The Office of the National Coordinator for Health Information Technology

Advancing Standards for Precision Medicine

FINAL REPORT

Prepared by: Audacious Inquiry on behalf of the Office of the National Coordinator for Health Information Technology under Contract No. HHSM-500-2017-000101 Task Order No. HHSP23320100013U

January 2021

Table of Contents

Acknowledgments

PROJECT LEADS

- Kevin Chaney, MGS, Office of the National Coordinator for Health IT (ONC)
- Allison Dennis, PhD, ONC
- Tracy H. Okubo, CSM, PMP, ONC
- Teresa Zayas Cabán, PhD, ONC

MOBILE HEALTH, SENSORS, AND WEARABLES DEMONSTRATION PROJECT PARTICIPANTS

- Lawrence Garber, MD, Reliant Medical Group
- Eric Soto, MS, Georgia Tech Research Institute
- Ida Sim, MD, PhD, Open mHealth
- Simona Carini, MA, Open mHealth
- Jennifer Bowers, BSN, OCN, CBCN, Get Real Health
- Christina Hendricks, MA, Get Real Health
- Ram Gokulachandran, Get Real Health
- Shelly Palacios, MBA, Get Real Health
- Robin Wiener, Get Real Health
- Kedar Ganta, MBA, athenahealth
- Torin Shepard, MS, athenahealth

SOCIAL DETERMINANTS OF HEALTH DEMONSTRATION PROJECT PARTICIPANTS

- Chris Grasso, MPH, Fenway Health
- Jon DiBiasio, Fenway Health
- Justin McReynolds, MS, University of Washington
- Paul Bugni, University of Washington
- Bill Lober, MD, MS, University of Washington
- Kedar Ganta, MBA, athenahealth
- Torin Shepard, MS, athenahealth
- Abhijeet Badale, BE, athenahealth

ADVANCING STANDARDS FOR PRECISION MEDICINE PROJECT TEAM

- Keith Boone, MBI, Audacious Inquiry
- Christina Caraballo, MBA, Audacious Inquiry
- Michelle Consolazio, MPA, Audacious Inquiry
- Katie Iser, Audacious Inquiry

Executive Summary

INTRODUCTION

The Office of the National Coordinator for Health Information Technology (ONC), in collaboration with the National Institutes of Health (NIH) *All of Us* Research Program (*All of Us*), actively supports safe and secure access and sharing of health data to expedite the success of the Precision Medicine Initiative (PMI), a nationwide initiative to move away from the "one-size-fits-all" approach to healthcare delivery toward tailored treatment and prevention strategies based on people's unique characteristics, including environment, lifestyle, and biology. The role of the Advancing Standards for Precision Medicine (ASPM) project is to identify high-impact health data needs to further develop and test standards relevant to the success of *All of Us* to advance precision medicine. In collaboration with standards development organizations (SDOs), key stakeholders, and demonstration projects, the ASPM project team developed and tested the corresponding data standards so the relevant data can be used as part of *All of Us* and to broadly benefit the PMI and precision medicine.

Through an assessment of data needed by *All of Us*, two data classes were identified as high impact and prioritized for advancement: (1) mobile health, sensor, and wearable data and; (2) social determinants of health data.

STANDARDS DEVELOPMENT AND DEMONSTRATION PROJECTS

Mobile Health, Sensors, and Wearables

- The ASPM project team developed a Health Level Seven International® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) Application Data Exchange (ADE) Assessment Framework and Functional Requirements for the Mobile Health Implementation Guide.
- Reliant Medical Group (Reliant) in Worcester, Massachusetts, participated as a demonstration site and conducted real-world testing with patient participants.
- Real-time testing was conducted in production environments using synthetic patient data between Get Real Health®, a patient engagement app, and athenahealth, a health information technology (health IT) developer.

Social Determinants of Health (SDOH)

- The ASPM project team developed an Integrating the Health Enterprise (IHE) Assessment Curation and Data Collection (ACDC) profile.
- Fenway Health in Boston in partnership with the University of Washington and athenaheatlh demonstrated the capture of SDOH data through assessments and questionnaires.

Findings and Lessons Learned

The ASPM project team identified several key findings and lessons learned from the standards development advancement process and demonstration projects that are highlighted below:

- **Knowledge of Standards Development Organizations' (SDOs') Processes and Timelines Are Essential for Standards Advancement:** It is important to understand SDOs' processes, which vary across organizations and include items such as the ballot cycle process and timing, Connectathon schedule, required paperwork, and approvals processes. Awareness of and alignment with different SDOs' deadlines, approvals, and requirements will ensure project milestones are met and standards are advanced.
- **Industry Awareness and Collaborative Relationships Contribute to Effective Standards Advancement:** The ASPM project team was able to better synthesize existing work to align with overall industry efforts and gain broader support by collaborating with participating organizations. In addition to awareness of initiatives that stakeholders are engaged in, it was essential to understand existing and emerging standards that may be leveraged, incorporated, and spearheaded, to make progress.
- **Well-Aligned and Engaged Demonstration Project Partners Enable Efficient Execution of Goals:** The ASPM project team selected demonstration projects with strategic goals that aligned with the ASPM project goals. These partners were technically competent and were willing to actively participate, dig into the details, and share lessons learned.
- **Technical Implementation Teams Need To Be Adaptable Due to Unexpected Challenges:** Preparing to implement the demonstration projects took longer than expected due to technical challenges (e.g., internal firewalls, connection challenges) and competing priorities (e.g., COVID-19 response, developer software upgrades).

RECOMMENDATIONS

The ASPM project team identified areas of opportunity for future advancement of standards for high-impact data. The key areas of opportunity are below, and specific recommendations for each are provided in the report.

- Many consumer device manufacturers have not embraced the use of standards to enable sharing (e.g., Open mHealth or HL7 FHIR). An initiative comprised of appropriate stakeholders should be established that encourages the adoption of standards for use of data outside of proprietary applications.
- Improved internal and external coordination is needed between SDOs, as the work conducted in each of these organizations tends to be performed separately.
- Additional work is needed to capture a more robust set of data elements beyond the vital signs that were captured as part of this demonstration project from mobile health, wearables, and sensors.
- Additional high-impact data classes were identified for standards advancement that were not prioritized for this project (e.g., sexual orientation and gender identity [SOGI], military status, and occupational history), which are areas of opportunity.

Introduction

BACKGROUND

The Precision Medicine Initiative (PMI) launched in 2015 as a nationwide initiative to move away from the "one-size-fits-all" approach to healthcare delivery toward tailored treatment and prevention strategies based on people's unique characteristics, including environment, lifestyle, and biology.[1-2] The cornerstone of PMI is the National Institutes of Health (NIH) *All of Us* Research Program (*All of Us)*, a longitudinal national research cohort of one million or more U.S. volunteers from which clinical, environmental, genetic, and behavioral data will be collected.[3] *All of Us* is focused on collecting data from multiple sources and gathers data using the following data collection mechanisms:[4]

- Surveys and questionnaires;
- Electronic health record (EHR) and personal health record (PHR) systems;
- Biospecimen collection including blood, urine, and saliva;
- Physical measurement; and
- Mobile and digital health technology.

ONC has been involved in PMI since its inception by:

- Accelerating innovative collaboration around piloting and testing of standards that support health information technology (health IT) interoperability for research;
- Adopting policies and standards to support the privacy and security of participant data; and
- Advancing standards that support a patient-directed sharing approach to patient data contribution.[2,5]

ONC has partnered with NIH and *All of Us* to continuously advance standards through projects such as Sync for Science[6] (clinical data) and Sync for Genes[7] (genomic data).

Launched in October 2018, ASPM is the most recent addition to ONC's PMI initiatives. This project aims to realize the vision of precision medicine where health data, such as SDOH, is portable and standardized to be easily shared between providers, researchers, patients, and research participants.[1] Achieving such a state for the healthcare system requires access to electronic clinical data (e.g., those contained in EHRs) along with relevant electronic data from other sources such as mobile health applications (apps), sensors, and wearables.

Collectively, these projects enhance precision medicine research by expanding the availability of standardized electronic health data.

PROJECT PURPOSE, GOALS, AND OBJECTIVES

The purpose of the ASPM project was to enable the collection and sharing of high-impact data through standards development and testing. The ASPM project benefits *All of Us* and other initiatives that rely on standardized data for easier sharing, curation, and synthesis. Specifically, the ASPM project:

- Researched, identified, and recommended high-impact data for further standards development and advancement.
- Advanced data standards in collaboration with standards development organizations (SDOs) and other key stakeholders.
- Facilitated testing, implementation, and the use of prioritized standards.

Through an assessment of data needed for *All of Us*, two data classes were identified as high impact and prioritized for advancement:

1. Mobile health, sensor, and wearable data; and
2. Social determinants of health data.

STANDARDS ADVANCEMENT AND DEMONSTRATION PROJECTS

Mobile Health, Sensors, and Wearables

Mobile health, sensors, and wearables enable the collection of individual health information, which can be used for research, illness prevention, and to improve health outcomes. The ASPM team sought to understand where the biggest gaps in standards existed and identified in discussions with industry stakeholders that more work is needed to standardize the collection and sharing of this information. While the healthcare industry is rapidly adopting the HL7 FHIR specification to meet interoperability needs, the ASPM project team identified that many mobile health, sensor, and wearable apps use application programming interfaces (APIs) and methods for collecting data, but do not support HL7 FHIR.[8] Therefore, the ASPM project team focused on enabling the collection of mobile health, sensor, and wearable data using HL7 FHIR and brought this work through the standards development process, conducted testing, and implemented with two demonstration projects as outlined below:

- The ASPM project team developed the HL7 FHIR Mobile Health Application Data Exchange Assessment Framework and Functional Requirements Implementation Guide[9] (mHealth ADE FHIR IG), which was used to inform the two demonstration projects.
- Reliant Medical Group (Reliant) in Worcester, Massachusetts, participated as a demonstration project conducting real-world testing and implementation.
- Get Real Health®, a patient engagement app, and athenahealth, a health IT developer, conducted testing in a sandbox environment using production software and synthetic patient data.

Social Determinants of Health

SDOH have been found to account for as many as 40 percent of individual health outcomes;[10] therefore, the ASPM project focused on strategies to capture and share SDOH data to address patients' unmet social needs (e.g., income, educational attainment, employment status, and access to food and housing). To improve treatment and care, SDOH data should be standardized and available at the point of care. This work went

through the standards development process and was tested and implemented with a demonstration project as summarized below:

- An IHE ACDC profile was developed by the ASPM project team.[11]
- Fenway Health in Boston captured SDOH data through assessments and questionnaires leveraging the IHE ACDC profile.

Mobile Health, Sensors, and Wearables

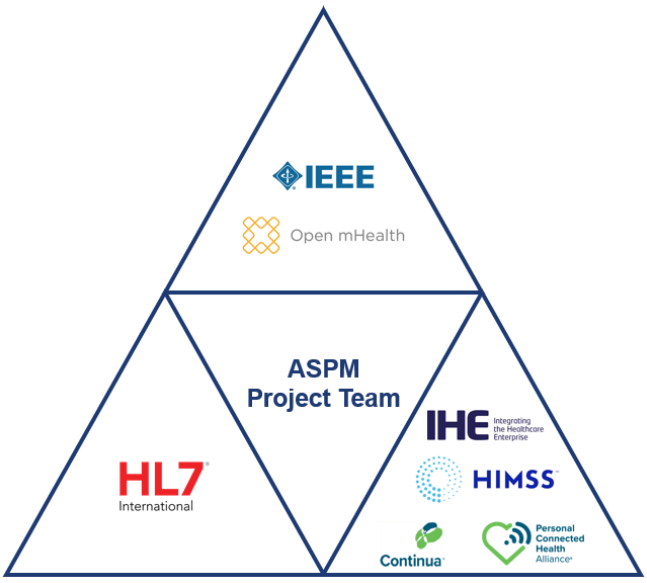
MOBILE HEALTH, SENSORS, AND WEARABLES: STANDARDS DEVELOPMENT

Overview

The ASPM project team took a collaborative approach to align efforts across industry stakeholders. As shown in Figure 1, collaborative partners included Open mHealth, HL7, Institute of Electrical and Electronics Engineers (IEEE), IHE, Personal Connected Health Alliance (PCHAlliance), and Healthcare Information and Management Systems Society (HIMSS).[12] The ASPM project team encouraged participation with device and application vendors to promote standards development, testing, and demonstration activities with IEEE, HL7, and IHE. HIMSS was instrumental in helping the ASPM project team socialize this work and helped convened stakeholders.

- The ASPM project team collaborated with Open mHealth and the IEEE P1752 Open Mobile Health Working Group (IEEE P1752 WG), which supports the exchange of data with a wide variety of mobile health apps, sensors, and wearables.[13]
- In tandem, the HL7 mHealth ADE FHIR implementation guide (IG)[9] was created under the HL7 Mobile Health Work Group. This IG provides functional requirements based on standards from HL7 FHIR, IHE, the PCHAlliance Continua Design Guidelines, and a framework for assessing these for implementation.

Figure 1: Standards Development Organizations Collaborating To Work on Mobile Health, Sensors, and Wearables



The following sections provide a detailed overview of the standards development activities prioritized for the mobile health, sensor, and wearable project and includes details of how these activities align:

- Open mHealth and IEEE
- HL7
- HIMSS, PCHAlliance, Continua, and IHE

Open mHealth and IEEE

Open mHealth developed schemas that are being balloted with IEEE for publication as standards. These schemas specify the format and content of data (e.g., body temperature, body weight, blood pressure, and heart rate). Open mHealth has several open-source projects that include packages such as Shimmer[14] and Granola[15] that enable the collection of data from apps (e.g., Google Fit, Fitbit, Withings, iHealth, RunKeeper). Open mHealth developed the Open mHealth to FHIR IG, which describes how to use Open mHealth schemas combined with FHIR to pull health data from popular third-party APIs.[16]

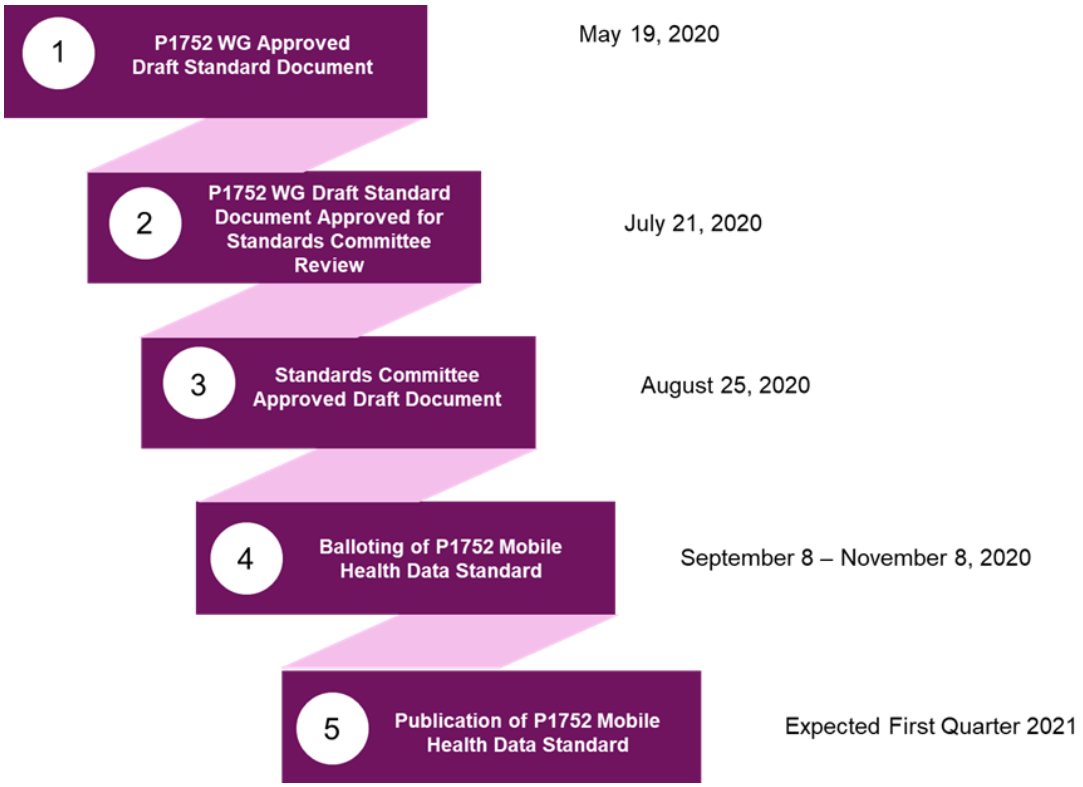
As summarized in Figure 2, the ASPM project team collaborated with Open mHealth and the IEEE P1752 Working Group (WG), where the work to standardize the schemas is occurring. The ASPM project team supported the advancement of Open mHealth's work by:

- Developing documentation and supporting balloting efforts to secure Open mHealth schemas as an official IEEE standard via the IEEE P1752 WG.
- Maintaining ongoing alignment with Open mHealth schemas and FHIR resources.
- Engaging key Open mHealth participants in HL7 mHealth WG discussions, including review of the mHealth ADE FHIR IG.
- Testing IEEE P1752 schemas with Reliant and providing ongoing feedback and lessons learned.

> "Open mHealth is excited to advance specifications for open mobile health data standards and the use of open standardized APIs. As we develop schemas in the IEEE P1752 Working Group, we are in parallel actively aligning to be compatible with FHIR to serve both the health IT and the broader technology community."[12]
>
> - Dr. Ida Sim, Open mHealth

Members of the Open mHealth team actively participated in HL7's Mobile Health WG to contribute to the development of the mHealth ADE FHIR IG.

Figure 2: Approval Process for P1752 - Standard for Mobile Health Data



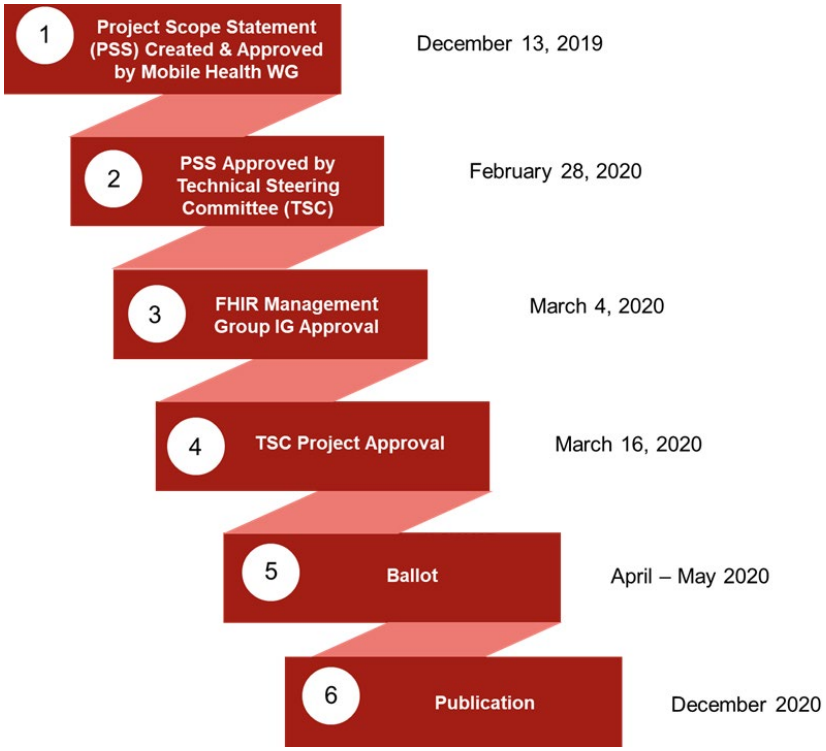
HL7

The ASPM project team identified that implementers of mobile health devices and apps would benefit from a clear framework that incorporates the use of FHIR. Thus, the project team collaborated with the HL7 Mobile Health Work Group to convene stakeholders and develop the HL7 mHealth ADE FHIR IG.

The ASPM project team participated in the HL7 Mobile Health WG and spearheaded the mHealth ADE Project, a subgroup under the Mobile Health WG. The HL7 mHealth FHIR ADE Project established reoccurring meetings to build a draft FHIR IG and convened stakeholders to participate in the balloting process. Under the ASPM project team's stewardship, an IG was developed to document functional requirements and provide a framework that supports app data exchange between mobile health devices, apps, and additional health IT (e.g., EHR, PHR). This IG incorporated a selection of standards from HL7 FHIR[17] and PCHAlliance.[18] Additionally, the ASPM project team mapped the work in the IEEE P1752 WG to the HL7 mHealth ADE FHIR IG. The framework can be used to assess mobile health devices, apps, and FHIR profiles to ensure that essential data needed for a variety of use cases (e.g., clinical care, personal management, and research) are present.

Details of the ballot process are depicted in Figure 3. Additional details of key HL7 WG Meetings and Connectathons, along with project goals, accomplishments, and milestones, are represented in Appendix A.

Figure 3: HL7 Mobile Health Data Exchange Framework & Functional Requirements FHIR Implementation Guide Ballot Process



PCHAlliance, Continua, and IHE

In the fall of 2019, PCHAlliance and IHE formed a joint task force to simplify health data exchange for consumer device monitoring and mobile health apps. In October 2019, the IHE joint task force formally launched the Personal Connected Health subdomain[19] with the IHE Patient Care Device domain[20] to develop IHE profiles that leverage and build upon the Continua Design Guidelines.[21] The IHE joint task force collaborated with leading industry efforts to align work and lead a consensus-based approach.

Additional details regarding PCHAlliance and IHE events along with goals and accomplishments are represented in Appendix B.

MOBILE HEALTH, SENSORS, AND WEARABLES: RELIANT DEMONSTRATION PROJECT

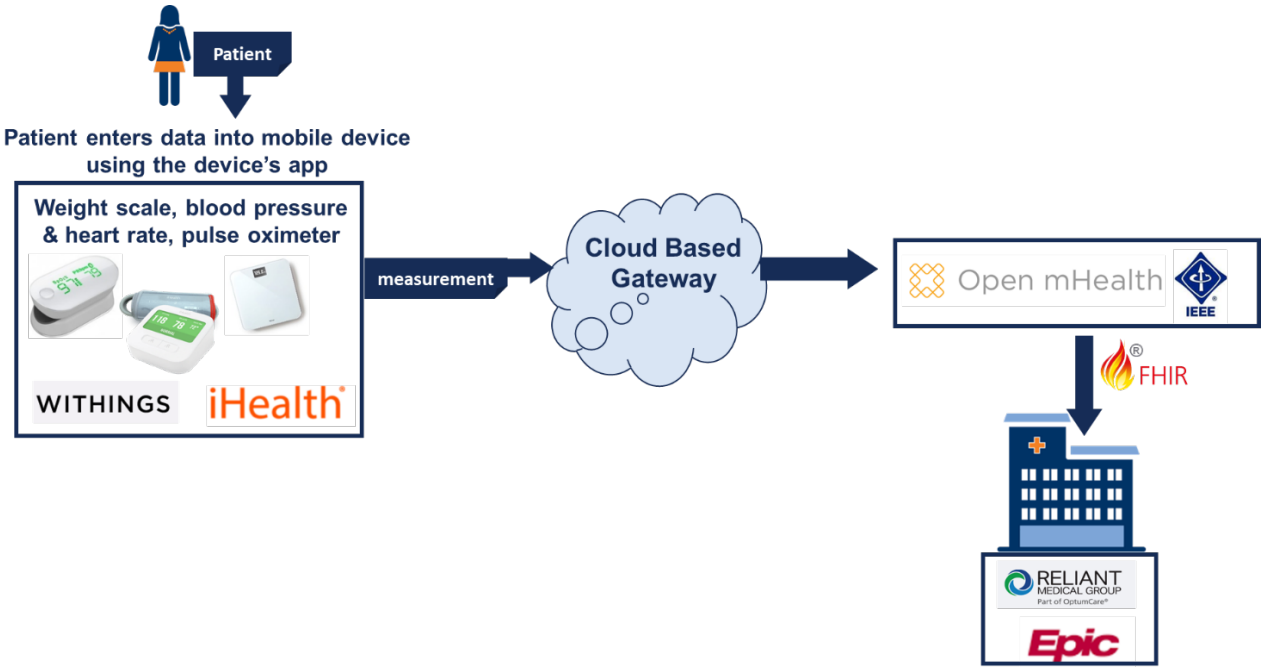
Background: Reliant

The sharing of mobile health, wearable, and sensor data for patient remote monitoring was tested with Reliant in Worcester, Massachusetts. Reliant is a 500-provider multi-specialty group practice with a mission to maximize the health of its patients and the community through expert medical care, compassion, innovative delivery models, medical research and education, and the appropriate use of healthcare resources.[22]

Leveraging clinical and technical expertise, the project aimed to demonstrate the use of Open mHealth schemas by capturing and monitoring patients vital sign measurements. The Georgia Tech Research Institute

(GTRI) collaborated with Open mHealth to develop the HL7 Open mHealth to FHIR IG to pull data from third-party APIs.[23] GTRI had previously implemented this approach, and Reliant leveraged that work to demonstrate the use of Open mHealth's standards-based approach to transmit mobile health, sensor, and wearable data into the EHR. A high-level depiction of how vital sign measurements flowed from the patient's mobile health, sensor, or wearable device(s) into Reliant's EHR is shown in Figure 4.

Figure 4: Data Flow from Patient's Mobile Health, Sensor, or Wearable to Reliant's EHR



The Reliant team focused on the following use cases, capturing vital signs for remote patient monitoring:

1. Patients diagnosed with the coronavirus disease 2019 (COVID-19)
    - Remote monitoring to proactively monitor diagnosed patients at home.
    - Oxygen saturation, blood pressure, and pulse were tracked.
2. Patients diagnosed with congestive heart failure (CHF)
    - Remote monitoring alerts in the EHR were triggered to proactively identify a 3-pound weight increase in one day or a 5-pound weight increase in one week. This weight increase is typically due to retaining fluids from worsening CHF.
    - Oxygen saturation, blood pressure, and pulse were tracked.

Demonstration Project Activities: Reliant

The diverse expertise of Reliant's team enabled an opportunity to gain insights from both clinical and technical perspectives. The Reliant team devoted significant time outside of working hours to prepare the practice for testing and implementation. Details of the implementation process, activities to prepare for the demonstration, and the experience of patients using consumer devices are detailed in the following sections.

Coding and Implementation Challenges

Through this process, several coding and implementation challenges were shared with stakeholders, as appropriate for future improvements, and are detailed in the following sections.

GTRI Implementation Challenges

As the Reliant team prepared for implementation, research was conducted to identify technological updates needed, and leveraged GTRI's implementation guide. During this process, several challenges emerged (e.g., the GTRI implementation website was down, seconds were recorded in different formats, and step count was hardcoded, but vital sign measurements were needed). These challenges were shared with GTRI for future updates.

Additionally, the GTRI implementation guide presumed that both the patient and healthcare provider shared the same computer screen or the use of patient-facing SMART®-on-FHIR. Unfortunately, most health IT developers do not expose SMART-on-FHIR to patients and if it they did, the patient would have needed an EHR patient portal account to use it. To resolve this challenge, the Reliant team created an enhancement in which patients registered devices during an in-office visit because the application to verify registration was only able to run while connected to the Reliant internal network. Additional configuration to support patients enrolling from their homes are in development.

Integration and Accessibility of Devices

Only specific devices could easily be used and integrated into the Open mHealth network. Open mHealth created a list of compatible devices that Reliant used to select devices. Once the devices for the demonstration project were selected, Reliant then had to source and purchase their selected devices. Some of these devices were difficult to find in stock, as they were in high demand due to COVID-19.

Internal IT Priorities

Internal IT-related competing priorities and processes took much longer than anticipated and delayed the launch of the demonstration project. These internal IT issues included responding to the needs of the pandemic (e.g., establishing telehealth infrastructure), an Epic EHR upgrade, and challenges on the internal IT side (e.g., internal firewall initially blocked the ability to download iHealth data).

Activities To Prepare for a Successful Demonstration Project

The Reliant team conducted the following to prepare the practice for a successful demonstration project:

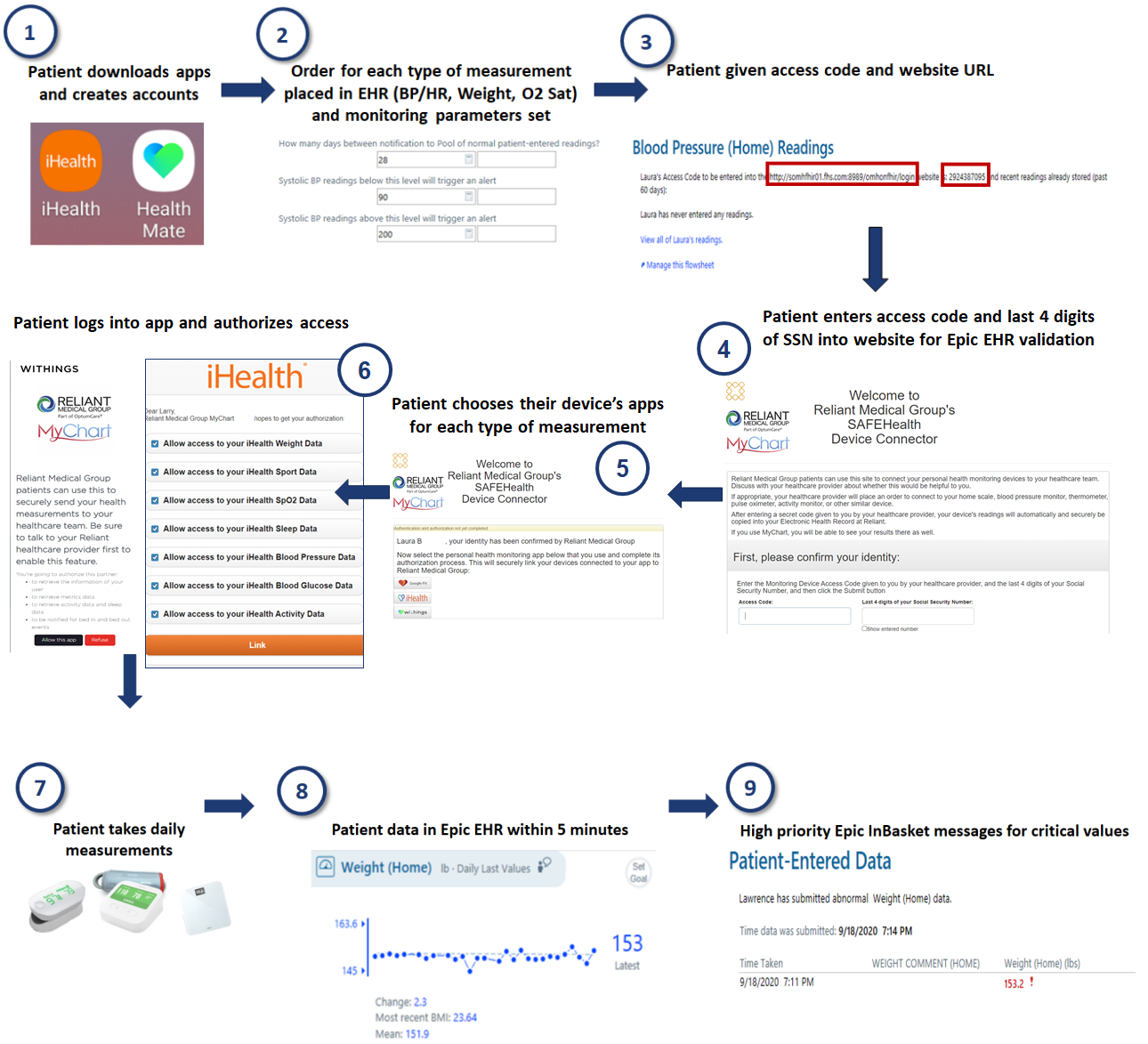
- Researched compatible consumer devices;
- Purchased identified consumer devices;
- Reviewed, implemented, and updated the GTRI, Open mHealth, and Epic EHR software;
- Trained staff and patient-participants; and
- Refined practice operations to meet the needs of the demonstration project.

To proactively respond to patient care needs, two types of messages were set-up in Epic as notifications to be sent to the Reliant clinical care team.

1. Routine Messages
    - Messages were sent within a pre-defined interval (e.g., 28 days) and included all the measurements that had been received from patient participants during the pre-defined interval.
2. Alert Message
    - An alert was triggered when a patient's data were outside the established clinical order parameters (e.g., 5 pounds gained in a week or an oxygen saturation below a critical level).

Details of the workflow established between the Reliant team and the patient are depicted in Figure 5.

Figure 5: Reliant Patient Workflow



Patient Use of Consumer Devices Challenges and Solutions

The demonstration project went live on October 2, 2020. Reliant purchased and distributed kits that included a Withings Wireless Internet (WiFi) home weight scale, Withings or iHealth WiFi blood pressure cuff that downloads blood pressure and heart rate, and iHealth Bluetooth Air pulse oximeters for oxygen saturation. Participating patients used these supplied consumer devices, but there is an extensive variety of other consumer devices that could have been used.

At the time of this report, the Reliant team had onboarded 18 patients (and continued to add more) who had access to a smartphone and WiFi access. As additional patients were onboarded, the process became more streamlined, but the training and set-up process took at least an hour per patient. Many patients had difficulty connecting the apps and consumer devices, which required a Reliant team member's assistance. Throughout the onboarding process, the Reliant team discovered that the set-up was not as intuitive as they expected. Although the implementation process was time-consuming, the Reliant team believed it was worthwhile because they were able to immediately provide significant patient care interventions.

The Reliant team was able to quickly make patient care interventions as new measurement results were automatically uploaded into the patient's record within five minutes of receipt. Remote monitoring allowed the Reliant team to proactively reach out to patients to adjust their medications due to results received from the patient's devices. As an example, after stepping on the scale one patient recorded significant weight gain (more than 5 pounds). Within 30 minutes of receiving this result, the patient was called by the Reliant team and her mediations were adjusted.

Summary of Key Findings and Outcomes: Reliant

The Reliant team spent significant time preparing for the demonstration project from research to technological upgrades, implementation, onboarding patients, and supporting patients. While time-consuming, the effort was worthwhile for the impact these interventions had on patient care. Through this process, several considerations for future implementers were identified.

One consideration for future implementers is to build additional time into the schedule to account for the internal IT process (e.g., technical development, internal firewalls blocking software). As with many technical implementations, the internal IT process took several weeks longer than initially anticipated due to unexpected delays.

The ability to use a broad selection of mobile health devices and apps, sensors, and wearables was identified as an important element for ease of implementation and use, but Open mHealth is currently limited in the number of consumer devices that are supported and compatible. Few consumer devices are compatible out of the box; therefore, supporting applications such as those from GTRI are needed for implementation. This process will likely improve as the Open mHealth schemas complete the standards development process through IEEE.

The Reliant team also identified that the patient onboarding process to connect consumer devices took significant time but was worthwhile to ensure that patients were properly set-up. The Reliant team spent significant time training and troubleshooting with patients. Though time-consuming, it was worthwhile due to the impact it had on patient care. The Reliant team encountered small nuances using consumer devices, revealing that consumer devices were not quite the same quality as professional devices. This caused

adoption challenges that were not anticipated (e.g., unable to capture pulse oximeter readings due to darker skin pigmentation). This also revealed there might be a need to identify creative ways for the patient to use the consumer devices, such as having the patient use a mirror to see the weight scale. When working with consumer devices, the Reliant team recognized the need to identify creative solutions that were adaptable to the patient population using the devices (e.g., technological capability, age, mobility, weight).

Although the implementation process was not entirely smooth, the Reliant team is excited about the results they have received to date. The Reliant team is already working to identify additional patients for onboarding and additional use cases for remote monitoring. In the time that remote monitoring has been implemented, the Reliant team has been able to make a significant positive impact on patient care and is looking forward to the opportunity to monitor additional patients.

MOBILE HEALTH, SENSORS, AND WEARABLES: GET REAL HEALTH AND ATHENAHEALTH DEMONSTRATION PROJECT

Background: Get Real Health and athenahealth

Due to the COVID-19 pandemic, an additional demonstration project was added to continue to achieve the ASPM's goals of ASPM while also addressing healthcare needs arising from the spread of COVID-19. The ASPM project team engaged Get Real Health and athenahealth as an additional demonstration project to conduct real-time testing in a production environment using test patient data. Testing was conducted to share data from mobile health, sensors, and wearables needed to support COVID-19 diagnosis and treatment (e.g., body temperature, blood pressure, heart rate, and physical activity).

Get Real Health is a global provider of comprehensive patient engagement tools that combine information from patients, devices, and apps with clinical data to help facilitate improved health outcomes and health population initiatives. Get Real Health's patient engagement solutions have established connections to the U.S. consumer device market leaders, including Fitbit, Withings, Garmin, Apple HealthKit, and iHealth.

The health IT developer athenahealth has a suite of integrated services that deliver measurable financial and clinical results for more than 160,000 healthcare providers. Athenahealth's vision is to create a thriving ecosystem that delivers accessible, high-quality, and sustainable healthcare for all, using their medical record, revenue cycle, patient engagement, and care coordination service offerings.[24]

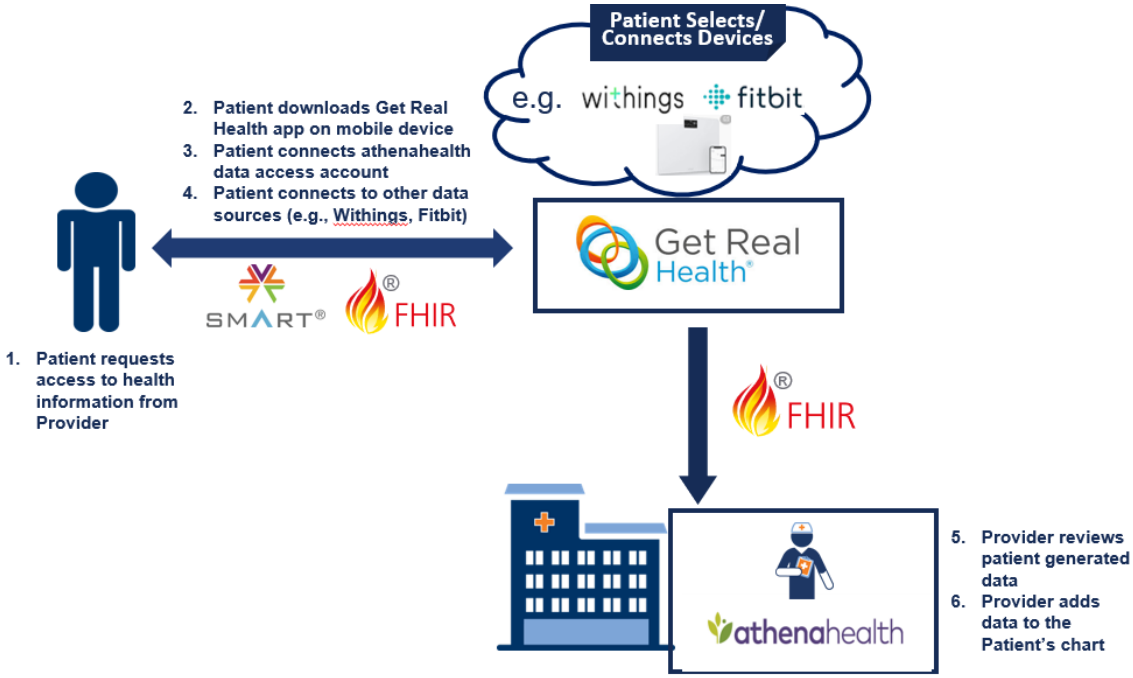
Demonstration Project Activities: Get Real Health and athenahealth

Get Real Health and athenahealth conducted production environment testing using synthetic data and performed a live demonstration to show how to share data between consumer devices and EHR systems. Get Real Health showed how to integrate device data and communicate that data to athenahealth's EHR system using FHIR.

SMART on FHIR was used to connect Get Real Health and athenahealth and enabled the sharing of patient data from consumer devices. The demonstration project showed capabilities of existing patient portal products and EHRs using the FHIR Draft Standard for Trial-Use (DSTU2).[25]

The demonstration project reported consumer device data entered as FHIR Observations[17] in the patient's medical record. To enable this, connections between the PHR, EHR, and devices needed to be established. This process is outlined below and depicted in Figure 6.

Figure 6: Connection Between athenahealth and Get Real Health



Summary of Key Findings and Outcomes: Get Real Health and athenahealth

The Get Real Health and athenahealth demonstration successfully showed how data can be captured from a patient's consumer device(s) and shared with a provider. Due to Get Real Health's ability to connect to a wide variety of consumer devices (connected through third-party APIs), the project was able to demonstrate the ability to capture and share consumer device data measuring several COVID-19 risk factors (e.g., temperature, blood pressure, heart rate, and weight).

The ASPM project team identified the following findings based on the Get Real Health and athenahealth demonstration project:

- **Ensure partners are using the same version of FHIR:** The Get Real Health app and athenahealth FHIR server used different versions of FHIR specifications (STU3 and DSTU2 respectively). Due to this difference, Get Real Health had to implement new FHIR transformers to support capability from STU3 to DSTU2.
- **Ensure partners are using the same codes and/or terminology:** The Observation codes[17] supported by athenahealth were defined and shared beforehand which enabled Get Real Health to incorporate those data into the implementation. However, due to the lack of national standards for collecting sleep and physical activity, athenahealth would have needed to create custom codes to exchange those data with Get Real Health.

- **Ensure consensus on frequency of data collection:** Get Real Health receives real-time notifications from consumer device, which then can be pushed into the EHR based on pre-defined intervals (e.g., real-time, daily basis, or a combination).
- **Streamline user authentication experience**: An improved patient experience is needed for user authentication across multiple systems. Authenticating devices with Get Real Health required the user to enter credentials several times. This presents potential challenges for patients and highlights that there is not a commonly implemented standard to authenticate users across different applications, a challenge in a wide variety of IT environments including healthcare.

Social Determinants of Health

SDOH: STANDARDS DEVELOPMENT

Overview

The ASPM project team conducted a landscape analysis and identified gaps in sharing SDOH data, which can be used to address patients' unmet social needs. The ASPM project team focused on strategies to capture and share SDOH to enable personalized care and treatment. For care improvement, SDOH data need to be shared in a standardized way and made available at the point-of-care. Assessments and questionnaires were identified as mechanisms to capture and share SDOH data; therefore, the ASPM project team established a standardized approach to exchange response data from a diverse array of assessments and questionnaires. The ASPM project team created the IHE ACDC profile to establish a standards-based approach to exchange assessment and questionnaire data. The IHE ACDC profile allows provider organizations to choose from a variety of assessments and/or questionnaires using standards to exchange and integrate response data so that it is available at the point-of-care.

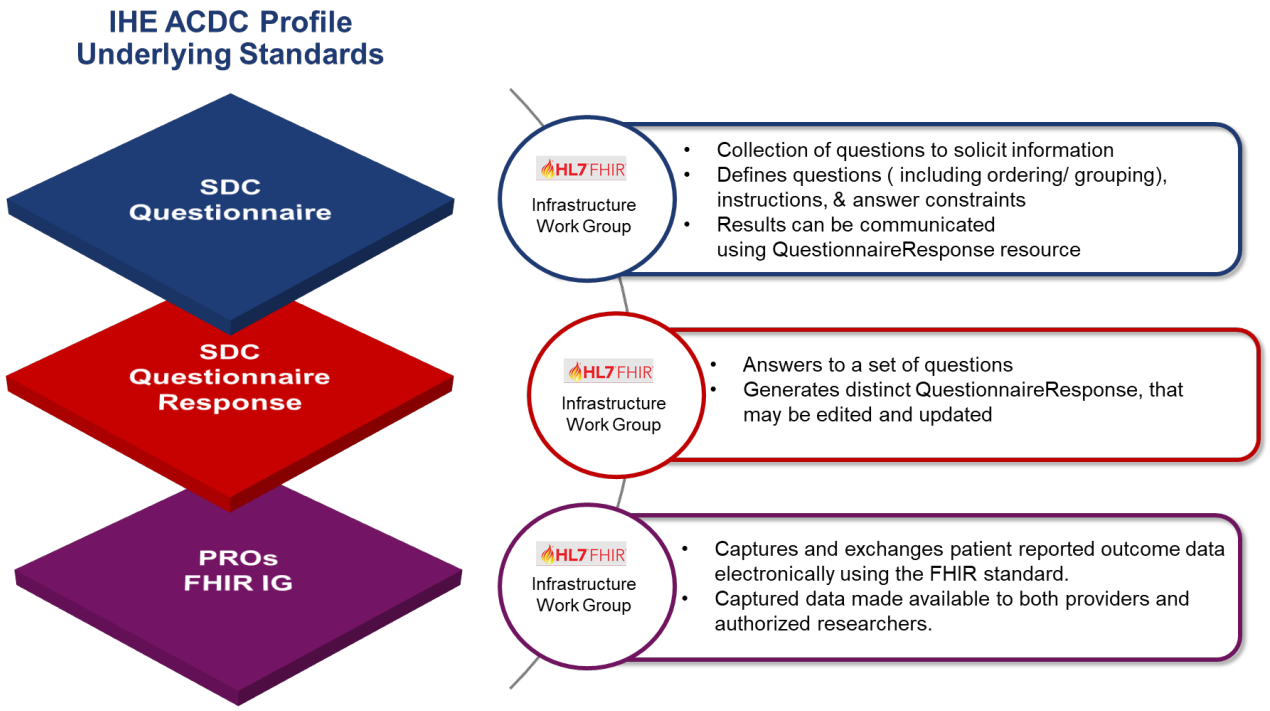
By leveraging resources from the HL7 FHIR Infrastructure Work Group[26] and creating the IHE ACDC profile, the ASPM project team laid the foundation for improved sharing of SDOH. These existing standards were used to capture and share response data from assessments and questionnaires which are used to capture SDOH and social needs. For example, the Centers for Medicare & Medicaid Services' (CMS) Accountable Health Communities (AHC) Health-Related Social Needs (HRSN) screening tool[27] uses a questionnaire to gather SDOH and social needs during intake.

The IHE ACDC profile was balloted and published for trial implementation and will be available for testing at future IHE Connectathons.

IHE ACDC Profile

The ASPM project team initiated the IHE ACDC profile, which enabled a means by which assessment response data can be exchanged in a standardized way using HL7 FHIR Infrastructure Work Group resources (i.e., Structured Data Capture [SDC] FHIR Profile Questionnaire,[28] SDC FHIR Profile QuestionnaireResponse,[28] and Patient Reported Outcomes [PRO] FHIR IG[29]), as detailed in Figure 7.

Figure 7: IHE ACDC Profile Underlying Standards



The IHE ACDC profile enables the use of a diverse array of assessments and questionnaires. The response data obtained can be exchanged in a standardized form by using the HL7 FHIR Questionnaire resource which enables data collection and storage. The IHE ACDC profile separates the curation and distribution functions from the data collection function.

- The assessment curation (AC) portion of the IHE ACDC profile enables access to content from a variety of assessment resources using the FHIR Questionnaire; and
- The data collection (DC) portion of the IHE ACDC profile enables data collection and storage to aggregate assessment content using the FHIR Questionnaire resource.

Assessment and questionnaire content are often intellectual property (IP) that requires licensing agreements or have specific implementation requirements to maintain the validity of the instrument response. These constraints often prevent sharing response data, but the IHE ACDC profile enables the sharing of response data in a standard format while still protecting IP.

The IHE ACDC profile enables access to a broader selection of data content without the need for developing customized implementations. The ASPM project team tested and implemented the IHE ACDC profile with Fenway Health, using it to capture and share SDOH information within the patient record and potentially across health systems.

Alignment with HL7's Gravity Project

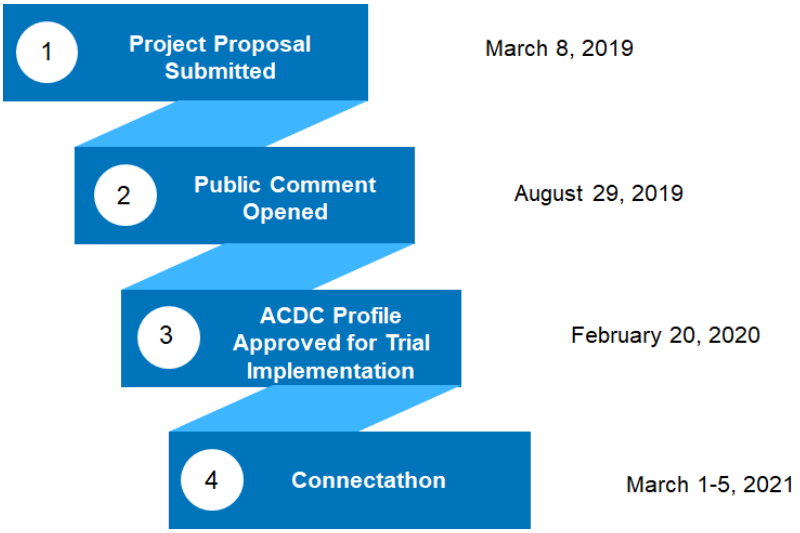
The Gravity Project, initiated in November 2018 by the University of California San Francisco's (UCSF) Social Interventions Research & Evaluation Network (SIREN) with funding from Robert Wood Johnson Foundation,

convened a broad group of stakeholders to identify and harmonize social risk data for interoperable health information exchange. In August 2019, HL7 announced the Gravity Project joined the HL7 FHIR Accelerator Program.[30] The Gravity Project's mission is to create and maintain a consensus-building community to expand available SDOH core data for interoperability and accelerate standards-based information exchange by using HL7 FHIR.[31] As part of the HL7 FHIR Accelerator Program, the HL7 Gravity Project broadened its focus to include standardizing terminology (e.g., Logical Observation Identifiers Names and Codes [LOINC®], Systematized Nomenclature of Medicine - Clinical Terms [SNOMED-CT®]) and supporting HL7 FHIR (i.e., HL7 FHIR SDOH Clinical Care IG). Recognizing the importance of the Gravity Project's work, the ASPM project team monitored and aligned with the Gravity Project throughout the project. Although the IHE ACDC profile was developed and published for trial implementation in February 2020, prior to publication of the Gravity Project's HL7 SDOH Clinical Care IG[32] in October 2020, it is compatible with the HL7 SDOH Clinical Care IG.

IHE Connectathons and Testing

The IHE ACDC profile was further developed through multiple events supported by IHE, leading to the status of approved for trial implementation. Details of the process can be found in Figure 8.

Figure 8: IHE ACDC Profile Milestones



SDOH DEMONSTRATION PROJECT: FENWAY HEALTH

Background

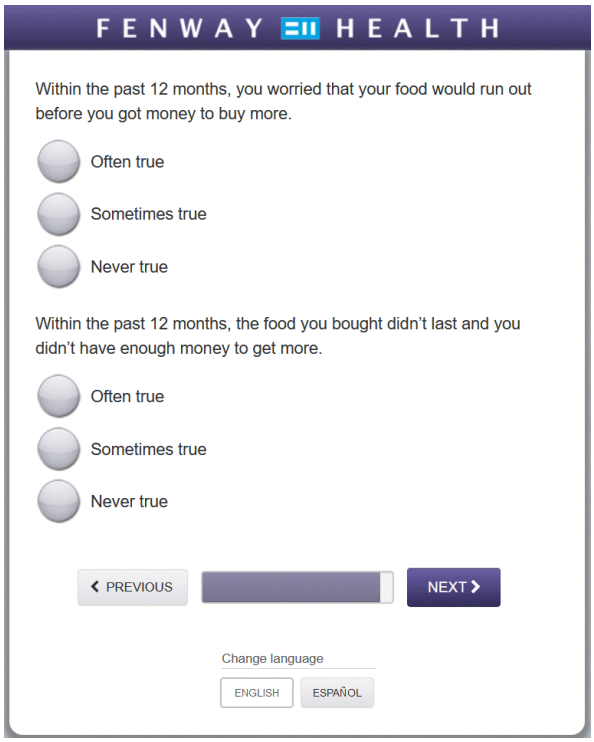
Since 1971, Fenway Health has been working to make life healthier for the people in its neighborhoods, the lesbian, gay, bisexual, transgender, queer or questioning, intersex, and asexual or allied (LGBTQIA+), people living with HIV/AIDS, and the broader population. Fenway was founded as part of the free clinic movement by students who believed that "health care should be a right, not a privilege." Fenway Health has a budget of more than $131 million, a staff of more than 600, and a patient population of more than 33,000.[33] Fenway Health is a Federally Qualified Community Health Center (FQHC) with a mission to enhance the wellbeing of the LGBTQIA+ community and all people in its neighborhoods and beyond through access to the highest quality healthcare, education, research, and advocacy. Capturing SDOH data and making them available at the point-of-care is important to Fenway Health's vulnerable patient population. The availability of SDOH data

can inform interventions at the point-of-care and help the provider identify local human services that may be beneficial to the patient. Fenway Health was selected to demonstrate how the IHE ACDC profile can be used to capture SDOH using a standards-based approach to integrate assessment and questionnaire data into its EHR.

Fenway Health, in partnership with the University of Washington and athenahealth (Fenway's health IT developer), participated in the ASPM project to capture and share SDOH data using a questionnaire. Fenway Health was interested in expanding the types of data (e.g., SDOH and social needs) that can be integrated into its EHR to create a more complete picture of patients by reflecting on their practical reality and the issues that impact their health (e.g., food insecurity, housing, and transportation). The goal was to give Fenway Health providers access to SDOH information at the point-of-care so that they can provide individualized treatment. The importance of this goal was further emphasized by the COVID-19 pandemic. Fenway's vulnerable population was disproportionately impacted by the pandemic, accentuating the need to capture SDOH and social needs to identify services that could potentially minimize the spread of the virus.

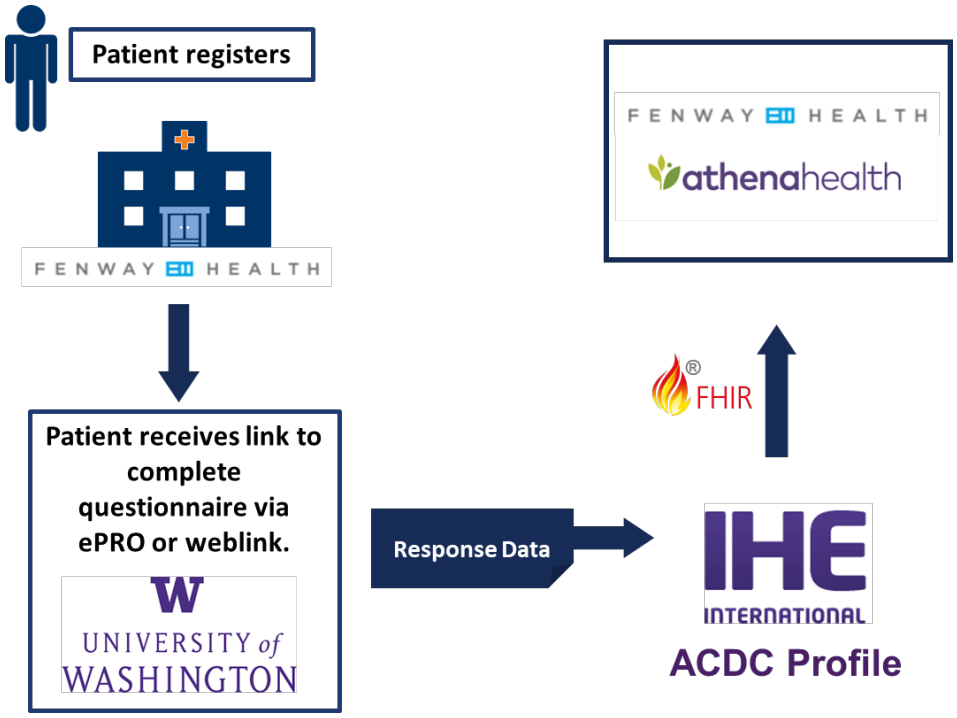
Fenway Health uses an SDOH assessment questionnaire, which was provided by the MassHealth (Massachusetts' Medicaid program) for participation as an accountable care organization (ACO). The questionnaire is loosely based on CMS' AHC HRSN assessment. Fenway Health uses a PRO software platform developed by the University of Washington called ePRO which is used to capture and share responses to the questionnaire. The SDOH questionnaire Fenway uses can be found in Appendix D, and an example of how the questionnaire looks in ePRO is shown below in Figure 9.

Figure 9: The SDOH Questionnaire in the ePRO User Interface, as Viewed by the Patient Via a Mobile Device.



To test the IHE ACDC profile, Fenway Health's questionnaire was used as a prototype for capturing and transmitting response data. Response data was captured using the ACDC profile and brought into the EHR in HL7 FHIR format, enabling the capability to easily share results. A depiction of how data were integrated can be found below in Figure 10.

Figure 10: Assessment Response Data Integrated into Fenway Health's EHR



Demonstration Project Activities: Fenway Health

The COVID-19 pandemic delayed the start of the demonstration project by several months. Due to the pandemic, Fenway Health shifted to mostly telehealth; therefore, the University of Washington team had to build capacity into ePRO to enable the ability for patients to respond to the questionnaire remotely, outside of the clinic setting. This caused unexpected delays but resulted in Fenway Health being able to capture questionnaire results more efficiently, as patients could complete it before their telehealth or office appointment.

As with most technical implementations, preparing for the demonstration project took significant time due to competing priorities in the technical team's queue. Fenway Health had to implement a significant upgrade of its health IT developer's software; therefore, technical resources had to focus on the upgrade before being able to focus on the technical set-up for the demonstration project. Once Fenway, the University of Washington, and athenahealth were able to engage, time was spent troubleshooting unexpected connection challenges that occurred due to security protocols between the organizations. The University of Washington encountered permission challenges when trying to connect to athenahealth. To solve this challenge, athenahealth had to closely analyze its security logs to identify the error. This was time-consuming because there were several connections (e.g., verifying access tokens, patient identify verification, and posting questionnaire responses) that had to be reviewed to determine the source of the error. Once the challenge

was identified, adjustments were made to athenahealth's security protocols, which allowed the University of Washington to connect to athenahealth's server.

Once all participants successfully connected, questionnaire responses were transmitted from the University of Washington, converted into FHIR Observations, and displayed in a flowsheet view within athenahealth as shown in Figures 11 and 12.

Figure 11: Questionnaire Results Appearing in the Patient's Record (test patient data are used in this example)

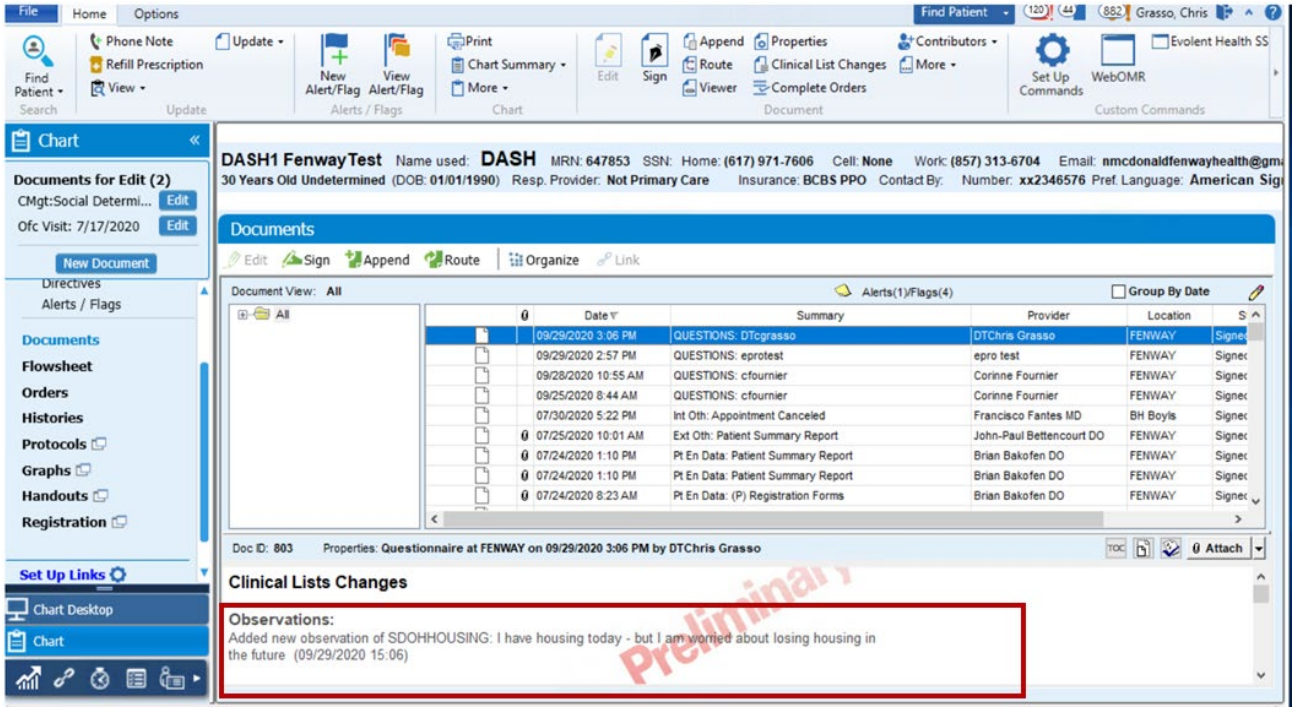


Figure 12: Zoomed in View of Questionnaire Results in Patient's Record

Summary of Key Findings and Outcomes

Fenway Health, the University of Washington, and athenahealth successfully demonstrated how the IHE ACDC profile can be used to capture and share questionnaire response data that is displayed in the EHR. Once all project partner team members were able to focus on the project, the implementation was smooth with no interruption to patients. The IHE ACDC profile was leveraged to ensure interoperability between the University of Washington and athenahealth. Once a patient completed the questionnaire, the University of Washington successfully converted patient responses to FHIR Observations. These FHIR Observations were then displayed in the patient's medical record within athenahealth, enabling an opportunity for providers to focus on patients' unmet social needs at the point-of-care.

The ASPM project team identified the following findings based on the Fenway Health, athenahealth, and the University of Washington demonstration project:

- **Time should be built into the schedule to account for unexpected delays and coordination of separate technical teams:** As a best practice for any health IT project, additional time was built into the schedule to ensure the technical teams from Fenway Health, athenahealth, and the University of Washington were available (time and resources) and ready to engage. Most technical teams have many competing priorities, which was especially true for this demonstration project due to the impacts of the COVID-19 pandemic. The actual work effort took no more than 25 hours. The coordination of the demonstration project participants availability to focus on the project was taken into consideration, and extra time was built into the project to accommodate all participants.

- **Ensure project partners are using complete and consistent codes and/or terminology:** Successful transmission of questionnaire responses is dependent on the terminology between organizations being properly mapped for an exact match. Any variance in how the questionnaire response appeared would inhibit transmission. The University of Washington and athenahealth encountered a capitalization issue that had to be rectified to have an exact match for responses to be transmitted appropriately. Additionally, there had to be a way to indicate if the respondent did not answer a question (which was allowed in the questionnaire). Answers were stored as observation values in the EHR; athenahealth had to indicate "no answer given" if the respondent omitted a question.

Overall Findings and Lesson Learned

Throughout the project, the ASPM project team created strong relationships and then used a collaborative approach to increase stakeholder involvement, support, and consensus. This was particularly evident when the COVID-19 pandemic threatened major delays in the project, and the ASPM team adapted quickly to pivot demonstration project efforts and engage additional demonstration project participants.

The ASPM project team identified several key findings and lessons learned from the standards development advancement process and demonstration projects that are detailed in the following sections.

STANDARDS DEVELOPMENT

Knowledge of SDO Processes and Timelines

The ASPM project team was confined by the timelines and protocols of the SDOs. To ensure project milestones are met and standards are advanced, it is important to understand each SDO's ballot cycle, Connectathon schedule,[34] required paperwork, and approvals processes. Any deadlines or approvals missed could result in special requests (i.e., out-of-cycle ballot) that could severely delay the timeline and potentially cause further misalignment with other SDOs, initiatives, and stakeholders.

Collaborative Relationships

One of the key lessons learned was that the best solutions require coordination across multiple stakeholder organizations (e.g., IHE, HL7, PCHA, and IEEE), rather than focusing on just one of them. This ensures broader support for the solution among developers and enabled the project team to synthesis efforts. In addition to a keen awareness of leading stakeholder efforts, it is essential to know which existing and emerging standards to leverage, incorporate and spearhead as appropriate. The ASPM project team ensured alignment with project goals and overall industry efforts.

DEMONSTRATION PROJECTS

Strong Demonstration Project Partners Are Essential

The ASPM selected demonstration projects with ongoing efforts in alignment with the demonstration project activities and goals, which was a key to success. It was essential to engage highly competent individuals with an understanding of the practical application and vision of the demonstration project who were willing to actively participate, dig into the details, and share lessons learned. Additionally, it was important to conduct a technical readiness assessment to understand vendor capabilities, engagement level, and upgrade schedules. Dedicated time to focus on the demonstration projects and engagement from available and committed subject matter experts was essential.

Finding demonstration project partners that were adaptable and easy to work with contributed to overall success despite the COVID-19 pandemic. The ASPM project team demonstration project partners were able to easily adjust and quickly expanded initiatives to support COVID-19 response. For example, Reliant was

able to expand its demonstration project to include a more robust telehealth implementation which incorporated remote monitoring efforts of the ASPM demonstration project.

Awareness of Technical Implementation Timelines

For both real-world demonstration projects, preparing for the demonstration project took longer than originally expected. This was in part due to the COVID-19 pandemic, but additional delays were identified due to the technical team having competing priorities and encountering technical challenges. These challenges are typical of any software implementation, and time should be built into the overall schedule that takes into consideration the complexity of the project to account for these delays. For example, an additional two months was built into the initial timeline for the Fenway Health, University of Washington, and athenahealth demonstration project. Timeline challenges include, but are not limited to developer software upgrades, internal firewalls blocking software, and connection challenges. In addition to software upgrades, developers may also need to be adaptable to the version of a standard that their counterpart is currently using (e.g., DSTU2 and STU3).

Improved User Experience for Authentication

An improved patient experience was needed for user authentication across multiple systems. When authenticating to share patient-generated health data with providers, patients had to remember numerous user identification names and passwords. This is a broader issue that impacts multiple industries; therefore, ONC should coordinate efforts with the National Institute of Standards and Technology (NIST) to address consumer challenges authenticating across multiple systems as this would be beneficial.

Recommendations

Based upon the findings and lessons learned, the ASPM project team identified recommendations to build on this work for the continued advancement of high-impact data needed for *All of Us* and the PMI.

PROBLEM	RECOMMENDATIONS
Standards: *Many consumer device manufacturers (e.g., iHealth, Fitbit) have not embraced the use of standards (e.g., Open mHealth or HL7 FHIR).*	• A landscape analysis of consumer device manufacturers and EHR/PHR developers should be conducted to understand the capabilities that have been implemented to address this standards challenge. Results of the landscape analysis should be shared through the HL7 Mobile Health Work Group for publishing as an HL7 informative document. • Additional demonstration projects should be used to assess the HL7 mHealth FHIR ADE IG to further enable the use of remote monitoring with mobile health, sensors, and wearables. • An initiative should be established that encourages consumer device manufacturers to adopt these standards; appropriate stakeholders should be convened to build consensus as part of this process.
SDOs: *Improved internal and external coordination is needed; the work tends to be siloed.*	• Efforts supporting similar goals and use cases need to be synergistic and coordinated among SDOs (e.g., working toward the same goal, each organization has discrete actions). Specifically, collaborative efforts to integrate SDOH data into health IT are needed (e.g., Aligning the IHE ACDC Profile and the Gravity Project's SDOH Clinical Care IG at future Connectathons).
Terminology: *Additional work is needed to capture a more robust set of data elements from mobile health, wearables, and sensors.*	• The ASPM project team focused on capturing vital signs from mobile health, wearables, and sensors through the Reliant demonstration project. Vital signs were selected because standards are not available for sleep and physical activity. To address this gap, work is needed to enhance standards and profiles developed in IEEE P1752 and HL7 FHIR.

Additional High-Impact Data in Need of Standards Advancement: *Additional data classes were identified for standards advancement that were not prioritized for this project (e.g., sexual orientation and gender identity [SOGI], military status, occupational history).*

- The U.S. Core Data for Interoperability (USCDI) process should be leveraged to drive the adoption of additional data elements that support research.

Conclusion

The ASPM project outcomes will help the *All of Us* Research Program collect data in a standardized and scalable approach. The ASPM project laid a foundation that can be easily expanded upon to continue to advance the standardized collection of mobile health, sensors, wearables, and SDOH. Specifically, the HL7 mHealth ADE FHIR IG was designed to continue to add data elements as they are available and ready to test and implement. The ACDC profile created a template that incorporates the use of leading standards efforts collecting SDOH data through standardized assessments and questionnaires.

These project activities helped realize the vision of precision medicine by accelerating collaboration around the implementation and testing of standards for mobile health, sensors, wearables, and SDOH. These projects advanced standards that made high-impact data portable and standardized to be easily shared among patients, providers, researchers, and research participants. The findings and lessons learned from the ASPM project can be applied to advance additional high-impact data priorities.

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Appendices

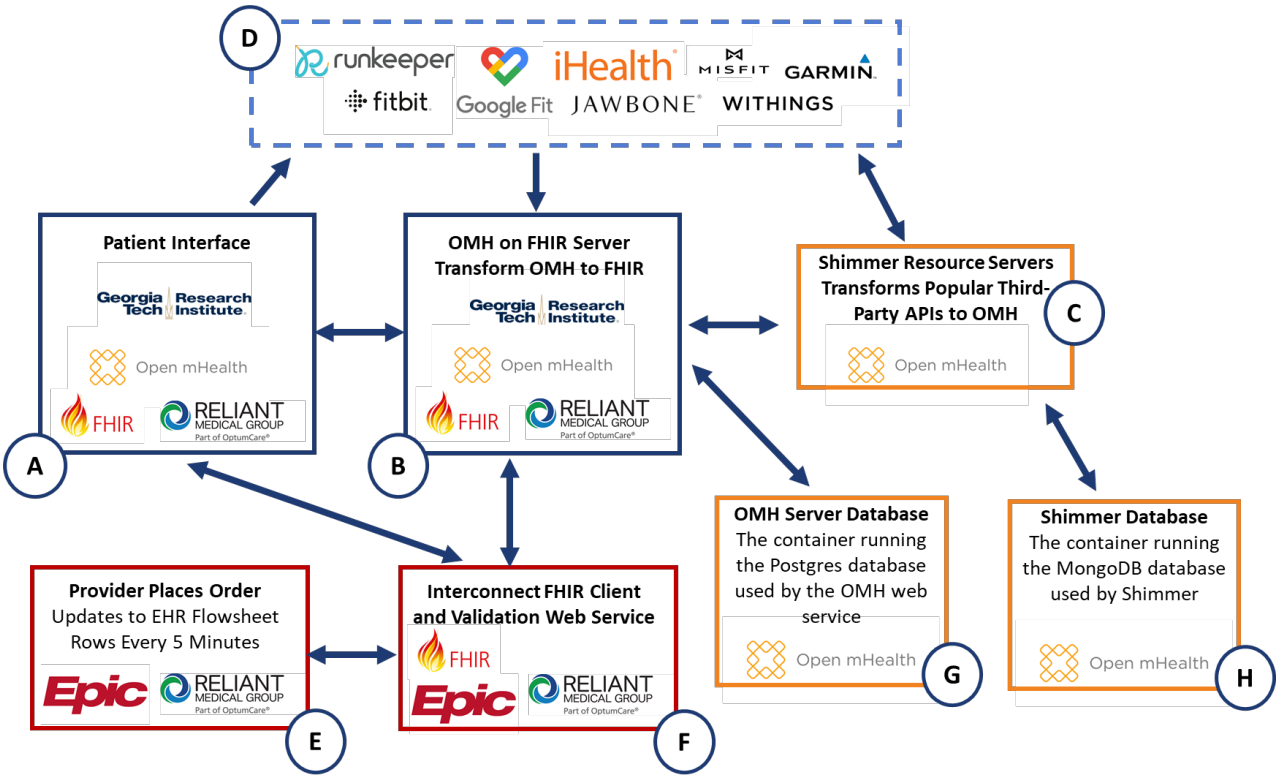
APPENDIX A: HL7 WORKING GROUP MEETINGS AND CONNECTATHONS

HL7 Meeting	Goals, Accomplishments, and Milestones
May 2019 Montreal, Canada Work Group Meeting	• Introduced the project, generated interest, and recruited membership participation
August 2019 HL7 ADE WG	• August 2, 2019 – Project Scope Statement (PSS) approved • August 14, 2019 – FHIR Management Group approved • August 23, 2019 – Call for participation in newly formed Mobile Health WG's Mobile Health App Data Exchange Project
September 14-20, 2019 Atlanta, Georgia Work Group Meeting	• Organized a track at the HL7 FHIR Connectathon to demonstrate the exchange of mobile application and device data using FHIR • Facilitated the "Health IT Data Standards for *All of Us*" session in coordination with the HL7 Mobile Health Work Group ○ **Mobile Health Data Exchange FHIR Connectathon Track** ▪ Focused on the capture of resource samples and exchange methods data from mobile health devices (e.g., heart rate, blood pressure, steps, and calories). ▪ Ranged between 6-10 participants with continual interaction between related tracks including Devices and Carin Blue Button. ○ **Breakout Session I: Saturday, September 14, 3 p.m.** ▪ Brian Reinhold presented the Continua/PCHAlliance Personal Health Device Implementation Guide. ▪ Monique van Berkum from the American Medical Association presented self-measured blood pressure using a remote monitoring device (SMBP) use case for standardization. ○ **Breakout Session II: Sunday, September 15, 9 a.m.** ▪ Eric Soto, Georgia Tech Research Institute, presented the Open mHealth standardization work. ○ **Outcomes and Next Steps** ▪ Approximately 50 resources were collected in six different categories from multiple sources. ▪ The next steps were to compare differences between resources.

HL7 Meeting	Goals, Accomplishments, and Milestones
May 2020 Virtual Work Group Meeting	• Balloted draft FHIR Implementation Guide, mHealth App Data Exchange Framework & Functional Requirements (mHealth ADE) • Received 177 comments that were reconciled with the mHealth ADE Project
July 2020	• Reconciled all comments • Published as standard for trial use (STU)

APPENDIX B: RELIANT: PATIENT WORKFLOW BACKEND DETAILS

Includes all steps from patient workflow in Figure 3 but provides additional details of what happens behind the scenes to authenticate the patient and to enable sharing of measurement results.



1. Patient downloads apps and creates accounts (iHealth, Withings)
2. Provider places the order for each type of measurement placed in Epic (e.g., BP/HR, weight, O2 sat) and monitoring parameters set
3. Through the patient interface, the patient enters the code generated by the provider's order along with the last four digits of his/her social security number for authentication
4. Patient interface (A) "talks" to the interconnect server (F) to validate the patient's identification
5. The FHIR Client and Validation web service (F) makes sure that everything matches for the specific patient
6. Patient interface (A) receives confirmation that it is okay to proceed
7. The patient selects an icon for the selected device (D) to start the authorization/authentication process
8. Via the Open mHealth (OMH) on FHIR server (B) over to the Shimmer server (C) to identify the URL that should be used
9. The patient interface now knows what interface to use, then goes through the cloud for the device (D) to authenticate/authorize (this process bounces between the Shimmer server [C] and the OMH server [G])
10. The Shimmer server (C) is keeping track of the refresh and access token

11. The refresh and access token comes back to the patient interfaces (A) because it is successful, passing back a Shimmer identification which is the identification that is necessary to use the access and refresh token that was retrieved
12. Patient interface (A) passed the Shimmer identification through the interconnect webservice (F) and then passes it back into Epic
13. Epic orders have been placed, and Shimmer identification has been associated; therefore, every five minutes the system is set-up to check to see if any measurement data is available using the interconnect FHIR client (F) talking to the OMH FHIR server (B)
    a. Which talks to the Shimmer server (C)
    b. Which talks to the device (D)
14. Measurement data is passed into Epic in flowsheet rows (E)
15. If a parameter alert is triggered, an Epic InBasket message is received for significantly abnormal results

APPENDIX C: FENWAY HEALTH QUESTIONNAIRE

Today's Date: ____/____/_____

What is your housing situation today?

- I do not have housing (staying with others, in a hotel, in a shelter, living outside on the street, on a beach, in a car, or in a park)
- I have housing today, but I am worried about losing housing in the future
- I have housing
- I am not sure

1. Think about the place you live. Do you have problems with any of the following? (check all that apply)
   - Pests such as bugs, ants, or mice
   - Mold
   - Lead paint or pipes
   - Inadequate heat
   - Oven or stove not working
   - No or not working smoke detectors
   - Water leaks
   - None of the above
   - I am not sure

2. Within the past 12 months, you worried that your food would run out before you got money to buy more.
   - Often true
   - Sometimes true
   - Never true

3. Within the past 12 months, the food you bought just didn't last and you didn't have enough money to get more.
   - Often true
   - Sometimes true
   - Never true

4. In the past 12 months, has lack of transportation kept you from medical appointments, meetings, work or from getting things needed for daily living? (Check all that apply)
   - Yes, it has kept me from medical appointments or getting medications
   - Yes, it has kept me from non-medical meetings, appointments, work, or getting things that I need
   - No
   - I am not sure

5. In the past 12 months has the electric, gas, oil, or water company threatened to shut off services in your home?
   - Yes
   - No
   - Already shut off
   - I am not sure

6. Do you want help finding or keeping work or a job?
   - Yes, help finding work
   - Yes, help keeping work
   - I do not need or want help
   - I am not sure

APPENDIX D: PCHALLIANCE AND IHE EVENTS

PCHAlliance and IHE Accomplishments	
Meeting	**Goals and Accomplishments**
October 16-18, 2019 PCHAlliance 11th Annual Connected Health Conference Boston, Massachusetts	• Developed a participation track for the Continua Plug-fest/Connectathon to demonstrate the exchange of device data

January 20-24, 2020
 	
2020 IHE North American Connectathon
 	
Cleveland, Ohio
	• Provided a venue for cross-industry collaboration
	  ○ Test environment where public and private stakeholders demonstrated the interoperability of their products developed using open standards and implementation profiles.
	• Key stakeholders leading efforts to advance device and mobile health data standards had the chance to share progress, discuss challenges, share best practices, obtain hands-on experience, and learn from subject matter experts.
	• The Connectathon included two “Standards Acceleration Tracks” that focused on emerging standards, profiles, and implementation guides related to Devices/Health Apps and Public Health.
	  ○ Audacious Inquiry helped define and create the track for the Devices/Health Apps, and Audacious Inquiry team members were key speakers throughout the event
	• **Device/Health Apps Standards Acceleration Track: Full-day event on January 23, 2020**
	  ▪ The morning sessions characterized the need for mobile health apps
	  ▪ The afternoon session employed an accelerated proposal process to outline opportunities for the newly formed Mobile Health Apps Work Group in the IHE Personal Connected Health subdomain

APPENDIX E: GLOSSARY OF ACRONYMS

Acronym	Definition
ACDC	Assessment Curation and Data Collection
ACO	Accountable Care Organization
AHC	Accountable Health Communities
All of Us	*All of Us* Research Program
API	Application Programming Interface
Apps	Applications
ASPM	Advancing Standards for Precision Medicine
CHF	Congestive Heart Failure
CMS	Centers for Medicare & Medicaid Services
COVID-19	Coronavirus Disease 2019
DSTU	Draft Standard for Trial Use
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources
GTRI	Georgia Tech Research Institute
Health IT	Health Information Technology
HIMSS	Healthcare Information and Management Systems Society
HL7	Health Level Seven International
HRSN	Health-Related Social Needs
IEEE	Institute of Electrical and Electronics Engineers

Acronym	Definition
IHE	Integrating the Health Enterprise
IG	Implementation Guide
IP	Intellectual Property
LGBTQIA+	Lesbian, Gay, Bisexual, Transgender, Queer or Questioning, Intersex, and Asexual or Allied
LOINC®	Logical Observation Identifiers, Names, and Codes
mHealth ADE	mHealth App Data Exchange
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
ONC	Office of the National Coordinator for Health Information Technology
PCHAlliance	Personal Connected Health Alliance
PHR	Personal Health Record
PMI	Precision Medicine Initiative
PRO	Patient-Reported Outcome
SDOs	Standards Development Organizations
SDOH	Social Determinants of Health
SNOMED-CT®	Systematized Nomenclature of Medicine - Clinical Terms
SOGI	Sexual Orientation and Gender Identity
USCDI	U.S. Core Data for Interoperability
UW	University of Washington
WG	Working Group

Acronym	Definition
WiFi	Wireless Internet

APPENDIX F: GLOSSARY OF TERMS

Term	Definition
Advancing Standards for Precision Medicine (ASPM) https://www.healthit.gov/topic/advancing-standards-precision-medicine	Launched in the fall of 2018, focused on advancing data standards and patient-provided sharing of health data. The project helped facilitate the goals of the PMI by identifying high-impact data and enabling the development and advancement of data standards, resources, and associated implementation guides (IGs) after testing and implementation with individual sites or through standards development organizations such as HL7 and Institute of Electrical and Electronic Engineers. The project focused on mobile health, sensor, and wearable data; and social determinants of health data.
Centers for Medicare & Medicaid Services' (CMS) Accountable Health Communities (AHC) Health-Related Social Needs (HRSN) https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf	Accountable Health Communities is an ongoing CMS innovation model based on emerging evidence that addresses health-related social needs through increased clinical-community linkages that can improve health outcomes and reduce costs. Unmet health-related social needs, such as food insecurity and inadequate or unstable housing, can increase the risk of developing chronic conditions, increase healthcare costs, and lead to avoidable healthcare utilization.
Consumer Device https://www.fda.gov/medical-devices/home-health-and-consumer-devices/consumer-products	Medical devices consumers use on their own to solve health issues and improve quality of life. Wearable monitoring devices and mobile applications can be considered consumer health devices. Consumer health and medical devices often use different standards to support the capture and sharing of data. Consumer health devices rely on low-cost personal network technology such as Bluetooth for communication from the sensor to one or more paired host devices.
FHIR Draft Standard for Trial-Use (DSTU2) http://hl7.org/fhir/index.html	FHIR aims to simplify implementation without sacrificing information integrity. It leverages existing logical and theoretical models to provide a consistent, easy-to-implement, and rigorous mechanism for exchanging data between healthcare applications. The current version, which supersedes this version, is 4.0.1.
Granola https://github.com/openmhealth/Granola	Open mHealth developed an open-source package that allows users to store an app's HealthKit data outside of HealthKit. Granola maps HealthKit's API to emit JavaScript Object Notation (JSON) that validates against Open mHealth schemas.
Healthcare Information and Management Systems Society (HIMSS)	Healthcare Information and Management Systems Society, Inc. is a global advisor and thought leader supporting the transformation of the health ecosystem through information and

Term	Definition
https://www.himss.org/	technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics to advise global leaders, stakeholders and influencers on best practices in health information and technology.
Health Level Seven International® (HL7®) https://www.hl7.org/index.cfm	Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services. HL7 is supported by more than 1,600 members from more than 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.
HL7 FHIR Accelerator Program https://www.hl7.org/about/fhir-accelerator/	The HL7 FHIR Accelerator Program is designed to assist communities and collaborative groups across the global healthcare spectrum in the creation and adoption of high-quality FHIR Implementation Guides or other standard artifacts to move toward the realization of global health data interoperability.
HL7 FHIR SDOH Clinical Care Implementation Guide http://build.fhir.org/ig/HL7/sdoh-cc/	This HL7® FHIR SDOH IG defines FHIR R4 profiles, extensions and value sets needed to exchange SDOH content defined by the Gravity Project. It defines how to represent coded content used to support the following care activities: screening, clinical assessment/diagnosis, goal setting, and the planning and performing of interventions. It addresses the need to gather SDOH information in the context of clinical encounters and describes how to share SDOH information and other relevant information with outside organizations for the purpose of coordinating services and support to address SDOH-related needs. It demonstrates how to share clinical data to support secondary purposes such as population health, quality, and research.
HL7® FHIR® Mobile Health Application Data Exchange Assessment Framework and Functional Requirements Implementation Guide	The guide provides an assessment framework and functional requirements for consumer medical devices and applications that support the exchange of observations and other data in support of consumer health monitoring. It focuses on functional requirements of devices, apps, and infrastructure regarding the observations and device-related communicating data about vital signs and physical activity.

Term	Definition
https://confluence.hl7.org/display/FHIR/mHealth+App+Data+Exchange+Functional+Requirements+IG	
HL7 Gravity Project https://www.hl7.org/gravity/	The Gravity Project was initiated in November 2018 by the University of California San Francisco's Social Interventions Research & Evaluation Network with funding from Robert Wood Johnson Foundation to convene a broad group of stakeholders to identify and harmonize social risk data for interoperable health information exchange. In August 2019, HL7 announced the Gravity Project as part of the HL7 FHIR Accelerator Program. The Gravity Project's mission is to create and maintain a consensus-building community to expand available SDOH core data for interoperability and accelerate standards-based information exchange by using HL7 FHIR.
HL7 Mobile Health Work Group http://www.hl7.org/Special/committees/mobile/index.cfm	The HL7 Mobile Health Work Group creates and promotes health information technology standards and frameworks for mobile health.
HL7 mHealth App Data Exchange Framework & Functional Requirements FHIR Implementation Guide https://www.hl7.org/Special/committees/mobile/index.cfm	The mHealth ADE Project established reoccurring meetings to build a draft FHIR IG and convened stakeholders to participate in the balloting process. The mHealth ADE FHIR IG was tested with Reliant in Worcester, Massachusetts, and production environment testing was conducted between Get Real Health and athenahealth.
HL7 Structured Data Capture (SDC) Questionnaire https://www.hl7.org/fhir/questionnaire.html	A Questionnaire is an organized collection of questions intended to solicit information from patients, providers or other individuals involved in the healthcare domain. They may be simple flat lists of questions or can be hierarchically organized in groups and sub-groups, each containing questions. The Questionnaire defines the questions to be asked, how they are ordered and grouped, any intervening instructional text and what the constraints are on the allowed answers. The results of a Questionnaire can be communicated using the QuestionnaireResponse resource.
HL7 SDC QuestionnaireResponse https://www.hl7.org/fhir/questionnaireresponse.html	Provides a complete or partial list of answers to a set of questions filled when responding to a questionnaire. Each time a questionnaire is completed for a different subject or at a different time, a distinct QuestionnaireResponse is generated,

Term	Definition
	though it may be possible for a previously entered set of answers to be edited or updated. Questionnaire responses cover the need to communicate data originating from forms used in medical history examinations, research questionnaires and sometimes full clinical specialty records. In many systems, data is collected using user-defined screens and forms. Questionnaire responses record specifics about data capture -- exactly what questions were asked, in what order, what answers were given, etc. Each of these questions is part of the Questionnaire, and as such the Questionnaire is a separately identifiable resource, whereas the individual questions are not.
Institute of Electrical and Electronics Engineers (IEEE®) https://www.ieee.org/	IEEE is the world's largest technical professional organization dedicated to advancing technology for the benefit of humanity. IEEE's core purpose is to foster technological innovation and excellence for the benefit of humanity.
IEEE P1752 Work Group https://standards.ieee.org/project/1752.html#Working	IEEE Work Group to define specifications for a mobile health data applications programming interface and standardized representations for mobile health data and metadata. Mobile health data encompasses personal health data collected from sensors and mobile applications.
Integrating the Healthcare Enterprise International (IHE®) https://www.ihe.net/	IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as Digital Imaging and Communication in Medicine (DICOM) and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively.
IHE Assessment Curation and Data Capture (ACDC) Profile https://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_ACDC.pdf	The IHE Assessment Curation and Data Collection profile supports the selection of assessment instruments from a repository and the integration of those instruments into a provider workflow for the capture of assessment data for a given patient.

Term	Definition
Open mHealth http://www.openmhealth.org	Open mHealth is a non-profit start-up working to break down integration barriers and bring clinical meaning to digital health data. Open mHealth's main objective is to provide a way to access digital health data from disparate sources and harmonize it. Open mHealth is establishing a community of developers, product managers, health IT decision-makers, and clinical researchers to build an open framework that is accessible to all.
Patient Reported Outcomes (PRO) FHIR Implementation Guide http://build.fhir.org/ig/HL7/patient-reported-outcomes/	The Patient Reported Outcomes FHIR Implementation Guide will focus on capturing and exchanging patient-reported outcome data electronically using the FHIR standard. The data that are captured will be made available to both providers and authorized researchers.
Personal Connected Health Alliance (PCHAlliance) https://www.pchalliance.org/	The Continua Design Guidelines specify an end-to-end ICT framework for personal connected health solutions based on recognized open standards, to create a secure and interoperable health data exchange. They enable the secure flow of Continua medical-grade data among sensors, gateways, and services by providing clear guidance on their interoperability, adding the necessary missing features within the underlying standards or specifications. To ensure interoperability, they offer a compliance and interoperability program to validate that devices interoperate with gateways and services.
Shimmer https://www.openmhealth.org/whats-shimmer-the-first-open-source-health-data-integration-tool/	Shimmer is an Open-Source Health Data Integration Tool developed by Open mHealth. The tool aims to help start-ups, clinical researchers, and health services integrate digital health data to help provide more context to their user's health behavior.
SMART on FHIR https://smarthealthit.org/smart-on-fhir-api/	A platform with substitutable apps constructed around core services is a promising approach to driving down healthcare technology costs, supporting standards evolution, accommodating differences in care workflow, fostering competition in the market, and accelerating innovation. With the cost of switching kept low, the platform enables a physician using an electronic health record, a chief information officer running a hospital IT infrastructure, or a patient using a

Term	Definition
	personally controlled health record to readily discard an under-performing app and install a better one.
Structured Data Capture (SDC) FHIR Profile Questionnaire and QuestionnaireResponse http://hl7.org/fhir/uv/sdc/2019May/	Questionnaires and forms are used across healthcare to capture administrative data, claims data, clinical information, research information, for public health reporting-- every type of data that is manipulated by healthcare systems. They provide a user-friendly mechanism for capturing data in a consistent way. In FHIR, forms are represented using the Questionnaire resource and completed forms are represented using the QuestionnaireResponse resource. The base FHIR specification defines these resources but does not provide much guidance around how they should be used, nor does it set minimal expectations for interoperation. This implementation guide provides a set of guidance around the use of Questionnaire/QuestionnaireResponse.
Sync for Science http://syncfor.science/	Launched in 2016 as a public-private collaboration to develop a simplified, scalable, and secure way for individuals to access and share their health data with scientific researchers in support of PMI and *All of Us*. Sync for Science (S4S) leverages and builds upon open source standards (e.g., HL7, FHIR) allowing an individual to share data. S4S aims to accelerate and guide national priorities for individual-mediated data access and sharing through application programming interfaces, while lowering the barriers for health IT developers and provider sites to participate in the mobile app ecosystem. S4S is piloting with several provider sites with participating health IT developers (i.e., Allscripts, Cerner, eClinicalWorks, and Epic) and is expanding participation to additional developers and associated provider sites.
Sync for Genes https://www.healthit.gov/topic/sync-genes	Launched in 2017, Sync for Genes aims to standardize the sharing of genomic information between laboratories, providers, patients, and researchers. Sync for Genes advances the development and use of industry standards that support the sharing and integration of genomic information in a consistent and usable way. ONC, in partnership with the National Institutes of Health, supports the sharing of genomic data essential to *All of Us'* expanding research needs.