



Self-Measured Blood Pressure Monitoring

*Key Findings from a National Health Information Technology
Landscape Analysis*

September 2021

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Acronyms

AHA	American Heart Association
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
API	Application programming interfaces
BP	Blood Pressure
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
DHDSP	Division for Heart Disease and Stroke Prevention
HHS	Department of Health and Human Services
EHR	Electronic health record
FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic
FHIR	Fast Healthcare Interoperability Resources
FTC	Federal Trade Commission
Health IT	Health Information Technology
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health
HL7	Health Level Seven
HRSA	Health Resources and Services Administration
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Healthcare Enterprise
IHMI	Integrated Health Model Initiative
ISO	International Organization for Standardization
IT	Information Technology
LOINC	Logical Observation Identifiers Names and Codes
mHealth	Mobile health
NACHC	National Association of Community Health Centers
NIH	National Institutes of Health
ONC	Office of the National Coordinator for Health Information Technology
PCHA	Personal Connected Health Alliance
PGHD	Patient-generated health data
PH	Public health
PHI	Personal health information
PHII	Public Health Informatics Institute
SMART	Substitutable Medical Applications, Reusable Technologies
SMBP	Self-Measured Blood Pressure Monitoring
SME	Subject matter expert

SNOMED-CT
USCDI

Systematized Nomenclature of Medicine -- Clinical Terms
United States Core Data for Interoperability

Executive Summary

Nearly half of adults in the United States (U.S.) have high blood pressure (BP) or are taking medication for hypertension, and less than a quarter of adults with hypertension have their condition under control. Hypertension is a preventable risk factor for heart disease and stroke, and other conditions.¹ Self-measured blood pressure monitoring (SMBP), sometimes known as home blood pressure monitoring, with clinical support is an evidence-based strategy that has been shown to lower blood pressure and improve control in persons with hypertension.^{2,3,4} Million Hearts, co-led by CDC and the Centers for Medicare & Medicaid Services (CMS); Target: BP, a national initiative by the American Medical Association (AMA) and the American Heart Association (AHA); the National Association of Community Health Centers (NACHC); and the Department of Health and Human Services (HHS) Office of Minority Health and HRSA National Hypertension Control Initiative all support the use of SMBP.

Despite the support and endorsement for SMBP, there is a lack of infrastructure to facilitate effective data movement between home BP devices and the clinician, referred to as the SMBP feedback loop. In an ideal world, health information technology (health IT) would support systems that are able to move data transmitted from a device directly into an electronic health record (EHR) to facilitate interaction between patients and clinicians. Several gaps and barriers exist as it relates to policy, interoperability standards and specifications, and SMBP in practice. To advance the collection, transfer, and use of patient-generated health data (PGHD) to improve hypertension management, PHII collaborated with the Division for Heart Disease and Stroke Prevention (DHDSP) in the National Center for Chronic Disease Prevention and Health Promotion of CDC to carry out a national assessment of the health IT and health informatics landscape supporting SMBP monitoring. A glossary of terms related to SMBP and health IT is included in this report as [Appendix A](#).

PGHD lacks consistent regulations between Health Insurance Portability and Accountability Act (HIPAA)- and non-HIPAA-covered entities, especially as it relates to mobile health (mHealth) applications.⁵ PGHD may be more at risk for security breaches and misleading use of the data outside of the original intent due to third-party vendors not having the same regulations as HIPAA-covered entities.⁶ The 21st Century Cures Act empowers patients and clinicians to control which applications and individuals have access to personal health data, requiring applications to educate users on privacy and security concerns.⁷ The Federal Trade Commission (FTC) Health Breach Notification Rule requires personal health record entities to notify users of a suspected data breach and can be enacted if personal health data were shared or accessed by an unauthorized entity.⁸ The Food and Drug Administration (FDA) provides minimal

¹ CDC, 2020. Facts about Hypertension. <https://www.cdc.gov/bloodpressure/facts.htm>

² Shimbo et al, 2020. Self-Measured Blood Pressure Monitoring at Home: A Joint Policy Statement from the American Heart Association and American Medical Association. *Circulation*. 142(4), e42-e63. <https://doi.org/10.1161/CIR.0000000000000803>

³ Uhlig et al, 2013. Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. *Annals Internal Medicine*. 159(3), 185-194. <https://doi.org/10.7326/0003-4819-159-3-201308060-00008>

⁴ CDC, 2017. Self-Measured Blood Pressure Monitoring with Clinical Support. <https://www.cdc.gov/dhdsp/pubs/guides/best-practices/smbp.htm>

⁵ HHS, 2016. Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA. https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf

⁶ ONC, 2018. Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024. https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf

⁷ ONC. About ONC's Cures Act Final Rule. <https://www.healthit.gov/curesrule/overview/about-oncs-cures-act-final-rule>

⁸ FTC, 2010. Complying with the FTC's Health Breach Notification Rule. <https://www.ftc.gov/tips-advice/business-center/guidance/complying-ftcs-health-breach-notification-rule>

oversight and regulatory enforcement over SMBP devices and companion mobile health applications due to the minimal risk.⁹ Additionally, clinicians might be hesitant to use PGHD and companion applications or devices to access SMBP data due to medical liability. To implement widespread adoption of PGHD in clinical care practice, policies addressing privacy and security concerns will be needed.

There is a complex web of inter-related standards and specifications relevant to SMBP data exchange; however, a common framework to support the movement of these data to EHRs is lacking. Fast Healthcare Interoperability Resources (FHIR) and Substitutable Medical Applications, Reusable Technologies (SMART) are key standards called out to support application programming interface (API)-based access to data held in health information systems and could potentially support the movement of SMBP data.^{7,10} Specifically, a SMART Markers framework is envisioned as a potential solution to support sharing of PGHD between a patient and a clinician. Multiple organizations, such as ONC, CMS, and Health Level 7 (HL7), are involved in standards and specifications development relevant to personal health devices and SMBP.¹⁰ However, there is currently no guidance on how to implement standards-based use of APIs to enter data into an EHR. There is also a need to improve internal and external coordination between standards development organizations, as each organization has varying processes for development and approval, as well as different views on other organizational standards. Additionally, given the number of standards and specifications, it may be challenging to identify those that are applicable to SMBP, especially those that are relevant to mobile health applications.

Although it is difficult to ascertain the level of adoption of standards, specifications, and technologies in practice, a few successful SMBP programs exist. These include SMBP remote patient monitoring programs from Ochsner Health, Reliant Health, and the Health Federation of Philadelphia. Ochsner Health engages in SMBP using a wireless BP device, and data are captured in an application on a smart device (e.g., smart phone, smart tablet) via Bluetooth that then sends the data to the EHR.^{11,12,13} Reliant Health engages in SMBP using a device-associated application that entails a device connector platform to move data from the consumer device application to the EHR.¹⁴ Lastly, Health Federation of Philadelphia engages in SMBP using a wireless BP cuff that connects to a device-associated application.¹⁵ These data are stored on the device and manually recorded at a clinic visit. As these examples indicate, there are many different avenues of moving SMBP and PGHD data; however, there is not a clear path recommended and even existing pathways could be streamlined or simplified.

This national Health IT assessment identified several gaps and barriers to consider for widespread adoption of SMBP. In an effort to alleviate or reduce the barriers to successful SMBP, PHII makes the following recommendations:

⁹ FTC, 2016. Mobile Health Apps Interactive Tool. <https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool#fdc>

¹⁰ CMS, 2020. Interoperability and Patient Access Fact Sheet. <https://www.cms.gov/newsroom/fact-sheets/interoperability-and-patient-access-fact-sheet>

¹¹ Tai-Seale et al, 2019. Technology-Enabled Consumer Engagement: Promising Practices at Four Health Care Delivery Organizations. *Health Affairs*. 38(3), 383-390. <https://doi.org/10.1377/hlthaff.2018.05027>

¹² Milani et al, 2017. Improving Hypertension Control and Patient Engagement Using Digital Tools. *The American Journal of Medicine*. 130(1), 14-20. <https://doi.org/10.1016/j.amjmed.2016.07.029>

¹³ Milani et al, 2020. Digital Management of Hypertension Improves Systolic Blood Pressure Variability. *The American Journal of Medicine*. 133(7):e355-e359. <https://doi.org/10.1016/j.amjmed.2019.10.043>

¹⁴ ONC, 2021. Advancing Standards for Precision Medicine. <https://www.healthit.gov/sites/default/files/page/2021-01/Advancing-Standards-in-Precision-Medicine.pdf>

¹⁵ Discussion with Debra McGrath, Health Federation of Philadelphia, 2020

Regulatory and policy recommendations

- Support the development of a privacy and security framework that would hold non-HIPAA-covered entities to the same standards as HIPAA-covered entities when it comes to PGHD.
- Create a business associate agreement by modifying existing ones and make it widely available to support organizations that aim to partner with HIPAA-covered entities to exchange patient-generated SMBP data.
- Ensure sufficient coverage for validated devices that meet nationally recommended criteria (e.g., automatic arm devices, Bluetooth enabled).
- Develop standards of care to assist clinicians in clinical decisions based on PGHD BP readings.
- Develop protocols and guidance for patients and clinicians around how and when SMBP data will be reviewed and used and when and how follow-up will occur.

Interoperability standards and specifications recommendations

- Develop an implementation framework to support the movement of SMBP data to EHRs.
- Develop implementation guidance focused on use of the FHIR write capability to enter data into an EHR.¹⁶
- Expand requirements for EHR certification to include write access.
- Incentivize device, mHealth, and EHR vendors to support adoption of standards and specifications for the exchange of PGHD.
- Consider an HL7 FHIR Accelerator approach to accelerate the development of new specifications focused on the use of PGHD in clinical care.¹⁷
- Align with ONC's unfulfilled recommendations from 2018⁶:
 - Accelerate the development of standards and specifications among standards development organizations to better keep pace with market innovations.
 - Identify a common implementation framework for capture and integration of PGHD in EHRs and other health systems.
 - Bolster industry certification programs to verify standards-based exchange capabilities against a common framework.

SMBP in practice recommendations

- Support the provision of technical support and resources (similar to “Geek Squad” or “Genius Bar”) to improve digital literacy and work towards resolving the digital divide.
- Support policies that make patients the owners of any patient data generated by them. “Any data in a device belonging to a patient is owned by the patient.”¹⁸

¹⁶ PEW Charitable Trust, 2021. Standard Technology Presents Opportunities for Medical Record Data Extraction. <https://www.pewtrusts.org/en/research-and-analysis/reports/2021/01/standard-technology-presents-opportunities-for-medical-record-data-extraction>

¹⁷ HL7, HL7® FHIR® Accelerator Program. <https://www.hl7.org/about/fhir-accelerator/>

¹⁸ Discussion with HL7 Patient Empowerment Group, 2021

- Develop user-friendly patient application[s] that can both obtain PGHD and SMBP measurements and seamlessly integrate that information into the EHR to make clinical workflow more efficient.
- Include blood pressure with other chronic disease initiatives to support interoperability and reduce complexity involved in the collection and storage of data (i.e., a patient with multiple chronic conditions should not have three apps to monitor their disease).

Introduction

This document provides a synopsis of the PHII project, in partnership with CDC/DHDSP, to complete a national assessment of the health IT and health informatics landscape supporting SMBP.

According to CDC, nearly half of adults in the U.S. have high blood pressure or are taking medication for hypertension; less than a quarter of adults with hypertension have their condition under control.¹ Hypertension is recognized as a major preventable risk factor for heart disease and stroke, two of the leading causes of death in the U.S. A recommended strategy for improving the management and control of hypertension is self-measurement of blood pressure by an individual, outside the clinical setting, coupled with clinical review and support.^{2,3,4}

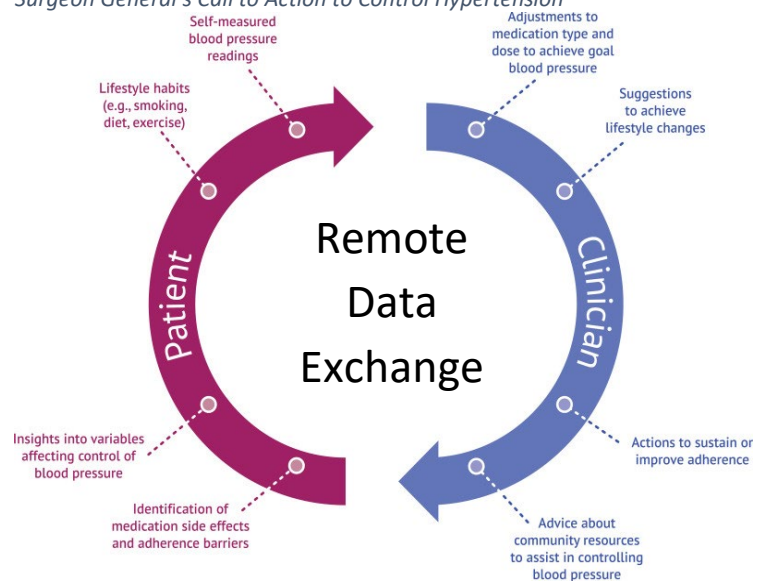
Effective SMBP relies on a feedback loop between a patient and clinician (Figure 1).¹⁹ This feedback loop, adapted from the Surgeon General's Call to Action to Control Hypertension, supports the remote transmission of BP readings from patient to his/her clinical team, as well as delivery of co-interventions based on those readings, such as patient education, counseling, and medication management, outside of a traditional face-to-face clinical visit. This exchange is proven to help people with hypertension lower their blood pressure and reduce the risk of death and disability associated with hypertension.²

Despite being recognized as an effective strategy for hypertension management, there is a lack of supportive infrastructure to facilitate an effective SMBP feedback loop. Patients are challenged in sharing SMBP readings with clinicians outside of traditional face-to-face visits, and clinicians are challenged in integrating SMBP readings into their clinical workflow to enable timely patient feedback.⁴

This project aims to conduct a national assessment of the health IT and health informatics landscape supporting the SMBP feedback loop, in particular the transfer of data between a home BP monitoring device and an ambulatory EHR system. A literature review and subject matter expert (SME) interviews informed the assessment and recommendations to address gaps/barriers across these domains. The project addressed the following domains and questions:

- **Regulatory/policy:** What is the regulatory/policy landscape in which SMBP data exchange needs to occur? What federal laws and regulations are relevant to the capture and transmission of SMBP data?

Figure 1. Self-monitored blood pressure feedback loop adapted from the Surgeon General's Call to Action to Control Hypertension



¹⁹ HHS, 2020. The Surgeon General's Call to Action to Control Hypertension. <https://www.cdc.gov/bloodpressure/docs/SG-CTA-HTN-Control-Report-508.pdf>.

- **Interoperability standards and specifications:** What are the interoperability standards and specifications relevant to SMBP data exchange? What terminology standards and vocabularies are used within these specifications?
- **SMBP in practice: data flows and technologies:** What are examples of SMBP data exchange in action? What are the data flows? What technologies are used to support the collection and transmission of SMBP data?

The overall goal of this work is to advance standards-based, interoperable exchange of data from home BP monitoring devices to EHRs, in support of SMBP and effective hypertension management.

This is especially important considering a convergence of factors that will likely shape the health care landscape for years to come. First, this is a time of rapid change in the health IT landscape. Consumer interest in the use of mobile health apps and health technologies continues to grow, driven by the increasing prevalence of mobile devices such as smartphones and tablets. With the “abundance” of PGHD, there is recognition of opportunities to use these data to support health care delivery and research.³ PGHD are health-related data created, recorded, or gathered by or for patients (or family members or caregivers) to help address health concerns. These data are distinct from data generated in clinical settings in that the patient (rather than a clinician) is responsible for capturing or recording the data and for decision-making around sharing of these data.²⁰

Furthermore, the 21st Century Cures Act looks to shape the future of healthcare interoperability. FHIR-based data exchange and use of APIs aim to simplify data sharing across the health care enterprise and to support patients’ access to their own health care data in particular.²¹ Finally, growth in telehealth and a shift in virtual delivery of care have dramatically increased in response to the COVID-19 pandemic,²² and CMS policy changes expanded access to telehealth among Medicare beneficiaries.²³ As former CMS administrator Seema Verma stated, “...*the pandemic accentuated just how transformative [telehealth] could be, and several months in, it’s clear that the health care system has adapted seamlessly to a historic telehealth expansion that inaugurates a new era in health care delivery.*”²⁴ Given these recent changes, it is prudent to consider the current status of health IT infrastructure supporting SMBP and opportunities to accelerate the use of SMBP.

Methods

To develop this report and recommendations for CDC/DHDSP, PHII conducted a national assessment consisting of a literature review and series of interviews with SMEs. The purpose of the literature review

²⁰ ONC, 2018. What are patient-generated health data? <https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data>

²¹ CMS, 2020. HHS Finalizes Historic Rules to Provide Patients More Control of Their Health Data. <https://www.cms.gov/newsroom/press-releases/hhs-finalizes-historic-rules-provide-patients-more-control-their-health-data>

²² Koonin et al, 2020. Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic – United States, January—March 2020. Morbidity and Mortality Weekly Report. 69(43), 1595-1599. <https://doi.org/10.15585/mmwr.mm6943a3>

²³ Verma, 2020. Early Impact of CMS Expansion of Medicare Telehealth During COVID-19. <https://www.healthaffairs.org/doi/10.1377/hblog20200715.454789/full/>

²⁴ CMS, 2020. Trump Administration Finalizes Permanent Expansion of Medicare Telehealth Services and Improved Payment for Time Doctors Spend with Patients. <https://www.cms.gov/newsroom/press-releases/trump-administration-finalizes-permanent-expansion-medicare-telehealth-services-and-improved-payment>

was two-fold: 1) to describe the health IT and health informatics landscape supporting the SMBP feedback loop, and 2) to describe challenges and opportunities related to the transfer of data between a home BP monitoring device and an ambulatory EHR system.

The literature review consisted of reviewing peer-reviewed articles, white papers, and grey literature. Materials were reviewed to identify federal laws and regulations relevant to the capture and transmission of SMBP data, interoperability standards, specifications relevant to SMBP data exchange, and terminology standards and vocabularies that are used within these specifications. The literature review also captured examples of SMBP data exchange in action, data flows, and technologies used to support the collection and transmission of SMBP data. Internet searches, review of journal articles, participation in HL7 work group calls, and a review of grey literature were used to inform the findings of the national assessment.

Table 1: The outlined process used during the literature review.

Literature Review Activity	Outcome
Identify categories in scope for the literature review and corresponding questions to be addressed, in consultation with CDC.	Draft framework for literature review note-taking: Workbook with tabs to collect data across various domains.
Review materials/references provided by CDC.	Add content to category tabs during review of materials (e.g., if an issue brief mentioned a health system/implementer of interest, it was noted).
Identify and participate in HL7 Work Groups and projects relevant to supporting the SMBP electronic feedback loop.	Connection with HL7/standards work groups and community contacts working in this space.
Outreach to HL7/standards contacts to help identify resources, standards, and initiatives to be included in the scan (co-chairs for devices, patient empowerment).	Feedback on standards, specifications, and projects of interest. Access to working documents/drafts in progress.
Internet search to identify resources of interest.	Identification of additional references.
Journal search to identify published research of interest; via Emory University Library.	Identification of additional references.
Review of additional resources of interest (grey and published literature, working drafts shared by standards development contacts).	Add content for a review of materials.
Outreach to ONC and NACHC about projects and activities related to SMBP.	Identification of SMBP in practice.

The resources from the literature review were compiled into an initial draft report for review by the CDC project team.

Once the literature review was completed, the project team identified SMEs to participate in a one-hour interview using teleconferencing technology. A total of eight interviews were conducted in April and May of 2021. Four of the interviews had individual participant SMEs, and four interviews were conducted in groups with two or more SMEs from the same organization or group. All interviews were audio recorded (with the permission of the interviewees), and qualitative data analysis techniques were used to identify key themes. All interviewees were offered the opportunity to review the initial summary of their interview before they were finalized with feedback for inclusion in this report (see [Appendix B](#)).

Key findings

In this section, the key findings are presented for each of the three domains of interest: 1) regulatory and policy, 2) interoperability standards and specifications, and 3) SMBP in practice: data flows and technologies.

Regulatory and policy

This domain focuses on better understanding the regulatory and policy landscape in which SMBP data exchange needs to occur and the federal laws and regulations that are relevant to the capture and transmission of SMBP data.

Summary

- Laws and regulations surrounding SMBP data include: 1) capture and transmission of personal health record data, 2) medical devices and mobile applications, and 3) medical liability.
- Regulations for HIPAA-covered and non-HIPAA-covered entities vary and could lead to an increased risk of security breaches if data are handled by a non-HIPAA-covered entity.
- Due to the minimal risk posed by home BP monitoring devices and companion mobile health applications, the FDA provides minimal oversight and regulatory enforcement.
- Clinicians, especially at the start, might be wary of having electronic access to SMBP data due to potential liability if they do not act upon a high BP reading.
- A widely accepted standard of care has not been established for use of PGHD in clinical care, but as it becomes more widely used, policies will need to be incorporated for best practice.

Findings

The three categories of law that are relevant to SMBP data include: 1) personal health record data, 2) medical devices and mobile applications, and 3) medical liability. Personal health record privacy and security rules apply to all medical records and would need to be considered with SMBP data.

Personal health record data

HIPAA is regulated by the Office for Civil Rights within HHS and must be followed when working with personal health record data. Organizations that assist in the collection and transfer of SMBP data on behalf of HIPAA-covered entities are considered business associates according to the Social Security Act, 45 Code of Federal Regulations (C.F.R.) § 160.103.²⁵ A business associate, which would include an application developer for SMBP data, is a subcontractor that works with a clinician to create, receive, maintain, or transmit protected health information.²⁶ Accordingly, the application developer would be required to follow the HIPAA privacy rule provisions, which are generally specified within a business associate agreement between the developer and the clinician who will receive and use the data. Within the agreement, all elements listed within 45 C.F.R. 164.504(e) must be included.²⁷

²⁵ HHS, 2013. § 160.103. <https://www.govinfo.gov/content/pkg/CFR-2013-title45-vol1/pdf/CFR-2013-title45-vol1-sec160-103.pdf>

²⁶ Cornell Law School, 2013. 45 CFR § 160.103 - Definitions. <https://www.law.cornell.edu/cfr/text/45/160.103>

²⁷ HHS, 2003. Business Associates. <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html>

A few examples of what to include within an agreement between the application developer and the clinician are: permitted and required uses of personal health information (PHI); use of PHI for only what is permitted within the contract; and use of appropriate safeguards to prevent disclosure of PHI other than what is permitted within the contract. While application developers would not be subject to the full HIPAA Privacy Rule if considered a business associate, they are subject to the provision of ensuring necessary safeguards for the information. While business associates are responsible for sections of the Privacy Rule, they must follow the entire HIPAA Security Rule as it pertains to electronic PHI that is created, received, maintained, or transmitted in electronic form.²⁸ Oral or written protected health information would not apply within this rule.

Medical devices and mobile applications

One concern with PGHD is the inconsistent regulations between HIPAA and non-HIPAA-covered entities, especially as it relates to mobile health applications. Many mobile health applications are not operated on behalf of a HIPAA-covered entity and may not hold data, so they would not fall under HIPAA regulations.⁵ Many patients assume their health data are protected, whereas the privacy and security of a third-party vendor might not be as strict as HIPAA-covered entities. PGHD might be more at risk for security breaches and misleading use of the data outside of the original intent due to third party vendors not having the same security laws as HIPAA-covered entities.³

Based on ONC's 21st Century Cures Act, patients are now empowered to receive and transmit their personal health data as they please. This act allows for convenience in using mobile applications to access personal health records from clinicians' EHR systems.⁷ The increased convenience comes with the potential risk of health data being accessed or submitted inappropriately. The Cures Act allows patients to choose which applications and individuals they send their personal health data to without blocking them from specific information. However, the Act requires application developers to educate patients on the privacy and security concerns of using an application to access and transmit personal health data, which many times is done with a consent pop-up within the application. Medical application developers seeking certification for their use of the API technology must meet the API Conditions of Certification from ONC to remain in good standing under the ONC Health IT certification program.²⁹ The Enhanced Oversight Accountability Final Rule provides ONC with regulatory oversight to review certified health IT under specific circumstances and ban certification of health IT developers.³⁰

While third party vendors may create mobile applications to collect SMBP and other PGHD, data might not fall under HIPAA regulations for SMBP; therefore, they would still need to abide by FTC's Health Breach Notification Rule. If not covered under HIPAA, FTC's Health Breach Notification Rule requires personal health record entities to notify affected customers, FTC, and in some cases, the media, if a breach of an individual's personal health record occurs.⁸ Additionally, this act can be enacted if there is unauthorized access of a personal health record or when a personal health record or information contained within it is not sent securely.

²⁸ HHS, 2020. The Security Rule. <https://www.hhs.gov/hipaa/for-professionals/security/index.html>

²⁹ ONC. What ONC's Cures Act Final Rule Means for Health IT Developers. <https://www.healthit.gov/curesrule/what-it-means-for-me/health-it-developers>

³⁰ ONC, 2020. ONC Health IT Certification Program Overview.

<https://www.healthit.gov/sites/default/files/PUBLICHealthITCertificationProgramOverview.pdf>

FTC oversees the FTC Act which prohibits misleading claims on the intention of an application or medical device, which would cause unfair advantage for its product over others including claims regarding privacy and security and the application's safety and performance.³¹ Under the FTC Act, devices cannot cause harm to an individual.

FDA works with software or mobile application developers to determine if their product is considered a medical device. Depending on the classification decision by FDA, the regulations will differ. First, according to the Federal Food, Drug, and Cosmetic (FD&C) Act, if a medical application is intended to carry out one of the following activities, then it would not constitute as a medical device data system and therefore would be excluded from the FD&C Act:

- Support administrative functions
- Encourage a healthy lifestyle
- Serve as an electronic patient record
- Assist in transferring, storing, or converting formats
- Display device data and results with limited clinical decision support

However, within the policy device software functions and mobile medical applications guidance, FDA lists a medical device would be one that “functions [to] allow a user to collect (electronically or manually entered) BP data and share this through email, track, and trend it, or upload it to a personal or EHR.”³² Based on the latter example, this software would need to abide by the FD&C Act regulated by FDA; however, FDA would not engage in regulatory oversight. Since the application would not update a patient's medication or change the way the BP monitor worked, there is minimal risk of the application harming an individual.⁹

Medical liability

SMBP may introduce questions of how and when the data will be reviewed and how and when follow-up will occur. Ultimately, the lack of widespread knowledge of standards of care for PGHD and the concern of liability for using PGHD may deter clinicians from initiating these programs.

States hold authority over medical malpractice laws. While the characteristics of medical negligence in each state are similar, the time a file needs to be created for medical negligence after the incident—known as the statute of limitations—differs across states. For medical negligence to be presented, the doctor must refuse due care or best practice for the patient. Generally, there are four objectives that must be met for medical negligence:³³

1. The patient has consented to the clinician's care and the clinician has decided to care for the patient.
2. The clinician breached their best standard of care.

³¹ FTC, 2006. Federal Trade Commission Act. <https://www.ftc.gov/enforcement/statutes/federal-trade-commission-act>

³² FDA, 2019. Policy for Device Software Functions and Mobile Medical Applications. <https://www.fda.gov/media/80958/download>

³³ Bal, 2009. An Introduction to Medical Malpractice in the United States. *Clinical Orthopedics and Related Research*. 467(2), 339-347. <https://doi.org/10.1007/s11999-008-0636-2>

3. Injury occurred to the patient because of the breach in care.
4. The injury resulted in damages.

Due to the emergence of PGHD, there aren't standard of care models where medical malpractice could easily be argued. However, as more PGHD are used, policymakers will need to ensure that once a standard of care is established, clinicians follow it appropriately and update policies to take that into account.¹⁷

Lastly, medical liability and malpractice insurance do not always apply to telehealth services. For some insurance plans, telehealth services are only covered with supplemental coverage. Additionally, if planning to practice in more than one state, additional confirmation will be needed to ensure the insurance policy covers the clinician at all locations.³⁴

Gaps and barriers

- Clinicians are concerned about the need to adhere to HIPAA when accessing and using data obtained and held by third parties. PGHD might be more at risk for security breaches and misleading use of the data outside of the original intent due to third party vendors not having the same security laws as HIPAA-covered entities.
- There is uncertainty around when a business associate agreement may be needed between a clinician and a mobile application developer.
- Clinicians are also concerned about medical liability in having potentially real-time access to SMBP and PGHD. Clinicians are concerned they need to respond to each abnormally high value reported.
- Clinicians are also concerned about medical liability in having documentation for their clinical decision-making. If they are basing their clinical decision-making on SMBP and PGHD, they may want these data stored within the EHR.
- The legal and regulatory framework for personal health record data are not consistent across HIPAA-covered and non-HIPAA-covered entities.

Recommendations

- Support the development of a privacy and security framework that would hold non-HIPAA-covered entities to the same standards as HIPAA-covered entities when it comes to PGHD.
- Create a business associate agreement by modifying existing ones and make it widely available to support organizations that aim to partner with HIPAA-covered entities to exchange patient-generated SMBP data.
- Ensure sufficient coverage for validated devices that meet nationally recommended criteria (e.g., automatic arm devices, Bluetooth enabled).
- Develop standards of care to assist clinicians in clinical decisions based on PGHD BP readings.
- Develop protocols and guidance for patients and clinicians around how and when SMBP data will be reviewed and used and when and how follow-up will occur.

³⁴ Health Resources & Services Administration. 2021. Legal considerations. <https://telehealth.hhs.gov/providers/legal-considerations/>

Interoperability standards and specifications

This domain focuses on better understanding the data exchange standards and specifications supporting SMBP data exchange and the terminology standards and vocabularies that are used within these specifications (see [Appendix C](#)).

Summary

- The 21st Century Cures Act and Cures Act Final Rules, issued by ONC and CMS, are driving the healthcare interoperability landscape. FHIR and SMART are key standards called out to support API-based access to data held in health information systems.
- Although the 21st Century Cures Act Final Rules do not explicitly call out the transmission of PGHD (such as SMBP), FHIR and SMART could potentially support the movement of this data. Implementation guides describe the use of FHIR resources to represent data obtained from personal health devices and represent vital signs data using FHIR. A SMART Markers framework, an extension of FHIR and SMART, is envisioned as a potential solution to support sharing of PGHD between a patient and his or her clinician.
- Vital signs, including systolic and diastolic blood pressure, are called out in the version of USCDI required as part of the ONC Cures Act Final Rule; average blood pressure will be considered for inclusion in a future version of USCDI. Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine -- Clinical Terms (SNOMED CT) codes are available to represent BP measurements in data being exchanged.
- There are multiple organizations involved in standards and specifications development relevant to personal health devices and SMBP.
- At present, there is no guidance on how to implement standards-based use of APIs to enter data into an EHR (FHIR write capability); rather, the implementation specifications focus on use of APIs to extract data already held in an EHR (read capability).

Findings

Overview of the 21st Century Cures Act Final Rules

Overall, the 21st Century Cures Act influences the current landscape of health information data exchange in the U.S. In March 2020, ONC and CMS issued specific provisions of this law detailed in two rules.⁹ The ONC Cures Act Final Rule and the CMS Interoperability and Patient Access Final Rules seek to modernize and simplify data sharing across the healthcare enterprise, with HL7 [FHIR Release 4.0.1](#) identified as the foundational standard to support data exchange via APIs.¹⁰ FHIR is built around the use of “resources” to define the content and structure of the information to be exchanged.

The ONC Final Rule requires the SMART standard, outlined in the [HL7 SMART App Launch Implementation Guide Release 1.0.0](#), to be used in conjunction with FHIR. The HL7 specification details using the SMART standard to facilitate API-based data access and sharing by providing an authentication and authorization scheme. The use of SMART on FHIR and FHIR-based APIs intends to support data sharing among an ecosystem of patient- and clinician-facing apps. For consumers, APIs intend to support access to personal health records using a smartphone application of their choice; for clinicians, APIs are intended to support access to a wide range of plug-and-play functionality outside of what is offered in a traditional EHR.¹⁸

The ONC Cures Act Final Rule also established USCDI. USCDI outlines a standard set of health data classes and data elements to support nationwide, interoperable health information exchange. A corresponding implementation guide, [HL7 US FHIR Core Implementation Guide FHIR Release 4](#), outlines how certified health IT must respond to queries for USCDI data using FHIR resources. Given this backdrop, the following section discusses the interoperability standards and specifications specific to SMBP data sharing.

21st Century Cures Act and PGHD/SMBP data sharing

The 21st Century Cures Act Final Rules do not explicitly address sharing of PGHD within the healthcare enterprise. Rather, the Rules focus on providing access to existing data in these health information systems. For PGHD, including data generated by home BP monitoring devices, data need to flow from the patient to the clinician. Although the Cures Act Final Rules are silent on the standards and specifications required to support transmission and use of PGHD, the foundation laid by the Rules could support this exchange.

For example, vital signs are included as a data class within USCDI Version 1, with diastolic blood pressure and systolic blood pressure listed as data elements.³⁵ In addition, “average blood pressure” was put forward by AMA as a new data element for inclusion in a future version of USCDI to support the exchange of this computed data.³⁶ The USCDI version update process allows for stakeholders, such as AMA, to make these suggestions for review.³⁷

Terminology standards also support the representation of BP data in health data exchange. The LOINC standard is used for the representation of diastolic and systolic blood pressure data elements in USCDI V1, and the SNOMED CT standard provides codes for the representation of calculated average blood pressure. See [Appendix C](#) for detailed information on the LOINC and SNOMED CT codes applicable to SMBP.

Additionally, key FHIR resources relevant to the exchange of SMBP data include patient, device, and observation. These building blocks could be used to transmit patient demographic information (patient resource), BP measurements (observation resource), and information about the device used to obtain the measurements (device resource). In fact, an [HL7 Personal Health Device FHIR Implementation Guide](#) defines the use of these FHIR resources to represent measurements from personal health devices. Similarly, a [Personal Health Device Observation Upload Profile](#) from Integrating the Healthcare Enterprise (IHE) also describes the use of FHIR resources to represent personal health device data. The HL7 and IHE personal health device specifications are both currently posted as standards for trial use and/or trial implementation.³⁸ Finally, the representation of vital signs data using the FHIR observation resource is further outlined in the [HL7 Vital Signs FHIR Implementation Guide](#).

³⁵ ONC, 2020. USCDI V1, Vital Signs. <https://www.healthit.gov/isa/uscdi-data/vital-signs#uscdi-v1>

³⁶ ONC. USCDI Submission Comment: Average Blood Pressure. <https://www.healthit.gov/isa/uscdi-data/average-blood-pressure>

³⁷ ONC, United States Core Data for Interoperability (USCDI) Version Update Process. <https://www.healthit.gov/isa/sites/isa/files/2020-07/USCDI-ONDEC-Fact-Sheet.pdf>

³⁸ HL7 describes specifications as informative, standard for trial use, or normative. Informative specifications provide non-binding guidance and are used to vet content; standards for trial use are non-binding but are intended to become so after revisions through additional trial implementations; normative standards are intended to be binding and authoritative. Standards and specifications advance through these stages through a balloting and commenting process. IHE describes the status of their profiles in terms of “states”: Final Text (stable), Trial Implementation (for trial use and potential revision), and Public Comment (for comment, not for implementation).

Extensions of FHIR and SMART on FHIR offer an opportunity to use these 21st Century Cures standards in the transmission of PGHD from a patient to a clinical team. Inspired by their work on consumer-facing mobile applications to collect and use patient-reported outcome data in clinical care, Boston Children’s Hospital envisioned the use of SMART markers within consumer and clinician-facing apps. SMART markers allow for a clinician to submit a request to a patient for their PGHD (such as home BP readings) and for the patient to respond to this request within a SMART on FHIR-enabled mobile application.³⁹

Device standards and specifications

Additional standards and specifications from the International Organization for Standardization (ISO), the Institute of Electrical and Electronics Engineers (IEEE) and the Personal Connected Health Alliance (PCHA) have informed device interoperability efforts to date.

The ISO/IEEE 11073 family of standards is intended to support medical/health device communication from point-of-care health devices and personal health devices (such as home BP monitors) to other systems. [Part 20601: Application profile--Optimized Exchange Protocol \(2019\)](#) provides an overall framework for interoperability that can be applied across different types of personal health devices. Unlike point-of-care devices used in acute care settings, personal health devices are often limited in resources of processing, memory, and communication.⁴⁰ Within the 11073 standards, devices such as BP monitors are referred to as “agents.” These agents communicate with “managers” (i.e., “compute engines”), such as personal computers or smartphones. [Part 10407: Device specialization--Blood pressure monitor \(2020\)](#) describes standards for personal BP monitoring devices. These ISO/IEEE standards provide a foundation to support data sharing between devices and other systems.

The [Continua Design Guidelines](#), developed by the PCHA, offer additional guidance to support interoperability across interfaces involved in health monitoring, such as between a personal health device and a smartphone application and on to a health information system such as an EHR.⁴¹ Additionally, the PCHA offers test tools and a testing program that allow vendors to self-test and declare their compliance or complete third party testing to receive certification. Certified products are listed on the PCHA website.⁴² Both the 11073 standards and the Continua Guidelines are referenced in the [IHE Personal Health Device Observation Upload Profile](#) and the [HL7 Personal Health Device FHIR Implementation Guide](#).

Mobile health standards and specifications

Finally, there are additional standards and specifications related to supporting the interoperability of mobile health data that are relevant to SMBP. The Open mHealth organization seeks to advance sharing of mobile health data between patients and their clinicians through an open software architecture. Open mHealth provides data standards (schemas) to specify the format and content of data (including blood pressure), an API to facilitate data sharing from an application or device, tools to support data aggregation from third party APIs, and tips and tools for data visualization.⁴³ A corresponding [Open](#)

³⁹ Sayeed et al, 2020. SMART Markers: collecting patient-generated health data as a standardized property of health information technology. *npj Digital Medicine*. 3,9. <https://doi.org/10.1038/s41746-020-0218-6>

⁴⁰ Clarke, 2009. Remote Cards of Patient-The Personal Health Devices Standard-ISO/IEEE 11073-20601. <https://healthmanagement.org/c/it/issuearticle/remote-cards-of-patient-the-personal-health-devices-standard-iso-ieee-11073-20601>

⁴¹ PCHA, 2019. Continua Design Guidelines. <https://www.pchalliance.org/continua-design-guidelines>

⁴² PCHA. Continua Certified Product Showcase. <https://www.pchalliance.org/product-showcase>

⁴³ Open mHealth. Documentation. <https://www.openmhealth.org/documentation/#/overview/get-started>

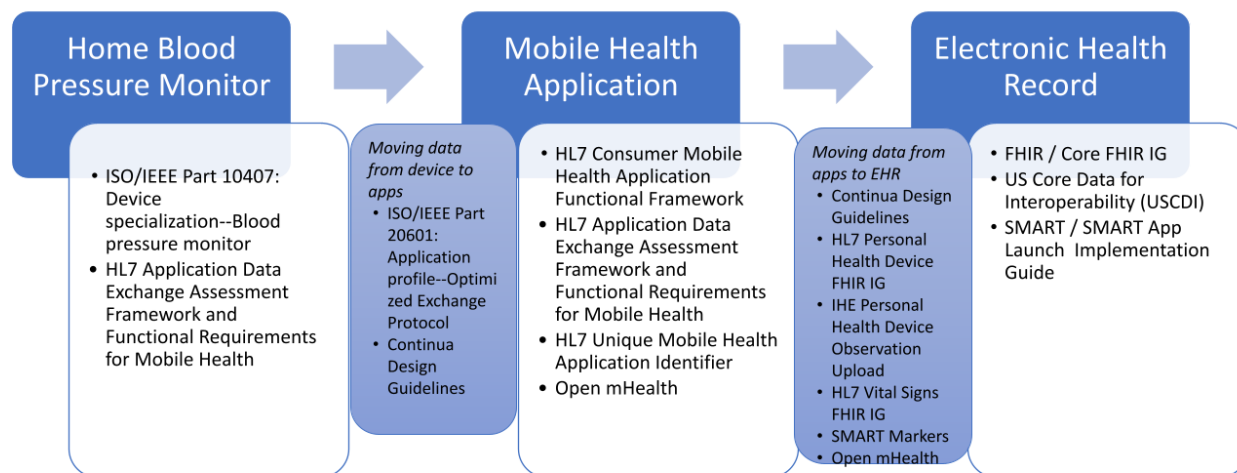
[mHealth to FHIR Implementation Guide](#) describes how to use FHIR and Open mHealth to “access data from third party APIs like Google FIT, FitBit, and Apple iHealth.”

Furthermore, the [HL7 Application Data Exchange Assessment Framework and Functional Requirements for Mobile Health](#) guide describes functional requirements to support the assessment of devices, mobile health applications, and other health IT infrastructure in ensuring sufficient data representation and FHIR-based data exchange across the healthcare system. This work was driven by ONC through their Advancing Standards for Precision Medicine Program, based on an identified need that “implementers of mobile health devices and apps would benefit from a clear framework that incorporates the use of FHIR.”⁴⁴

Similarly, the [HL7 Functional Framework for Consumer Mobile Health Applications](#) describes functional and non-functional requirements for mobile application developers. These requirements are intended to help ensure security, privacy, data access, data export, and transparency and disclosure of conditions, providing a standard against which an application’s characteristics can be assessed for potential certification (voluntary or regulatory). In a related effort, HL7 is also pursuing a project to introduce a unique mobile health application identifier to be used in certification and data exchange.⁴⁴

As described, there are multiple standards and specifications relevant to the transmission of personal health device data—from a device, to a mobile application, and on to healthcare information systems. Figure 2 depicts a simplified view of this landscape with relevant standards and specifications listed under the applicable system or interface between systems. This is an area of rapid development with multiple organizations active in the advancement of standards and specifications.

Figure 2. Standards, specifications and frameworks relevant to the transmission of SMBP data



Gaps and barriers

- There is a complex web of inter-related standards and specifications relevant to SMBP data exchange. While the standards and specifications address the various systems and interfaces

⁴⁴ ONC. USCDI Submission Comment: Unique Mobile Health Application Identifier. <https://www.healthit.gov/isa/uscdi-data/unique-mobile-health-application-identifier-umhai>

involved in sharing of personal health device data, a common or overarching implementation framework to support the movement of this data to EHRs is not immediately evident.

- Given the number of standards and specifications and the multiple organizations involved in their development, it may be challenging to ascertain and identify applicable standards. This is especially true for those not traditionally involved in standards development processes, such as consumer mobile health application developers.
- This is an area of active development with newly emerging frameworks and specifications that have not yet been widely tested or adopted.
- There is a lack of incentives for device manufacturers, mobile health application developers, and EHR vendors to support the adoption of standards and specifications and to support the exchange of PGHD within the healthcare enterprise.
- There is a lack of implementation guidance specifying how FHIR-based APIs can be used to enter data, such as home-monitored BP readings and other PGHD, into an EHR.
- Standards development efforts would benefit from participation and input from additional stakeholders traditionally not involved in the standards development process, e.g., patients, clinical and population health representatives, and mobile health application vendors.
- It is difficult to ascertain the level of adoption of standards and specifications in practice.
- According to ONC³⁷:
 - Improved internal and external coordination is needed between standards development organizations as the work conducted in each of these organizations tends to be performed separately with varying processes for development, comment, and approval.
 - Standards development can be a lengthy process that requires a series of review and approval cycles over several years before a standard or specification is identified as normative. This pace often cannot keep up with PGHD solutions introduced in the market.

Recommendations

- Develop an implementation framework to support the movement of SMBP data to EHRs.
- Develop implementation guidance focused on use of the FHIR write capability to enter data into an EHR.¹⁶
- Expand requirements for EHR certification to include write access.
- Incentivize device, mHealth, and EHR vendors to support adoption of standards and specifications to support the exchange of PGHD.
- Consider an HL7 FHIR Accelerator approach to accelerate the development of new specifications focused on the use of PGHD in clinical care.¹⁷
- Align with ONC's unfulfilled recommendations from 2018⁶:
 - Accelerate the development of standards and specifications among standards development organizations to better keep pace with market innovations.
 - Identify a common implementation framework for capture and integration of PGHD in EHRs and other health systems.

- Bolster industry certification programs to verify standards-based exchange capabilities against a common framework.

SMBP in practice: program examples and findings from the field

This domain focuses on better understanding: 1) examples of SMBP data exchange in action in clinical settings, 2) data flows, 3) technologies and interoperability standards that are used to support the collection, transmission, and use of SMBP data, and 4) the technology landscape supporting the use of PGHD in clinical care.

Summary

- Several technologies may be used to support the electronic capture, transmission, and use of SMBP and other PGHD: personal health devices, mobile health applications, clinical portals, personal health data aggregators, data integration engines, patient portals, EHRs, and SMART on FHIR applications.
- While these technologies and systems can facilitate data flow from the patient to clinician, there is no clear recommended path for the flow of these data.
- Interoperability between technologies and platforms presents a challenge, especially for connecting the SMBP/PGHD to EHR technology.
- Healthcare organizations must invest in developing custom interfaces to support SMBP/PGHD data collection and use, and in data integration services to address this need.
- Data integration services are emerging to address the unmet need of facilitating connections across data platforms and EHR technology. These services act as hubs and health information exchanges for personal health devices and mobile health data.
- SMART on FHIR applications present an opportunity to provide data analysis, data visualization, and clinical decision support tools for SMBP/PGHD within the clinical workflow.

Findings

Examples of SMBP programs

The following three examples of SMBP programs with electronic data sharing between the patient and the clinician illustrate the process flows and technologies used in a sampling of practices. These examples include the SMBP and remote patient monitoring programs from Ochsner Health, Reliant Health, and the Health Federation of Philadelphia. For each program, this review examines pre-conditions for program participation along with key steps in the processes involved in generating, capturing, transmitting, analyzing, reviewing, and using the data. Technologies and standards used to support these processes are also highlighted where known.

Ochsner Health is Louisiana’s largest nonprofit, academic healthcare system recognized for their commitment to using innovative technologies to support patient care and patient engagement. Their digital hypertension program “collects large samples of BP values from home, providing real-time assessment and intervention, leading to greater reduction in both blood pressure variability and average blood pressure compared to office-based care.”¹³

The technologies used in the Ochsner program include patients’ smartphones, wireless home BP monitors, applications affiliated with the BP devices, a consumer mobile health data aggregator, their patient portal, and EHRs. The patient portal is used to support patient consent and additional

information gathering from the patient at the initiation of the program. Participating patients purchased a wireless BP monitor from a list of pre-selected vendors, downloaded the application associated with the device, and in some cases also set up consent for data sharing between the device application and a consumer mobile health data aggregator.^{11,12,13} A description of the process flow steps in the program is provided in Table 2.

Next, Reliant is a healthcare organization serving central Massachusetts. It served as a pilot site for an effort led by ONC to advance interoperability standards for precision medicine. As a demonstration site for this project, Reliant piloted use of Open mHealth standards to capture and monitor patients’ vital signs measurements from various devices, including a BP monitor.³⁷

The technologies used in the Reliant approach included wireless home BP monitors and other home-monitoring devices, mobile health applications associated with the devices, an in-house “device connector” platform, patient portal, and the EHR. To initiate participation in the program, a clinician “ordered” home monitoring in the EHR; this generated an access code to be shared with the patient for their entry into a Reliant “device connector” website. Patients navigated to the “device connector” website to enter the provided access code to gain access to this system. Once logged in, the patient selected application(s) they were planning to use. As a final step, patients downloaded the mobile health application(s) associated with their device(s) and authorized data sharing with Reliant within these apps.⁴⁵ Process flow steps for this program are further described in Table 2.

Finally, the Health Federation of Philadelphia is a nonprofit public health organization and membership association for safety net community health centers in southeastern Pennsylvania. They coordinated a SMBP program for multiple health centers designed to improve hypertension management and control for African Americans.

The technologies used by the Health Federation and the participating health centers included a wireless BP monitor, the mHealth application associated with the device, a clinical portal associated with the device, and multiple EHR systems. Participating patients were provided with the BP monitor, downloaded the device application, and consented for their readings to be uploaded and shared with their care team via the device clinical portal. Table 2 provides a description of the key steps involved in this program’s process flow.¹⁵

Table 2. SMBP program process flows

Program: 1. Data generation and capture	2. Data transmission to the clinician	3. Data analysis and review	4. Care team outreach
<p>Ochsner Health: Patients engage in SMBP using a wireless BP device purchased by the patient (based on a list of products Ochsner recommends). Data are captured in an application</p>	<p>Data are transmitted from the BP device application to the EHR via a direct interface between the device application and EHR or an interface connecting the consumer mobile</p>	<p>Incoming BP data are analyzed by an algorithm developed internally to assess validity and directional change and alert the care team to patients needing intervention. Custom visual tools within the EHR</p>	<p>Intervention and outreach are based on the algorithm and alerts. Pharmacists and health coaches provide medication adjustments and lifestyle coaching.</p>

⁴⁵ Garber, 2020. Using Standards to Wirelessly Connect Consumer Health Devices to the EHR [slide deck]. GPIN Virtual Health Presentation

associated with the device. In some cases, these data are also captured in a patient’s mobile health data aggregator.	health data aggregator to the EHR to facilitate real-time reporting of BP readings.	display trending blood pressure over time and other data. Patients’ data are also available in the patient portal with monthly reports showing their progress and customized tips. Physicians also received monthly reports on their patients’ progress.	
Reliant Health ⁴⁵ : Patient engages in SMBP and other home monitoring. Data are captured in application(s) associated with the device(s) used.	Data sharing (set up in the “device connector” platform), allows blood pressure and other PGHD to flow from the consumer-facing application(s) to the EHR.	Critical values are flagged for care team follow-up. Data visualizations are provided to support care team review of readings. Patients are able to review their data within the patient portal.	Care team outreach to follow up on critical values and trends from the monitoring period.
Health Federation of Philadelphia ⁴⁶ : Patients engage in SMBP using a provided wireless BP cuff. Data are captured in an application associated with the device.	Data are accessed within the clinical portal associated with the BP cuff. Staff manually record average BP readings for a given monitoring period (based on data in the clinical portal) within the EHR.	Staff log into the clinical portal for daily review of BP readings. Staff contact the patient’s primary care clinician if a reading is above a critical threshold. Primary care clinicians review average BP readings documented in the EHR for each completed monitoring period.	Primary care clinicians followed up in instances where singular BP readings were above a critical threshold. Primary care clinicians follow up after a monitoring period to adjust medication and discuss hypertension management as needed.

Additional findings from the field: technology landscape supporting SMBP

Technological advances present an opportunity for clinicians to remotely monitor patients with hypertension and provide more timely, individualized care based on SMBP data. Dr. Richard Milani, the Chief Clinical Transformation Officer and Vice-Chairman of the Department of Cardiology at Ochsner Health System, notes the opportunity for consumers to use wireless home BP monitors and review trends in their readings over time in smartphone applications. Milani also notes the opportunity for these data to “populate a patient’s electronic [health] record.”⁴⁷ Within EHR technology, algorithms can help analyze and visualize the BP readings as well as other PGHD.

However, despite these advances, technological challenges remain in the implementation of SMBP programs. In a University of Pennsylvania and Pennsylvania Hospital program using text messaging to

⁴⁶ Health Federation of Philadelphia, 2020. SMBP Program Packet

⁴⁷ Milani et al, 2016. New Concepts in Hypertension Management: A Population-Based Perspective. Progress in Cardiovascular Diseases. 59(3):289-294. <https://doi.org/10.1016/j.pcad.2016.09.005>

support SMBP among postpartum women with pregnancy-related hypertension, technology was noted as a “major hurdle,” even without the use of wireless/connected BP devices.⁴⁸ This program relied on manual patient submission of BP readings via text with an in-house patient engagement platform used to analyze the readings and inform outreach and follow-up.

In a clinical community care collaborative model where SMBP was implemented in nine health centers in Kentucky, Missouri, and New York, Meador noted, “Most health centers did not have standard places in the vital signs section of their EHR for out-of-office BP measurements or other standard places to document SMBP-related data elements. Five health centers customized their health IT systems to allow for the entry of out-of-office measurement and related SMBP data elements to their systems...”⁴⁹ Finally, in a qualitative study examining primary care clinician preferences in using SMBP data, researchers noted two key challenges in integrating SMBP data into EHRs: 1) identification of PGHD most pertinent to the management and treatment of hypertension and 2) the need for a user-friendly patient application that can both obtain PGHD and SMBP measurements and seamlessly integrate that information into the EHR.”⁵⁰

Technology landscape supporting use of PGHD in clinical care

These findings are in line with the literature examining use of PGHD in clinical care. Although PGHD are perceived as providing value to “support care decisions, improve patient-provider communication and engagement, and [fulfill] the promise of applying PGHD to formal care pathways and measurement-based care,”⁵¹ the health IT infrastructure remains a challenge.

These challenges stem from a number of sources, including the following:

- The diverse types of PGHD and modalities of collection.
- The lack of standards around how these data are stored and tracked, as well as the lack of interoperability across devices and platforms.
- Difficulties in integrating PGHD within EHRs.
- The need for sophisticated tools to aid evidence-based interpretation of the data.^{51,52}

A systematic review examining the use of PGHD in clinical practice revealed “integration of these data into EHRs was extremely limited” with “basic” decision support capabilities.⁵³ Abdolkhani noted an overall “lack of cohesion” on a data management strategy for use of PGHD to support report patient

⁴⁸ Hirschberg et al, 2019. Heart Safe Motherhood: Applying Innovation Methodology for Improved Maternal Outcomes. NEJM Catalyst. <https://catalyst.nejm.org/doi/full/10.1056/CAT.19.0660>

⁴⁹ Meador et al, 2021. Accelerating Use of Self-measured Blood Pressure Monitoring (SMBP) Through Clinical-Community Care Models. Journal of Community Health. 46(1), 127-138. <https://doi.org/10.1007/s10900-020-00858-0>

⁵⁰ Rodriguez et al, 2019. Connecting Home-Based Self-Monitoring of Blood Pressure Data into Electronic Health Records for Hypertension Care: A Qualitative Inquiry with Primary Care Providers. JMIR Formative Research. 3(2), e10388. <https://doi.org/10.2196/10388>

⁵¹ Lavalley et al, 2020. mHealth and Patient Generated Health Data: Stakeholder Perspectives on Opportunities and Barriers for Transforming Healthcare. mHealth. 6,8. <https://doi.org/10.21037/mhealth.2019.09.17>

⁵² Lai et al, 2017. Present and Future Trends in Consumer Health Informatics and Patient-Generated Health Data. Yearbook of Medical Informatics. 26(1), 152-159. <https://doi.org/10.15265/IY-2017-016>

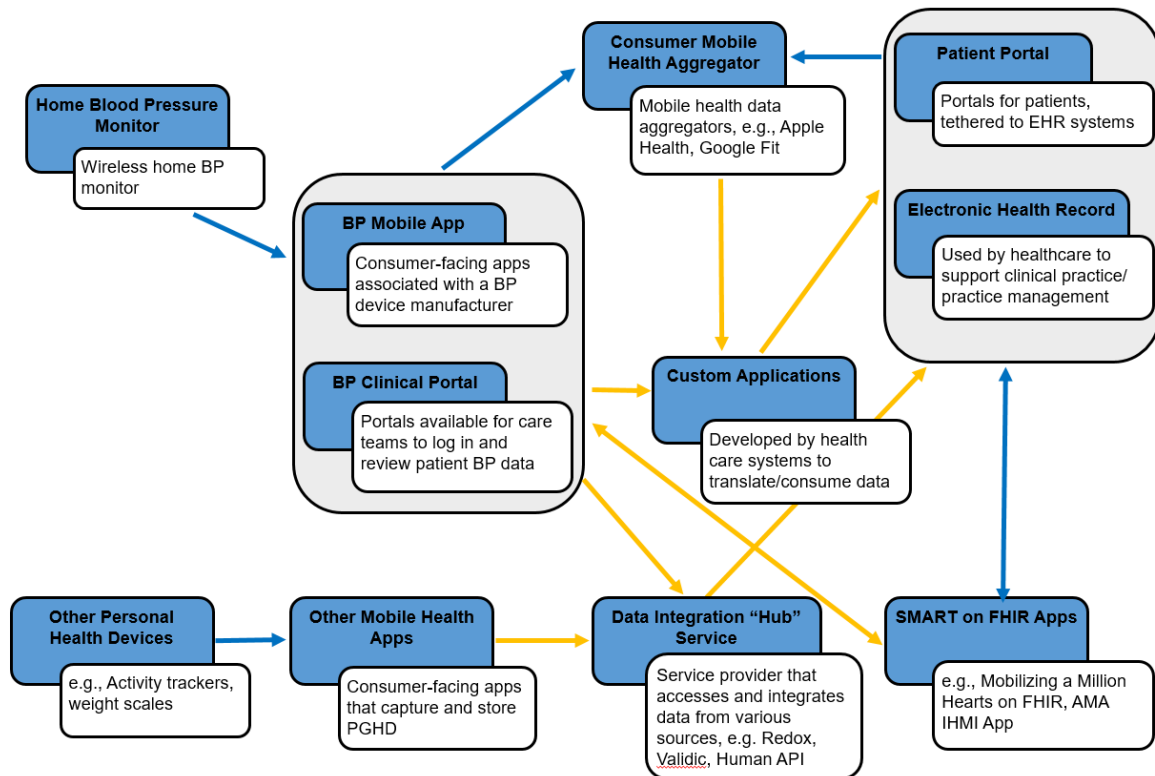
⁵³ Demirus et al, 2019. Patient Generated Health Data Use in Clinical Practice: A Systematic Review. Nursing Outlook. 67(4), 311-330. <https://doi.org/10.1016/j.outlook.2019.04.005>

monitoring.⁵⁴ Given these challenges, integrations between personal health monitoring devices/mobile health applications and EHRs are often based on proprietary “black box” approaches supported by a third party platform.⁵⁵

Technologies supporting the flow and use of SMBP values and PGHD

There are various technologies and systems that may be involved in the capture, transmission, and use of SMBP values and PGHD in clinical care. Figure 3 provides a visual depiction of this landscape from the perspective of an individual patient. Each technology will be reviewed below.

Figure 3. Technology landscape supporting the capture, transmission, and use of SMBP values and PGHD in clinical care



- **Home blood pressure monitor:** A patient using a wireless home BP monitor can generate readings that are transmitted, usually via Bluetooth, to a companion consumer-facing mobile application (e.g., BP devices from Withings, Omron, Welch Allyn, A&D Medical, etc.).

⁵⁴ Abdolkhani et al, 2019. Patient-generated health data management and quality challenges in remote patient monitoring. JAMIA Open. 2(4), 471-478. <https://doi.org/10.1093/jamiaopen/ooz036>

⁵⁵ Blum, 2018. Patient-Generated Health Data and EHR Integration. <https://www.lantanagroup.com/patient-generated-health-data-and-ehr-integration/>

- **BP mobile app:** A patient can download and use a mobile application associated with a wireless home BP monitor to review their BP readings over time (e.g., Omron Connect app⁵⁶, Welch Allyn patient app⁵⁷, Withings Health Mate⁵⁸, etc.).
- **BP clinical portal:** Some BP device manufacturers also offer clinical portals. These are websites available for care teams to log in and review their patients' BP data (e.g., Welch Allyn Clinical Portal).
- **Other personal health devices:** A patient may also use other personal health devices that generate data of interest to care teams (e.g., FitBit, Apple Watch, etc.).
- **Other mobile health apps:** A patient may use mobile health apps associated with other personal health devices to review data generated. Mobile health apps not affiliated with devices may also be used by patients to record symptoms, medication adherence, etc.
- **Consumer mobile health data aggregator:** A patient may choose to have a personal health data aggregator receive and store information generated by personal health devices stored in mobile health applications. A patient may also use their mobile health data aggregator to request and store information obtained in clinicians' EHRs (e.g., Apple Health⁵⁹, Google Fit⁶⁰).
- **Custom applications:** Healthcare organizations may develop custom applications to support interfaces between consumer mobile health data aggregators and/or individual consumer mobile health applications and their EHR technology.
- **Data integration services:** Software developers may use data integration services to support connections between their applications and healthcare organizations' EHR technology. Healthcare organizations may use data integration services to obtain data from multiple disparate sources from a data integrator acting as a "hub" to facilitate exchange (e.g., Redox, Validic⁶¹, Human API⁶²).
- **Patient portal:** A patient may use a patient portal to access his or her medical information associated with a particular clinician or to communicate with his or her care team (e.g., MyChart (Epic Systems), HealtheLife (Cerner), etc.).
- **Electronic health record:** Clinicians use EHRs to record information about a patient's medical history and clinical care and to provide clinical decision support e.g., EpicCare Ambulatory (Epic Systems), PowerChart (Cerner), etc.).
- **SMART on FHIR apps:** These apps allow third party applications to access data stored within the EHR to support a specific function or capability. Clinicians may call on SMART on FHIR apps within their clinical workflows to support clinical decision making or data analysis and visualization (e.g., Mobilizing Million Hearts app, AMA Integrated Health Model Initiative (IHMI) App⁶³).

⁵⁶ <https://omronhealthcare.com/service-and-support/connected-health/>

⁵⁷ <https://www.welchallyn.com/en/products/categories/welch-allyn-home/connected-blood-pressure-monitors/home-bp-monitor.html>

⁵⁸ <https://www.withings.com/us/en/health-mate>

⁵⁹ <https://www.apple.com/ios/health/>

⁶⁰ <https://www.google.com/fit/>

⁶¹ <https://validic.com/hospitals-and-health-systems/>

⁶² <https://www.humanapi.co/>

⁶³ <https://www.healthit.gov/topic/scientific-initiatives/leap/mobilizing-million-hearts>

Gaps and barriers

- There are no clear, recommended paths for the movement of SMBP and PGHD data, but there are multiple pathways currently available.
- There is a lack of clarity around which specific data clinicians want to access at point-of-care.
- There is a lack of clarity around which data clinicians want to have integrated (consumed) into the EHR.
- There are manual workarounds to address gaps in interoperability.

Recommendations

- Support the provision of technical support and resources (similar to “Geek Squad” or “Genius Bar”) to improve digital literacy and work towards resolving the digital divide.
- Support policies that make patients the owners of any patient data generated by them. “Any data in a device belonging to a patient is owned by the patient.”
- Develop user-friendly patient application[s] that can both obtain PGHD and SMBP measurements and seamlessly integrate that information into the EHR to make clinical workflow more efficient.⁵¹
- Include blood pressure with other chronic disease initiatives to support interoperability and reduce complexity involved in the collection and storage of data (i.e., a patient with multiple chronic conditions should not have three apps to monitor their disease).⁵²

SMBP health IT data flow use case

Use cases are a type of textual requirements specification that capture how a user will interact with an information solution to achieve a specific goal. They describe the step-by-step process a user goes through to complete the goal.

Narrative

A patient obtains a validated upper arm BP device in order to measure their blood pressure at home, per their clinician’s recommendation. The patient works with the clinician to validate the accuracy of the home device, download and set up the device data system (i.e., mobile health application) to consent to data sharing with the clinician, and receive training on proper SMBP device technique and usage.

A patient engages in SMBP. The cuff generates BP readings and these data are transferred, generally wirelessly via Bluetooth, to a mobile health application on the patient’s mobile device. The device’s data system converts the SMBP data into a format suitable for transfer. Once converted, the data are transferred to the clinician’s EHR.

With the data available for review within the EHR workflow, the clinical care team reviews the patient-generated BP readings. The care team may also adjust the patient’s medication, if needed, triggering submission of an updated medication order to the patient’s pharmacy. The care team engages the patient via phone, text, secure message, and/or telehealth visit to share feedback and discuss hypertension management strategies. The patient continues with SMBP and the cycle continues.

The goal is seamless, interoperable communication between patient and clinician in support of SMBP and effective hypertension management.

Primary actors

- Patient
- Clinical care team

Primary systems

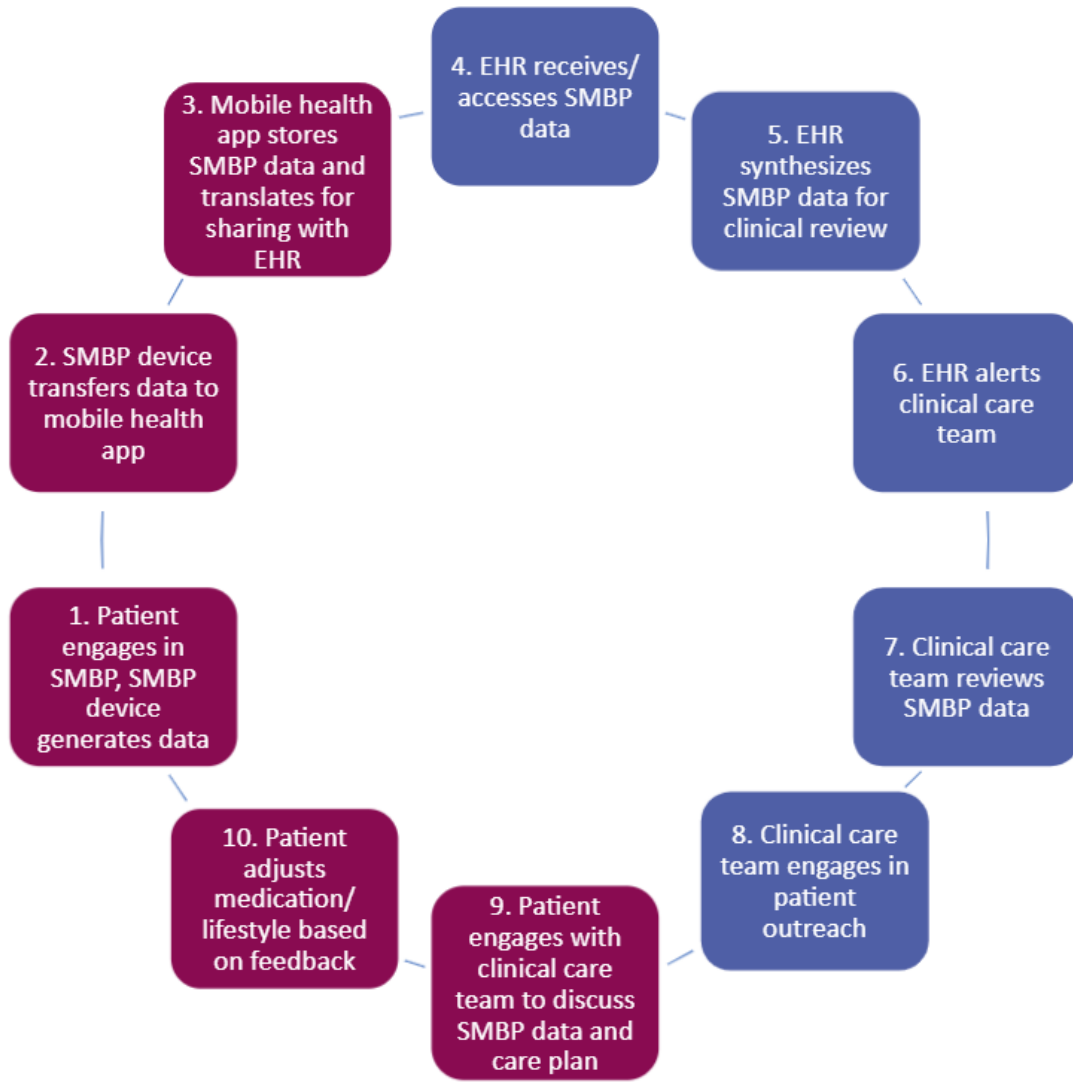
- SMBP device: An upper arm BP cuff used by a patient in an out of clinic setting capable of transmitting data to a device data system (e.g., mobile health application).
- Mobile health app/device data system: An application that collects, stores, displays, and transfers SMBP device readings.
- Ambulatory EHR: A system that collects and maintains real-time, patient-centered health records and supports clinicians in providing ambulatory care.

Preconditions

The following are assumed to be true when the use case begins:

- The patient has regular access to health care services: clinical care and pharmacy.
- The patient has a reliable broadband internet connection.
- The patient is using a SMBP device validated for clinical accuracy and capable of transmitting data to a mobile health application.
- The patient has authorized SMBP data sharing with the clinical care team and the clinical ambulatory EHR.
- The patient has access to reliable technology to support electronic communication (e.g., phone, portal/personal health record).

Figure 4. Process flow for clinician-directed SMBP



Step	Action	Clinical Notes	Potential Questions for SME/KI Interviews
1	Patient engages in SMBP; SMBP device generates data	<p>Recommended monitoring protocol: Measurement twice in the morning and twice in the evening (i.e., 4 readings per day), for a minimum of 3 days (12 readings total) or optimally for 7 days (28 readings total).¹</p> <p>According to a systematic review of monitoring schedules, 3 days of readings is sufficient “unless mean blood pressure after 3 days is close</p>	<ul style="list-style-type: none"> • What data are captured by these devices? • How much variation exists across devices from different manufacturers in terms of content/format of data captured?

		to a treatment or diagnostic threshold,” in which case, additional monitoring should be pursued. ⁶⁴	
2	SMBP device transfers data to mobile health app		<p>Wireless connection: Bluetooth or WIFI</p> <ul style="list-style-type: none"> • What data are transferred to the mobile app? • How much variation exists across devices from different manufacturers in terms of content/format of data transferred? • What, if any, interoperability standards are used in the transfer of data from device to app?
3	Mobile health app stores SMBP data and translate it/make accessible for sharing with EHR	Small sample of clinicians reported interest in additional PGHD, beyond SMBP readings, to better understand and interpret the readings. Additional information cited included: medication adherence, food diaries, weight, stressors, patient emotional state, alcohol consumption, heart rate, symptoms. However, there was also concern regarding “information overload.” ⁵¹	<p>Note: Usually cloud-based storage of data.</p> <ul style="list-style-type: none"> • How are the data generated by the device stored? Are structured formats used? • Where should the additional PGHD be collected?
4	EHR receives/accesses SMBP data	Need authorization and authentication protocols in place to allow for this.	<ul style="list-style-type: none"> • How is this happening in practice at this point? What technologies are used? What do the data flows look like? What interoperability standards are used? • What, if any, of the SMBP data should be written into the EHR?

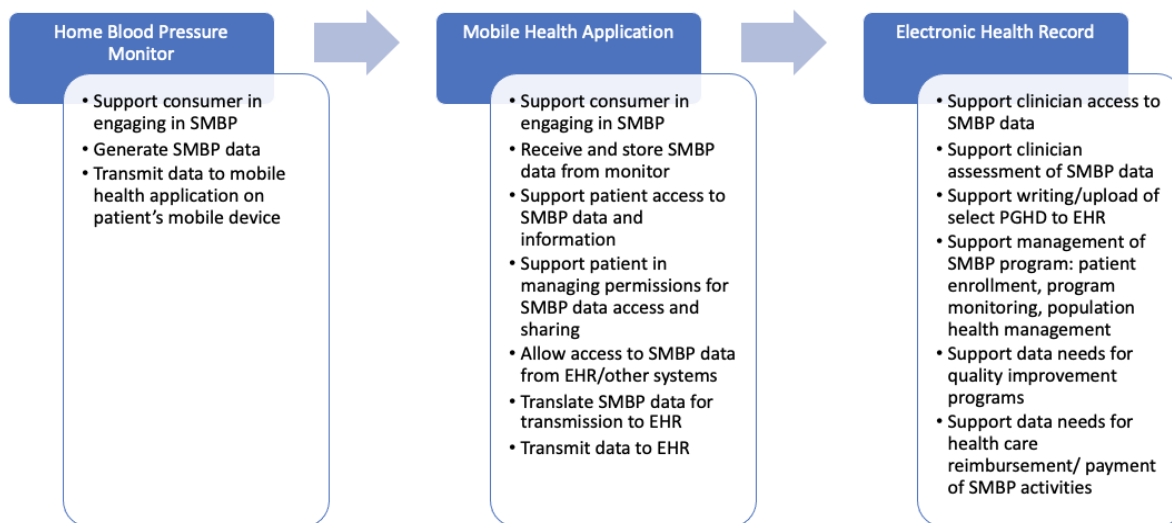
⁶⁴Hodgkinson et al, 2019. Schedules for Self-Monitoring Blood Pressure: A Systematic Review. American Journal of Hypertension. 32(4), 350-364. <https://doi.org/10.1093/ajh/hpy185>

5	EHR synthesizes SMBP data for clinician review	<p>Clinical assessment of BP for a SMBP period should be based on the average of all systolic and diastolic BP readings. However, clinicians may also want to review: “Individual BP readings... and process quality control measures such as the timing of readings, number of readings, and duration of the monitoring period.”¹</p> <p>SMART on FHIR apps could assist with this data analysis and visualization.</p>	
6	EHR alerts clinical team for review		
7	Clinical care team reviews SMBP data to support decision-making	<p>Clinical assessment of BP for a SMBP period should be based on the average of all systolic and diastolic blood pressure readings. However, clinicians may also want to review: “Individual BP readings... and process quality control measures such as the timing of readings, number of readings, and duration of the monitoring period.”¹</p> <p>Clinicians may also be interested in additional PGHD to better understand SMBP measurements, e.g., medication adherence, food diaries, weight, stressors, patient emotional state, alcohol consumption, heart rate, symptoms. However, there was also concern regarding “information overload.”⁵¹</p>	
8	Clinical care team engages patient via outreach		
9	Patient engages with clinical care team to discuss SMBP data and care plan		
10	Patient adjusts medications/lifestyle		

	based on care team feedback	
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High-level requirements

Figure 5. High-level requirements and data process flow for SMBP data



In addition to the system-specific requirements noted above, the following are general requirements that apply across the continuum:

- Use of open standards to support interoperability and minimize the need for and implementation of unique, proprietary solutions.
- Support device-agnostic exchange, i.e., the ability for health information systems/clinical care teams to receive data from devices from different manufacturers.
- Support user authentication and authorization processes.
- Support data provenance, to identify and track the origins and transit route of SMBP data.
- Support security and privacy of SMBP data.

Recommendations

This national assessment identified several gaps and barriers to consider in widespread adoption of SMBP. In an effort to alleviate or reduce the barriers to successful SMBP, PHII makes the following recommendations:

A. Regulatory and policy recommendations

- Support the development of a privacy and security framework that would hold non-HIPAA-covered entities to the same standards as HIPAA-covered entities when it comes to PGHD.
- Create a business associate agreement by modifying existing ones and make it widely available to support organizations that aim to partner with HIPAA-covered entities to exchange patient-generated SMBP data.
- Ensure sufficient coverage for validated devices that meet nationally recommended criteria (e.g., automatic arm devices, Bluetooth enabled).
- Develop standards of care to assist clinicians in clinical decisions based on PGHD BP readings.
- Develop protocols and guidance for patients and clinicians around how and when SMBP data will be reviewed and used and when and how follow-up will occur.

B. Interoperability standards and specifications recommendations

- Develop an implementation framework to support the movement of SMBP data to EHRs.
- Develop implementation guidance focused on use of the FHIR write capability to enter data into an EHR.¹⁶
- Expand requirements for EHR certification to include write access.
- Incentivize device, mHealth, and EHR vendors to support adoption of standards and specifications to support the exchange of PGHD.
- Consider an HL7 FHIR Accelerator approach to accelerate the development of new specifications focused on the use of PGHD in clinical care.¹⁷
- Align with ONC's unfulfilled recommendations from 2018⁶:
 - Accelerate the development of standards and specifications among standards development organizations to better keep pace with market innovations.
 - Identify a common implementation framework for capture and integration of PGHD in EHRs and other health systems.
 - Bolster industry certification programs to verify standards-based exchange capabilities against a common framework.

C. SMBP in practice recommendations

- Support the provision of technical support and resources (similar to “Geek Squad” or “Genius Bar”) to improve digital literacy and work towards resolving the digital divide.
- Support policies that make patients the owners of any patient data generated by them. “Any data in a device belonging to a patient is owned by the patient.”¹⁸
- Develop user-friendly patient application[s] that can both obtain PGHD and SMBP measurements and seamlessly integrate that information into the EHR to make clinical workflow more efficient.

- Include blood pressure with other chronic disease initiatives to support interoperability and reduce complexity involved in the collection and storage of data (i.e., a patient with multiple chronic conditions should not have three apps to monitor their disease).

Appendix A. SMBP Health IT Glossary

<i>Term</i>	<i>Description</i>
Application programming interface (API)	<p>An API is a set of software code, protocols, and tools that facilitates communication across software programs/applications. An API works behind the scenes, to place a call from one software application to another, to request data, code, software, or services and facilitate a response, allowing for seamless connectivity between software/services.</p> <p>FHIR is the designated interoperability standard for healthcare-related APIs, per the ONC Cures Act Final Rule.</p>
Blood pressure cuff	<p>A cardiovascular diagnostic device that has an inflatable bladder in an elastic sleeve (cuff) with a mechanism for inflating the bladder. The cuff is used to determine a subject's blood pressure. Identified as a class II device by FDA. Source: FDA</p>
Broadband Internet	<p>A service that allows users to access the Internet and Internet-related services at higher speeds compared to “dial-up.” Enabled through a digital subscriber line (DSL), cable modem, optical fiber, wireless, and satellite. Source: FCC</p>
Electronic health record (EHR)	<p>An EHR is a computer system that stores real-time, patient-centered electronic medical records. An EHR system includes the medical history of a patient, as well as information about immunizations, allergies, laboratory results, radiology images, and other records related to the patient’s health history.</p> <p>A FHIR-compatible/compatible EHR is an EHR environment that allows for interaction with a 3rd party SMART application. These EHRs have the SMART on FHIR API built into their products and support SMART on FHIR core capabilities.</p>
Fast Healthcare Interoperability Resources (FHIR)	<p>An interoperability standard that defines how healthcare information can be exchanged between different computer systems. Source: ONC. The designated standard for API access to health IT systems, as per the ONC Cures Final Rule. Developed and maintained by HL7.</p>
Medical device data system (MDDS)	<p>Medical Device Data Systems (MDDS) are systems (hardware or software products) to collect, store, transfer, convert formats, and display medical device data. FDA class I (low risk). Source: FDA</p>
Mobile app aka mobile application	<p>A consumer-facing software application/program downloaded by an individual to be run or accessed on his/her smartphone or other mobile device. It may be supported by additional infrastructure to support data processing, storage, etc.</p>
mHealth aka mobile health	<p>The use of mobile and wireless devices (cell phones, tablets, monitoring devices, etc.) to improve health outcomes, health care services, and health research. Source: NIH</p>

Patient health record	A personal health record, or PHR, is an electronic application through which patients can maintain and manage their health information (and that of others for whom they are authorized) in a private, secure, and confidential environment. Source: ONC
Patient reported outcome measures (PROM)	Standardized, validated questionnaires (aka instruments) completed by patients to measure their perception of their functional well-being and health status. Used to collect patient reported outcomes.
Patient reported outcomes (PRO)	A report of the status of a patient’s health condition that comes directly from the patient, without interpretation. A subset of patient-generated health data.
Patient-generated health data (PGHD)	Patient-generated health data (PGHD) are health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) outside the clinical setting to help address a health concern. Source: ONC
Personal health device (PHD)	A device used in personal health applications. Source: ISO . Blood pressure cuffs designed for patient use are an example of a personal health device.
Remote patient monitoring (RPM)	An example of telehealth in which personal health and medical data collection from an individual in one location via electronic communication technologies, which is transmitted to a clinician in a different location for use in care and related support. Source: CCHP
SMART (Substitutable Medical Applications, Reusable Technologies)	An interoperability standard that works in conjunction with and on top of FHIR that allows for seamless interaction between a 3rd party application and a FHIR-compatible EHR; also a general authentication scheme for FHIR APIs. SMART defines how the interaction between a 3rd party application and an EHR should occur and provides a way to authorize access to specific data within that interaction. Originally developed by the Harvard Medical School and Boston Children’s Hospital.
SMART on FHIR API	An implementation of the SMART standard. An open-source API that provides the framework to allow for interaction between a 3rd party SMART application and a FHIR-compatible EHR and the authorization scheme to allow for this interaction. (Defines the mechanism for interoperability between a SMART app and EHR, by providing a way to authorize access to information and represent the information being exchanged).
SMART App / SMART on FHIR App	Applications that are built using the SMART standard and FHIR-based API functionality, to allow for interaction with a FHIR-compatible EHR. Apple Health Records is an example of a SMART App that uses a SMART on FHIR API to allow a patient to retrieve and aggregate health information from various health care providers.
SMART Markers	An extension of the SMART standard and SMART on FHIR API. A FHIR-based software framework that enables sharing of patient-generated health data with clinicians. Built around a practitioner request for data and a

	<p>corresponding response by the patient. Source: Boston Children’s Hospital Computational Health Informatics Program</p>
Self-measured blood pressure monitoring (SMBP)	<p>The regular measurement of blood pressure by the patient outside the clinical setting, either at home or elsewhere. SMBP requires the use of a home blood pressure measurement device by the patient to measure blood pressure at different points in time. Source: Million Hearts</p>
Self-measured blood pressure monitoring (SMBP) feedback loop	<p>Refers to the secure communication and exchange of information between a patient and clinician as part of a self-measured blood pressure monitoring program. Includes the communication of SMBP readings and other information from a patient to their clinician/care team and the subsequent communication of timely treatment advice/adjustments from the clinician/care team to the patient. Source: Million Hearts</p>
Self-measured blood pressure monitoring period	<p>The time period during which a patient engages in regular SMBP to generate data sufficient for clinical assessment. The minimum recommended monitoring period is 3 days, with two measurements in the morning and two measurements in the evening on each day (12 readings total). An optimal monitoring period is 7 days, with two measurements in the morning and two measurements in the evening on each day (28 readings total). The average of all SBP and DBP readings during the monitoring period is used in the clinical assessment of a patient’s BP. Source: AHA/AMA</p> <p>A monitoring period is recommended two to four weeks after a medical class or dosing change and during the week prior to a clinical encounter.</p>
Self-measured blood pressure monitoring use period	<p>The time between when a patient is instructed by the care team to use a home BP monitor to measure their own blood pressure and when the patient engages with the care team for follow-up assessment and management (e.g. follow-up visit, telephone call, or other practice access to the SMBP data and action upon it). Source: NACHC</p>
Telehealth	<p>Telehealth refers broadly to the use of electronic and telecommunications technologies and services to provide care and services at-a-distance. Source: CCHP</p>
Validated Device Listing (VDL)	<p>A listing of blood pressure devices for use in clinical, community, or home settings that are validated for clinical accuracy. These devices meet criteria established by the American Medical Association, as determined by an independent review process. Also referred to as the US Blood Pressure Validated Device Listing. Source: AMA</p>

Appendix B. Summaries of Conversations with SMEs

Boston Children's Hospital

Interviewee(s) and Affiliation: (1) **Ken Mandl, MD, MPH**, Director, Computational Health Informatics Program, Boston Children's Hospital and Donald A.B. Lindberg Professor of Pediatrics and Professor of Biomedical Informatics, Harvard Medical School; and (2) **Rayeel Sayeed, MD** Computational Health Informatics Program, Boston Children's Hospital and Department of Pediatrics, Harvard Medical School

Date of Interview: April 14, 2021

A. Current State of the landscape

1. How would you describe the current landscape of standards and specifications as it relates to supporting the use of PGHD (patient-generated health data/or patient contributed health data)?

Dr. Mandl and Dr. Sayeed presented on how SMART on FHIR came to be, including a history of the regulation and policy that has supported the work. In the presentation, they shared that the Affordable Care Act and associated HiTECH ACT, which brought us meaningful use, has focused the wide scale adoption of EHRs and the inclusion of patient-generated health data (PGHD) into the EHR.

Drs. Mandl and Kohane introduced the idea that an iPhone app can be used to perform important functions, despite not having any direct communications with Apple to request data from the phone.

Examples:

- **ONC Project** - Can EHRs behave like iPhones or Androids in that innovators could readily create and widely distribute substitute apps across thousands of installs? An example of this type of app would be the SMART Cardiac risk app, which pulls in data (smoking status, age, demographics, cholesterol levels) across API. This was reusable.
- **Meducation** was the winner of a user-friendly patient facing app for medication instructions.
- **BP Centiles** app running on Cerner for managing children's blood pressure at Boston Children's. They no longer use paper charts/paper and filling in circles, they use this to improve BP management.
- **Meaningful Use Stage 3 (MU S3)** is based on the JASON report and relates to patient access to data. For MU S3, you need an API to allow patients to access a copy of their data. They didn't specify SMART or FHIR (written in 2016).
- **Argonaut Project** at HL7. SMART is now leading EHR projects. Apple used SMART to connect more than 600 health systems using SMART on FHIR API.
- **21st Century Cures Act** - SMART API will be realized in 2022. These apps will run universally on Health IT. 21st Century Cures says there has to be an "API and allow health information from such technology to be accessed, exchanged and used without special effort through the

use of API interfaces or successor technology and standards, and provided under applicable law, including providing access to all data elements of a patient’s EHR to the extent permissible under applicable privacy laws.”

- Push button population health, bulk FHIR access API. Data can be pulled out very easily. CMS created two APIs; one for providers and one for ACOs to provide CMS data.
- United States Core Data for Interoperability (USCDI) highlights data elements that are required to be exposed across the APIs. This provides an opportunity to have a real 21st century health IT system.
- SMART Markers; Framework for Capturing Patient Generated Digital Endpoints. The framework is entirely about patient-generated health data.

There is something called the App Gallery, which is the - the official app store for health apps in the U.S.

B. Barriers/Challenges

2. What are the barriers to interoperable, standards-based exchange in PGHD? Any specifics on SMBP?

There are many types of data that users would like to bring into the EHR, such as data related to care pathways, research projects, clinical decision support. These data types are varied and are often from outside the EHR.

The problem is that we have a “walled garden” around the point of care. EHRs are not very good at integrating with other software and the challenge of integration is big.

3. What is the most critical barrier/challenge?

n/a

C. Opportunities and Vision

4. In an ideal world, what does the future look like to you in terms of use of patient-generated/patient contributed health data in clinical care?

SMART Markers is a software framework that developers can use to rapidly develop health apps. They can use this framework to request PGHD and respond to those requests and send data back to the requestor. The data that is generated from the patient side is requested by the practitioner. SMART specifications and SMART on FHIR are used to implement this work. SMART Markers is entirely open source. SMART has an interoperable architecture for PGHD. On the end-user side, there are SMART apps powered by SMART markers. They are standardized and reusable. It only talks in FHIR. The repository is FHIR conformant. Preserve the data to ensure that it is reusable downstream. Has to be non-proprietary data and friendly to data exchanges.

Data must be rendered in FHIR and stored in the health system. It would have to be an interoperable system. Compliance with FHIR makes this possible. PGHD instruments can be stored in FHIR. The data would be in a format that is accessible.

Patients would have to store the data online to push it back. There are also issues related to implied consent - how does this get addressed? We would need to modify data to the FHIR format to make sure it works as the implementation guide describes.

D. Recommendations

5. What is needed to advance and support interoperable, standards-based exchange related to PGHD or SMBP?

“The power of regulation.”

How should the data be packaged to show up for the patient and clinician? That question is critical. Policy needs to define the data that are shared.

BP needs to be electronically available and transmissible in a format that is easy for practitioners to use. It should be a web friendly data model.

FHIR data block from manufacturers would be ideal, even if some FHIR changes need to be made.

Recommend the development of apps to gather information from different devices. SMART on FHIR spirit is captured.

In an ideal world: Practitioners have EHRs, context specific applications (BP centiles, genomics) and a practitioner facing app in the EMR (it launches within the EMR). The clinician could be in the patient chart, launch an app inside EHR, select the desired data that has been coded in LOINC or standard (all devices refer back to the same terminology). From the patient perspective, the patient gets a notification to open the app (iPhone app/web app). After the patient completes the data, the clinician gets the data in the EHR.

This process is very dependent on how the health system is structured. In an ideal world, all data are stored in a framework.

Today the EHRs don't have a write back feature. You could have a cloud vendor or a health system. There are many ways to get to the same approach.

6. What actions are needed to advance these recommendations?
- Who needs to take these actions/who is responsible for these actions?
 - What is your sense of timing for when these could be addressed?

Q) What federal levers need to be pulled?

A) Federal levers may not be the fastest route.

Health systems are not going to wait. There are many approaches including cloud services, such as Amazon, Google, that have SMART on FHIR services. There is a need to leverage cloud vendors to create a repository for PGHD. There is a need to get the HIPAA protected data back into the EMRs. This is entirely possible. As long as you have a common data model (FHIR) and common specification (SMART) it will work.

There is a need for public facing APIs. EMRS need to open up the write back capability. That is not a significant area. All data should be part of the EMR.

Genius of SMART is that it allows an app to run on top of the EMR. It can grab data from another FHIR server that the hospital controls. Even if the hospital is using AWS, the SMART app can talk to that server or another FHIR server to get the data back. One day the EMRs will be able to ingest the PGHD, even if stored separately, to make it part of the patient chart.

Q) Where is your leverage point?

- A) Questions relate to conversations around the US Core - how much data are in the US Core and how much can be written back. Plug into ONC. This is an additional use case. High profile use case - Million Hearts. MedStar has done Million hearts and created a cardiac risk app with Cerner system. Interoperability will be happening over time.

- 7. What are your recommendations for clinicians/health care organizations looking to implement SMBP programs using standards-based exchange?

n/a

- 8. What are your recommendations for patients looking to seamlessly share SMBP data with their clinicians?

n/a

- 9. What are your recommendations for Health IT?

n/a

- 10. What are your recommendations for Federal agencies?

n/a

E. Wrap-up and Next Steps

- 11. Is there anything else you would like to add?

n/a

Health Federation of Philadelphia

Interviewee(s) and Affiliation: **Debra McGrath**; Health Federation of Philadelphia

Date of Interview: April 21, 2021

A. Current State of the landscape

1. How would you describe the current landscape of standards and specifications as it relates to supporting the use of PGHD (patient-generated health data/or patient contributed health data)?

The EHRs aren't ready for SMBP data. We need an average blood pressure reading and EHRs are not ready to do that. EHRs are not ready to take that data from an app or patient. There isn't a layer in between for review before it goes into the medical chart. There are concerns with patients sharing monitors. We need to have someone monitoring the blood pressure they are taking from the perspective of "are they taking them?" For example, in every one of the cases where we are helping to stand up a SMBP program, we are having to customize EHRs to do this. We build a remote monitoring platform. There has to be a place in the database for this data to go. Because this blood pressure is a standard vital sign, we are using that as the standard; it needs a new label.

The other aspect of this is that FQHCs have to produce a report every year. In order for them to count this, it has to be a Bluetooth cuff or they have to visualize the cuff and take the readings off of it. The workload of doing this is huge. All readings stored on a cuff must be manually entered into a spreadsheet prior to calculating an average.

In some cases, the data comes from a patient into a patient portal - not the patient chart - so a provider must log into a separate screen to see the blood pressure readings. The average is calculated in the app (Healow) and the provider has to trigger the calculation. There is no feedback loop that includes the patient.

There are three very important pieces:

1. Standard front end for the patient and training staff on how to do this. You must have a single "ask" for the patient. Currently, each manufacturer has an app. If you stand up a SMBP program, you go to the manufacturer to buy cuffs. But invariably someone else will come along with a better cuff and/or price, then patients will be asked to switch cuffs. You end up with too many different programs and devices. We use Sphygmo by mmHG. Many different brands and models of cuffs work with the Sphygmo app and portal. In fact, Sphygmo is the patient app for Omron and A&D Medical. A cuff agnostic app will allow a practice to pivot to different cuffs if necessary.
2. There needs to be a clinical portal where all blood pressure readings are stored and viewed, and hopefully downloaded into the EHR. The manager/care worker needs to be able to go to one place and see all patients and blood pressure readings. They need to be able to sort/filter them as a way to prioritize.
3. There must be communication back to the patient.

The landscape is in its infancy. There are systems out there, but at the end of the day we have to get the right data to the right person in a format they can use.

As far as regulatory and policy, it is a free for all out there. There are information sharing

requirements that apply to practices and HIEs and vendors. However, it is unclear how all that comes together to say “must” or “will” needs to be part of the functionality of an EHR. Some vendors do not see PGHD as a legitimate vital reading.

Manual entry of blood pressure readings by a patient is a concern, they might just be telling you what you want to hear and there is no way of knowing if the patient actually took at BP.

Some Software as a Service (SAAS) model EHRs that are purchased on a prescription or percentage of revenue model can be challenging. This is a system you never have to take care of, “all for one and one for all.” If FQHCs need “x”, it goes to everyone in the system whether you need it or not. In order to get blood pressure in this space, they will have to purchase additional 3rd party software that can be expensive.

B. Barriers/Challenges

2. What are the barriers to interoperable, standards-based exchange in PGHD? Any specifics on SMBP?

Digital literacy barrier from the perspective of the patient and staff. For example, when a patient comes in with an android phone and I am an iPhone user, do I know enough to help the patient with technical issues? What happens when we don't have the bandwidth to support downloading an app? What happens when Bluetooth doesn't connect or disconnects later? What happens if the patient does not have the broadband to send the data through the app?

3. What is the most critical barrier/challenge?

Requiring EHR vendors to provide for remote patient vital sign entry. PGHD is extremely valuable. The EHRs are behind the timeline.

Second, there is a population of patients that get left behind, we need to address access to devices, broadband and bandwidth.

Patient access, EHR access and education of providers.

C. Opportunities and Vision

4. In an ideal world, what does the future look like to you in terms of use of patient-generated/patient contributed health data in clinical care?

- Regulations and policy must be in place to ensure providers rather than the insurers can select the cuffs and that Bluetooth enabled cuffs are provided and validated.
- Standards for integration with RPM devices need to be in place so that we can work toward building a standard system.

- EHRs should contain easily available and validated data from home vital sign devices so that providers can view the data in the context of the patient's chart and so that it can be used for clinical decision making.

D. Recommendations

5. What is needed to advance and support interoperable, standards-based exchange related to: PGHD or SMBP?

Policy/Regulation: Insurers are paying for blood pressure cuffs, but providers should ideally get to select the cuffs. This makes SMBP not scalable, you need to have control of this at point of care. Also, insurers (including Medicaid) need to provide Bluetooth enabled cuffs that are validated.

Standards: There needs to be a standard that EHRs can work toward. Create a validated list, set up clear validation standards so vendors are building to a standard. Require a connection standard for the vital sign device. We are finding that the Bluetooth standards vary among the wireless phone devices and the BP devices.

Technology: There needs to be external storage of these values before they are put into the EHR. There needs to be trained eyes on the values to allow for validation before the data are brought into the EHR. We need high/low and average blood pressure readings to have providers accept and use the data.

6. What actions are needed to advance these recommendations?
 - Who needs to take these actions/who is responsible for these actions?
 - What is your sense of timing for when these could be addressed?

We are doing it, we are pulling data together and making comparisons. We are getting blood pressure cuffs to patients. We need to help insurers get onboard. Need to be out of the business of issuing cuffs. The manufacturers should not send the devices directly to the patients. We cannot count on a patient knowing what to do and how to do it, there needs to be a program to do this part.

There is a lot out there from AMA that we need to get to the operational level. We need to support providers and the network that will help them. We need a hub for collaboration.

7. What are your recommendations for clinicians/health care organizations looking to implement SMBP programs using standards-based exchange?

Health care organizations need to create educational opportunities for staff. CMOs need to get behind it, hold staff and providers accountable and provide the tools for success.

Providers need to educate themselves on this (SMBP) as a tool. CDS related to medications and what is available on formulary for single pill combinations for example should be integrated in the EHR. We need standardization of the medications that are covered as a baseline. Give nurses and pharmacists autonomy and teach them how to do a titration.

8. What are your recommendations for patients looking to seamlessly share SMBP data with their clinicians?

n/a

9. What are your recommendations for Health IT?

n/a

10. What are your recommendations for Federal agencies?

n/a

E. Wrap-up and Next Steps

11. Is there anything else you would like to add?

I would like to stay engaged in any way that might be helpful. I need to be educated on what we could be doing at a policy/regulatory level. It has been gratifying because we hear from patients who feel confident and powerful. You can't replace that.

HL7 Devices Work Group

Interviewee(s) and Affiliation: Patient Empowerment HL7 Work Group

Co-Chairs/Participants: John Garguilo, Ken Fuchs, Todd Cooper

Date of Interview: May 5, 2021

A. Current State of the landscape

1. How would you describe the current landscape of standards and specifications as it relates to supporting the use of PGHD (patient-generated health data/or patient contributed health data)?

Personal devices initially had a few big companies using lack of interoperability to keep their “piece of the pie.” This is still true today, but the players have changed (e.g., Microsoft, Apple, Google, etc.). These players create their own ecosystem; it is not a technology problem. The technology, in the form of open standards and reference implementations exists, but there is very little will to adopt.

IEEE 11073 is an SDO focused on core interoperability, technology and nomenclature standards for patient connected health device interoperability. Currently, we have very device- specific technology, protocol and nomenclature standards. HL7 tends to be more focused on integration of health IT systems (such as lab systems, ADT systems, EMR systems, Order systems, etc.) and standards to help integrate a type of system. For example, we would use ISO/IEEE 11073 to connect devices and to an aggregator. But we would use HL7 *Version 2* or FHIR to get the data from the aggregator into an EHR. HL7 focuses more on the EHR enterprise at integration where they want to consume enterprise data. IHE focuses on working through specific use cases and create profiles that can use HL7, IEEE 11073, DICOM and other standards. Part of the IHE process is to actually prototype and test these profiles among different manufacturers in Connectathons.

IEEE relates directly to the devices and is focused around device data and getting data from devices to “something” else. Point of care devices not only need to collect data but also to connect to other devices, introducing privacy and security concerns. Personal devices tend to be more resource limited and thus require less bandwidth with different security concerns (PHD devices definitely need to consider cybersecurity issues. Some may connect directly to the internet via cellular connections).

B. Barriers/Challenges

2. What are the barriers to interoperable, standards-based exchange in PGHD? Any specifics on SMBP?

Business drivers. There is rarely any value to product developers for doing standards-based implementations. There are definite up-front costs without clear demand from their customers or value proposition, so there is little or no incentive for them to do standards-based implementation (This is generally true for upper layer interoperability such as nomenclature or semantics. Lower layer (physical layer) standards such as Wi-Fi or Bluetooth are widely adopted due to their prevalence and low cost. Inventing a new wireless approach is probably a fool’s errand unless you have money or very special requirements.)

The technology and standards are in place. The issue is that we haven't had the catalyst to push wide adoption. We are successful in the IHE space (i.e., integrating healthcare enterprise). There are many implementations at the gateway level. In this case bedside or personal health medical devices communicate to a gateway using proprietary approaches (which is not the ideal approach). The gateway, in turn, converts these data streams to an IHE compliant standards-based protocol and communicates with a health IT solution typically an EHR or Clinical Information System. In terms of interoperability of personal devices, it hasn't happened because it is hard to convince manufacturers without an incentive of some sort to adopt standards. Device manufacturers typically do what is easiest, which is working within their own ecosystem. They like to push the can down the road, and it is healthcare systems and researchers that end up paying for the lack of open interoperability.

Consider a CSV file/common file representation as an example of partial interoperability. Someone can send you a CSV file and an application can open it. However, unless the file complies with a specific use of each field with specific nomenclatures the receiving application will not be able to use it. A human can open the file and manually reformat and rename fields in order for the application to use it. This is similar to the role of the gateway.

Technology advancements leading to a demand for interoperability typically occur from the procurement/consuming side. Many times, when hospital systems need to replace something or add to a system/device functionality, the CIOs and clinical integration teams do not know how to write procurements to ask for interoperability. There are some efforts toward this now. There is a similar issue with personal health devices, the procurement is done by consumers who don't know what to ask for and are not aware of the possibilities fully interoperable devices could bring. Those in charge of procurement need to write RFPs asking for devices that support and conform to specified open interoperability standards to drive the business side.

The business model and challenges are the same: you have to buy into one of those business-driven families and you don't get standards based "anything" unless one will provide a FHIR portal or something similar.

3. What is the most critical barrier/challenge?

n/a

C. Opportunities and Vision

4. In an ideal world, what does the future look like to you in terms of use of patient-generated/patient contributed health data in clinical care?

There have been many ideal situations in the last five years because the foundation is there (e.g., syntax, nomenclature and technology). Semantically capturing information that means the same thing to the sender and receiver is important and interoperability requires the same language. A big part of this is terminology mapping and this is happening. In coordination with IEEE 11073, different parts of nomenclature are being harmonized for complex devices. Building an infrastructure out of

standardization and harmonization is important because people adopt the same methodologies and terminologies.

We are at a very different place than we were ten years ago. Standardization development is much better. FHIR rattled the cages, allowing for computable elements. The way in which we address regulatory models is maturing and the space, from an architectural sense, is getting smaller. Business drivers will always be a key challenge because technical standards are developed by technical people, whereas the reality of generating PGHD and integrating into infrastructure is more related to policy and incentives. It all depends on coming up with architecture to support the movement of data in a clean and easy-to-use way. Pulling standards together is the easy part.

D. Recommendations

5. What is needed to advance and support interoperable, standards-based exchange related to: PGHD or SMBP?

The CDC requiring standards-based reporting in real-time is huge. CDC disaster code sets being collected and used at a level of granularity to identify trends is also huge. These things are actionable. Having federal partners at the table with boots on the ground makes a difference as long as they specify compliance with interoperability standards to a very precise level.

This work is consumer driven. If the VA or Tricare said we aren't buying anything that doesn't meet open standards, people would take notice. There must be an advantage to the consumers and needs to be driven on the demand side. The technology is there; the problem is that it has been tested very little. There are some standards, they just aren't widely adopted, we need to have overall/broad standards across devices rather than one to three for every device.

6. What actions are needed to advance these recommendations?
 - Who needs to take these actions/who is responsible for these actions?
 - What is your sense of timing for when these could be addressed?

n/a

7. What are your recommendations for clinicians/health care organizations looking to implement SMBP programs using standards-based exchange?

n/a

8. What are your recommendations for patients looking to seamlessly share SMBP data with their clinicians?

n/a

9. What are your recommendations for Health IT?

n/a

10. What are your recommendations for Federal agencies?

n/a

E. Wrap-up and Next Steps

11. Is there anything else you would like to add?

n/a

Ochsner Health System

Interviewee(s) and Affiliation: **Richard Milani, MD**, Chief Clinical Transformation Officer at Ochsner Health System

Date of Interview: May 6, 2021

A. Current State of the landscape

1. How would you describe the current landscape of standards and specifications as it relates to supporting the use of PGHD (patient-generated health data/or patient contributed health data)?

The U.S. healthcare system as a whole does not do a good job managing chronic diseases, mainly because structurally it is not designed for success. Rather, the current system is built and well suited to manage acute conditions. Chronic diseases are generally lifelong and how well a person is controlled frequently changes over time. Even if someone's chronic disease is currently well controlled, research indicates that they will lose control at some point. The average person in the U.S. with out-of-control hypertension averages four blood pressure readings documented in their medical record over a year, and this does not give the provider enough information to adequately manage their condition. In fact, for patients with out-of-control hypertension, we observe a statistically significant increase in strokes within just six weeks. So having more frequent data that captures disease control in near real-time is essential. Additionally, primary care physicians, the backbone of the health care system, have very little time to adequately assess and manage many of the nuances involved in caring for patients with chronic disease. Because of this, the likelihood of patients with a chronic disease being on a care plan concurrent with current guidelines is 50% or less.

The infrastructure necessary to optimally manage chronic disease consist of three fundamental components:

First, we need an adequate sample of data that captures the known fluctuations related to that disease process. Because of this, the data must be collected from home, such as weekly blood pressure readings or glucose readings that are sent directly into the medical record. Second, we need a dedicated team of advanced practice clinicians and/or pharmacists that can review the data and prescribe based on current guideline recommendations. Finally, we need to identify relevant social determinants and utilize trained health coaches to provide resources and strategies to improve lifestyle and other factors related to that condition. Simply handing a patient a pamphlet of information and expecting them to follow it without further guidance and instruction typically does not work. It takes time to impact the various behavioral, health literacy and stressors of each patient that ultimately influences control of a chronic disease. A fifteen-minute office visit does not allow for this.

At Ochsner Health we are not trying to modify the existing system. We denoted the problems within the current system and constructed an entirely new delivery model to address those problems. We've taken a "focus factory" approach by assigning a team that consists of a PharmD who is trained in the pharmacologic management of a chronic disease per the current guidelines, and a health coach. The health coaches are trained (by Ochsner) in behavioral science, health literacy, lifestyle modification, etc. Once enrolled in our program, each patient is equipped with a digitally connected blood pressure cuff, and they are instructed to obtain a minimum of one blood pressure reading each week. We

recommend three to five readings per week, and we currently average about 3.2 readings each week for each patient. This gives us an average of 100-250 blood pressure readings for each patient, each year. Initially, this was costly, because only the Withings cuff worked for our program (~\$125/patient) but now there are less expensive options available (~\$30-35/patient). Patients only need the Bluetooth cuff (that Ochsner provides) and a smart device (smartphone, tablet), either Apple or android will work. Blood pressure data is automatically transferred from the cuff to an app on a smart device via Bluetooth. The app then sends the data to our Epic system, (patients do not have to initiate data exchange). Patients receive a monthly report in two formats, digital and print out/mail, which explain what their chronic disease is, causes, treatment, their readings for the month and tips for management. Within the EMR, the data is visualized by the PharmD and health coach team, and adjustments are delivered virtually. This set up allows us to have more one on one time with patients, as needed. We are able to capture information such as health literacy and financial stressors that are taken into consideration in their care plan. For example, if a patient has a financial stressor, we might tackle reducing the cost of their medications before we start working on major lifestyle changes. Assistance can be provided through use of the O Bar, which is similar to Apple Bar, just for health tracking and monitoring.

B. Barriers/Challenges

2. What are the barriers to interoperable, standards-based exchange in PGHD? Any specifics on SMBP?

Health IT and standards are not the overriding issue. There are some ways we could make it easier, but that won't fix the larger problem. The biggest barrier is that we are trying to put a subtle fix on an outdated system. The infrastructure of care delivery must first be addressed if we expect to observe any meaningful change.

3. What is the most critical barrier/challenge?

n/a

C. Opportunities and Vision

4. In an ideal world, what does the future look like to you in terms of use of patient-generated/patient contributed health data in clinical care?

We have to help primary care providers with this. As mentioned previously, they cannot manage chronic disease adequately using face-to-face encounters 2-3 times/year. We need close to real-time data delivered to a dedicated team that can assist the primary care provider in total disease management.

D. Recommendations

5. What is needed to advance and support interoperable, standards-based exchange related to: PGHD or SMBP?

n/a

6. What actions are needed to advance these recommendations?
- Who needs to take these actions/who is responsible for these actions?
 - What is your sense of timing for when these could be addressed?

n/a

7. What are your recommendations for clinicians/health care organizations looking to implement SMBP programs using standards-based exchange?

It has to start with the care piece. There has to be an incentive to improve care that is provided to the patient with the chronic disease. A 50% control rate is not acceptable, there should be a required threshold of 80-90% control.

Financial reimbursements are currently poorly designed based on time spent over a month. If you spend 20 minutes with a patient, you get paid but if you spend 19 minutes with a patient you are not paid. Some patients may need 60 minutes while others need 5-10 minutes. Reimbursements should be made based on outcomes, not time. Additionally, we should eliminate copays, as this represents another barrier to providing care.

8. What are your recommendations for patients looking to seamlessly share SMBP data with their clinicians?

n/a

9. What are your recommendations for Health IT?

n/a

10. What are your recommendations for Federal agencies?

The federal government, especially CMS, needs to find ways to make access to care easier and more affordable. People shouldn't have to choose between a taxi to go to the doctor and a whether they can buy groceries. Virtual care without the added burden of copays are essential and have been shown to enhance medication adherence.

E. Wrap-up and Next Steps

11. Is there anything else you would like to add?

n/a

Patient Empowerment HL7 Work Group

Interviewee(s) and Affiliation: Patient Empowerment HL7 Work Group

Co-Chairs: Virginia Lorenzi, Debi Willis, Dave deBronkart, Abigail Watson

Participants: Jessica Skopac, Stanley Nachimson, John Moehrke, John Keys, Hemant Bundele, Adrienne Pichon, Britt Massei, Maria Moen, Dave Hill, Jan Oldenburg, Haley Stolp, Lloyd McKenzie, Matt Elrod, Rachel Richardson

Date of Interview: April 15, 2021

A. Current State of the landscape

1. How would you describe the current landscape of standards and specifications as it relates to supporting the use of PGHD (patient-generated health data/or patient contributed health data)?

There are no specifications for how this work should be done. Organizations who are interested in this work should not be held up by those who are not. There is no vision of how interoperability should work and a lack of laws and standards.

B. Barriers/Challenges

2. What are the barriers to interoperable, standards-based exchange in PGHD? Any specifics on SMBP?

Electronic health records (EHRs) are not opening up the ability for patients to contribute data via a third-party app. During past discussions, developers have implied that they will charge for that feature. It will only be free to the patient if it is mandated by ONC, otherwise the device developers would charge the app developer for this mechanism.

Providers don't want all of the data, rather they would prefer to have it compiled and analyzed prior to receiving it. Providers also do not want the liability that comes with device monitoring. Providers aren't sure about device accuracy. Since accuracy issues occur between labs, they are also likely to occur between devices. Data validity is also a legitimate concern.

There is a lack of laws and standardization around how interoperability and standards-based exchange should work. There should be a construct or FHIR resource to assist with rolling up a collection of observations into a baseline. There are many policy concerns. It is more important that we work to write the specifications for how it should be done.

There are no standards supporting the patient provider feedback loop, therefore there is no standard way of recording that information.

3. What is the most critical barrier/challenge?

- a. Vendors don't have to support their own APIs. Any vendor making ONC certified technology can be considered an information blocker. We need to adapt or find new ways to take data in

and reconcile it.

- b. There are no laws around who owns data. Makers of devices don't consider the data to be patient owned. There should be laws around any device that is attached to a patient. When the patient is creating information to send it "somewhere" the data should be owned by the patient. However, this is not currently the case.
- c. The personal health record in the local FHIR store is important. Defining an Implementation Guide that expresses how (technically) data would flow from Patient Generated Health Data (PGHD) flows into the Electronic Medical Record is the step that HL7 "can" define. There are organizations wanting this. We should NOT stop progress because some organizations do not want to support PGHD.

C. Opportunities and Vision

- 4. In an ideal world, what does the future look like to you in terms of use of patient-generated/patient contributed health data in clinical care?

It is important to have data flowing from patients to providers, and there must be a feedback loop. After a patient receives direction from a provider on where to "keep numbers," they should also be able to monitor day-to-day even if they don't capture or log.

D. Recommendations

- 5. What is needed to advance and support interoperable, standards-based exchange related to: PGHD or SMBP?

There are standards about how to represent data, but we need more annotations to the data BP loop, multiple organizations need to agree to standard workflows.

- 6. What actions are needed to advance these recommendations?
 - Who needs to take these actions/who is responsible for these actions?
 - What is your sense of timing for when these could be addressed?

There are standards about how to represent data, but we need more annotations to the data. The key is workflow. What is the data flow from one system to another, is it push/pull and how do you acknowledge and close the loop? We don't have standards or consensus around this work. We need multiple organizations to agree to standard workflows and this is hard to do.

- 7. What are your recommendations for clinicians/health care organizations looking to implement SMBP programs using standards-based exchange?

There needs to be a patient/provider partnership. For SMBP to work, it has to be acceptable to both parties. Some patients are going to spend more time recording/logging their data, some providers are

willing to review/analyze the data; it has to be a happy medium.

8. What are your recommendations for patients looking to seamlessly share SMBP data with their clinicians?

n/a

9. What are your recommendations for Health IT?

There should be feedback loops between consumer app developers and the ONC for them to report issues where there are loopholes in regulations that negatively impact patients, insight/requests from patients regarding their health IT needs, and suggestions concerning areas which might need more oversight from the ONC. (Note: This is not the same as reporting information blocking. This is more about consumer needs.) This feedback might be accomplished via a website or virtual meetings.

10. What are your recommendations for Federal agencies?

Part of ONC is about creating a policy environment that supports those standards. It is this relationship that helps pull health care into the future. There should be a recommendation to federal agencies to support policies that make patients the owner of any patient data they generate. Patients should have the right to access data from any device implanted in his/her body. Additionally, any data in a device belonging to a patient should be considered to be owned by the patient.

E. Wrap-up and Next Steps

11. Is there anything else you would like to add?

There has to be some overwhelming reason to do this work. Some of this comes from regulations and government monitoring. Other parts of this come from the patient side. If patients don't understand they have the ability to do this, there is a lack of demand for apps and developers. Therefore, we need to educate patients about their rights to the data they generate.

Reliant Medical Group

Interviewee(s) and Affiliation: **Larry Garber**, Reliant Medical Group

Date of Interview: April 22, 2021

A. Current State of the landscape

1. How would you describe the current landscape of standards and specifications as it relates to supporting the use of PGHD (patient-generated health data/or patient contributed health data)?

The current landscape is an interoperability desert, very barren. There is no standard way for electronic health records (EHRs) to connect with personal health devices. Information technology should not be this hard.

The EHR from Epic Systems Corporation has patient-entered flow sheets to capture data entered by the patient. We use this feature in Epic to load data from FHIR queries. Physicians don't get raw data, such as each individual step if a watch or other wearable device is linked, and physicians don't want to see all of this anyway. As a physician, we want summarized data in our records over time. Epic is set up to do just that. I am able to set a time period for a patient, as well as parameters I wish to be alerted for. For example, in patients with congestive heart failure, we use home scales to track significant weight gains each day. The data is aggregated in a monthly "in-basket message" within the EHR to view a long-term trend. However, most of the data are filed silently into the EHR each day unless a result exceeds a pre-defined, patient-specific parameter. These abnormal data are sent to the nurse initially for evaluation and they can contact the patient or escalate a problem to a healthcare provider if necessary. This is extremely convenient for patients and providers. If we receive critical values, we will call a patient.

Our program was funded by ONC, we provide blood pressure monitors, weight scales and pulse oximeters to the patients in our program. The blood pressure monitors and weight scales are extremely convenient because they are WIFI enabled. The pulse oximeters use Bluetooth so require the patient to use a smartphone.

B. Barriers/Challenges

2. What are the barriers to interoperable, standards-based exchange in PGHD? Any specifics on SMBP?

Device manufacturers and data aggregators each have their own proprietary interfaces. This makes it impossible to perform queries using a single standard such as FHIR. It is not that there are no standards, rather that standards aren't being used.

We have it set up so that I place an order in Epic to receive data and then the order generates a code; I give this code to a patient and the patient enters the code and the last four digits of their social security number into a website we set up. The code and social security number are sent back to Epic to authenticate the patient. The website then displays three buttons (iHealth, Withings, Google Health) which they click on for the device they have (e.g. an iHealth pulse oximeter) and they are

directed to that device or data aggregator's login page. Once logged in, they are shown the data I am requesting, they can authorize me to receive the data and now their device is linked (e.g. iHealth is now linked to Epic for that patient). Our link leverages open source software from Open mHealth (www.openmhealth.org) and Georgia Tech Research Institute to transform the device data from various device manufacturers and data aggregators into the FHIR standard. Epic then automatically starts querying for data (e.g. pulse oximeter readings) using a FHIR client. Patients don't need epic's myChart patient portal to use this.

3. What is the most critical barrier/challenge?

Because of the lack of consistently used standards for consumer health devices, we had to use and modify several pieces of software. This was time consuming and not a skill set available to most healthcare provider organizations.

C. Opportunities and Vision

4. In an ideal world, what does the future look like to you in terms of use of patient-generated/patient contributed health data in clinical care?

The key components are that it has to work for consumer devices and needs to be integrated into EHRs. There are so many devices you can buy that are proprietary and connected to specific services; we should not be building to that model. We should target the consumer market which is less expensive and ubiquitous. Additionally, there are services out there with their own nurses, but this doesn't work well because patients do not want to talk to strangers; they want to talk with someone they know. The way my program is set up, my patients speak either to my nurse, my nurse practitioner, or me. People that the patient knows and trusts, and people who know everything about the patient because we have full access to their EHR record.

There are a lot more devices with better sensors for different types of data coming out onto the market now. I am most concerned about my elderly, medically fragile patients but getting them to wear devices is difficult. There are actually sensors and passive monitors, such as Alexa and voice assistants, that are able to send out a high frequency sound on the speaker then the microphone listens to it and reads a heart rate of someone sitting in the room based on that sensor! These sensors can also detect breathing and coughing, even domestic violence. There are also 3D cameras that can detect heart rate, activity, and level of pain. These will be valuable for the patients that want to be monitored.

D. Recommendations

5. What is needed to advance and support interoperable, standards-based exchange related to: PGHD or SMBP?

There are two ways to improve interoperability for consumer devices. In the short term, the Open mHealth and Georgia Tech Research Institute software should be updated and maintained so that connecting an EHR FHIR client could become more plug-and-play. In the long term, regulations could be leveraged to encourage device manufacturers and data aggregators to expose their data using FHIR. If this was the case, we wouldn't need an intermediary. Additionally, it should be set up as a subscription so multiple queries are not needed to pull in data, but rather data would be pushed only

when something is newly available.

In addition to interoperability standards, you must satisfy three things: 1) perceived value; 2) usability; 3) trust. The device manufacturers should also be HIPAA covered entities so that they are obligated to respect patient privacy without having to sign a business agreement with each vendor. Additionally, EHR vendors and physicians need to communicate to find a solution to set up the ability for devices to share data with the EHRs. Physicians are not likely to know how to do this.

Health IT should have more funding to carry out studies to prove the value of patient-generated data transmission into the EHR to prove the value is beyond convenience.

Federal partners, such as CMS, should consider revising the reimbursement schedule. If a patient is currently under the care of a pulmonologist and a cardiologist, along with their primary care physician, and a cardiologist sends the patient home with a blood pressure cuff, the pulmonologist sends them home with a pulse oximeter, and the primary care physician sends them home with weight scales, only one of the providers is reimbursed through CMS. This needs to be fixed. It should be based on the devices we are monitoring, not global per patient.

6. What actions are needed to advance these recommendations?
- Who needs to take these actions/who is responsible for these actions?
 - What is your sense of timing for when these could be addressed?

See #5 above

7. What are your recommendations for clinicians/health care organizations looking to implement SMBP programs using standards-based exchange?

Talk to your EHR vendor

8. What are your recommendations for patients looking to seamlessly share SMBP data with their clinicians?

Talk to their healthcare provider, and if they don't have a solution, ask them to talk to their EHR vendor.

9. What are your recommendations for Health IT?

See #5 above

10. What are your recommendations for Federal agencies?

See #5 above

E. Wrap-up and Next Steps

11. Is there anything else you would like to add?

n/a

University of California San Francisco

Interviewee(s) and Affiliation: **Ida Sim, MD**, University of California San Francisco, Professor of Medicine, Division of General Internal Medicine, Co-Director, Informatics and Research Innovation, UCSF Clinical and Translational Sciences Institute.

Date of Interview: May 4, 2021

A. Current State of the landscape

1. How would you describe the current landscape of standards and specifications as it relates to supporting the use of PGHD (patient-generated health data/or patient contributed health data)?

There is a lot of interest in this, but it is too soon for implementation. There are multiple barriers that make it challenging for patients to participate. We are mindful that this type of work could be really fantastic, it is going to radically expand the digital health gap, however it is very challenging for many people to use the technologies. A lot of people are looking with excitement, but it has not started yet.

There are many pipelines related to data, payment, accountability and workflow. All of these pipelines come with challenges that must be met prior to implementing this successfully.

B. Barriers/Challenges

2. What are the barriers to interoperable, standards-based exchange in PGHD? Any specifics on SMBP?

Barriers include payment, technical, regulatory and workflow implications. The workflow issues and patient/clinician issues are challenging. The whole pipeline needs to work for this to make sense. There are different pipelines too, data pipeline, payment and accountability pipeline and workflow pipeline. The data pipeline includes the device (connectivity), consent, data, aggregation, sharing data and getting data into a system. The payment and accountability pipeline includes chain of custody, data ownership and legal obligations of the medical center. Medical centers tend to think that the data belongs to them, however, patient-generated data belongs to the patient. Therefore, sharing should reside with the patient. The workflow pipeline has two pieces related to: 1) the patient, and 2) the provider. The patient buys the cuff, syncs it and agrees to consent. The physician has to access and analyze the incoming data coming. In the middle of all this, the medical center has to maintain these integrations, which is costly and time consuming. The payment pipeline introduces its own problems. Providers only get paid/reimbursed by CMS if they buy and distribute the blood pressure cuff. In so many cases, we are managing a patient whose blood pressure is stable (i.e., maintained by medication) so it's arbitrary that they have to collect their blood pressure for 16 days just so their physician can be paid. It doesn't make sense to make the patient do this for us. All of these pipelines are built for one variable, meaning there are different pipelines for every condition.

Another barrier is that the structure that a health system builds needs to be easy to access. Patient reported data can consist of many different types of data. There will be digital biomarkers that are thought of as self-report that become or are automated, therefore we need to build systems that are

agnostic to how the data come in. We shouldn't need to worry about whether it is a heart rate or a self-reported heart rate, but we do need to know if this is a resting heart rate or not.

3. What is the most critical barrier/challenge?

There is no market for the sensors to generate their data in a standard way. Our approach has been to use aggregators, but this is a chicken and egg issue. Sensor makers say if I change all of my devices to spit out data using a standard, who is going to use the standard? The more important part is metadata standards. How do we show device type/function/brand? We use this data clinically and for research, but if we don't have the metadata it is going to be garbage. The data has to be comparable; I don't see how you can regulate devices and smart markers if you don't have metadata.

C. Opportunities and Vision

4. In an ideal world, what does the future look like to you in terms of use of patient-generated/patient contributed health data in clinical care?

There need to be standards around digital biomarkers (multiple data streams that get computed over time). The FDA has a role in how we create that environment and where we can get people to use it. Currently, we are not close to that, but we need a metadata infrastructure. There is very little metadata, and where it does exist it is overwhelming. For example, the smart watch for afibrillation is a consumer device that takes heart rate data one time every minute. That data comes into Epic, we don't need that much data, we need to figure out how to suppress that.

D. Recommendations

5. What is needed to advance and support interoperable, standards-based exchange related to: PGHD or SMBP?

Promoting open mHealth and scaling up the community process for building these schemas for additional digital biomarkers. We need to work with the FDA to get information out there that there is market value to doing this. CDI must be expanded to have a common data model. Additionally, the issue of metadata needs to be addressed and all players (clinical, scientific, technical and regulatory) should be involved.

6. What actions are needed to advance these recommendations?

- Who needs to take these actions/who is responsible for these actions?
- What is your sense of timing for when these could be addressed?

Clinicians need to collect data into clinical workflows. Data needs to be integrated into the clinical workflow. I cannot go to a separate website to search for the patient data. It needs to go into Epic, that's what we use. Visualizations with an EHR need to be improved within the EHR so that it is helpful to clinicians to make decisions around care coordination. We also need write capability in an EHR.

Current work with AHRQ, pulling data into EHR using Bridge as part of a research project. Gives a

timeline view of blood pressure, heart rate, anxiety, fatigue, social determinants of health and medication. We are designing a bridge dashboard to be able to get a snapshot of a patient's current life. We need minimum, maximum and average blood pressure readings. That is not what we get, we get data streams. We cannot pull weekly data in Epic; in Bridge we are going to summarize the data. The data will be centered on the patient. Data starts with a patient, and it needs to be grounded with the patient.

We need standards approved by IEEE.

7. What are your recommendations for clinicians/health care organizations looking to implement SMBP programs using standards-based exchange?

n/a

8. What are your recommendations for patients looking to seamlessly share SMBP data with their clinicians?

n/a

9. What are your recommendations for Health IT?

n/a

10. What are your recommendations for Federal agencies?

We need standards and modular systems. We need not overload as standard either. There needs to be more work/research funded on managing multiple chronic diseases. The default is disease by disease work. A patient with three conditions is not going to have multiple apps for measuring/monitoring health data.

E. Wrap-up and Next Steps

11. Is there anything else you would like to add?

I worry about usability for patients who are not physically able. These apps are usually built by technologists or IT. The technology needs to work for the design process we have. We currently have a lot of technology but there is also a lot that isn't usable.

Appendix C. Terminology and Value Sets

Terminology standards support semantic interoperability in the exchange of data between information systems (i.e., the shared understanding of the data exchanged to support accurate interpretation and effective use). Value sets specify a set of codes intended for use in a particular context. Terminology standards and value sets relevant to the exchange of SMBP data include the following:

- **Logical Observation Identifiers Names and Codes (LOINC)**

LOINC is recognized as the standard for representation of vital signs within USCDI. It is maintained by Regenstrief Institute.

- [Blood pressure panel](#): 35094-2
- [Blood pressure panel with all children optional](#): 85354-9
- [Vital signs, weight, height, head circumference, oxygen saturation and BMI panel](#): 85353-1
- [Blood pressure home reading](#): 72076-3 (trial status)

- **Systematized Nomenclature of Medicine -- Clinical Terms (SNOMED CT)**

Maintained by the International Health Terminology Standards Development Organization (IHTSDO), aka SNOMED International. Currently there are no LOINC codes to represent average blood pressure, average systolic blood pressure or average diastolic blood pressure.⁶⁵ The codes below represent the calculated average blood pressure from a set of individual measurements.

- Average blood pressure: 723232008
- Average systolic blood pressure: 314440001
- Average diastolic blood pressure: 314453003

- **Value sets (for use in FHIR)⁶⁶**

- [Blood pressure measurement device](#): Contains concepts used to result the type of device used to measure a body blood pressure, referencing the SNOMED Code 23591000205102 "Blood pressure device type (observable entity)" and the LOINC term "Type of Blood pressure device" 41901-0.
- [Blood pressure measurement device and cuff size](#)
- [Blood pressure cuff size](#)
- [Blood pressure measurement body location](#): Contains a constrained list body location values used to result the body location where a blood pressure was measured, referencing the SNOMED Code 2281000205100 "Blood pressure measurement site (observable entity)" and the LOINC term "Blood pressure measurement site", 41904-4.
- [Blood pressure measurement method](#): Contains concepts used to represent the method used for a blood pressure measurement, referencing the SNOMED Code 2291000205103 "Blood pressure method (observable entity)" and the LOINC term "Blood pressure method" 8357-6.

⁶⁵ <http://hl7.org/fhir/us/vitals/2020Sep/#each-observation-must-have>

⁶⁶ As noted in the [HL7 Vital Signs Implementation Guide, Release 0.1.0](#)