.[115] One lawsuit argues that these programs, in their essence, are obligatory because it can be costly to not participate and forego the associated discounts.[116] 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 a clinician receives them. 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

A PGHD policy framework could suggest that payers and employers consider taking the following enabling actions:

Urge payers to continue to motivate clinicians to use PGHD as part of clinical care through supportive policies in reimbursement programs. A framework could urge payers to alter their reimbursement programs to compensate clinicians for improving health outcomes from insights drawn from 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. A framework could 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. A framework could provide guidance to payers on how to overcome and eliminate the potential for discrimination based on PGHD.[117]

Advise payers and employers to continue to incorporate feedback mechanisms and incentives into 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 encourages patients to view their data and compare them to healthy levels and to other patients' data. These portals and mobile apps may provide coaching, action plans, and gamification to patients to encourage them to engage in healthier behaviors. Some patients may respond better to reward 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 more pervasive, offering more opportunities for patients to capture, use, and share their PGHD in support of health care delivery and research. The capture of PGHD alone is not sufficient to cause change within the health IT ecosystem. Joint action from across the ecosystem is necessary to overcome cultural, technical, and regulatory barriers. However, through collaboration, these barriers can be addressed, resulting in improved insights for clinicians and researchers and improved care for patients.

This bold future vision starts by demonstrating the value of PGHD use and ensuring there are viable business cases 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 could prioritize those areas and develop an approach to integrate PGHD into the clinical workflows and research designs where it is most valuable. Payers could expand reimbursement models to cover use of PGHD to drive positive health outcomes and add value to patient care. Researchers could be encouraged to publish reports on their experience with and the impact of the use of PGHD in their studies and on how identified challenges to wider adoption have been overcome.

As the business case for PGHD use continues to be determined and its value to care advancement continues to be documented, health care systems and research institutions could 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 would better understand the opportunities and work in partnership with the health IT ecosystem 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 support PGHD use by patients and how to make it digitally sharable with clinicians and researchers and interoperable across the diverse health ecosystem in a way that is beneficial to and respects the privacy requirements of all stakeholder groups.

Policymakers could strengthen coordination with industry leaders to create a consensus on policies and practices that address newer consumer technologies and support the private and secure capture, use,

and sharing of PGHD. Federal government agencies could 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 developed in coordination with patients, clinicians, and researchers will help all stakeholder groups, including the broader patient community, understand the impact of PGHD use and where it can best enhance care delivery and research. Through collaboration among stakeholder groups, increased capture, use, and sharing of PGHD as part of a learning health system can become a reality.

Appendix A: Pilot Demonstrations Summaries

Validic/Sutter Health

Introduction

The Validic/Sutter Health pilot demonstration was a six-month project to evaluate key research questions related to the capture, use, and sharing of PGHD in clinical care delivery and research models. With a focus on the flow of data from the patient to the clinician to the researcher, this project made extensive use of existing methodologies, workflows, and technologies created by the partners and adapted for use in diabetes treatment. An important goal of this pilot was to provide patients and clinicians with actionable intelligence that enabled care teams to recommend and take specific actions and motivate patients to sustain behavior changes for improved outcomes.

To achieve this objective, the remotely collected data needed to fit within existing clinician workflows and processes. This would create better operational efficiencies for organizational care coordination and population management initiatives. The remote monitoring approach enabled care teams to manage groups of patients remotely instead of one-to-one and in-person.

This pilot demonstration was designed to illustrate technical infrastructure and care delivery models that can achieve better care coordination and population management and illustrate the challenges and barriers that exist within current systems and processes. Through the deployment of advanced clinical workflows leveraging PGHD, the pilot demonstration results informed necessary innovations and improvements needed for clinical care delivery and research models.

Partnership

Validic provides a data connectivity platform connecting clinicians, pharmaceutical companies, payers, wellness companies, and health IT developers to health data gathered from hundreds of in-home clinical devices, wearables, and consumer health care applications. The cloud-based solution offers a one-to-many application-programming interface (API) connection to access consumer and clinical health data. The solution is intended to deliver standardized and actionable insights to drive better health outcomes. The Validic platform provides secure access to PGHD collected from nearly 400 models of personal health devices and apps. Validic accesses data available through public and private API connections, Bluetooth connections, health data aggregators, such as Samsung S Health and Apple HealthKit, and a patent-pending technology, VitalSnap, which digitizes data via optical character recognition (OCR).

From clinician offices to hospitals to outpatient care centers and home services, not-for-profit Sutter Health supports more than 3 million people in their care—nearly 1 percent of the U.S. population—in Northern California. Sutter Health teams adopt new technologies, make novel discoveries, and embrace creative thinking to help patients and communities achieve their best health.

Sutter Health's Palo Alto Medical Foundation and Validic have worked collaboratively since 2013 on the development and use of Validic's data services interfaced with Sutter's Mpower™ personal healthcare platform that connects patients with care-teams and provides a shared view of progress against clinical goals.

The Office of the National Coordinator for Health Information Technology

Technology and Infrastructure

In this pilot demonstration, creating a technical infrastructure for PGHD required integrating Validic's data connectivity solutions with Sutter Health's Mpower program and technology. The following tools and technologies were employed in the pilot demonstration:
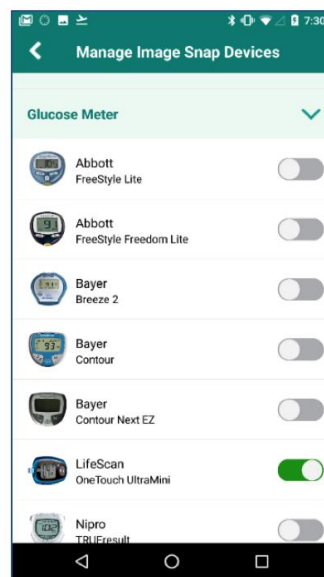
- Validic data connectivity platform for device ecosystem and data management integrated with Mpower platform
- Selected glucometers provided by the patients known to provide reliable uploads to Validic
- Mpower mobile app that includes direct data upload capabilities via Validic's VitalSnap and Bluetooth technologies, as well as visualization of progress against the care plan goals set by the patient's personal physician
- Epic Clinical Record with integrated Mpower clinician dashboard
- Epic Personal Health Record (MyChart) with integrated Mpower patient dashboard

The integration of these technologies enabled the capturing of PGHD from patients' personal health devices, the standardization and aggregation of the collected PGHD, and the delivery of PGHD in a single stream into the Mpower system and Epic EHR. As is now common in large systems, Mpower achieves integration with other key health information sources and systems (e.g., Epic, Validic, mobile app) through web services that enable a bidirectional flow of data to and from the central Mpower system. This data exchange includes pulling and pushing data from the various device manufacturers cloud services to Validic's centralized repository of organized, normalized PGHD, and from this repository to end-user systems, such as Sutter Health's Mpower system.
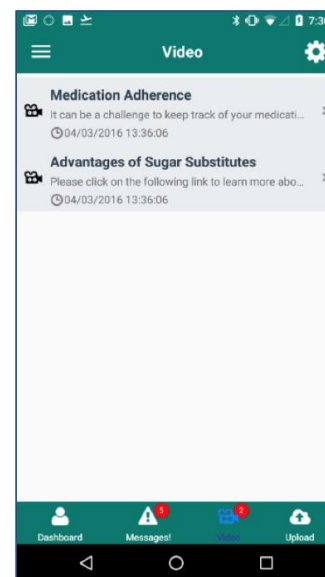
Validic's data connectivity platform serves as a proprietary standardization process built for scale, customization, and behind-the-scenes integration into most systems. Some common standards Validic uses include JavaScript Object Notation (JSON), a universally-recognized data standard that provides a set format for the transfer of data objects; the metric system for units of measurement; and, the ISO-8601 standard for timestamps, an international standard for times and dates. The standardized data then are available to Validic clients via the Validic API.
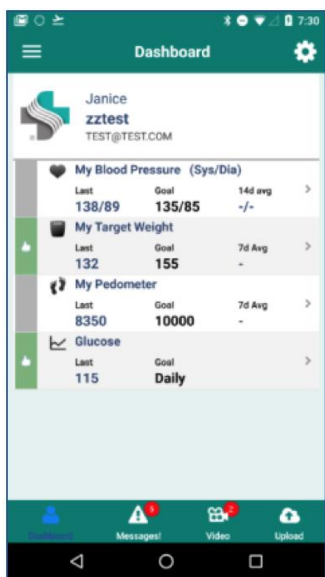
| View goals and performance | Upload data | Receive nudges and nuggets |

Mpower is a Sutter Health-developed system for personalized care that targets large-scale populations and supports health maintenance and disease management. It includes a patient-facing app to provide real-time data directly to patients and reports direct knowledge of the ongoing health status of each member of the population to the care team. The approach is based on 10 years of development and includes patented methodologies for personalization (US patent 7,493,299).

The patient-facing app delivers personalized programs of care reflecting each individual's situation, clinical need, and preferences. By continually tracking patient status and pushing personalized, context-relevant motivational "nuggets" of information (e.g., "Well done! You have maintained your blood glucose within your personal goal for last week. Keep at it!"), patients are engaged in their health and welfare, which drives sustained improvement in outcomes.

For clinicians, the data were displayed in a dashboard enabling a care team to see a continuously updated, risk-stratified view of the population they manage. The visualization helped evaluate patient health trends and identify patients who needed direct communication, further education, and modified interventions. Visually displaying the panel of patients for whom a clinician was responsible in a manner that integrated and displayed several parameters that assess patient progress and performance was important for clinicians. It provided clinicians with an efficient way to identify individuals who needed attention. This process assisted the clinical team in being efficient in their day-to-day patient management. The dashboard enabled direct access to "drill-down" to increasingly detailed layers of performance data for an individual patient, which was of value to physicians during patient encounters.
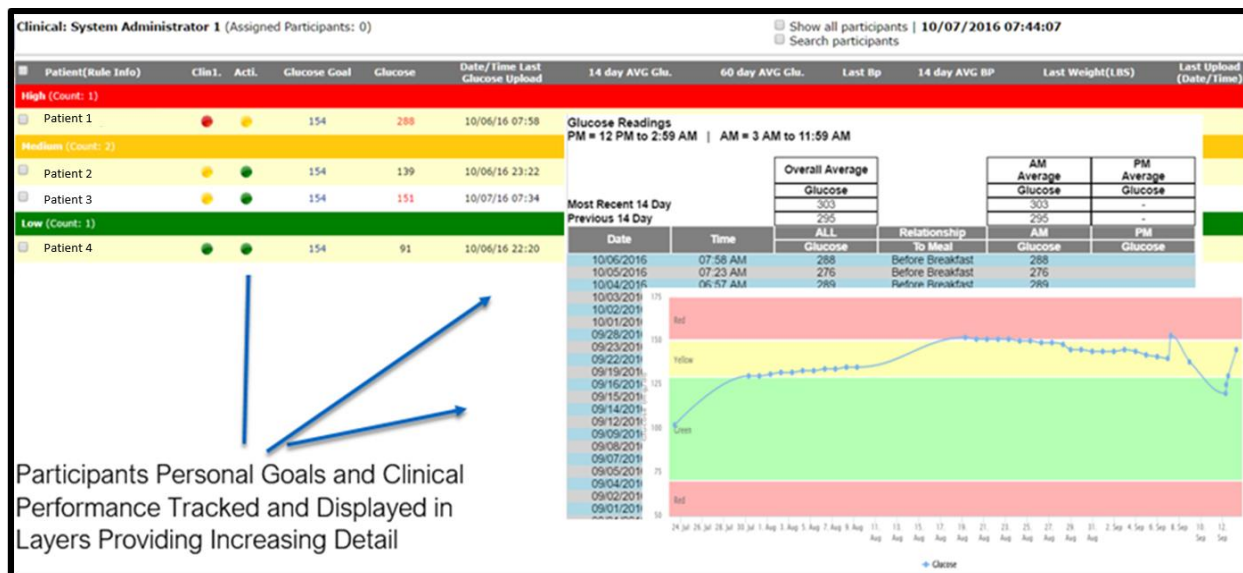

Methodology

The four-phased pilot demonstration used care teams. These teams were responsible for recruitment, enrollment, and management of patients with Type II diabetes and for receiving care delivered to standard protocols for management of patients with diabetes in Sutter Health's ambulatory setting. Phase I's goal (Alpha Testing that was six weeks in length) was to test the Mpower model with ten patients and conclude with rapid ethnography research, which involved observing patients and care team members using the Mpower model in their everyday lives. Phase II (Refine Program, six weeks long) required the recruitment of an additional 15 to 20 patients to the program and used compiled research and documented process/technical challenges to refine the program. Phase III (Conduct Pilot, lasting three months with 29 patients) was a full-scale launch of the program and ethnography research.

The concluding Phase IV (Analyze & Report) focused on analyzing the acquired data and results from the study.

The pilot was conducted using rapid-cycle development. Each phase had defined objectives, goals, and measurements used by the Validic/Sutter Health team to make regular assessments of progress with technology and processes. Using this approach, Mpower program managers made modifications of
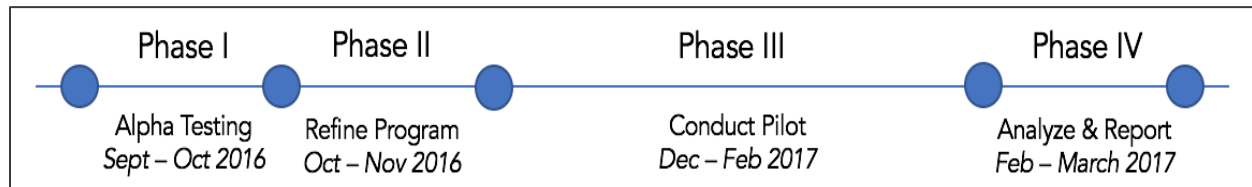
intervention methods and tools based on lessons learned from the previous phases.

For Phase I, the goal of the single pilot demonstration site was to recruit and enroll five to ten patients based on the criteria above. The objective was to test the capabilities of Mpower model applied to the management of a diabetic population and identify any issues. Validic/Sutter Health completed Phase I of the pilot demonstration on time. Sutter Health recruited and commenced this phase with five patients as intended; however, one patient terminated involvement as he changed employers and lost the use of a smartphone on which participation was dependent. The remaining four patients completed Phase I through its entirety, and the phase achieved its defined objectives.

For Phase II, key issues identified in Phase I were addressed, and the model was holistically assessed. This process involved refining the recruitment and enrollment processes; fixing bugs; identifying new data needed; and implementing technical updates and product requirements and improvements to workflows, system functionality, data attributes, data management, and data visualization.

Phase III involved two pilot demonstration sites. The goal was to recruit and enroll an additional 20 to 25 patients, including the Phase I patients who indicated interest in continuing to be managed through the Mpower project, with the aim of having at least 20 patients under active management at the end of this phase. This objective was achieved with 29 patients active at the end of the pilot demonstration. To recruit these patients, more than 200 patients from the clinics, identified by the care team as suitable for participation, were contacted by secure messaging through Sutter Health's patient portal "MyHealth Online," and invited to participate. Five patients from the Phase I pilot demonstration and 24 new patients from Phase III were enrolled.

Selected patients followed a standardized recruitment workflow. Patients meeting the agreed-upon criteria were selected by primary care physicians (PCPs) and referred to Mpower using an automated referral workflow already created in the Epic EHR system. The cohort included patients diagnosed with Type II, non-insulin-dependent diabetes between 21 and 79 years of age whose care is being managed in the primary care setting. To give insight to the applicability of this model to more complex patients, several patients with Type II diabetes managed with insulin were included later in the pilot demonstration.

After enrollment to the Mpower program, patients were provided with technical support for the installation of the Mpower app on their smartphones and the connection of selected devices to the app. These devices included a blood glucose meter for all participants, with options to connect a blood pressure monitor, activity tracker, and weight scale.

The patient and care team followed a standardized care management workflow. Seven days after the program's installation, the case manager reviewed the patient's situation and assigned the patient to a care manager who was a practice-based registered nurse (RN) or nurse practitioner (NP), who collaborated with other care team members to manage the triage of patients from all patient program recruitment workflows. The care manager was responsible for ensuring patients entered the onboarding process and moved to their initial clinic visit in a timely manner. The RN or NP was responsible for ensuring information on patient progress was available at practice huddles and at the time of review visits.

To better understand barriers to engagement in a personalized plan of care, baseline surveys were an integral part of the workflow and illustrated use of PGHD not collected via devices. Sutter Health conducted ethnographic research to help understand barriers to the use of PGHD as well as success factors. The research method involved observing patients and care team members using the Mpower model in their daily lives to elicit input and was aimed at identifying a broad spectrum of barriers to and opportunities for the productive use of PGHD.

Workflow
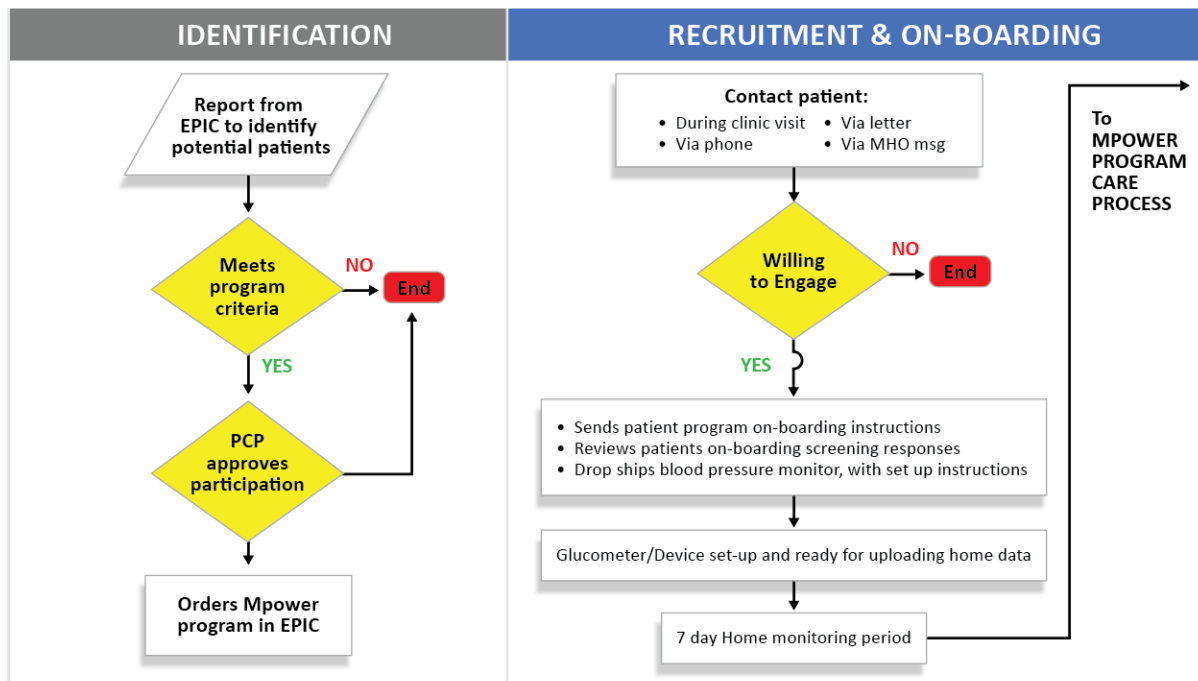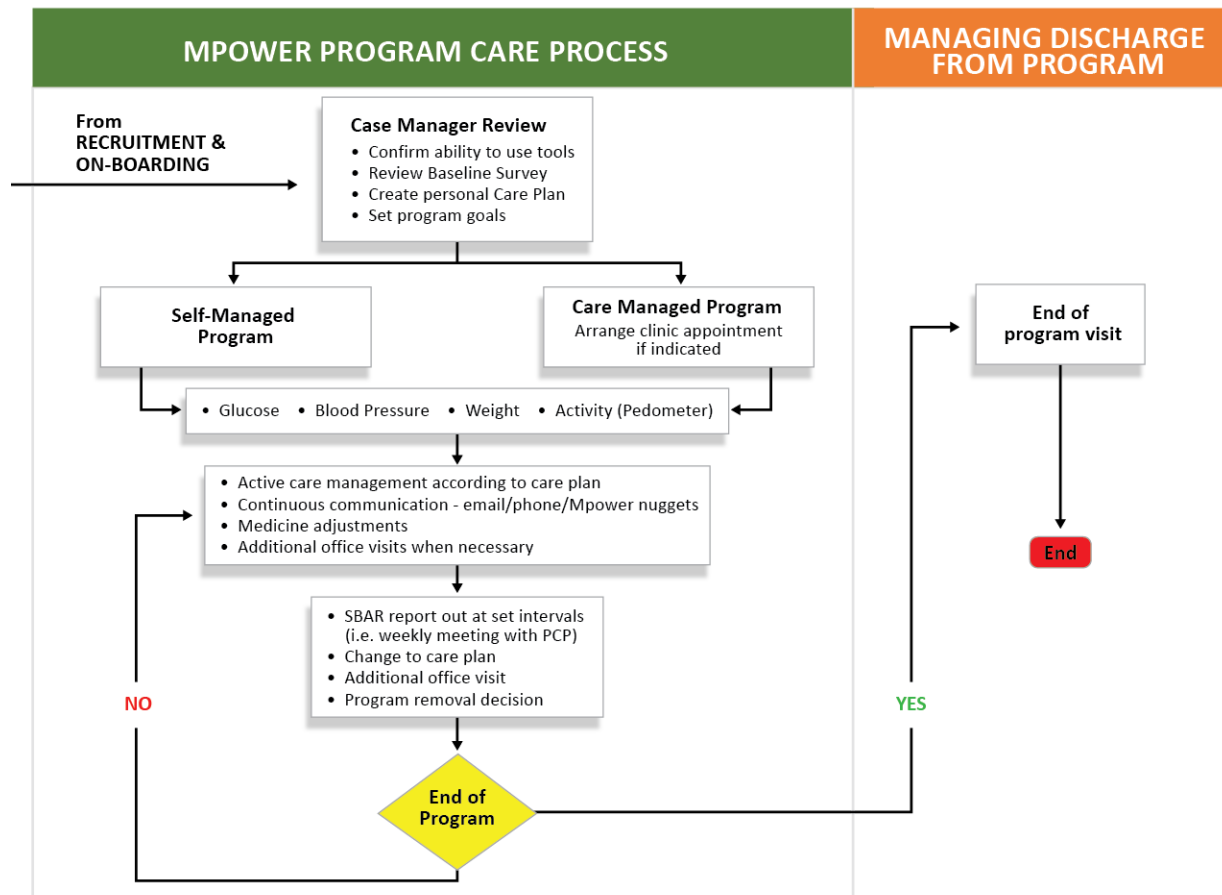
TapCloud/AMITA Health

Introduction

The TapCloud/AMITA Health pilot demonstration strived to prove how a single technology platform effectively enables the use of PGHD for a variety of medical conditions, clinical settings, clinician roles, and patient populations. Activities of the pilot demonstration included recruiting patients and then capturing, using, and sharing PGHD to provide better patient health outcomes. To assess whether a single technology can enable PGHD across diverse medical conditions and populations, the pilot demonstration spanned multiple clinical use cases, namely orthopedic surgery, behavioral health, bariatric, and stroke. TapCloud/AMITA Health selected the service line or area of care in the organization that met the preferred criteria below:

- Patient population that is typically willing to communicate with clinicians via the app on a smartphone, tablet, or computer
- Area impacted by changes driving PGHD usage: bundled payments, high-cost procedures, and new mandated standards
- Area conducts complex surgical procedures with multiple clinicians across departments
- Opportunity to improve patient health outcomes
- Clinicians invested in streamlining patient communication and management with new technology
- Opportunity to identify potential patient care concerns early and target appropriate intervention

Partnership

TapCloud is a health care technology company focused on helping patients and their clinicians communicate crucial information to achieve better health outcomes, reduce readmissions, manage utilization, and improve patient satisfaction. TapCloud's proprietary platform combines cutting-edge mobile technology and personalized services to help patients and their doctors manage chronic conditions, assess treatment and medication effectiveness, and improve at-home recovery after an invasive surgery. The platform spans more than 100 different health conditions and delves into numerous aspects of PGHD use. TapCloud makes PGHD available, accessible, and actionable using a platform that enables patient engagement and clinician use while supporting data analysis and data privacy.

AMITA Health is an integrated health care system serving communities in western and northwestern suburban Chicago. AMITA Health is a joint operating company formed in February 2015 by Adventist Midwest Health, based in Hinsdale, Ill., and Alexian Brothers Health System, based in Arlington Heights, Ill. The company encompasses nine hospitals and an extensive physician network of more than 3,000 physicians. AMITA Health's Center for Innovation, which is responsible for finding innovative solutions that improve the patient experience, collaborated with TapCloud because of its ability to communicate quickly and easily with patients with a simple, user-friendly app. AMITA Health's priorities include connecting patients and clinicians, collecting PGHD to use to respond to patient concerns and symptoms quickly, and enhancing care.

Technology and Infrastructure

In this pilot demonstration, the technical infrastructure consisted of the following tools and technologies:

- TapCloud data platform and application
    - Patient-facing module for collection of PGHD
    - Care team facing module for analyzing PGHD
- Smartphones, tablets, computer
- AMITA Health's EHR system (Meditech, Cerner)
- Patients may have used devices to collect additional PGHD, however, this was not a focus of this pilot demonstration

The TapCloud platform conveyed health information between patients and clinicians. Patients used a smart device, tablet, or home computer to do the following:

- Collect and track their PGHD, including data about their well-being, pain, symptoms, and medication or treatment adherence
- Provide photos (e.g., of incision site) and PGHD from connected devices
- Receive personalized care plans and medication reminders, and tracked adherence to those plans and medications
- Communicate with clinicians

Care Plan   Well-being   Symptom Cloud

Patients opened the TapCloud app and viewed their care plan for the day, which was their "to-do" list, checking off items as they completed them. They recorded how they were feeling that day compared to how they felt the prior day, their pain level (if any) using the Wong-Baker® pain scale, medications taken, and symptoms they were experiencing. The symptoms are displayed in a word cloud, which is created using algorithms based on medical conditions, care trajectories (the typical progression of symptoms during treatment – i.e., from sharp pain to some redness to minor aches), recent symptoms, and medication side effects.

For clinicians, TapCloud provided a patient population alert system, symptom tracking, care coordination, and patient communication vehicle. Using a dashboard view, TapCloud helped prioritize patients and identify those needing care team engagement. The dashboard view of each individual patient displays detailed PGHD that enables a clinician to rapidly understand what is happening with the patient, when it happened, and how long it continued. The dashboard converts a large set of data points into a simple visualization for clinicians. For example, TapCloud creates a "split-screen" visualization anytime a new medication is added to a patient's profile. This allows a clinician to visualize whether the medication is producing the intended results and to identify any side effects that are related to the medication.
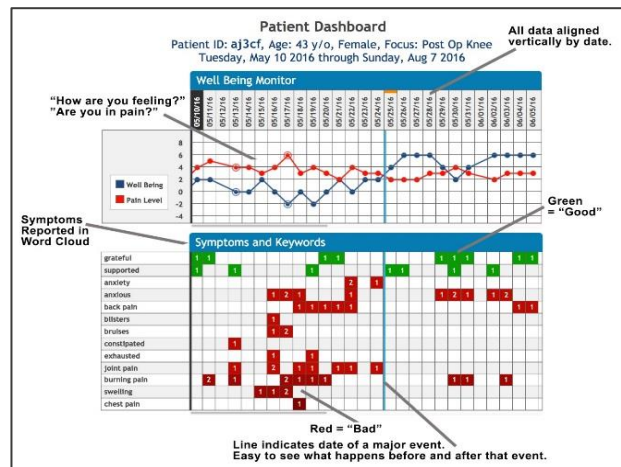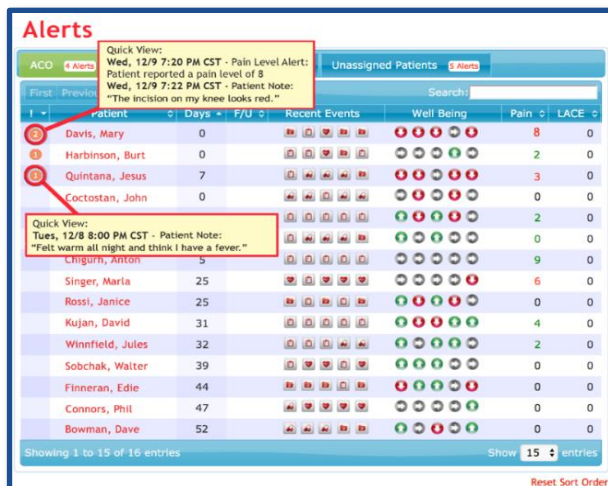
Methodology

Although the TapCloud/AMITA Health pilot demonstration launched in September 2016 and ran through March 2017 (seven months), AMITA Health used the TapCloud platform for patient care for more than a year. TapCloud was implemented with the Orthopedic Surgery service line at AMITA Health in January 2016 and the Behavioral Medicine service line in June 2016. Data collected before the pilot demonstration launch in September 2016 are included to provide a more robust analysis. Through the initial pilot demonstration, the platform was expanded across other medical conditions to include the Bariatric Surgery and Stroke service lines.

| Ortho Surgery Jan 2016 Hip/Knee Replacement | Behavioral Jun 2016 Depression, Anxiety | Bariatric Jan 2017 Bariatric Surgery | Stroke Feb 2017 Post Stroke Rehab |

The TapCloud/AMITA Health pilot demonstration methodically delved into the full life cycle of PGHD collection, use, and sharing – from the initial patient recruitment through data collection, data transfer, data analysis, and ultimately clinical data usage. The TapCloud/AMITA Health pilot demonstration methodology is described below.

Recruit
Patients recruited by care team. Benefits explained. Secure credential provided. Assistance provided to download app.

Use
Care teams monitor alerts, acting on all which require follow up. Individual care team members use specific patient data to enhance patient appointments.

Collect
Patients get care plans on their device, indicate activity completion, and provide daily info on well being, pain, symptoms, prescriptions.

Analyze
Care teams use the dashboard to manage total population. For patients with concerning issues, clinicians drill down for detailed info.

Share/Transfer
Data uploaded through cloud system. Then converted to visualizations for specific clinical uses. Data transfer is real-time and 24/7.

Workflow

RECRUIT	COLLECT	SHARE

Sources of Potential Patients
- Surgery Schedule
- Pre-Op Classes
- Appointments

↓

Clinician Recommends TapCloud Use

↓

Patient Decides to Use. — NO → **End**

↓ YES

Patient Starts Use
- Download App
- Receive Instructions
- Login

Clinician Prepares Patient Care Plan

↓

Patient gets Care Plan and Reminders

↓

Patient Usage
- Complete Activities
- Complete daily Check-In

↓

Treatment Period Complete — YES → **End**

↓ NO

Continue Usage

Patient Data Uploaded
- Real-Time
- 24/7
- Backed Up

↓

Data Converted
- Raw Data Converted into Clinician Terminology

↓

Data Population
- Data Populates Various Clinician Facing Tools

↓

Data Visualization
- Data Displayed in Easy "at-a-glance" Format
- Color Coding, Prioritization, and Hover Capabilities Added

↓

To Analyze

ANALYZE	USE

From COLLECT PATIENT USAGE →

Patient Panel
- Dashboard
- Alerts
- Triage

↓

Patient Drill Down
- Detailed Information for 1+ Years
- Activities, Medications, Symptoms, Photos
- Notes and Texts
- Critical Dates

↓

Management Reports
- Patient Usage
- Clinician Usage
- Demographics, Symptoms

Clinician Monitors Patients

↓

ACTION REQUIRED? — NO →

↓ YES

Clinician Action
- Contact Patient
- Change Care Plans / Medications
- Referral
- Respond to Patient Communications
- Use in Clinical Setting

Appendix B: 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 clinician. http://apps.who.int/medicinedocs/en/d/Js4883e/8.9.1.html

Advance Directive
Legal documents or a living will in which one specifies end-of-life care and medical treatment decisions ahead of time. It is used as a mechanism for one to communicate wishes to family, friends, and health care professionals at the end of life. https://medlineplus.gov/advancedirectives.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 App Store
A software-based online digital media store operated by Apple Inc. that enables users to download music, videos, and iOS applications (apps) for iPhone and iPad. https://www.apple.com/ios/app-store/

Apple ResearchKit
A software framework developed by Apple Inc. that medical researchers can use 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 set of routines, protocols, and tools for building software applications. APIs enable the user experience to be seamless between two or more software applications since the APIs are working behind the actual user interface. http://www.webopedia.com/TERM/A/API.html

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. http://searchsecurity.techtarget.com/definition/authentication

Big Data
High-volume, high-velocity, and/or high-variety information assets that support innovative forms of information processing resulting in enhanced insight, decision-making, and process automation. http://www.forbes.com/sites/gartnergroup/2013/03/27/gartners-big-data-definition-consists-of-three-parts-not-to-be-confused-with-three-vs/#3f03b5ee42f6

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
This service gives users access to the Internet and Internet-related services at significantly higher speeds than those available through "dial-up" services. Broadband enables users 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 order and record regarding BIAS in October 2016. https://apps.fcc.gov/edocs_public/attachmatch/FCC-16-148A1.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

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
An adult with significant responsibility for managing the well-being of a child or the needs of person diagnosed with a chronic or debilitating medical condition. https://definitions.uslegal.com/c/caregiver

Centers for Medicare and Medicaid Services (CMS)
An HHS agency 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/Home UseDevices/default.htm

Clinical Research Trials and Studies
Research studies in which people participate as patients or volunteers, 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. The U.S. National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA) have put strict rules for clinical studies and trials in place. 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 controls the deployed apps and configuration settings. In the Platform as a Service model, the consumer can 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 are used to examine raw data, 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://oncprojectracking.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 using 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 clinician'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.lsoft.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

Fast 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 ONC on a variety of topics related to health IT. https://www.healthit.gov/facas/

Federal Communications Commission (FCC)
An independent agency of the 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 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 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 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/

General Wellness Device
A general wellness product has 1) an intended use that relates to maintaining or encouraging a general state of health or healthy activity, or 2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition. https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf

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 with 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 clinicians 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 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 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 (PHI). The HIPAA Breach Notification Rule requires covered entities and business associates to provide notification following a breach of unsecured PHI. 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 program helps ensure that EHR technologies meet the standards and certification criteria adopted by HHS, thereby facilitating clinicians and hospitals in achieving meaningful use of EHRs and participating 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, HL7 is 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 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/Interoperibility-Road-Map-Supplemental.pdf

Machine Learning
A method of data analysis that uses algorithms that iteratively learn from data so that computers can 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 Payment System (MIPS)
A new program under MACRA that measures providers' performance on quality, resource use, clinical practice improvement criteria, 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 several separate pieces of identity-related evidence to an authentication mechanism. These pieces of evidence can be knowledge-based, possession-based, and inherence-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

National Institutes of Health (NIH)
An HHS division that serves as the nation's medical research agency.
https://www.nih.gov/about-nih/who-we-are

Natural Language Processing
Computer software that can analyze, understand, and generate language that humans use naturally. It can be used to extract key terms or phrases from bodies of unstructured text, proving insights faster than a human can.
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 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 then can 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/CertificationandComplianc/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 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 clinicians.
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 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 clinicians 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 mostly 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 which receives the treatment or drug, and a control group which 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

Registered Medical Devices
"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm

Remote Monitoring/Telemonitoring
Use digital technologies to collect medical and other forms of health data from individuals and electronically transmit that information securely to clinicians 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. https://www.nist.gov/services-resources/standards-and-measurements

Standards Development Organization (SDO)
A member-based organization where 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 access to a system.
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.
https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/8_Transition_of_Care_Summary.pdf

Unsolicited PGHD
Data received by the care team with 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.

Wearable Device
Electronic technologies or computers that are incorporated into items of clothing and accessories which can comfortably be worn on the body. http://www.wearabledevices.com/what-is-a-wearable-device/

Visualization Tools

Tools used to gain understanding of large datasets 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 C: 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 many industry sectors, including care delivery, research, patient advocacy, technology development, and health law.

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

Data Donation
Ethan Basch, MD, MSc – University of North Carolina, Chapel Hill
Kevin Fowler – The Voice of the Patient, Inc.
Jaye Bea Smalley, MPA – Patient-Centered Outcomes Research Institute (PCORI)
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

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

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

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
Leslie Kelly Hall – Healthwise, Inc.
Robert Havasy, MS – Continua/HIMSS' Personal Connected Health Alliance
Holly Miller, MD, MBA – MedAllies
John Sharp, MSSA – Continua/HIMSS' Personal Connected Health Alliance
Paul White, MBA – AsthmaBrain Corporation

Big Data Analysis
Amy Abernethy, MD, PhD – Flatiron Health, Inc.
Bradford Hesse, PhD – NIH, National Cancer Institute, Health Communications and Research Branch
Joseph Kvedar, MD – Partners Healthcare
Jonathan Wald, MD, MPH – RTI International

Additionally, the Accenture team spoke with 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
Stanford University Children's Hospital
University of California, San Francisco
Vanderbilt Health System

Community-Based Clinics / Rural Hospitals
Anne Arundel Medical Center
Fenway Health
Marshfield Clinic

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 D: References

[1] "Patient-Generated Health Data | Policy Researchers & Implementers," September 30, 2015, https://www.healthit.gov/policy-researchers-implementers/patient-generated-health-data.

[2] Joseph Kvedar, Molly Joel Coye, and Wendy Everett, "Connected Health: A Review Of Technologies And Strategies To Improve Patient Care With Telemedicine And Telehealth," *Health Affairs* 33, no. 2 (February 1, 2014): 194–99, https://doi.org/10.1377/hlthaff.2013.0992.

[3] "Patient-Generated Health Data and Its Impact on Health Information Management," Healthport, October 2015, https://www.healthport.com/docs/default-source/whitepapers/wp_patientgeneratedhealthdata_120415_web.pdf?sfvrsn=2.

[4] Cinnamon S. Bloss et al., "A Prospective Randomized Trial Examining Health Care Utilization in Individuals Using Multiple Smartphone-Enabled Biosensors," *PeerJ*, January 14, 2016, doi: http://dx.doi.org/10.7717/peerj.1554.

[5] Dan Ledger and Daniel McCaffrey, "Inside Wearables: How the Science of Human Behavior Change Offers the Secret to Long-Term Engagement," Endeavour Partners, January 2014, http://endeavourpartners.net/assets/Endeavour-Partners-Wearables-White-Paper-20141.pdf.

[6] Office of the National Coordinator for Health IT, "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap," October 2015, https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf.

[7] Office of the National Coordinator for Health IT, "Building Data Infrastructure to Support Patient-Centered Outcomes Research (PCOR)," May 31, 2016, https://healthit.gov/pcor.

[8] Office of the National Coordinator for Health IT, "Building Data Infrastructure to Support Patient-Centered Outcomes Research (PCOR)."

[9] Angela McIntyre, Nick Ingelbrecht, and Brian Blau, "Forecast: Wearable Electronic Devices, Worldwide, 2017" (Gartner, August 3, 2017), https://www.gartner.com/document/3778064/meter/charge.

[10] Vi Shaffer et al., "Predicts 2016: Healthcare Provider CIOs Must Address the Clear Signposts of IT's Sea Change," November 30, 2015, https://www.gartner.com/doc/3173157/predicts--healthcare-provider-cios

[11] "Federal Register | Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017," accessed July 11, 2016, https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications - p-1678.

[12] Office of the National Coordinator for Health IT, "2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange," Federal Register, September 11, 2014, https://www.federalregister.gov/documents/2014/09/11/2014-21633/2014-edition-release-2-electronic-health-record-ehr-certification-criteria-and-the-onc-hit.

[13] Centers for Medicare and Medicaid Services, "Community-Based Care Transitions Program," July 20, 2016, https://innovation.cms.gov/initiatives/CCTP/.

[14] Centers for Medicare and Medicaid Services, "Chronic Care Management Services,", May 2015, https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf.

[15] Centers for Medicare and Medicaid Services, "Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models," November 4, 2016, https://www.gpo.gov/fdsys/pkg/FR-2016-11-04/pdf/2016-25240.pdf.

[16] Michael Shapiro et al., "Patient-Generated Health Data" (RTI International, April 2012), https://www.rti.org/sites/default/files/resources/patientgeneratedhealthdata.pdf.

[17] Christine Bechtel and Leslie Kelly Hall, "Joint PGHD Recommendations: Consumer Empowerment WG and Consumer Technology WG," 2012, https://www.healthit.gov/FACAS/sites/faca/files/HITPC120413CECT_WG_Recommendations_0.pdf.

[18] "Patient-Generated Health Information Technical Expert Panel" (National eHealth Collaborative, December 2013), https://www.healthit.gov/FACAS/sites/faca/files/HITPC120413CECT_WG_Recommendations_0.pdf.

[19] Mary Jo Deering, "Issue Brief: Patient-Generated Health Data and Health IT," December 20, 2013, https://www.healthit.gov/sites/default/files/pghd_brief_final122013.pdf.

[20] Office of the National Coordinator for Health IT, "Federal Health IT Strategic Plan 2015-2020," September 2015, https://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf.

[21] Office of the National Coordinator for Health IT, "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap."

[22] Office of the National Coordinator for Health IT, "Model Privacy Notice," December 2, 2016, https://www.healthit.gov/policy-researchers-implementers/model-privacy-notice-mpn.

[23] Deering, "Issue Brief: Patient-Generated Health Data and Health IT."

[24] Aaron Smith, "U.S. Smartphone Use in 2015," *Pew Research Center: Internet, Science & Tech* (blog), April 1, 2015, http://www.pewinternet.org/2015/04/01/us-smartphone-use-in-2015/.

[25] "Sit Less, Move More with Hourly Activity & Stationary Time Tracking – Fitbit Blog," April 4, 2016, https://blog.fitbit.com/sit-less-move-more-with-hourly-activity-stationary-time-tracking/.

[26] Haruka Murakami et al., "Accuracy of Wearable Devices for Estimating Total Energy Expenditure: Comparison With Metabolic Chamber and Doubly Labeled Water Method | May 01, 2016 | JAMA Internal Medicine | JAMA Network," accessed July 15, 2016, http://archinte.jamanetwork.com/article.aspx?articleid=2500062.

[27] Kashif Habib, Arild Torjusen, and Wolfgang Leister, "A Novel Authentication Framework Based on Biometric and Radio Fingerprinting for the IoT in EHealth," 2014, 6.

[28] Habib, Torjusen, and Leister.

[29] U.S. Department of Health and Human Services, "Examining Oversight of the Privacy and Security of Health Data Collected by Entities Not Regulated by HIPAA," July 19, 2016, https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf.

[30] "Sixth Annual Benchmark Study on Privacy and Security of Healthcare Data" (Ponemon Institute, May 2016), https://www.ponemon.org/local/upload/file/Sixth Annual Patient Privacy %26 Data Security Report FINAL 6.pdf.

[31] Simson L. Garfinkle, "De-Identification of Personal Information" (National Institute of Standards and Technology, October 2015), http://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf.

[32] Patty Kostkova et al., "Who Owns the Data? Open Data for Healthcare," *Frontiers in Public Health* 4 (2016), https://doi.org/10.3389/fpubh.2016.00007.

[33] Ben Moscovitch, "Next Steps for Health IT Interoperability After 21st Century Cures Act," March 8, 2017, http://pew.org/2nfbqA3.

[34] Office of the National Coordinator for Health IT, "Patient Matching, Aggregating and Linking (PMAL)," May 31, 2016, https://www.healthit.gov/policy-researchers-implementers/patient-matching-aggregating-and-linking-pmal.

[35] "Announcing the Blockchain Challenge | Newsroom | HealthIT.Gov," August 29, 2016, https://www.healthit.gov/newsroom/blockchain-challenge.

[36] "The Direct Project | Policy Researchers & Implementers | HealthIT.Gov," accessed June 20, 2017, https://www.healthit.gov/policy-researchers-implementers/direct-project.

[37] "Deep 6 Analytics - Clinical Analytics for Researchers and Doctors," Deep 6 Analytics, accessed August 25, 2016, https://deep6analytics.com/.

[38] Andrew Broderick and David Lindeman, "Scaling Telehealth Programs: Lessons from Early Adopters" (The Commonwealth Fund, n.d.), http://www.commonwealthfund.org/~/media/Files/Publications/Case Study/2013/Jan/1654_Broderick_telehealth_adoption_synthesis.pdf.

[39] Andrew Broderick, "Partners HealthCare: Connecting Heart Failure Patients to Providers through Remote Monitoring," Commonwealth Fund, January 30, 2013, http://www.commonwealthfund.org/~/media/files/publications/case-study/2013/jan/1656_broderick_telehealth_adoption_partners_case_study.pdf.

[40] Karen Appold, "Five Ways Technology Can Increase Patient Compliance," Managed Healthcare Executive, January 29, 2016, http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/news/five-ways-technology-can-increase-patient-compliance.

[41] Mark Johnson and Brad Tritle, "The Emerging Value of Patient Generated Health Data," HIMSS, April 26, 2016, http://www.himss.org/emerging-value-patient-generated-health-data.

[42] Hoang D. Nguyen and Danny Chiang Choon Poo, "Analysis and Design of Mobile Health Interventions towards Informed Shared Decision Making: An Activity Theory-Driven Perspective," *Journal of Decision Systems* 25 (2016): 397–409.

[43] Daniel Castro, Ben Miller, and Adams Nager, "Unlocking the Potential of Physician-to-Patient Telehealth Services," The Information Technology and Innovation Foundation, May 2014, http://www2.itif.org/2014-unlocking-potential-physician-patient-telehealth.pdf.

[44] Imran Cronk, "The Transportation Barrier," *The Atlantic*, August 9, 2015, http://www.theatlantic.com/health/archive/2015/08/the-transportation-barrier/399728/.

[45] Sarah Massey, "Virtual Clinical Trials – Can Remote Trials Change The Clinical Trial Landscape?," Xtalks, October 29, 2015, http://xtalks.com/Virtual-Clinical-Trials-1.ashx.

[46] "The Shift to Managing More Patients with Less Resources," Healthcare IT News, July 14, 2016, http://www.healthcareitnews.com/sponsored-content/shift-managing-more-patients-less-resources-0.

[47] Kathleen A. Armstrong et al., "Effect of Home Monitoring via Mobile App on the Number of In-Person Visits Following Ambulatory Surgery: A Randomized Clinical Trial," *JAMA Surgery* 152, no. 7 (July 1, 2017): 622–27, https://doi.org/10.1001/jamasurg.2017.0111.

[48] "Caregiver Law and Legal Definition | USLegal, Inc.," accessed June 20, 2017, https://definitions.uslegal.com/c/caregiver.

[42] Federal Communications Commission, "2016 Broadband Progress Report," January 27, 2016, https://www.fcc.gov/reports-research/reports/broadband-progress-reports/2016-broadband-progress-report.

[50] Monica Anderson, "6 Facts about Americans and Their Smartphones," *Pew Research Center* (blog), April 1, 2015, http://www.pewresearch.org/fact-tank/2015/04/01/6-facts-about-americans-and-their-smartphones/.

[51] "Strong Sales, but High Abandonment for Fitness Trackers | The Big Story," accessed July 13, 2016, http://bigstory.ap.org/article/2700956044de4517a471a47c3243078b/strong-sales-high-abandonment-fitness-trackers.

[52] "Gartner Survey Shows Wearable Devices Need to Be More Useful," n.d., http://www.gartner.com/newsroom/id/3537117.

[53] Dan Ledger and Daniel McCaffrey, "Inside Wearables: How the Science of Human Behavior Change Offers The Secret to Long-Term Engagement," Endeavour Partners, January 2014, http://endeavourpartners.net/assets/Endeavour-Partners-Wearables-White-Paper-20141.pdf.

[54] Mitesh S. Patel, David A. Asch, and Kevin G. Volpp, "Wearable Devices as Facilitators, Not Drivers, of Health Behavior Change," *Journal of the American Medical Association* 313, no. 5 (February 3, 2015): 459–69.

[55] Francisco Grajales et al., "Social Networking Sites and the Continuously Learning Health System: A Survey," National Academy of Sciences, January 23, 2014, https://nam.edu/wp-content/uploads/2015/06/VSRT-PatientDataSharing.pdf.

[56] Grajales et al.

[57] U.S. Department of Health and Human Services, "Examining Oversight of the Privacy and Security of Health Data Collected by Entities Not Regulated by HIPAA."

[58] Jordan Broderick et al., "Designing Health Literate Mobile Apps" National Academy of Sciences, January 28, 2014, https://health.gov/communication/literacy/BPH-HealthLiterateApps.pdf.

[59] MaryAnne Sterling, "What Family Caregivers Need from Health IT and the Heatlcare System to Be Effective Health Managers," Connected Health Resources, 2014, http://www.connectedhealthresources.com/What_Family_Caregivers_Need_from_Health_IT_and_the_Healthcare_System_to_be_Effective_Health_Managers_Sterling_December_2014_v2.pdf.

[60] Sterling.

[61] Prashila M. Dullabh et al., "How Patients Can Improve the Accuracy of Their Medical Records," *EGEMs* 2, no. 3 (October 1, 2014), https://doi.org/10.13063/2327-9214.1080.

[62] Kvedar, Coye, and Everett, "Connected Health."

[63] Emma Court, "America's Facing a Shortage of Primary-Care Doctors," MarketWatch, April 4, 2016, http://www.marketwatch.com/story/americas-1-million-doctor-shortage-is-right-upon-us-2016-04-01.

[64] IHS Inc., "The Complexities of Physician Supply and Demand: Projections from 2013 to 2025," March 2015, https://www.aamc.org/download/426242/data/ihsreportdownload.pdf?cm_mmc=AAMC-_-ScientificAffairs-_-PDF-_-ihsreport.

[65] Geneia LLC, "Geneia Study Finds Remote Patient Monitoring Could Save More Than $8,000 Per Patient Annually," June 15, 2016, http://www.prnewswire.com/news-releases/geneia-study-finds-remote-patient-monitoring-could-save-more-than-8000-per-patient-annually-300284802.html.

[66] Salesforce Research, "2016 Connected Patient Report," Salesforce, July 2016, https://www.salesforce.com/form/industries/2016-state-connected-patient.jsp.

[67] Deven McGraw et al., "Going Digital with Patients: Managing Potential Liability Risks of Patient-Generated Electronic Health Information," December 18, 2013, http://www.jopm.org/perspective/narratives/2013/12/18/going-digital-with-patients-managing-potential-liability-risks-of-patient-generated-electronic-health-information/.

[68] Christina Caraballo, "Patient Generated Health Data: Addressing Concerns and Moving Forward," HIMSS, April 8, 2016, http://www.himss.org/news/patient-generated-health-data-addressing-concerns-and-moving-forward.

[69] Sara Heath, "What Keeps Providers from Using Patient-Generated Health Data?," PatientEngagementHIT, April 21, 2016, http://patientengagementhit.com/news/what-keeps-providers-from-using-patient-generated-health-data.

[70] "Going Digital With Patients: Managing Potential Liability Risks Of Patient-Generated Electronic Health Information | Journal Of Participatory Medicine," accessed July 15, 2016,

http://www.jopm.org/perspective/narratives/2013/12/18/going-digital-with-patients-managing-potential-liability-risks-of-patient-generated-electronic-health-information/.

[71] McGraw et al., "Going Digital with Patients: Managing Potential Liability Risks of Patient-Generated Electronic Health Information."

[72] Caraballo, "Patient Generated Health Data."

[73] Carolyn L. Kerrigan, "Dartmouth Experience: Proudly Accepting PGHD," HIMSS 2015, Chicago, IL, April 15, 2015, http://s3.amazonaws.com/rdcms-himss/files/production/public/FileDownloads/Proudly Accepting PGHD.pdf.

[74] Office of the Commissioner, "Recruiting Study Subjects - Information Sheet," WebContent, January 25, 2016, http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm.

[75] Ariana Eunjung Cha, "Is 10,000-Steps Goal More Myth than Science? Study Seeks Fitness Truths through Our Phones and More - The Washington Post," The Washington Post, May 26, 2016, https://www.washingtonpost.com/news/to-your-health/wp/2016/05/26/is-10000-steps-goal-more-myth-than-science-study-seeks-fitness-truths-through-our-phones-and-more/?tid=a_inl.

[76] Cha.

[77] Niklas Morton David Blackman, "The Growing Availability of Wearable Devices: A Perspective on Current Applications in Clinical Trials," accessed August 24, 2016, http://www.appliedclinicaltrialsonline.com/growing-availability-wearable-devices-perspective-current-applications-clinical-trials.

[78] "Trial Strategies to Reduce the Frequency of Missing Data," *The Prevention and Treatment of Missing Data in Clinical Trials* (National Academies Press, 2010), http://www.nap.edu/read/12955/chapter/5.

[79] Kristina Lopienski, "Subject Retention in Clinical Trials: Keeping Patients on Protocols (Infographic)," *Forte Research Systems* (blog), June 1, 2015, http://forteresearch.com/news/infographic-retention-in-clinical-trials-keeping-patients-on-protocols/.

[80] Blackman, "The Growing Availability of Wearable Devices."

[81] National Institutes for Health, "Infographics," September 8, 2015, https://www.nih.gov/research-training/allofus-research-program.

[82] National Institutes for Health.

[83] March 21 et al., "NIH and ONC Launch the Sync for Science (S4S) Pilot: Enabling Individual Health Data Access and Donation," *Health IT Buzz* (blog), March 21, 2016, https://www.healthit.gov/buzz-blog/health-innovation/nih-and-onc-launch-the-sync-for-science-pilot/.

[84] Paloma Martínez et al., "Turning User Generated Health-Related Content into Actionable Knowledge through Text Analytics Services," *Computers in Industry*, December 31, 2015, https://doi.org/10.1016/j.compind.2015.10.006.

85 Mauricio Santillana et al., "Combining Search, Social Media, and Traditional Data Sources to Improve Influenza Surveillance," *PLoS Computational Biology* 11, no. 10 (October 2015): e1004513, https://doi.org/10.1371/journal.pcbi.1004513.

86 Santillana et al.

87 Arielle Duhaime-Ross, "Apple's New ResearchKit: 'Ethics Quagmire' or Medical Research Aid?," The Verge, March 10, 2015, http://www.theverge.com/2015/3/10/8177683/apple-research-kit-app-ethics-medical-research.

88 "Federal Register - Federal Policy for the Protection of Human Subjects Notice of Proposed Rulemaking," September 8, 2015, https://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf.

89 "Reg4ALL®," accessed November 17, 2016, https://www.reg4all.org/more.php.

90 21 et al., "NIH and ONC Launch the Sync for Science (S4S) Pilot."

91 U.S. Department of Health and Human Services, "The Belmont Report," Text, HHS.gov, January 28, 2010, http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

92 U.S. Department of Health and Human Services, "Examining Oversight of the Privacy and Security of Health Data Collected by Entities Not Regulated by HIPAA."

93 Federal Trade Commission, "Federal Trade Commission Act, Section 5: Unfair or Deceptive Acts or Practices" (n.d.), https://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf.

94 U.S. Department of Health and Human Services, "Examining Oversight of the Privacy and Security of Health Data Collected by Entities Not Regulated by HIPAA."

95 Centers for Medicare and Medicaid Services, "Chronic Care Management Services."

96 U.S. Food and Drug Administration, "Design Considerations for Devices Intended for Home Use - Guidance for Industry and Food and Drug Administration Staff," November 24, 2014, http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm331681.pdf.

97 U.S. Food and Drug Administration, "General Wellness: Policy for Low Risk Devices - Guidance for Industry and Food and Drug Administration Staff," January 20, 2016, http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf.

98 Office of the Commissioner, "FDA Basics - What Is the Difference between the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA Regulations, and FDA Guidance?," WebContent, March 4, 2016, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194909.htm.

99 David Raths, "Digital Health Dilemma: Regulators Struggle to Keep Pace with Health-Care Technology Innovation," accessed December 21, 2016, http://www.govtech.com/health/Digital-Health-Dilemma-Regulators-Struggle-to-Keep-Pace-with-Health-Care-Technology-Innovation.html.

[100] "Guiding Principles on the Privacy and Security of Personal Wellness Data" (Consumer Electronics Association (CEA), October 2015), https://fpf.org/wp-content/uploads/2015/10/CEA-Guiding-Principles-on-the-Privacy-and-Security-of-Personal-Wellness-Data-102215.pdf.

[101] Future Policy Forum, "Best Practices for Consumer Wearables and Wellness Apps and Devices," August 17, 2016.

[102] "Medical Liability | Medical Malpractice 2013 Legislation," accessed November 22, 2016, http://www.ncsl.org/research/financial-services-and-commerce/medical-liability-medical-malpractice-2013-legislation.aspx.

[103] "CTA - Press Releases," CTA, accessed July 16, 2016, https://www.cta.tech/News/Press-Releases/2015/September/CEA-Launches-New-Wearable-Tech-Projects,-Honors-Tw.aspx.

[104] "Guiding Principles on the Privacy and Security of Personal Wellness Data."

[105] "Overview - FHIR v1.0.2," October 24, 2015, https://www.hl7.org/fhir/overview.html.

[106] "Mission | Continua," accessed August 25, 2016, http://www.continuaalliance.org/about-the-alliance/mission-and-objectives.

[107] Sarah Silbert, "Why Fitbit Is Still Winning Wearables," *Fortune* (blog), December 10, 2015, http://fortune.com/2015/12/10/why-fitbit-winning/.

[108] Gottlieb, Scott, "FDA Announces New Steps to Empower Consumers and Advance Digital Healthcare," *FDA Voice* (blog), July 27, 2017, https://blogs.fda.gov/fdavoice/index.php/2017/07/fda-announces-new-steps-to-empower-consumers-and-advance-digital-healthcare/.

[109] Future Policy Forum, "Best Practices for Consumer Wearables and Wellness Apps and Devices."

[110] U.S. Department of Health and Human Services, "Examining Oversight of the Privacy and Security of Health Data Collected by Entities Not Regulated by HIPAA."

[111] Office of the National Coordinator for Health IT, "Model Privacy Notice," December 13, 2016, https://www.healthit.gov/policy-researchers-implementers/model-privacy-notice-mpn.

[112] Bass Berry | Sims, "21st Century Cures Act - HIPAA & Other Privacy Considerations," December 16, 2016, http://www.bassberry.com/publications/2016/12/21st-century-cures-act.

[113] Jenna McGregor, "Fitness Trackers Chase after the Corporate Market," Washington Post, December 18, 2014, https://www.washingtonpost.com/news/on-leadership/wp/2014/12/18/fitness-trackers-chase-after-the-corporate-market/.

[114] Julia Bort, "Company Saved Money With Fitbits - Business Insider," July 7, 2014, http://www.businessinsider.com/company-saved-money-with-fitbits-2014-7.

[115] Grajales et al., "Social Networking Sites and the Continuously Learning Health System: A Survey."

[116] Reed Abelson, "AARP Sues U.S. Over Rules for Wellness Programs," *The New York Times*, October 24, 2016, http://www.nytimes.com/2016/10/25/business/employee-wellness-programs-prompt-aarp-lawsuit.html.

[117] Executive Office of the President, "Big Data: A Report on Algorithmic Systems, Opportunity, and Civil Rights" May 2016, https://www.whitehouse.gov/sites/default/files/microsites/ostp/2016_0504_data_discrimination.pdf.