PRISM (PROMIS Reporting and Insight System from Minnesota) Final Report

April 20, 2020

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Final Report for the Completion of the AHRQ Step Up App Challenge

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NOTE: Section numbers and Appendix numbers were kept the same as the corresponding section in the Medstar Final Report.

Executive Summary

Goal: PRISM (**P**ROMIS **R**eporting and **I**nsight **S**ystem from **M**innesota) was the winner of AHRQ's Step Up Challenge and had the goal to implement and pilot test the mobile app for use at nine primary and specialty care practices at Medstar Health in Washington DC, Maryland, and Virginia. PRISM is an application that enhances the quality of clinical discussion between healthcare providers and patients by allowing for continued patient engagement outside of the clinical setting. The platform supports any PRO instrument and allows seamless data integration with electronic health records (EHRs) via Fast Healthcare Interoperability Resources (FHIR). The overarching goal of this pilot was to identify facilitators and barriers of this technical integration in diverse ambulatory settings, and to rigorously evaluate its implementation and use by key stakeholders including patients and providers.

Methods: Guided by a socio-technical systems (STS) approach, we used rigorous mixed methods to evaluate the facilitators and barriers to implementing the app in nine diverse primary and specialty care practices. Participating sites were of various sizes, geographic locations, with varied workflows, and using two different EHRs. Sites were allocated to three different levels of technical assistance by the research team. Three sites functioned independently following training, three sites functioned with partial technical assistance, and the three remaining sites functioned with full technical assistance. Practice level assessments included readiness for change and clinic workflow observations. Patient level assessments focused on usability, functionality and general preferences using a structured survey and semi-structured interviews. Ten patients were targeted to pilot test the app at each site with a total of n=58 successfully completing the final PROMIS PF survey across all sites. Provider and Health Information Technology (IT) staff assessments focused on app usability, functionality, and general lessons learned from the implementation.

Key Findings by Stakeholder:

App Developers and Technical Integration Teams: The FHIR standards allowed for the PRISM app to quickly and easily switch from one FHIR server to another; and enabled a successful abstraction layer to bridge the mobile app and two different EHRs. Key considerations for future developers for this type of technical implementation include:

1. Setting up a new Amazon Web Services (AWS) cloud instance of the app can be time consuming, and support for the app under AWS can be time and resource intensive.

2. Regardless of the size of the implementation, dedicated technical staff are needed to customize and troubleshoot app integration to ensure successful adoption for different clinic workflows.

3. Any apps that use Substitutable Medical Applications, Reusable Technologies (SMART) on Fast Healthcare Interoperability Resource (FHIR) technology need to also support access from alternative devices that do not rely on app downloads (e.g., web-based apps or embedded apps on clinic tablets).

Ambulatory Practices and Clinics: Effective teamwork is one of the most important facilitators of implementation. Efficient and consistent communication between the different levels of clinic staff is critical for successful adoption of this technology and integration into each clinic's workflow. Key considerations with implications for scaling this include:

1. Practices looking to adopt and implement this PRO technology would benefit from having dedicated staff to facilitate patient use and adoption, and a clear delineation of roles and responsibilities for support staff.

2. Practices with a high patient volume may not have enough resources or staff to engage and provide patients with technical assistance.

3. The availability of Wi-Fi and cellular service are critical to adoption and sustained use of this technology. This can be particularly challenging for clinics in rural areas with poor cellular service, or individual practices with specific architectural or physical constraints (e.g. lead walls installed for protection from nuclear medicine).

Primary and Specialty Care Patients: In general, patients found the PRISM app to be usable and easy to navigate for completion of the PROMIS survey. The app facilitated efficient survey completion (74 seconds on average) highlighting the potential for this technology to be scaled for a large battery of clinically relevant PROs. Key findings with implications for scale include:

1. Successful engagement with the app in the pilot test setting was often dependent on the patient generally being in good health, having the appropriate smartphone, and having the infrastructure necessary to make the technology work (e.g., a reliable cellular network or strong Wi-Fi connection).

2. Password issues when registering an account or downloading from the App Store or Google Play were a common challenge for many patients attempting to engage with the app.

3. Security and privacy concerns remain paramount for many patients and would likely impact their willingness to continuously use this type of technology to collect PROs.

Primary and Specialty Care Providers: Providers play a key role in patients' willingness to use PRO apps to collect PF data as patients were more willing to use the app if they knew the provider was looking at their data. We found that surfacing PRO data via a dynamic template in the EHR proved to be a viable solution allowing providers to easily access and consume the PRO data in the EHR. However, some providers still expressed hesitation about interpreting the data because it ultimately represented a patient's perception, rather than an objective physiological measure. Key findings with implications for scale include:

1. Many primary and specialty care provider workflows are not conducive to accessing the patient's PRO data in the EHR prior to the patient encounter (e.g., providers who do not review patient charts until after the encounter, or where patient volume limits this option). Alternate workflows need to be considered.

2. Provider notification or an EHR alert of a patient's survey completion is needed so as not to hinder workflow and to prevent providers from missing the data.

3. Providers need flexibility incorporating the PRO data into their EHR workflows. For example, the option to copy and paste the data into notes if they want to review the data at another time after the patient encounter.

Health Systems and Institutions: While SMART on FHIR technology is generally relatively easy to implement, many health systems do not currently have the tools or technology resources on hand to support it. Further, several EHRs do not currently support the latest SMART on FHIR standards and some clinic sites may not be willing to invest in these apps. Key recommendations with implications for scale include:

1. Systems should anticipate significant challenges with using cloud-based services including the need for security assessments, HIPAA, Business Associate Agreements (BAAs) and related internal processes such as gaining approval from IT and internal app privacy and security assessments.

2. Institutions and health systems with complex and uniform vetting processes for adopting any new technology may benefit from standardized, expedited approval processes for integrating novel patient-facing Health IT.

3. Involving all system stakeholders including legal and compliance as early in the implementation process as possible is critical to successful and timely adoption of this PRO technology given the multiple policies and regulatory considerations.

Conclusion:

This pilot study was an important step toward testing the application of ONC's PRO FHIR Implementation Guide, and a demonstration of the various factors critical to the successful adoption, potential scaling, and sustained use of this technology in ambulatory settings. Our pilot successfully implemented a patient-facing PRO app and an EHR-based provider-facing app by leveraging the modern standards of SMART on FHIR to implement a patient-facing app and an EHR-based provider-facing app**.** Importantly, through this testing process we were able to demonstrate the types of settings and system factors which are most conducive to this type of technical implementation, and settings where this technology is most likely to be successfully adopted. Our pilot findings all highlight critical points at which the coordination of human and technical processes using a systems approach is crucial to ensure the successful use of PRO data. It is important to note that even a successful implementation of a PRO data collection system does not necessarily guarantee or imply long-term adoption or meaningful use of the data. Successful use of PROs is complex – tending to be context-dependent and strongly coupled to the existing relationships between patients and their providers.

Background

Current State and Challenges with Collecting Patient-Reported Outcomes

Patient-reported outcomes (PROs) are assessments that directly reflect the "voice of the patient" and provide an increasingly important avenue for patient engagement. The Patient-Reported Outcomes Measurement Information System (PROMIS) set of measures provide validated tools to collect and analyze PROs. They have been widely used for research purposes for over 10 years and present a person-centric way to monitor or assess outcomes such as physical function (PF). Gaps in the adoption and clinical integration of PROs remain. Data show that while some ambulatory clinics in the US have seen upwards of a 90% adoption rate in the routine electronic collection of PROMIS scores following check-in, older patients in these instances were generally less compliant than younger patients.[1] Often these surveys are only available electronically through the patient portal and then on paper in the clinic at check-in if it remained unfinished (which then had to be transcribed into the EHR). Additionally, adoption rates were lower when the surveys were only available electronically through the patient portal compared with paper versions provided in the clinic at check-in.[2,3] Few existing examples demonstrate how to best optimize the collection of PRO data from the perspective of key stakeholders including patients, providers, and health IT (HIT) professionals. Fewer examples exists for how data collection of PRO data from the perspective of key stakeholders can be done both during and outside of a clinical encounter; in addition to how access to these data can change clinical workflows and patient care. Contributing to this knowledge base, the Agency for Healthcare Research and Quality (AHRQ) sponsored the "Step Up App" Challenge competition in 2018 a nationwide contest to develop a smartphone-based app that leveraged digital technologies to empower patients, improve patient outcomes and increase value in the healthcare system. This report details the learnings from a pilot test of the wining app (PRISM) within the MedStar Health system.

Contract Goals and Objectives

The overarching goal of this contract is to assess the Office of the National Coordinator for Health Information Technology (ONC's) Fast Healthcare Interoperability Resources (FHIR) technical specifications for PRO app development and implementation, and to assess the usability of such an app and the PRO data by providers and patients. In this pilot, the PRISM team worked to integrate and pilot test the PRISM app in nine primary and specialty care settings across the MedStar Health system. With focus on a single Physical Function (PF) PRO measure, the pilot involved two distinct phases, with the following specific goals:

- **Phase I: PRISM App technical integration at MedStar Health**
    - Project goal #1: To successfully integrate the PRISM app with three different EHRs.
    - Project goal #2: To identify facilitators and barriers to integration.
- **Phase II: App utilization in diverse clinical sites**
    - Project Goal #3: To determine whether the app enables the collection of standardized PRO data for clinical use.
    - Project Goal #4: To identify the facilitators and barriers to implementing the app at nine clinical sites for use by patients and providers.

Document Organization

This report presents the findings from a 14-month project in which we pilot tested a new app which uses the PRO FHIR Implementation Guide (http://hl7.org/fhir/us/patient-reported-outcomes/2019May/) to collect PF data and integrate these data with the EHR (Figure 1). We document findings from a pilot implementation of this app at nine primary and specialty care practices in Washington DC, Maryland, and Virginia.

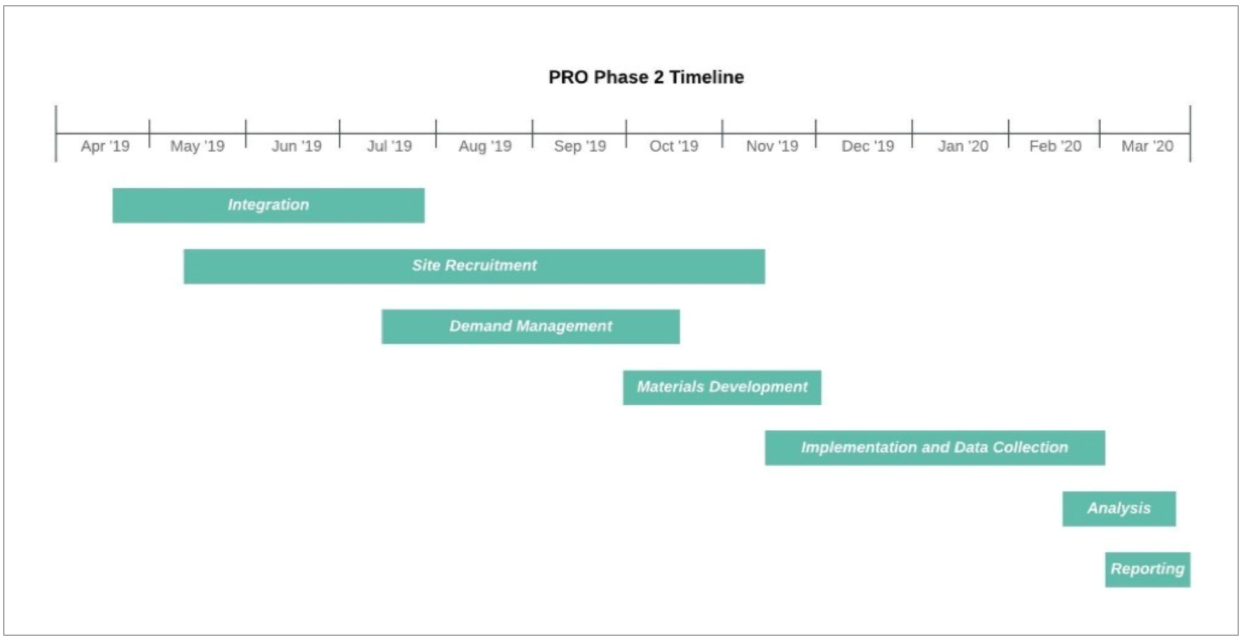

Figure 1. Phase 2 timeline

The report is divided into eight main sections to describe findings and lessons learned at each stage of the technical integration of the PRISM app, followed by the implementation and use of the app in nine clinics. **Section I** provides a summary of the development of the PRISM app including an overview of the Challenge competition. **Section II** then describes findings from the process of integrating the PRISM app and the resulting PRO PF data with EHRs across nine MedStar Health primary and specialty care sites. This section also briefly describes the iterative development of the provider visualization developed for Phase I of this contract (See Deliverable 5.2C) and also used for this pilot test. **Section V** describes findings from the technical implementation. **Section VI** describes findings from the nine clinical sites including the usage of the app by patients, the usage of the data visualization by providers, and all the associated metrics. **Section VII** presents the overall key takeaways by stakeholder group, lessons-learned and general recommendations. **Section VIII** describes overall study conclusions, discussion and limitations. **Section IX** describes PRISM's sustainability goals.

Section I: The PRISM App

Background for Challenge Competition

The primary goal of PRISM (PROMIS Reporting and Insight System from Minnesota) is to address the current deficiencies in collecting and using validated PROs as part of routine clinical care by developing a

mobile app and saving these data in the electronic health record (EHR). The goal is to amplify the patient's voice in their care and allow providers to easily access and use the information in ambulatory settings. This vision is directly aligned with AHRQ's strategic priority to leverage digital technologies to empower patients, improve patient outcomes and increase value in the healthcare system. The winning multi-disciplinary team received 1st prize nationally at AHRQ's Step Up App Challenge (2018) by developing an easy-to-use mobile app that collects PROs via Computerized Adaptive Testing (CAT) and a streamlined user interface, to make data collection and integration with EHRs quick and easy.

Widespread adoption of EHRs as well as development of new standards offer opportunities to incorporate PROs in clinical care. The routine electronic collection of PROMIS scores around ambulatory clinical encounters have traditionally had mixed success.[1–3] PROs must be integrated into the EHR for the information to be useful to clinicians. Limited research examines what the collection of these data outside of a scheduled clinical encounter could look like and how it could change the clinical workflow, for example, a drastic change in physical function or pain intensity triggering clinical decision systems for a clinician to proactively reach out to the patient.

Challenge Competition Overview

A multi-disciplinary team from the University of Minnesota, Fairview/HealthEast Kidney Stone Institute (KSI) as well as a Minnesota-based technology company, Perk Health, developed PRISM, an easy-to-use mobile app that collects PROs from patients utilizing Computerized Adaptive Testing (patients are asked the fewest questions possible to get a valid score) and a streamlined user interface, to make data collection and integration into EHRs quick and easy.

In **Phase I** of the AHRQ competition, the PRISM team developed a business case for PRISM including critical features of the proposed app, a business model, development plan and timeline, metrics of success and risk mitigation strategies. PRISM was selected as a finalist advancing to Phase II of the competition.

In **Phase II**, the PRISM team developed a prototype of the app and conducted usability testing. PRISM's design greatly benefited from the experience KSI brought to the project in their successful use of PROs[4–6] and it is an example of what can be achieved with PROMIS instruments from the individual through the population level, which could be replicated in a generalizable fashion across specialties and varying PROMIS instruments including the Physical Function 10a.

Broadscale adoption of these measures for use in individual treatment plans remains limited due to poor value propositions for both patients and providers. Typically, the PROMIS measures are administered on paper or through an external electronic survey at the point of care. Results are scanned into the electronic health record and since they are not entered into discrete fields, clinical decision support cannot be driven from it. It also requires additional clicks from providers to view, which has been shown to impact utilization rates. Finally, this method requires patients to be in the provider's office and many PROs vary day-to-day, so this variation is not always recorded. To address these gaps, there needs to be a more user-friendly way to collect PRO data from patients while they are at home and integrate it into discrete fields within an EHR to drive individual clinical decisions.

The lessons learned from KSI's patient population have been incorporated into the design of the PRISM app, comprising key features which include:

1. Make it very easy and intuitive to fill out the questions for the measure surveys

2. Give the patient feedback for how they scored, what that means and how that compares to an "average" patient

3. Discuss the scores and the PROMIS surveys during office visits so that the patients are more engaged and know that their answers matter and are part of their care

For the development of the PRISM mobile app, the PRISM team conducted extensive user experience design and feedback sessions. Patients from diverse populations (across different age ranges, clinical conditions and technology comfort levels) provided feedback on various iterations of PRISM user interfaces. Based on this feedback, the team was able to incorporate user experience aspects that were critical from a patient's point of view. Features of the app include score trending, peer group comparisons, relevant recommendations for follow-up actions, and provision of educational materials aimed at further engaging patients in their care. PROs captured by the app are seamlessly integrated with the EHR and available for providers to use, in real-time, in their clinical care and shared decision making with the patient.

The team documented the user testing summary, developed an implementation plan and a video showcasing PRISM's features and architecture:

Long video: https://www.youtube.com/watch?v=0F9jL7X-Z-c

Short video: https://www.youtube.com/watch?v=x2jU_B3bFUY

In March 2019, AHRQ announced that PRISM won 1st prize nationally and advanced to the final phase of the competition, Phase 3 – the pilot stage in collaboration with MedStar.

PRISM Collaboration with Medstar

In Phase 3 of the Challenge competition, PRISM collaborated with the Medstar Health System in Washington D.C. to pilot the app in nine clinics across three different EHR systems. This pilot provided the PRISM team with hands-on implementation experience in all aspects of the workflow starting with determining patient eligibility for the study, patient consent/enrollment, patient use of the app for completing the physician function survey, patient-physician encounter and finally, patient assessment of the app from the System Usability Survey. The rest of this report details this pilot test.

PRISM App Overview and Technical Integration

Development of the PRISM App

Based on the goals of the PRISM app for collecting patient-reported outcomes, the app needed to meet several key requirements:

1. Provide patients multiple ways to answer the PROMIS questions, before or during a visit including having clinic staff help fill it out. Be accessible via multiple devices (including mobile phone, iPad, patient desktops and clinic desktops), and be supported via a secure mobile or web app.

2. Display a patient's historical trends of their PROMIS measure scores over time, a comparison of the patient's score relative to other patient populations, and personalized recommendations of educational materials. These comparisons add value for patients in understanding PROMIS

measures, which promotes patient engagement with the app and allows them to see the value in filling out the surveys.

3. Make it easy and quick to answer PROMIS questions, including using the Computer Adaptive Testing (CAT) application program interface (API) from the Assessment Center to reduce the number of questions a patient must answer while still maintaining validity of the results.

4. Automatically update the EHR using the HL7 FHIR standard. If providers cannot easily find and review the PROs, then their value in the care process is lost.

5. Easy for organizations to deploy the app into their clinical operations. The Amazon AWS cloud was chosen to deploy the app, giving organizations a standard and secure way to create their own instance of the PRISM app and have it integrated with their EHR and comply with HIPAA.

A high-level overview of the PRISM architecture is shown in Figure 2.

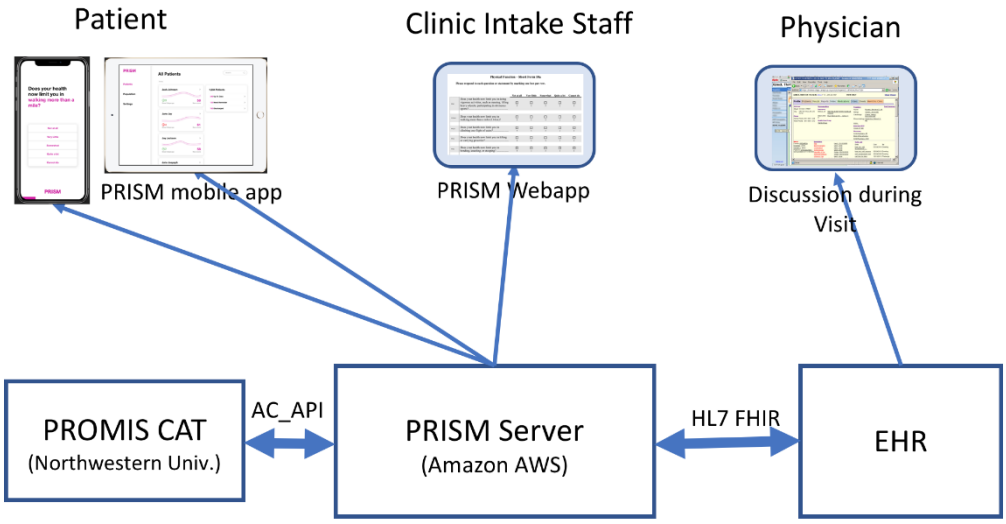

Figure 2. High-level app architecture

The resulting mobile app is easy and intuitive for patients to use. The app uses short message services (SMS) messaging to remind the patient to complete a survey and then walks them through the survey questions and finishes by calculating and displaying a score (Figure 3).

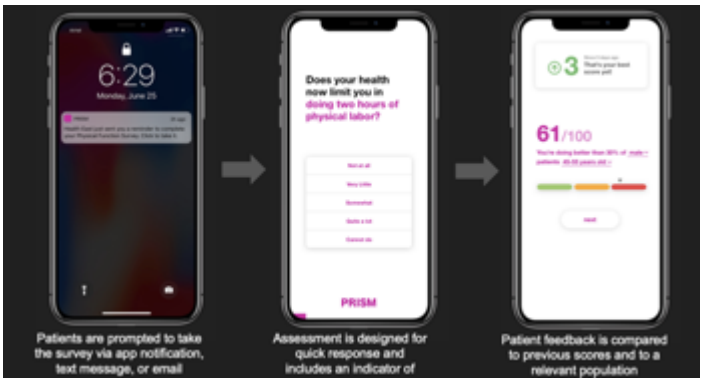

Figure 3. Examples of SMS messaging, survey, and final score screens

The app also maintains a history of all the patient's scores and can display graphs showing trends and recommend educational material for follow-up (Figure 4).

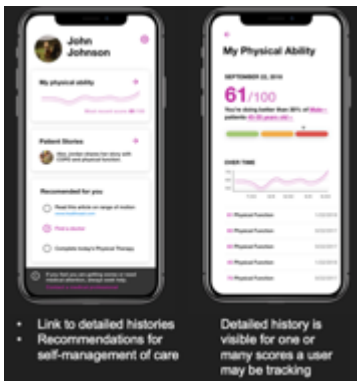

Figure 4. Examples of patient's score history

PRISM Usability Testing and Development Process

PRISM's development path took a multi-step approach. The team took the initial plans that were submitted for Phase 1 of the challenge competition and iteratively improved on the app during Phase 2 with the goal of understanding how the app could be implemented into the current workflows of several types of practices, as well as to assess providers' and administrators' initial reactions to it. All team members participated in a half-day training seminar from the University of Minnesota User Experience center. The training was focused on best practice techniques for facilitating user interface and user experience sessions to prepare our team to conduct the usability testing.

Phase 1 Usability Testing: Clinician Perspective on Usability and Workflow Impact

Methodology:

Team members met with physicians from HealthEast Kidney Stone Institute (KSI), Internal Medicine, Cardiology, and Orthopedic clinics, in Saint Paul, MN. They reviewed the current clinic workflows to assess if and how the clinics are currently collecting patient-reported outcomes. Additionally, the clinics were assessed for how they could benefit from using a program like PRISM in their practice.

Key Takeaways:

It was determined that KSI currently administers PROs on paper when patients are roomed by the nurse, but the other clinics do not collect any PROs. In all cases, clinicians liked the idea of being able to track scores over time, particularly while the patient is at home. They noted that the results would need to be integrated with their particular EHR system (EPIC) as multiple systems were perceived to be an obstacle to clinical care.

From these learnings, the prototype was further developed into a clickable wireframe that was tested using a structured interview protocol with a range of patients at both the HealthEast Kidney Stone Institute and Internal Medicine Clinics.

Phase 2 Usability Testing: Patient Perspective on Usability

Methodology:

UX testing research has shown that five participants will expose 80% of issues and the variance in identified issues decreases as the number of participants increases. A 2003 study determined that conducting UX testing with 10-15 subjects resulted in dramatic improvement of data confidence. Based on this, a formal protocol was created and reviewed by both the University of Minnesota Institutional Review Board (IRB) and the HealthEast IRB, both of which deemed it "Not Human Subjects Research" and not subject to 45 CFR part 46. Based on their decision, three cohorts of patients were interviewed January 7, 2019 at KSI and the Internal Medicine Clinic on January 9, 2019.

Patients were contacted in advance of scheduled clinic encounters and offered the opportunity to participate in an interview lasting approximately 30 minutes. Participating patients were brought to a private room where two research team members, a facilitator and a note-taker, introduced the project in more detail and obtained the patient's verbal consent to participate. At this point the patient was shown the clickable prototype and asked to go through the registration process using fictious data. The facilitator prompted the patient to "think out loud" describing what they anticipated each screen meant, what information they envisioned they could find on the screen, and how the process could be made easier for the patient. After each cohort of patients, team reviewed observations and made iterative changes to prototype to offer to next patient cohort.

Key Takeaways:

Through the 3 cohorts it was clear that patients were highly motivated to complete questionnaires when asked to complete them by their provider and saw value in their provider having more info from them in between visits. In general, they found the app easy to use and found the text message and push notification features to be highly favorable; however, they asked that the scoring and the social comparison be explained better. As a result, we added a pre-assessment screen that describes to the patient more clearly what will be assessed, how many questions to expect, the meaning of the PROMIS scores, and mentions to expect a score at the end. Patients also expressed doubt about what to do if their symptoms relate more to another condition (e.g., kidney does not hurt but something else does) thus we added a back button and help functionality on each question page.

The 13 patients interviewed over the 2-day period were predominantly male, and in the baby-boomer generation (54-72 years of age). Similar to recent Pew Survey Results almost 80% of those interviewed

had cell phones with data plans, yet few claimed to be experts when it came to the use of apps further highlighting the need for a very easy to use system (Figure 5).

Figure 5. Participant demographics and technology experience

After patients walked through the app, their impressions of the usability were assessed using the System Usability Scale. Overwhelmingly, the app scored highly (average score = 80) with only 1 individual having any trouble, rating it poorly. Coincidentally, this was a man over the age of 65 who did not have a phone with a data plan, stated that he does not even turn his cell phone on, and considered himself a novice with email, text messaging, and apps. Given this, we determined that those who lack access to cell phones with data plans or email would not be target users for PRISM.

The functionality that we learned was crucial to adoption remains the app's ease of registration and use, text/push reminder notifications, long-term results tracking, educational materials, and seamless integration into EHR systems. Based on these results, a final iteration of the prototype was developed for use in Phase 3.

PRISM App Architecture

The PRISM app was designed and built using modern open web standards. The other guiding principle in designing this app was not to reinvent the wheel and to use pre-built, industry standard resources for hosting, security and data persistence. This principle led to the development of a serverless architecture where the chosen cloud provider hosts and scales the code. Serverless architecture provides a number of benefits including speed of development, security, and scalability (Figure 6).

Security: In a HIPAA regulated environment, ensuring security and data integrity is paramount. Using the serverless app design paradigm enables the system to be reliant on the experts at AWS and their capability to ensure servers are up to date with OS patches, firewalls etc. The architecture also leverages their best-in-class authentication framework AWS Cognito and IAM to ensure that all access to the app is authenticated and authorized.

Scalability: AWS Cognito, Lambda, and DynamoDB are all enterprise-ready fully-managed scalable solutions. By enforcing small, independent code functions, our lambda functions can scale horizontally almost infinitely on AWS' infrastructure.

Rapid Development & Deployment: By leveraging many pre-built components the PRISM team was able to focus on developing domain specific parts of the app and not on standard components such as

authentication or routing. This also enables more rapid deployment of new instances for subsequent health system implementations.

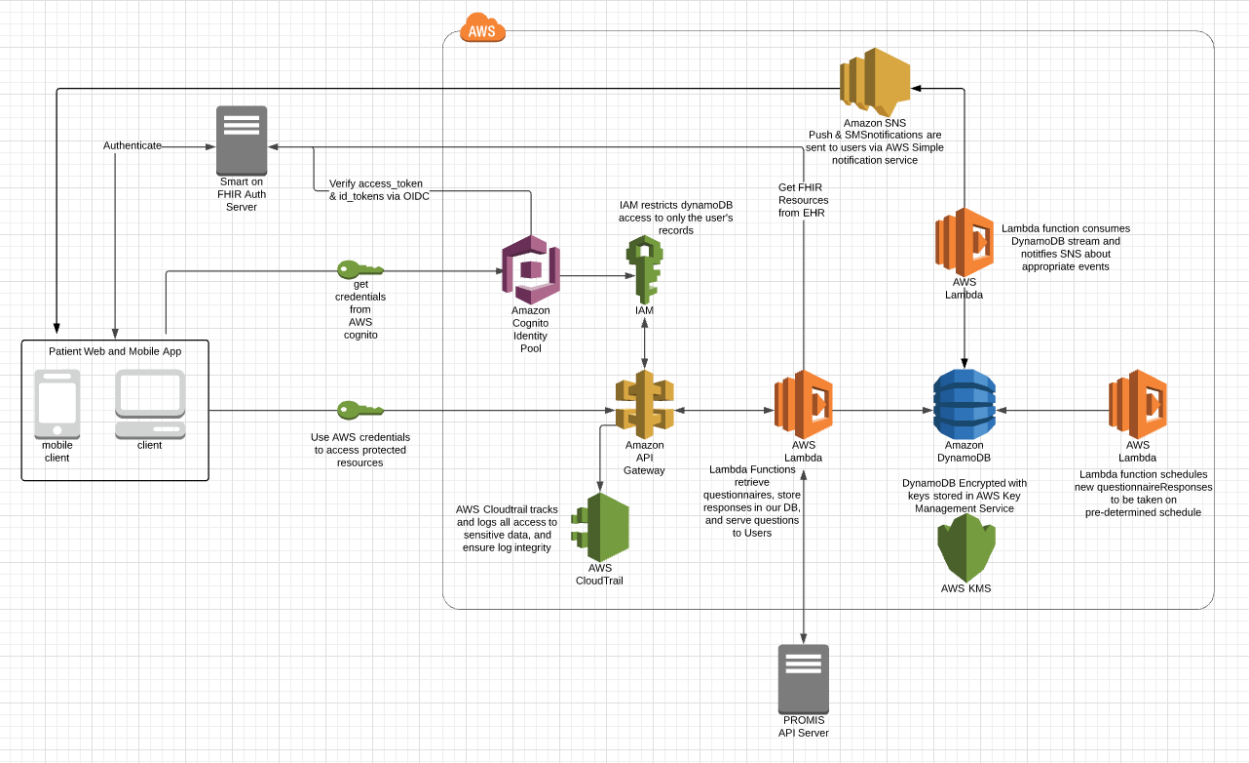

Figure 6. PRISM AWS app architecture

HIPAA Compliance

The PRISM app complies with HIPAA and is architected to allow protected health information (PHI) and the PROMIS Measures collected by the app to be stored and maintained both within the EHR and outside of the EHR. The app is hosted on secure HIPAA compliant servers from Amazon Web Services (AWS) and uses industry best practices for healthcare software development and delivery to ensure HIPAA compliance.

HIPAA compliance is ensured in the following ways:

1. AWS will sign a Business Associate Agreement (BAA) with any Covered Entity that wishes to use the PRISM app productionally with real patient data.

2. The PRISM app is architected to only use the AWS services that are covered by the AWS BAA, including DynamoDB, Cognito, AppSync, X-Ray, API Gateway, Lambda, CloudTrail and SNS.

3. Neither PHI nor PROMIS data is ever stored on the mobile device or by a web browser client. After any PHI data is displayed or input, it is removed from the device memory.

4. Any data transmitted between the AWS servers that run PRISM encrypt the data using TLS. Data in motion and data at rest are always encrypted using AES-256-bit encryption. The TLS protocol also ensures that the data cannot be tampered with during transmission.

5. The PRISM app audits all transaction activity and writes log entries to AWS X-Ray and AWS CloudWatch.

6. PRISM implements HIPAA compliant Authorization and Access control by utilizing AWS Cognito. Alternatively, PRISM can access any HIPAA compliant identity provider using the FHIR based OAuth 2.0 Password Grant Flow.

7. Amazon AWS ensures compliance with Facility Access Controls, Device and Media Controls, contingency plans and disaster recovery of the facilities, hardware and software, data backup and restore, security incident monitoring and reporting. A full list of how AWS services enable compliance with HIPAA can be obtained at https://aws.amazon.com/quickstart/architecture/compliance-hipaa/.

8. Some requirements for HIPAA compliance must be implemented by the organization deploying the PRISM app. These requirements include ensuring a proper business continuity plan, ensuring emergency access to PHI data, operations security awareness and training, security management and security training, disclosure and breach management, workforce security and HIPAA training.

FHIR Standards and EHR Integration

The PRISM app uses the latest FHIR protocol (R4 (v4.0.0) of the FHIR spec released December 27, 2018). HL7 FHIR for structured data capture (http://build.fhir.org/ig/HL7/sdc/) is used in multiple areas of the PRISM app. PRISM uses the FHIR Questionnaire bundle to retrieve PROMIS measure questions and deliver them to the patient via the mobile app. PRISM also uses the FHIR QuestionnaireResult bundle to send the answers (PROs) to be stored using the FHIR protocol for subsequent display within the EHR.

Authentication and Authorization: When a user launches the app by opening the native mobile app, the first step in the SMART Standalone App Launch[7] (http://www.hl7.org/fhir/smart-app-launch/) is to authenticate with their EHR's FHIR authorization server and authorize the SMART app. We use the SMART Patient Stand Alone Launch Sequence and the OAuth Authorization code grant flow to improve security and usability.

Login Redirect Screen Sequence: The SMART Patient Stand Alone Launch Sequence and the OAuth Authorization code grant flow screens from the PRISM app are shown in Figure 7 (example using the Cerner SMART Launch service).

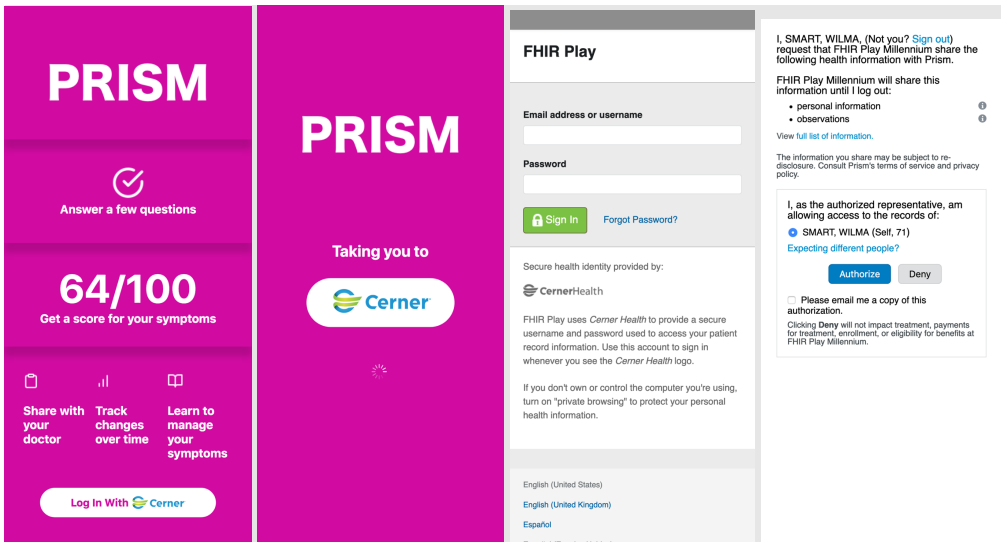

Figure 7. SMART patient stand-alone launch sequence and OAuth authorization code grant flow screens

After authenticating and authorizing with the FHIR Authorization server per the SMART standalone launch sequence specifications, the client is redirected back to the redirect URL with the state parameter and authorization code. Since we are using the Authorization Code Grant Flow, these interactions are handled on AWS servers to protect both a client secret key and refresh tokens return. Using the state, code and token URL the solution POSTs to the endpoint of the Authorization server to retrieve the access_token and identity_token. After retrieving both access tokens and the patient's id, the hub can retrieve the patient's record in FHIR format. The access token and patient record can then be safely sent to the frontend client. Upon completing the launch sequence, the user is authenticated and can begin using the app.

Retrieving and Displaying PROMIS Surveys:

After completing authentication, the user's device begins communicating with the server using the FHIR API. First, the client retrieves the patient record stored in the hub. The device then searches for all QuestionnaireResponses for the patient using query parameters `/?status=completed`. These QuestionnaireResponses are used to create the history graph in the user's profile page. The app brings the user to the Patient Home screen which displays the history of QuestionnaireResponse scores (Figure 8).

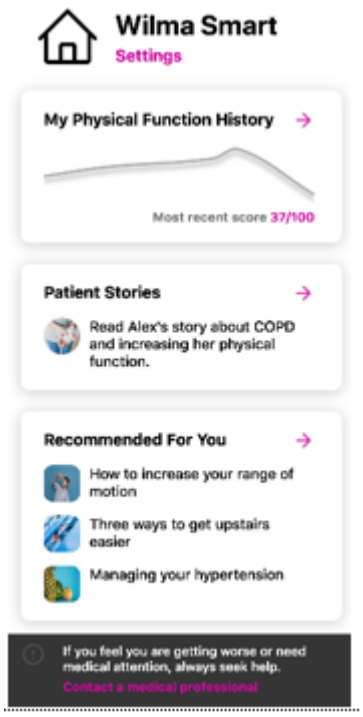

Figure 8. Patient's home screen

The client then queries for any in-progress QuestionnaireResponses using the same API as above but with the query parameter `/?status=in-progress` using the FHIR code for in progress QuestionnaireResponses and will return any that are found. Upon completion of this check, the patient sees the user interface (UI) to administer the questionnaire.

During the PROMIS survey administration, the client interacts with the PROMIS API to administer the CAT. As the user completes each question, their answer is sent to the CAT server (using FHIR to interact with the server hosted at Northwestern University) and gets back the next question. Each progressive answer and next item is saved in the items and contained questionnaire in the QuestionnaireResponse per the FHIR Adaptive Structured Data Capture (SDC) specification.

Upon survey completion the CAT server returns an empty array for the items signaling that the CAT algorithm has reached its stopping criteria. At this point the QuestionnaireResponse are saved and returned to the client. Results are calculated such as how long it has been since the last QuestionnaireResponse was taken for this Questionnaire and what the t-Score difference was. At this point the Questionnaire is returned to the FHIR EHR endpoint for long term storage.

Section II: PRISM App Integration with Different Electronic Health Records

App technical integration

- **Project Goal #3**: To successfully integrate the PRISM app with different EHRs.
- **Project Goal #4:** To identify facilitators and barriers to integration.

This section describes how the PRISM app was integrated with different EHRs for the pilot test. Of the participating pilot sites, six sites were on Cerner's EHR and three were on NextGen. We customized our technical approach as outlined in the Phase 1 technical implementation plan (Deliverable 4.1). The technical teams purposefully started the integration phase with MedStar Health's Cerner instance. This allowed for more rapid and iterative development due to our degree of familiarity with the platform. Lessons learned in the first EHR integration were used to refine the process for integration into the NextGen EHR. The primary focus for this technical integration was using the client app on different user devices (bring your own device – BYOD) and EHR integration . We customized our technical approach as outlined in the Phase 1 technical implementation plan. In this section we describe the architecture for the integration, the process of integration of the provider-facing app in EHR, and the lessons learned.

Scalable Architecture for EHR Integration

As described in a prior deliverable report (Deliverable 5.2C), the solution's architecture was designed to be scalable, modular, and web-based thereby reducing the level of effort to deploy the provider-facing visualization in the EHR. In this implementation, OBERD's backend solution was replaced by Perk Health's backend solution, referred to as **"The Hub"**.

As we implemented the provider-facing app to communicate with the original backend with SMART on FHIR specifications, and as the Hub was implemented to follow the same outbound specifications for FHIR APIs, we did not expect many changes, nor did we anticipate having any issues during implementation.

Initial Challenges:

Though we did not need to make many changes to the architecture for connectivity and data transfer, we did undergo significant challenges making the Hub work with the NextGen EHR based provider-facing app. This was due to an inability to connect and transfer data when the connection was moved from OBERD to the Hub. Most of these issues were related to very old Internet Explorer (IE) control that NextGen was using to render the provider-facing app's visualization. Even after multiple joint debugging sessions, this issue was difficult to resolve as the NextGen EHR did not offer descriptive error logs or mechanisms to probe deeper into the underlying connectivity issues. ***Solution:*** We ultimately resolved this issue by creating another SMART on FHIR wrapper in a different technology stack which was able to communicate successfully with NextGen. That wrapper in turn communicated with The Hub. EHR vendors support for SMART and FHIR should continue to improve over the next couple of years, so issues like this are not as likely to present such a challenge in the future.

As described in Deliverable 5.2C, we developed a "data on demand" architecture which reduced points of integration, helped with variances between EHR systems, and reduced the effort of local IT support. We found all those benefits not only remained true during this integration, and in a way got validated based on how little additional work was required to make the Cerner integration work. However, the NextGen integration presented some new challenges which we detail further in *Section V: Technical Implementation Findings - PRISM Integration with The Hub*.

Integration of the PRISM App

This pilot included replacing the app from the previous pilot test with the BYOD based PRISM app running on personal mobile devices. Data captured by the PRISM app was surfaced in the provider-facing visualization inside the EHR. The original OBERD client-facing app was a vendor hosted web app that the

patient was able to access while on clinical site, which was a different format compared with the PRISM app which the patient could download on his/her personal device using standard app installation procedures. The app then allowed the user to login using his/her own credentials (user ID and password) that the patient created during the first launch of the app.

The provider-facing visualization was developed iteratively during Phase 1 of this pilot (described in detail in Deliverable 5.2C). This integration required very minor modification to the provider-facing app for Cerner integration as the client app was not tightly coupled with the provider-facing app at the core technical integration level. However, it was discovered that the NextGen EHR sites were running very old versions of NextGen, which in turn used Internet Explorer 7 based control for communication and rendering of data. While the rendering part and resulting UI remained the same, communication using modern web protocols did not work as expected with the Hub. To resolve this, we created another FHIR wrapper backend to enable communication.

Both NextGen and Cerner systems have pathways to surface custom visualizations using modern web programming languages including HyperText Markup Language (HTML), Cascading Style Sheets (CSS), and JavaScript (detailed in Deliverable 5.2C). These custom visualizations can natively communicate with Representational State Transfer (RESTful) APIs using JavaScript Object Notation (JSON) upon which the FHIR standard is modeled. The modification of the app is detailed as it was completed for each system.

- **Cerner**: Cerner provides customized visualizations known as Cerner Millennium Pages (mPages). The Cerner mPages have access to both the Document Object Model (DOM) in which the custom code resides and the launch context of the chart in which the visualization is surfaced.

- **NextGen**: The NextGen system provides a native functionality to allow system developers to create composable interfaces called Dynamic Templates. These templates can include custom web components (DOMs) which are able to dynamically load client-side HTML, CSS, and JavaScript. These dynamic templates can dynamically retrieve content by communicating with external hosts.

Figure 9 shows the PRO visualization inside the Cerner PowerChart app as an mPage on a test patient. This visualization is accessible inside the patient's chart by clicking on the tab on the bottom left marked "MedStar Patient Mpages".

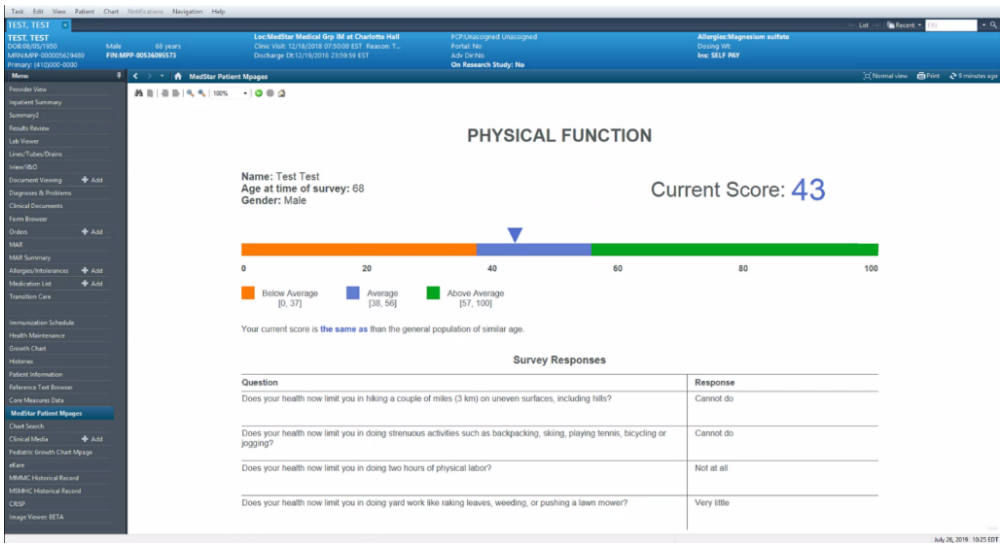

Figure 9. EHR integrated provider-facing visualization shown as a Cerner mPage on a test patient

Initial MedStar Health Systems Level Approvals and Processes

There were several levels of institution level approvals required to implement the PRISM app in the MedStar Health system. Introducing a new non-native app into the MedStar Information Systems environment required us to apply for security vetting through MedStar's "Demand Management" process- the primary goal of which is to ensure any new app does not pose a security threat to existing systems or introduce any new vulnerabilities. We encountered several unforeseen complexities during this process which were not an issue in the initial pilot. The primary reason for these new challenges was due to the similarity in technical specifications for the solution and more specifically the channels of communication between the primary artifacts (i.e., mobile devices, data hub, and the individual EHR). While the approval processes in the first pilot test were largely the same, the level of scrutiny differed due to specific details of the solution for this pilot, regardless of architectural similarities between the two solutions.

The following decision points added the greatest complexity to the approvals processes:

- **Use of cloud platforms**: Cloud platforms are largely preferred in solution architecture for their flexibility, scalability, and functionality. They are easier to instantiate compared to physical servers and they provide pre-built functionality specific to SMART on FHIR apps. Although generally preferred in most industries, these environments lack adoption and familiarity in healthcare. While the use of cloud platforms has the ability to expedite development, deployment, and cost, their additional scrutiny from security may cause undo delays as was the case in this pilot.

- **Patient-facing language and disclaimers**: Launching a patient-facing native mobile app required additional approvals beyond security. The MedStar legal and compliance teams required the inclusion of additional language, which added an additional step to our approval process. When a patient opts in to use their own device and downloads the app, compliance mandated there be a message related to what the app and any data collected can be used for by the health system. This language was drafted jointly by the MedStar Health and PRISM teams but required time consuming revisions and review by multiple entities at the MedStar corporate level.

The additional delays faced during the approvals process speak to the reality of attempting to implement a time-limited pilot for a research project within an IT infrastructure that is essentially set up to vet and clear the implementation of long term, permanent technology solutions. The health system does not currently have an expedited means to review and clear new technology being used for a limited time within a smaller scope and as such is subject to the same lengthy process. The MedStar and PRISM team were required to justify the need and demonstrate the utility and security of an app as if it were to be implemented system wide, and available to hundreds of thousands of patients, rather than the limited use required for this pilot. This institutional barrier caused delays in "spinning up" solutions for time limited pilots. For future implementations in health systems with similar approval requirements, projects of this nature could be more seamlessly implemented using a discovery meeting where the project's major artifacts are discussed and then reviewed in a less rigorous process commensurate with its actual footprint on the institution.

Section V: Technical Implementation Findings

In this section we outline the findings from the technical team based on experiences during integration of the PRISM app with two different EHRs in the MedStar system. We outline challenges and subsequent lessons learned from implementing the prism app. We then detail findings from integrating the app with Cerner and NextGen. Finally, we outline technical challenges and solutions arising during the patient's use of the app.

PRISM App Implementation: Challenges and Lessons Learned

As designed, the PRISM app is intended to be very easy to setup and maintain. When a health system wishes to start using the PRISM app they will create a new secure instance of the PRISM server environment and then configure the environment to interact with their specific EHR. The steps below detailed necessary steps (parameters are set either as environment variables or set in the environment configurations):

1. Deploy a new instance of the app within the health system's AWS environment (the entire system runs on Amazon AWS). This is accomplished by using the provided AWS CloudFormation deployment scripts.

2. Configure the web services to have a public IP and domain that belongs to the health system.

3. Add the PRO measure. The system comes pre-populated with the PROMIS Physical Function measure. The health system can add any additional PRO profiles to the system.

4. Configure the username/password for the health system's credentials to the CAT server.

5. Configure the file transfer protocol (FTP)/FHIR endpoint where the completed PROMIS surveys will be sent.

6. Configure the AWS Cognito instance to point to the health system's OpenID compliant Identity Provider.

Challenges

Setting up a new AWS instance can be time consuming: Medstar fortunately already had a relationship with Amazon and therefor had a BAA agreement already in place which covered the work proposed for this pilot. For organizations that do not have an existing account with Amazon, the process of agreeing to a BAA may take several weeks and is dependent on the organization accepting the standard AWS BAA.

Support for the app under AWS can be time and resource intensive: It was relatively straightforward to work with the MedStar technical operations staff to have them launch the CloudFormation scripts to setup a new PRISM instance. They were then able to delegate administrative control to the PRISM team in order to support the app during the pilot. However, if Medstar had to support the PRISM app under AWS on its own, more training would have been required of the Medstar staff on how to monitor the health of the app and address issues that arose.

PRISM Integration with The Hub

As part of the deployment of the PRISM app at Medstar, the FHIR Server the App was using had to be switched from the Cerner Sandbox to The Hub. The Hub was meant to be a bridge between the patient-facing PRISM app and the different EHRs that were in use at Medstar. The Hub would be used to bridge the version differences and adjust for other issues. In general, this process went quite smoothly, however there were some minor sticking points due to differences in versions causing slight incompatibilities.

1. The PRISM app was built using FHIR R4, but for expediency, The Hub was built using STU3. This led to some communication issues when archiving the completed QuestionnaireResponses back to The Hub.

2. SMART App Launch Context: The Cerner Sandbox supports OpenID connect, an optional extension to the SMART App Launch Sequence. The PRISM App leverages this to federate identity from the EHR identity provider to the app. The Cerner Sandbox used the deprecated `openid profile` scope. This had to be changed to the `openid fhirUser` scope when integrating with the Hub

overall, having well laid out standards allowed the PRISM app to quickly and easily switch from one FHIR Server to another. A process that would be far more complicated without the standards.

Cerner vs. NextGen Specific Differences in Provider App Implementation

Implementation of the provider-facing app at the nine clinical sights yielded some key insights related to their differences. The implementation process in the two different EHR, NextGen and Cerner, were found to have different underlying browser stacks which led to the need to create what was almost two completely different provider-facing visualizations. While Cerner's custom data visualizations were rendered using an underlying implementation of Internet Explorer 11, NextGen's underlying browser stack was Internet Explorer 7 which was released in 2006. We found the importance of having an accurate target platform for app development is critical to cross-site provider-facing visualization implementation.

Another finding was the importance of having direct access to a testing environment. As a developer, it is critical to have access to test independently to prevent bottle necks in development. As the MedStar technical team was unable to secure direct access to even a NextGen development environment, each testing session had to be led by a member of the NextGen's IT team. This finding underscores the impact of delays in development and the ability to rapidly iterate on the visualization.

Key Findings and Lessons Learned from the technical integration of the PRISM App with Two EHRs

During this pilot test the technical team encountered several challenges yielding important lessons learned for other developers or technical teams attempting to achieve a similar implementation. These unanticipated EHR integration challenges were instructive regarding the variability in EHR implementations and the variability that can occur even while implementing two nearly identical in-situ provider-facing solutions. Between the first pilot test MedStar conducted and this pilot with the PRISM app, only the patient-facing devices and hosting of the data hub changed. The architecture and deployment of the provider-facing visualization otherwise remained the same, yet the technical team encountered the following challenges. We highlight each one in turn and relate each set of challenges to the related dimension within the socio-technical systems model where appropriate.

Cerner:

- **Key challenges:**
  (Related STS Dimensions: (1) hardware and software computing infrastructure)

  One unanticipated challenge was switching the "data hub" from the instance built by OBERD to one built by PRISM and Perk Health Teams. In both phases, the "data hub" was responsible for communicating the PROMIS measures recorded by the patient's completion of the survey. Surprisingly while functionality and architecture remained the same between the two phases as well as their conformance to the IG specifications some modifications were required to make the app work. For example, in order to ensure proper functionality, the technical team needed to program the system to calculate the PROMIS score based on the QuestionnaireReponse resource's extension *valueDecimal* (i.e., theta) because the score was not automatically provided by the PROMIS server.

  Further information on the PRO FHIR Implementation Guide (IG) can be found here: http://hl7.org/fhir/us/patient-reported-outcomes/2019May/#introduction.

- **Lessons learned:**

The lesson learned from this challenge is to include as much detail as possible up front when delivering functional specifications to vendors who are tasked with building a data store for PROMIS measure questions, responses, and scores. Although vendors in Phase 1 and 2 were able to independently conform their solution to the PRO FHIR IG, it is critical to anticipate variance because the specification allows elements that are required vs optional and apps need to be able to handle the differences in implementations.

NextGen:

- **Key challenges:**
  (Related STS Dimensions: (1) hardware and software computing infrastructure)

  The most significant challenges in implementation of the EHR provider-facing visualization surfaced during implementation of the solution in NextGen. Although the functionality and protocol for communication with the data hub remained the same between Phase 1 and Phase 2, there were additional unexpected consequences of changing their respective Internet Protocol (IP) addresses. Each health system's EHR has specific firewall rules governing which IP addresses

or sets are open for communication. As per lessons learned in first pilot test with OBERD (Deliverable 5.2C), the MedStar technical teams' takeaway was to test connectivity between components, the "plumbing", early. Despite this foresight into this risk, the MedStar and Perk Health teams were unable to prevent this barrier to implementation. While testing the solution using our Integration Testing App, built to detect and diagnose communication issues, the teams established that the provider-facing visualization in the EHR was unable to communicate with the data hub through the pathway in Pilot Phase 1. Though repeated attempts were made by both the Perk Health and MedStar team to diagnose the problem, the teams were unable to troubleshoot due to the lack of modern debugging tools in the EHR. Please reference the Pilot Phase 1 report for additional details on this key challenge (Deliverable 5.2C). The problem was finally resolved by communicating with a FHIR API surfaced on a different IP as part of the same server which contained the data hub.

- **Lessons Learned:**

  The lessons learned from these unexpected challenges were that they may cause greater impact on development time even when anticipated. Simply identifying a potential issue in advance does not ensure it will be resolved expeditiously. Despite building and deploying a digital communications testing suite to detect communication and extensive server logging, the lack of modern debugging tools in the EHR made this process not only cumbersome but ultimately futile. The solution reached by the Perk Health and MedStar team underscores the importance of not only anticipating challenges but also the need for contingency planning in the event they materialize. Although the MedStar and PRISM team deployed custom testing suites to compensate for lack of modern debugging tools, the problem was only solved by formulating a contingency plan.

Integration of the Provider-Facing Visualization: Challenges and Lessons Learned

As the initial architecture integrated the provider-facing app using loosely coupled architecture using 3-tiered system, we anticipated very minimal changes in the base code while integrating this app with Perk Health's Hub from the original modified app's backend.

For the Cerner integration we changed security artifacts including security keys, secrets and certificates on the backend. This enabled full communication. We were able to get FHIR data using same function signatures and were able to render without any issues.

For the NextGen integration, significant and unexpected issues were faced. The primary issue was because the NextGen EHR being operated during this pilot was older than the instance used during the first pilot test. The version of Internet Explorer control being used to surface the provider-facing app during the initial pilot was antiquated and did not support modern web functionality. This posed significant challenges as soon as a security layer (HTML headers) was added, resulting in communication being stopped.

This challenge was exacerbated by the fact that the EHR did not have any tooling for debugging or error trapping. Despite several attempts to fix this, communication between the Hub and EHR did not work. The final solution required us to develop a wrapper around the HUB's FHIR API which enabled communication and an ability to surface the visualization in NextGen which mirrored the solution enabled in Cerner.

NextGen:

- **Key challenges:**
  (Related STS Dimensions)

  Older web browsers can present a significant challenge: The most significant and unanticipated challenge related to the existence of older / deprecated web browser controls being used with the NextGen EHR. If a sophisticated, modern, web-based app is to be deployed inside an EHR, it is necessary to be able to see "under the hood" when communication or networking issues arise. Any EHR using older technology, may require developers to resort back to integration using the EHR's backend which makes integration very time consuming and specific to that EHR. The alternative is to find some other solution that works with an EHR's specific setup and the specific version that is being integrated.

- **Lesson learned:** Early access to and knowledge of the exact EHR setup for testing communication and rendering capabilities can help with anticipating and designing mitigation strategies for any possible communication errors. Successful mitigation strategies depend on access to the exact setup and the multiple installation variables make and decisions and the implementation of alternative strategies nearly impossible without it.

Technical Implementation: Developer Perspective and High-level Recommendations

EHR Integration – General Context

Based on our prior experience designing provider-facing apps which cater to a single patient, we decided to use the EHR as a gateway for user authentication. This alleviated the need for users (providers in this case) to authenticate again and reduced the need for IT to manage another set of login information. In addition, we determined that ideally, data displayed should be related to a patient context visible in the EHR; that is, having PRO data displayed for the same patient within the same screen already open in the EHR for that patient. This ensured that the provider only looked at the current patient's related PRO scores and information. These factors determined placement for UI elements for the PRO app initiation. Our experience suggested the ideal workflow for the provider-facing app was as follows:

1. Provider logs into the EHR using provider specific credentials.

2. Provider finds the patient in the EHR.

3. If the provider is authorized to see the Provider-facing FHIR app, a UI element will appear which will open this app.

4. Provider clicks on the linking UI element and the app opens within the EHR with current patient context.

This workflow allowed us to use the EHR's authorization mechanism to validate the user. This also enabled us to retrieve patient and provider context directly from the launch sequence from within the EHR. As a result, we ensured that the launch sequence and subsequent UI appeared as an integrated screen within the EHR and not a separate screen outside of the EHR. This was key to ensuring that if a provider changed the patient context, the app automatically closed out.

Recommendations for Optimizing The User Experience

We learned several important lessons related to the user experience, resulting in three key recommendations based on our implementation with three EHR instances:

1. **Design the solution to have the shortest pathway or number of actions necessary to reach the app within the patient context:**

    - There are several ways in which EHRs can launch external apps. External apps can be launched using a hyperlink or button from a patient list or they can be launched from a menu item or from a UI element visible only when you are in a single patient.

    - Unless the child app needs to perform a quick comparison of the same data for multiple patients, it does not make sense to launch that app from a patient list. As each PRO app is specific to a patient, we determined the optimal way to launch it was from a patient-detail level window.

    - In our implementation, both at Cerner Millennium and at NextGen, the PRO app opened with a single click once a provider was in a specific patient's detail screen. As there was no need for any input or further authentication, we did not need any additional dialog or UI element in a workflow that opened the PRO app.

2. **Develop a presentation layer that does not require further scrolling or any other visual manipulation to see the data.**

    - Once the PRO app was visible within the EHR window, we wanted to avoid further need for the provider to scroll or zoom to see the main data points.

    - This requirement is highly dependent on the EHR's capabilities and sometimes it is not technically possible to render a UI without requiring scrolling. In such cases, we attempted to design our UI so that the data were presented in the web app that only needed vertical scrolling.

    - We avoided putting any zooming / enhancing UI elements for presenting data as this feature made it harder for visualizing the overall context quickly and in one first glance.

3. **Keep the presentation layer locked down to the patient context.**

    - It is possible for web apps to show up in a floating (non-modal) window. However, creating such a design incurs the risk of displaying data without being bound to the current patient. For instance, it may allow the user to change the EHR's patient context while the app is displaying data, creating a potential hazard whereby the app and EHR patients are not in synch.

    - We worked with integration teams from both EHRs to find a way to display the PRO app in a way that it shows up as an embedded UI control within the EHR, and then when changing to a different patient the PRO app closes. Though this approach might potentially limit us to render a UI in a smaller real estate, we thought the benefit of making sure the PRO always

displays data for the current patient far outweighed the risk of showing disjointed information.

Implementation

1. **Design for the least amount of client variability**

    - EHRs run on local workstations as thick-client apps, hybrid apps, or as web-clients. Sometimes, EHRs are implemented on a remote display such as Citrix or Virtual Desktop Infrastructure (VDI). In all these cases, except in the web-client scenario, client workstation level variability can affect performance and rendering of any third-party app unless that rendering is tightly coupled with client.

    - We decided to implement the PRO provider-facing app in a way that:

        - Allowed us to avoid client level variability as much as possible, or

        - Made it easy to fix the issues created due to variability without requiring help from EHR vendor, as much as possible.

    - Our implementation thus relied on launching a remote web app within the EHR by passing patient context.

2. **Avoid user re-authentication and use the EHR as the trusted app**

    - As the provider was already logged in to the EHR, it made sense for us to launch the provider-facing app within the EHR and avoid user re-authentication by treating the EHR as a trusted app.

    - We locked down our web app to specific EHR IP(s), thus making it work securely from within the EHR.

    - The provider-facing app that was visible from within the EHR never stored any data locally and always used HTTPs for secured transmission of data. All these functions were achieved with minimum modification to the actual EHR making it relatively easy to install on different EHRs.

Anticipating Challenges and Mitigation Strategies

Throughout the technical implementation we faced some unexpected and unforeseen challenges. While any technical integration is likely to have some unanticipated outcomes, our experience provided us with some general mitigation strategies which may assist future developers with a similar implementation. Here we review recommendations and key mitigation strategies that would potentially prevent significant delays to a similar implementation if scaled and summarize the incidents that lead to each one.

1. **Finish EHR “plumbing” (technical integration) work early in the process**

    - Different ambulatory practices will have different ways to manage their EHRs. Some will rely entirely on the EHR vendors, others have internal teams who can directly facilitate

customizations, and others will have a mix of both required in order to make any kind of changes. Ensuring that the basic steps such as launching the UI with the click of a button, or passing patient context, works as early as possible helps with deciding the level of effort or vendor support required to make EHR specific changes – if needed.

- During this implementation, we found that one facility had their EHR managed by the vendor in a remotely hosted environment and that environment required ports to be opened by the vendor for our app to be accessible from the EHR. Because integration testing of the app occurred early in the process it enabled us to evaluate accessibility before an issue arose.

2. Anticipate that EHR version differences add to client variability

- We encountered an issue with the app whereby the PRO client-facing app that worked in the EHR at one facility, did not work in the other facility despite them having the same EHR software.

- Further investigation and troubleshooting revealed that differences in EHR versions between the two facilities was causing rendering issues as one facility was running an older version of the EHR. This older version used Internet Explorer 7 based rendering control which did not work well with our PRO provider web app.

- As noted earlier in the implementation guidelines, our design allowed us to make changes remotely to handle this older client's rendering control and we were able to make the PRO provider side app work with no change on the EHR side.

3. Incorporate testing from the beginning of the solution design

- We tested each part of the PRO provider app alone first before testing the whole app and this allowed us to save a significant amount of time since it prevented us from going through a long troubleshooting cycle and having to identify exactly where the issue was.

- The PRO app had multiple security features which included client context passing, which relied on client-side rendering (CSS, Javascript, HTML) for UI rendering, and it worked within the confines of the EHR. We developed a testing tool that helped test security and integration, client context passing, and rendering separately. We used these tools while in initial phases of implementation which helped significantly when we integrated all the pieces together for a final test.

4. Implement security from the beginning – it should not be an afterthought

- The Implementation guide described specific security architecture that we needed to use during the entire lifecycle of the PRO app.

- From the beginning, our discussions with the vendor included major portions dedicated to security implementation which included design of JSON Web Token (JWT), access token, HTTPs channel requirements (TLS version, encryption support levels), and federation by using the EHR as user authenticator and authorization.

- All our functional design and implementation had security pieces stubbed out from the beginning which was very helpful in later runs when we started layering in security pieces. This also allowed troubleshooting when the app did not function due to security related issues.

5. Factor change management plans into both technical and project planning

- Any EHR change in production generally involves a change management approval process. Depending on the institution, these processes can range from being very informal to highly structured, but some level of approvals and reviews by the app owners will always be required.

- During our implementation, we encountered change management, which at one institution only required a simple explanation and demo in a test system. In another institution, it was a much more complex processes which required completion and submission of multiple forms and participating in technical as well as architectural change management calls with institutional officials to fulfill the necessary requirements and obtain approval to implement our app.

- These processes can take significant time and must be factored into timelines for both technical planning as well as in overall project planning.

6. Use source control and backup for all technical artifacts

- Source control (such as Team Foundation Service—TFS, GitHub, and Subversion—SVN) make managing sources and its version much easier.

- We integrated source control from the beginning of the development process which helped us to track progress as well as identify any changes that might have been responsible for test failures.

- Our IT implemented both online as well as offline backups and though we were fortunate and never needed to go back to our backup, having that would prove helpful in the event of any accidental deletion / corruption code and binaries.

7. Anticipate that system and software updates will add variability

- Though EHR systems in this implementation only displayed provider side data using a web app, we encountered issues when there was an unanticipated system update.

- In this instance the EHR system at one site underwent an update. This wiped out changes we had made in its template which stored the provider-facing web app's URL and other parameter configuration. We had a backup of the original template from that EHR system which helped us get it back online with very little downtime.

- The key lesson learned is that although the outside system and its configuration changes are not under our control, it helps to get documentation or exports of any changes as a backup so that in the event of data loss, it is easy to recover from downtime.

Technical Challenges for patients using the PRISM app: Bugs and Issues with the Mobile Platforms

The PRISM App encountered several bugs and issues during the pilot. The team was able to trouble-shoot these issues in real time and in every instance resolve the issue to facilitate continued data collection. The identified bugs and their resolution are detailed below.

Passwords

- **Challenge:** The workflow for a patient was to receive an SMS message with a unique link, follow that link to a page where they needed to set their password, download the mobile app, then log in using the password that was just created. A significant number of patients ran into difficulty remembering the password that they had just created.

- **Lessons Learned:** There are two ways to mitigate this issue. First, use a mobile web app instead of a mobile app so that the patients do not have to log in a second time. Second use different OAuth web containers for iOS (ASWebAuthenticationSession) and Android (AppAuth) to leverage the existing session in the mobile browser to log in.

Font Sizing

- **Challenge:** Some users, especially older patients, had set their device font sizes to be much larger than standard to aid in their seeing the screen. This would lead to text flowing off the screen and not being readable while they were attempting to use the PRISM app.

- **Lesson Learned:** Testing on many different devices and testing each device with various font size settings is important to ensure that apps display correctly on all devices.

Google Play Store Links

- **Challenge:** Some Android users did not have the Google Play store installed on their device. This made the process of downloading an app slow and difficult as it added an extra layer of activity.

- **Lessons Learned:** Downloading an app can be difficult for some patients. A simpler alternative to downloading an app is using a web browser to access the FHIR App. This can be helpful in accelerating the adoption of a mobile app.

Lack of Cell Phone Service and Connectivity

- **Challenge:** Two of the nine sites did not have adequate cell reception for mobile data based on their geographic location and did not have public Wi-Fi available. In these situations, the mobile app was rendered completely unable to function.

- **Lessons Learned:** To be inclusive and accessible to patients even in areas with limited cell service or internet connectivity, the app should be amenable to function via a web-based platform that can be accessed via an amplified Wi-Fi signal if clinics are able to use a hotspot or other means to enable internet connectivity which does not solely depended on cell-phone service.

Observed Challenges

There were additional challenges observed to inform important findings such as the importance of end-to-end testing of the system. When building an ecosystem architecture to facilitate the capture of PROMIS measures initiated in the clinical setting, completed by the patient, then visualized by the provider a walkthrough is key to successful launch. Although the MedStar, PRISM, and Perk Health teams performed rigorous module testing of each component, there was less integration testing to ensure each component of the patient and provider-facing architectural components functioned properly together. One such example, was the importance of practicing and implementing a system for provisioning providers to access the visualization. The MedStar team codified a process by which upcoming sites go-live. This key finding speaks to the importance of establishing all systems prior to go-live aside from the apps functionality itself.

IS Demand Management and Approval Process Hold Ups

The process of site-specific approvals shows the importance of anticipating the length of the process and engaging the security review teams early in the process. The process of approvals can be lengthy, and it is critical to understand the implications of all decisions including the use of cloud services which may have unintended consequences versus the use of on premises servers. While cloud-based servers are easier to instantiate and provide out-of-the-box functionality specific to SMART on FHIR patient and provider-facing apps. Although these services expedite the development process for the architects and developers it may impede overall development if it impacts approvals. Additionally, there should be a readily available "discovery" meeting where the approval teams have open discussions regarding major artifacts to ensure that these decisions do not have unintended consequences.

Section VI: Clinical Implementation Findings

In this section we present the findings from the assessments described in Section IV of the Medstar Final Report (not included here). We first summarize the findings from each assessment completed at the practice sites including the readiness to change assessments and an overview of common observations across clinics. Next, we summarize the findings from each stakeholder perspective beginning with the patient assessments, followed by emergent themes from the provider and Health IT staff interviews. Each of these assessments address the feasibility of the app to collect standardized PRO data (project goal #5) and identify facilitators and barriers to implementation (project goal #6). Finally, where key challenges are highlighted, we identify the relevant dimensions of the STS model that are related to that challenge.

Practice Site Assessments

Readiness for Change Themes

Based on our review of the readiness for change data, we made several general observations which helped us characterize our participating sites according to the three core categories on this assessment.

1. Overall acceptance of Health IT across pilot sites

The majority of sites were generally accepting of and had positive attitudes towards new Health IT. All sites either strongly agreed or agreed with the statements within the domain "Overall perception of e-health": "e-health technology can improve patient outcomes," "e-health technology can enhance a team

to approach care," and "I usually try hard to learn how to use new e-health technology." However, individual responses revealed an underlying feeling of dissatisfaction with the state of current Health IT systems. For example, three sites agreed with the statements, "I feel a lot of pressure to be more effective by using e-health technology," and "I find constantly changing e-health technology in my work environment difficult to manage." Similarly, four sites responded that they disagreed or strongly disagreed with the statement "I am satisfied with currently available e-health technology."

2. Pilot site perceptions of organizational readiness

These items assessed the extent to which sites felt ready to implement and use e-health technology in their practice. There was wide variability among sites regarding their perception of organizational readiness. For example, three sites (Sites A, E, and F) strongly agreed or agreed with the statement, "Overall, I think my organization is generally successful with implementing e-health technology changes." These same three sites also strongly disagreed or disagreed with the following prompts: "Overall, I think my organization provides adequate resources for e-health technology," "Overall, I think my organization has an adequate number of IT staff for technical support," "Overall, I think my organization provides timely and flexible support to users of e-health technology." Notably, five sites (Sites A, C, D, E, and G) responded that they agreed with "Overall, I think my organization has experienced too much change over the past year," and all but one site (Sites A, B, D, E, F, G) strongly agreed or agreed with, "Overall, I think my organization is committed to meeting the needs of the community through the use of e-health technology."

3. Pilot site prior experiences with Health IT

While almost all sites reported positive experiences with prior and existing e-health technology, two sites (Sites A and F) notably remarked on having negative experiences in the past. For example, both sites disagreed with the following statements: "Overall, I think e-health technology in my organization…" 1) "Generally performs at an adequate speed", 2) "Is reliable", and 3) "Is flexible, allowing for growth and change."

Readiness for Change Scores

Appendix F shows the total score for each category of the Readiness for Change assessment at each practice, as well as the total score for each practice. Low scores are indicative of responding more favorably and more readily to e-health, whereas higher scores align with being more resistant towards e-health technology. Overall, the median score was 121 (with the lowest possible score being 57 and the highest being 285). Scores across sites suggested a wide variability in terms of prior experiences with e-Health as an organization with no trends in tiers. It is also worth noting that the practice manager (or corresponding individual) filled out the survey measure for each site. Results should therefore be interpreted cautiously due to the subjective nature of the questions.

Summary of Recruitment and Clinic Observations

The following results describe the overall recruitment and clinic observations from the study across all sites and by tier. First, the workflow observations describe important variables at each site, such as age and socio-economic status of the population. The section also details facilitators and barriers to successful data collection at the site. The data below also show the most common reasons that patients did not

complete the study, including reasons that patients declined to participate, and problems encountered while attempting to download and use the app.

Site Characteristics Across All Tiers

Recruitment Across All Sites

Of the 173 total patients approached to participate in this study, 84 patients consented to participate, and 58 patients successfully completed the survey process (Figure 10). The most common reason patients declined to participate in the study was due to cell phone issues (49%), or patient specific issues (22%). The most common workflow breakdown occurrences were a result of technical issues (42%) and patient complications (39%). The definition of each of these terms can be found in Appendix L.

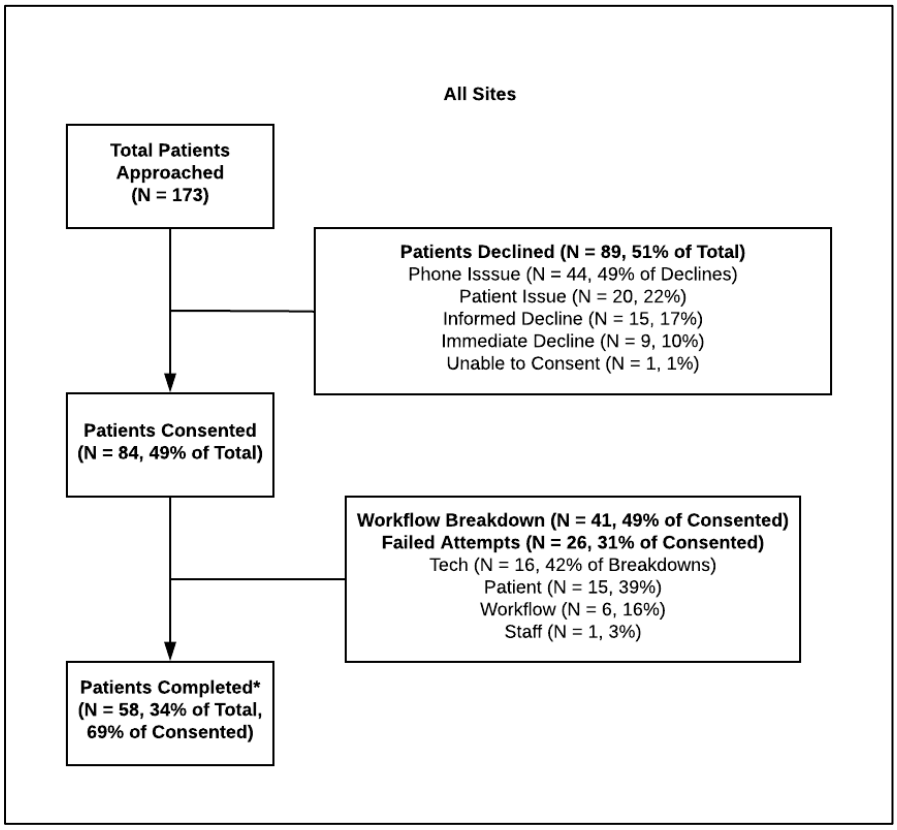

Figure 10. Patient approach, consent, and study completion across all nine sites

Table 1 shows the number of patients who participated in the study at each site. Not all sites reached the target accrual of 10 patients due to insurmountable barriers to data collection (i.e., no cell service or lack of eligible patients). These data are explored further in the sections below which highlight barriers and facilitators to recruitment, enrollment, and completion by practice tier groups.

Table 1. Number of patients who completed the PROMIS survey by site

Site ID	Site Name	# of Patients Completed the PROMIS Survey

A	MedStar Health at Lafayette Centre	10
B	MedStar Medical Group Family Medicine at Fort Lincoln	5
C	Family Health Center at MedStar Franklin Square	5
D	MedStar Medical Group at Bethesda	10
E	MedStar Medical Group Washington Primary Care Physicians	10
F	MedStar Health Family Medicine at Spring Valley	10
G	MedStar Shah J. Patrick Jarboe Medical Center	7
H	MedStar Shah at Waldorf	1
I	MedStar Shah Philip J. Bean Medical Center	0
Total		**58**

Figure 11 illustrates the total number of patients who consented to the study (n=84) and at what phase breakdowns occurred that prevented patients from completing the survey. In this graph, workflow breakdowns include twelve patients who would not have been able to complete the survey without assistance (i.e., could not download the app and used the researcher's phone instead). Looking at all sites, the most common reasons that the patients failed to complete the study were receiving the link to the registration page (n=9), creating a password (n=8), and inability to download the app (n=7).

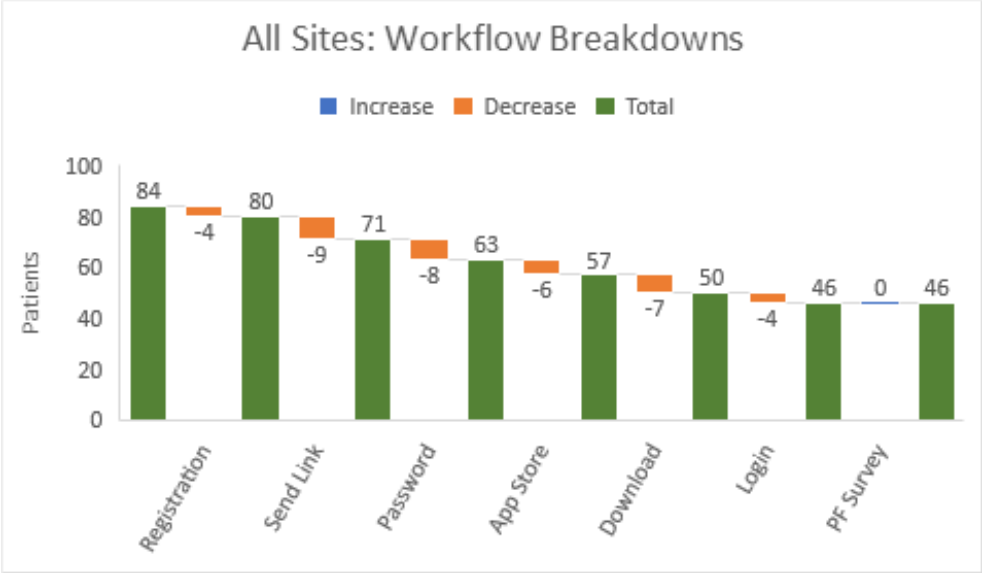

Figure 11. Reasons for workflow breakdown across all sites

Barriers and Facilitators Across All Tiers

Based on observations and approach log data across sites, major facilitators and barriers to data collection were identified. A summary of the facilitators and barriers across tiers is presented below.

Facilitators Across All Tiers

1. **Dedicated Research Staff.** Having dedicated support for data collection facilitated the process because this person could focus their time on the study tasks and the patient's needs for the study. In the independent tier, a staff member (non-MedStar research team member) whose job function included acting as a research liaison, was responsible for and available to assist the sites with nearly all elements of data collection (e.g., registration, sending the text, notifying the provider). For the fully assisted sites, a researcher from the MedStar team served this role. In the partially assisted tier, the sites designated a key member of their own team to work with a MedStar researcher to aid in data collection. The partially-assisted sites decided which aspect of data collection they most needed assistance with. Another advantage of having a dedicated staff member was limiting the need for communication between the researcher and clinic staff at multiple steps of the process which could either delay data collection or result in missed opportunity to enroll a patient.

2. **Staff Preparation and Workflow Accommodation.** Staff at multiple sites were able to contribute to data collection by performing preparatory tasks and adapting workflows to streamline the process. At Site E, the front desk staff flagged patients in the EHR on mornings of data collection so that all staff would know they were eligible for the study; this increased the likelihood of the front desk staff or and MA notifying the researcher of patient arrival. Additionally, staff at all partially assisted sites were able to pre-register patients in the admin hub before data collection, shortening the time it took to register and invite patients after they had consented. Finally, staff were often able to accommodate the additional tasks of the study by modifying their workflow to allow patients extra time in the waiting room or exam room to complete the study.

3. **Clear Roles and Responsibilities.** At most sites, researchers and clinic staff were able to clearly define roles and responsibilities. These clear goals and responsibilities made sure that steps in the data collection process were completed in a timely fashion.

4. **Pre-existing Cell Communication Processes**. Sites that used text message reminders for appointments typically had patient's cell numbers on file. The patient's cell number is a required input when registering patients in the admin hub and it is essential for sending the patient a link to the password creation screen. Sites that had patients' cell numbers on file were able to preregister patients before they arrived, streamlining the process.

5. **Staff Rapport with Patients and Providers**. Clinic staff at some sites recommended who the researchers should target throughout the day based on inclusion criteria (English speaking and ability to consent) as well as general knowledge of the patient's personality, technology usage, and relationship with the clinic. This resulted in more efficient data collection efforts.

6. **Provider Interest/Clinical Champion.** Sites with highly engaged providers and staff were more accommodating to the research study and input additional time and effort into completing tasks (e.g., prescreening and preregistering patients) that lead to successful data collection. Engaged providers screened patients for whom they thought the study would be useful and encouraged patients to talk with the research staff. Provider buy-in also encouraged practice staff to accommodate workflow or allow more time for the study.

Barriers Across All Tiers

1. **Staff Workload.** In fully assisted and partially assisted tiers, app tasks typically fell to the front desk staff, who would often already have extremely high workload demands answering phones, checking-in patients, and supporting the practice otherwise. Because of their high workload and low priority of the research study compared to core clinic functions, the front desk staff were not always able to complete study related tasks such as inputting patients into the admin hub, sending the text message, or communicating survey completion with the provider.

2. **Tight Clinic Schedules.** There was significant variability in the timeliness of the different clinics. Some clinics were always on schedule and MAs began the intake process as soon as the patient arrived. Other clinics ran behind which would give time for patients to complete the study in the waiting room. It was more difficult to recruit patients at clinics with timely schedules because the patients had less time to complete the study before their arrival and their appointment. Workarounds included approaching patients in the exam room instead of the waiting room or not approaching patients in the morning when the clinics were typically on schedule.

3. **Unclear Roles/Responsibilities.** There was some confusion about who was responsible for completing tasks involved in the study. At one site, there was confusion about who would input patients into the admin hub; initially it was the responsibility of the practice manager, but when it became clear that she did not have time to complete the tasks it was pushed to multiple other parties, none of whom truly knew who was responsible for the task. Consequently, preregistration was not always completed at this site before data collection.

4. **Lack of Pre-existing Cell Communication Processes.** Some sites did not have patients' cell numbers on file. This required the research team to get the patient's phone number from them after consent, relaying the number to the front desk staff, and waiting for staff to update the cell number in the admin hub before finally send the text message. This process took between two and ten minutes depending on the workload of the front desk staff, lengthening the time of the patient's participation and making it more likely that the patient would be called back for their appointment before completing the study.

5. **Poor Cell and Internet Service.** Sites that experienced poor cellular connection struggled to complete data collection. Due to poor cell service, patients were unable to receive the text message link to begin the registration process, nor were they able to download the app from the App Store. This was a critical hindrance to patient accrual and data collection in two of the independent sites, which were all located in rural areas with limited cellular signal.

6. **Clinical Workflow Delay.** At one site, the provider noted after the kick-off that they would not be able to look at the data before or during the appointment as they were concerned about the study delaying their appointments. Another provider allowed the research team to approach patients if they were early enough for their appointment but made it clear not to approach patients if it would delay their scheduled visit time at all.

Site Characteristics Within Tiers

Below is a description of the different patient population characteristics of the clinics. These characteristics are not inherently barriers or facilitators; however, they did appear to influence the success of data collection to varying degrees.

1. **Socioeconomic Status/Technology Restrictions.** There was significant variability in the socioeconomic status of patients approached during the study. Anecdotally, the patients recruited in typically higher socioeconomic status areas were more likely to have iPhones rather than Android phones. The opposite was true for patients recruited in clinics that were in areas with lower socioeconomic status. Here Android phones were more common. When asked if they had a smart phone, a handful of patients in the lower socioeconomic status areas shared that they could not afford one. Consequently, it appears that socioeconomic status is a key factor determining whether patients have the necessary technology to access the PRISM app.

2. **High Patient Volume.** Pilot sites where there was a high patient volume had more eligible patients, however, staff members at these sites also experienced higher workloads and therefore had competing demands trying to ensure the passage of patients through the clinic, while also incorporating research activities. Staff with higher workloads struggled to complete tasks associated with the study in addition to their normal duties.

3. **High Acuity Patients.** In some cases, the patient's illness or level of function due to illness or age prevented them from participating in the study. Some patients struggled to talk or move. Others had serious medical conditions that put them in severe pain or gave them trouble breathing. In some cases, the front desk recommended that the research team not approach a particularly unwell patient. In another case, an eligible patient was rushed to the emergency room.

4. **Cancellation/No-Show Rate**. Clinics had many no shows or cancellations. This greatly reduced the number of patients that researchers could approach for the study and minimized the chances of reaching goal recruitment.

5. **Age.** In general, the younger patients encountered during this pilot tended to be more tech savvy and need less assistance with typical smart phone tasks such as clicking the registration link and downloading the app. Interestingly, these patients still faced trouble creating passwords and remembering their App Store ID.

Fully Assisted Tier

Of the 61 total patients approached to participate in this study, 27 patients consented to participate, and 20 patients successfully completed the survey process. The most common decline reasons were due to a phone issue (50%) or a patient issue (18%). The most common workflow breakdown occurrences were a result of technical issues (45%) and patient complications (36%). The definition of each of these terms can be found in Appendix L.

Figure 12 illustrates the total number of patients who consented to the study (n=27) and at what phase breakdowns occurred that prevented patients from completing the survey. In this graph, the workflow breakdowns include the patients who would not have been able to complete the survey without assistance (i.e., could not download the app and used the researcher's phone instead).

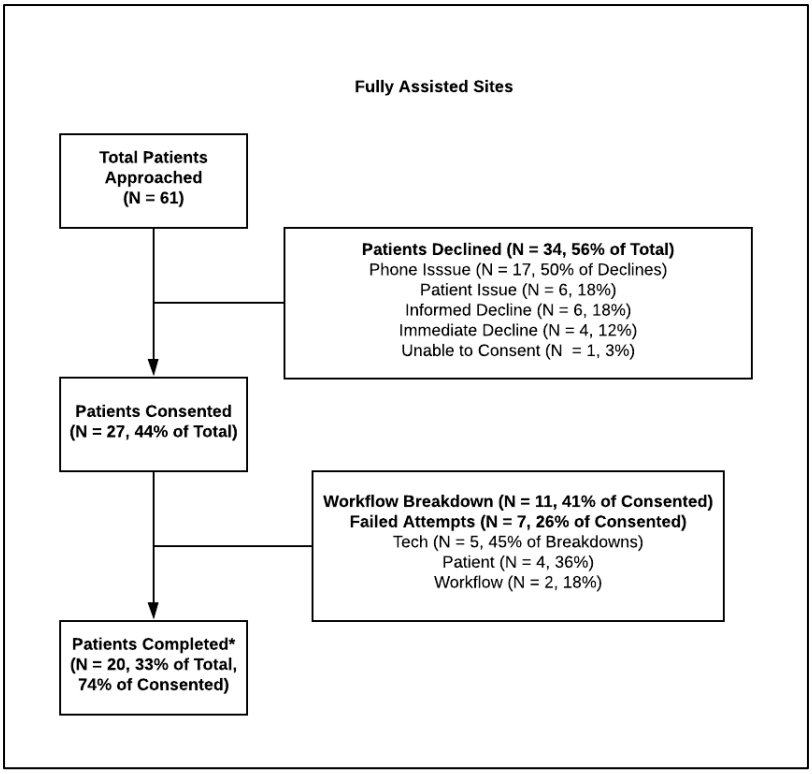

Figure 12. Patient approach, consent, and study completion within the three fully assisted sites

For fully assisted sites, the most common reason that the patients failed to complete the study was creating a password (n=3) (Figure 13).

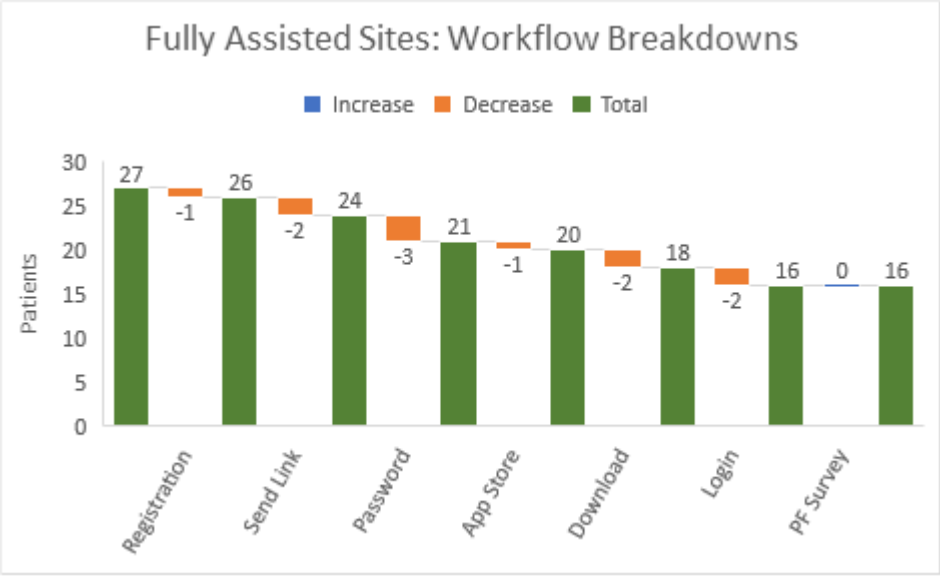

Figure 13. Reasons for workflow breakdown within the three fully supported sites (i.e., Sites A, B, and C)

Facilitators of Recruitment in the Fully Assisted Tier

1. **Dedicated Research Staff.** In the fully assisted tier, researchers were responsible for nearly all elements of data collection. This facilitated data collection because the researchers were not expected to complete any other tasks during data collection and could focus solely on the patient and their needs for the study. Additionally, it limited the need for communication between the researcher and clinic staff at multiple steps of the process (i.e., researcher instructing clinic staff to input patients into admin hub, researcher relaying patient phone number to clinic staff, researcher asking clinic staff to send text message, researcher asking clinic staff to notify the provider.

2. **Staff preparation and Coordination for Patient Identification.** The front desk staff at Site B were able to consistently notify the researcher when patients were available. In the morning, one member of the front desk staff would flag that patients in the computer so that they saw that the patient was eligible for the study while checking them in. This system proved to be consistent and reliable notification of patient arrival. Additionally, MAs at Site B worked with the researchers to make sure patients had time to complete the study. This typically involved the MA finding the research when they were finished with intake and introducing the researcher to the patient in the exam room.

Barriers to recruitment in the Fully Assisted Tier

1. **Staff Workload.** The front desk staff at the fully assisted sites were responsible for notifying researchers when the patients arrived in the clinic. The front desk staff struggled to notify the researchers of patient arrival consistently, which lead to researchers missing eligible patients. This is likely because of the high workload of the front desk staff, which made it difficult for them to take on additional duties that the research study entailed.

2. **Tight Clinic Schedule.** Patients spent very little time in the waiting room at the fully assisted sites as the MAs were very efficient at completing intake and rooming the patients. This made it difficult to complete the study with patients in the waiting room and workarounds needed to be implemented to recruit patients for the study.

Partially Assisted Tier

Of the 82 total patients approached to participate in this study, 43 patients consented to participate, and 30 patients successfully completed the survey process (Figure 14). The most common decline reasons were due to a phone issue (41%) or a patient issue (36%). The most common workflow breakdown occurrences were a result of patient complications (52%) and technical issues (24%). The definition of each of these terms can be found in Appendix L.

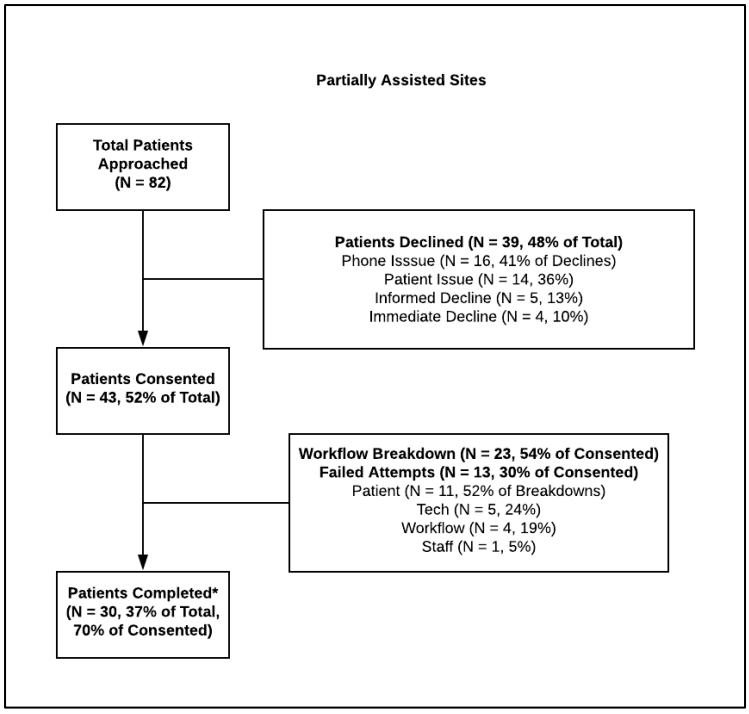

Figure 14. Patient approach, consent, and study completion within the three partially assisted sites

Figure 15 illustrates the total number of patients who consented to the study (n=43) and at what phase breakdowns occurred that prevented patients from completing the survey. In this graph, the workflow breakdowns include the patients who would not have been able to complete the survey without assistance (i.e., could not download the app and used the researcher's phone instead). At partially assisted sites, the most common reasons that the patients failed to complete the study were creating a password (n=5), app store issues (n=4), and inability to download the app (n=5).

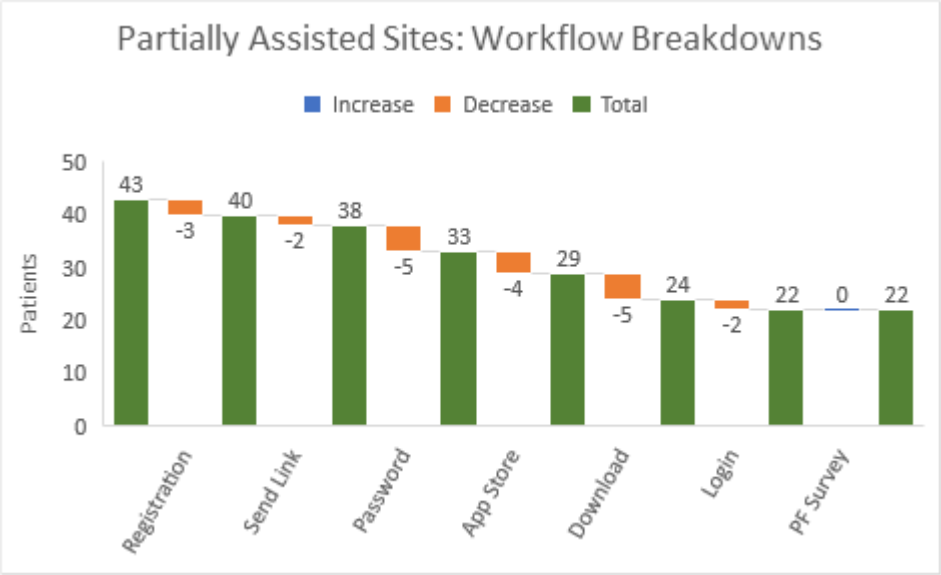

Figure 15. Reasons for workflow breakdown within the three partially assisted sites

Facilitators of Recruitment: Partially Assisted Tier

1. **Dedicated Research Staff.** At one of the partial sites (Site E), a key staff member was chosen to aid in data collection. At Sites D and F, a key group of staff members were chosen to facilitate the process. Having one person devote time to data collection facilitated the process because the dedicated staff member could focus their time on the patient and their needs for the study. We were able to work with these staff members make sure they understood the workflow and could facilitate these different parts of the study.

2. **Staff Preparation/ Coordination.** At Site D, clinic staff recommended who the researchers should target throughout the day based on inclusion criteria (English speaking and ability to consent) as well as general knowledge of the patient's personality and relationship with technology. This helped the site be more efficient with data collection efforts. Additionally, clinic staff at the Partially Assisted sites were sometimes able to pre-register patients in the admin hub before the study.

3. **Pre-existing Cell Communication**. Sites that used text message reminders for appointments (Sites E and F) typically had patient's cell numbers on file. The patients cell number is a required input when registering patients in the admin hub and it is essential for sending the patient a link to the password creation screen. Sites that had patient's cell numbers on file were able to preregister patients before they arrived, streamlining the process.

Barriers to recruitment: Partially Assisted Tier

1. **Staff Workload.** In fully assisted tier, the clinic tasks typically fell to the front desk staff. The front desk staff experienced extremely high workload demands answering phones, checking-in patients, and additional duties. Because of their high workload, the front desk staff were not

always able to participate in study related tasks such as inputting patients into the admin hub, sending the text message, or communicating survey completion with the provider.

2. **Tight Clinic Schedules.** There was significant variability in the timeliness of the different clinics. Some clinics were always on time and MAs began the intake process as soon as the patient arrived. Other clinics ran behind by a few minutes and the patient waited in the waiting room during that time. It was more difficult to recruit patients at clinics with timely schedules because the patients had less time to complete the study before their arrival and their appointment. Workarounds included approaching patients in the exam room instead of the waiting room or not approaching patients in the morning when the clinics were typically on schedule.

3. **Unclear Roles/ Responsibilities.** There was some confusion about whose was responsible for completing tasks involved in the study. At one site (Site D), there was confusion about who would input patients into the admin hub; initially it was the responsibility of the practice manager, but when it became clear that she did not have time to complete the tasks it was pushed to multiple other parties, none of whom truly knew who was responsible for the task. Consequently, preregistration was not always completed at this site before data collection.

Independent Tier

Of the 30 total patients approached to participate in this study, 14 patients consented to participate, and 8 patients successfully completed the survey process (Figure 16). The most common decline reasons were due to a phone issue (69%) or an informed decline (31%). The most common workflow breakdown was a result of technical issues (100%). The definition of each of these terms can be found in Appendix L.

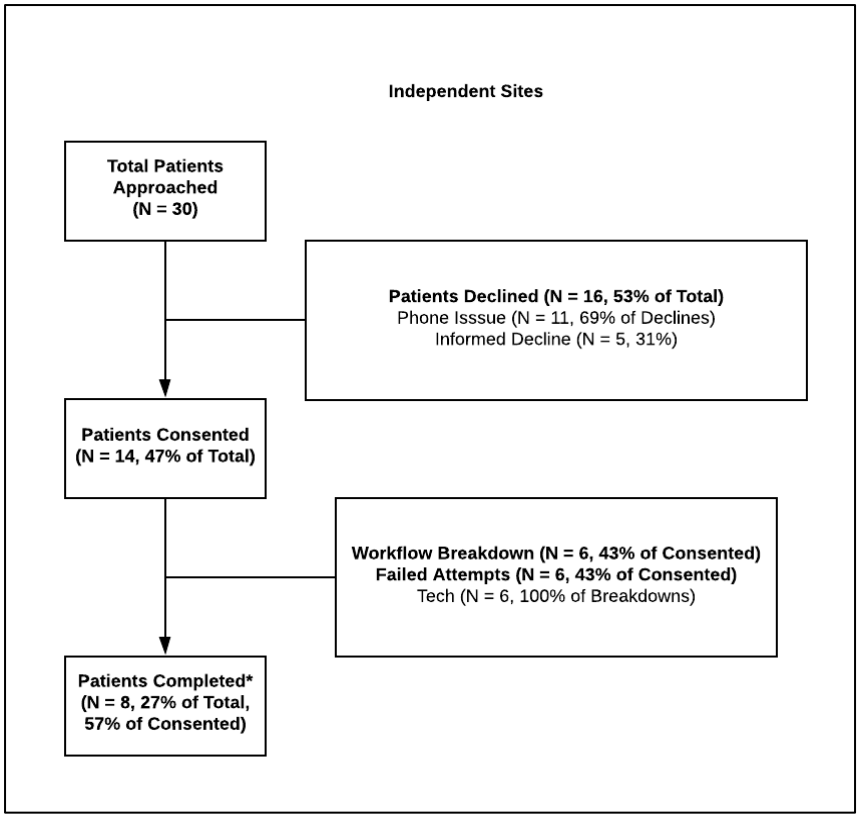

Figure 16. patient approach, consent, and study completion within the three independent sites

Figure 17 illustrates the total number of patients who consented to the study (14) and at what phase breakdowns occurred that prevented patients from completing the survey. In this graph, the workflow breakdowns include the patients who would not have been able to complete the survey without assistance (i.e., could not download the app and used the researcher's phone instead). Looking at the independent sites, the most common reason that the patients failed to complete the study was not being able to receive the link to the registration page (n=5).

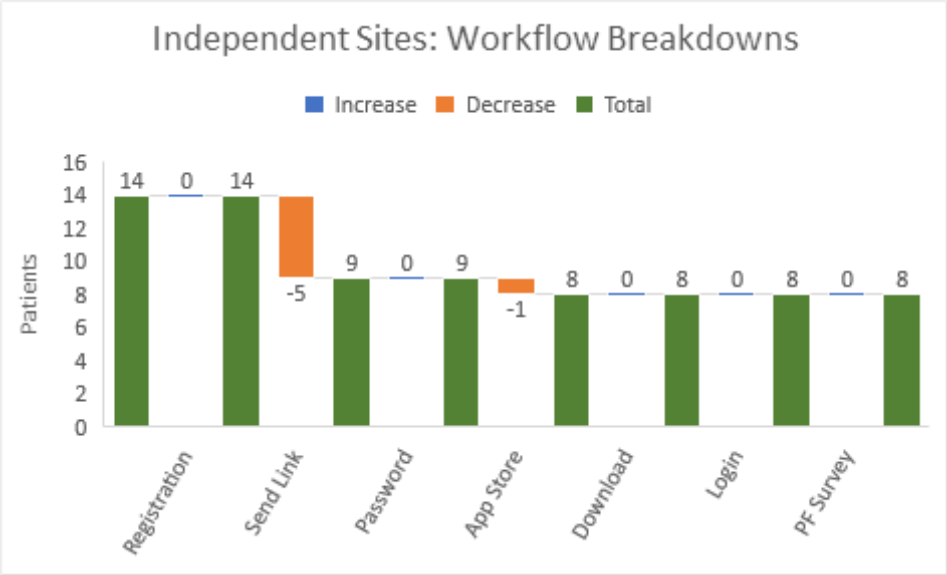

Figure 17. Reasons for workflow breakdown within the fully independent sites

Facilitators of recruitment: Independent Tier

1. **Dedicated Staff Member.** In the independent tier, one staff member whose job function included facilitating research efforts and practice improvement efforts for their practices, was responsible for nearly all elements of data collection (i.e., registration, sending the text, notifying the provider). Having one person devote time to data collection facilitated the process because the dedicated staff member could focus on setting the patient up for the study while the other practice staff continued their normal function (e.g., checking patients in for their visit and completing required paperwork). Additionally, it limited the need for communication between the research team and clinic staff at multiple steps of the process (i.e., researcher instructing clinic staff to input patients into admin hub, researcher relaying patient phone number to clinic staff, researcher asking clinic staff to send text message, researcher asking clinic staff to notify the provider).

2. **Staff Knowledge/ Rapport with Patients and Providers.** The dedicated staff member who functioned as the study liaison had an established relationship with the other practice site staff, the provider, and the patients. This facilitated data collection because the coordinator brought prior knowledge which proved valuable to facilitate to the data collection tasks, such as the typical timing and flow of the clinic, the location of the exam rooms, and the personalities of the patients and providers in that practice.

Barriers to Recruitment: Independent Tier

1. **Poor Cell and Internet Service.** Sites at which patients experienced poor cellular connection struggled to complete data collection. Because of inadequate cell service, patients were not able to receive the text message link to begin the registration process, nor were they able to download the app from the App Store. This proved to be a critical barrier to full implementation at two of the three independent sites which were located in rural areas.

Patient Level Assessments

Below we describe the findings from the patient level assessments including decline reasons from the approach log, usability survey, patient observations, and the patient semi-structured interviews. We first describe the standard ranges of the SUS score, and then present the median and inter-quartile ranges of the scores from the subset of patients at each site.

Decline Reasons

Of the 173 patients approached to participate in the study, 89 declined to participate. The most common reasons for decline were phone issues (n=44), patient issues (n=20), informed decline (n=15), immediate decline (n=9), and unable to consent (n=1). Decline issues in detail can be found in Table 2.

Table 2. Reasons patients declined to participate in the study (n=89)

Reason		**# of Participants (Percentage)**
Phone Issue	Incompatible/No Device	42 (95%)
	No Battery	2 (5%)
	Total	**44 (49%)**
Patient Issue	App Download	9 (45%)
	Inappropriate Time	4 (20%)
	Too Complicated	4 (20%)
	Privacy Concern	2 (10%)
	Poor Health	1 (5%)
	Total	**20 (22%)**
Patient Issue		**15 (17%)**
Immediate Decline		**9 (10%)**
Unable to Consent		**1 (1%)**
Not enough time		1 (100%)

Phone issue declines included incompatible devices (e.g., a non-smart phone or internet enabled device or device left at home) or issues with phone battery. This was the most common reason for decline among patients. As one patient said, "I'm old school, my phone is just a regular flip top."

Patient issues included concerns about the app download process, issues with appropriateness of the timing (e.g., patient preoccupied with another task or focus), poor health (e.g., patient not feeling well enough to participate or physical function preventing technology use), privacy concerns, and concerns with the process being too complicated. Quotes highlighting some of these reasons are included below:

- App Download: "[I already receive] so many appointment notifications and messages. It takes me too long to clear everything off of it."

- Privacy concern: "I don't put apps on my phone. Everything on my phone is confidential."
- Too complicated: "Do I have to put something on my phone? I don't know how to use it."

Patients who heard the study description before choosing to not participate were categorized as informed declines. In these cases, the exact reason for declining was unspecified by the patient. Most commonly, informed declines were accompanied by a general lack of interest in participating in research.

Immediate declines were categorized as patients declining to participate before hearing out the description of the study. Patients who immediately declined were simply not interested in anything outside of their scheduled visit and had no interest in conversation with the research staff.

The final reason for decline was an inability to consent. Only one patient was recorded as such, as they were called back to the exam room after the researcher introduced themselves but before the patient was given the opportunity to consent.

A data dictionary for decline reasons can be found in Appendix L.

Systems Usability Survey (SUS)

The SUS is scored between 0 and 100, which is a score specific to SUS and not a percentile. Bangor et al. (2008) ascribed the acceptability of SUS scores compared to the average[12], as seen in Table 3.

Table 3. Acceptability of SUS scores[13]

0-10	11-20	21-30	31-40	41-50	51-60	61-70	71-80	81-90	91-100
Unacceptable					Marginal		Acceptable		

Figure 18 shows the median and interquartile range of the SUS overall by site. The median score at each site ranged from 21.25 to 82.50, which places the scores between unacceptable and acceptable. The median score for all sites was 67.5, which places the score in the marginal range. This means that the usability of the PRO survey has room for improvement, although results of the survey should be interpreted cautiously as explained in the limitations section.

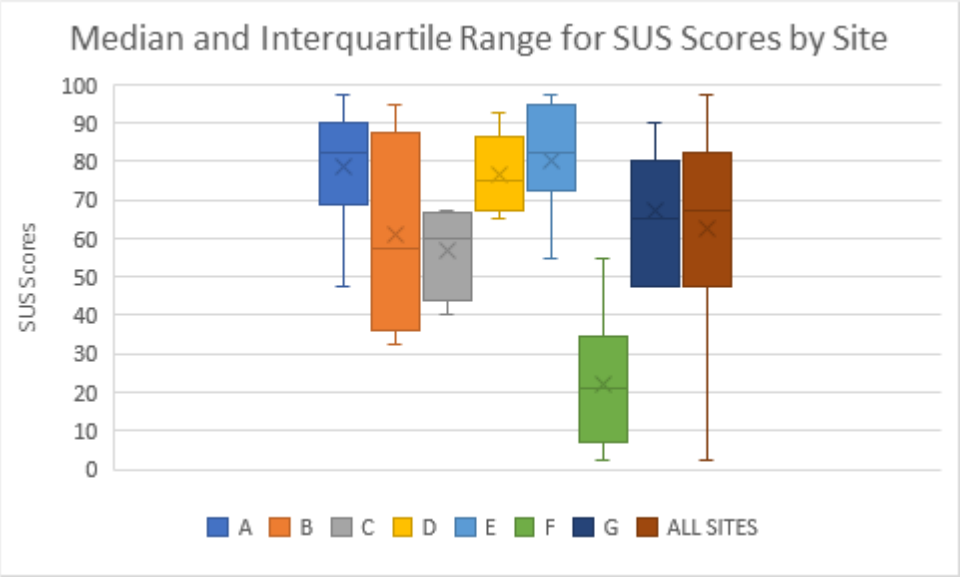

Figure 18. Median and interquartile range for SUS scores by site (data only captured for seven sites)

Data analysis was performed on seven sites the completed the SUS evaluations, resulting in a total of 51 SUS evaluations. Sites that reached 10 patients did not necessarily report 10 SUS scores. Some scores were not able to be captured as patients failed to complete the entire survey. Scores from Sites H and I were not captured as PRO data was not captured for these sites.

The SUS results from Site F are notably lower than the other sites (Table 4). Looking at the observation and approach log data, it appears that this site reported similar usability and data collection issues than other sites. Based on the data collected there are no clear indicators for why participants from Site F reported exceptionally low scores. This, along with the general lack of clear trends in SUS data may be related to ambiguity around the interpretation of the SUS data by participants – many participants expressed that it was not clear what the aspects of the study experience the SUS was asking about. Notably, the SUS data from participants in the pilot were significantly lower than those reported during initial usability testing of the PRISM app. It is worth noting that initial usability testing of the PRISM app did not require participants to download the app or set up the app on their devices. Conceivably the patients in the pilot were recording scores and providing feedback on the usability data based on the full experience, including challenges they may have had with the downloading the app and installing it, rather than just reporting on usability of the PRISM app itself.

Table 4. SUS data collected for seven sites

Site ID	Site Name	# of Patients Completing the SUS and Included in Analysis	Lower Interquartile Range	Median	Upper Interquartile Range
A	MedStar Health at Lafayette Centre	9	72.50	82.50	85.00

Site ID	Site Name	# of Patients Completing the SUS and Included in Analysis	Lower Interquartile Range	Median	Upper Interquartile Range
B	MedStar Medical Group Family Medicine at Fort Lincoln	5	40.00	57.50	80.00
C	Family Health Center at MedStar Franklin Square	4	51.25	60.00	65.63
D	MedStar Medical Group at Bethesda	9	67.50	75.00	85.00
E	MedStar Medical Group Washington Primary Care Physicians	7	72.50	82.50	90.00
F	MedStar Health Family Medicine at Spring Valley	10	7.50	21.25	28.75
G	MedStar Shah J. Patrick Jarboe Medical Center	7	56.25	65.00	77.50
H	MedStar Shah at Waldorf	0	--	--	--
I	MedStar Shah Philip J. Bean Medical Center	0	--	--	--
All Sites		90	51.00	47.50	67.50

Patient Observations: Usability

Based on observations of participants interacting with the app and recordings from the Approach Log, we identified several usability issues. These included password creation, App Store ID, and Comprehension and Applicability of Survey Items.

1. **Password Creation**
   (Related STS Dimensions: 3) human computer interface; 4) people)

   During data collection, participants were required to create a password for their PRISM account. This password needed to have a number and capital letter. Identical passwords also needed to be input twice. We found that many users struggled to input a password and the reasons for this were variable. This appeared to be because of three problems. One, the users did not understand the password requirements before creating their first attempt at a password. Researchers often needed to step in to clarify the requirements. This may have been because the text for the password requirements was relatively small. Two, users did not accurately input two identical

passwords, which is a common user error further exacerbated by problem three. Problem three, older users and those with mobility issues struggled to use the keyboard on the small phone screen. Consequently, they pressed incorrect keys on accident, making it extremely difficult to create a password. In total, approximately 24 of the 84 patients (28.6%) who consented to participate in the survey struggled to create their password. This was a critical failure point for five users who did not complete the study after consenting because of password issues.

Below are two unique examples of password difficulties in the observation logs:

> "When originally prompted to create a password for the app, patient's phone did a 'password suggestion' which she accepted. When prompted to recall the password, she couldn't remember it and she reset her password by inputting numbers and letters herself. The second password didn't work, so she tried to reset again, and it didn't work. Researcher directed patient to the saved password section in her iPhone where we found the original password, which worked."

> "...the patient takes a couple minutes to create a password and when he creates one there is an error message. No capital letter. Patient retries, which takes a couple minutes, and also gets an error message. No number. He enters the password a third time and successfully enters the system. The google play store won't load so he hits the back button. But he hits the back button twice by accident and it takes him back to the password screen again. The patient politely declined to continue the study. The whole process from approach to ending took thirty minutes."

2. **App Store ID**
   (Related STS Dimensions: 3) human computer interface; 4) people)

   A less common, but highly disruptive, occurrence was patients not having or not knowing their apple/ google play ID or password. To download an app in either store, it is required that the user have an account with the company. Some patients did not have an app store account. Other patients had clearly created an account, however, they did not know the password associated with the account. In five cases, this led to the study being stopped prematurely as without downloading the app the survey could not be completed. In two cases, the researcher provided their own phone for the patient to use to complete the study.

3. **Comprehension and Relevance of Survey Items**
   (Related STS Dimensions: 2) clinical context)

   A commonly observed usability issue for most patients across sites were challenges with comprehension and readability of the PF survey questions. Patients often expressed that the survey content was not directly applicable to their lifestyle or context, and thus had trouble conceptualizing the questions to provide the most accurate response. For example, when one patient was asked whether he could row a boat vigorously for 30-minutes, he remarked that the question was ridiculous as he had never rowed a boat before. Another patient asked what "two hours of hard labor" meant in the context of the question.

   In addition, while filling out the survey, patients commented that the wording of questions and the formatting of the SUS was confusing. As mentioned above, this confusion introduces an important caveat and potential limitation to interpreting the SUS data.

Semi-Structured Interviews

A total of 5 patients opted-in to complete a follow up interview to provide additional context and general feedback on their experience using the app. Demographic data for patients who were interviewed can be found in Table 5. Patients were interviewed and transcripts for these interviews were analyzed to extract commonalities and identify emergent facilitators and barriers. The full patient interview guide can be found in Appendix H.

Table 5. Number of patients interviewed at each site

Site ID	Site Name	# of Patients Interviewed	Age Range of Interviewed Patients [Min, Max] (Years)
A	MedStar Health at Lafayette Centre	1	[61, 70]
B	MedStar Medical Group Family Medicine at Fort Lincoln	-	N/A
C	Family Health Center at MedStar Franklin Square	-	N/A
D	MedStar Medical Group at Bethesda	1	[61, 70]
E	MedStar Medical Group Washington Primary Care Physicians	1	[61, 70]
F	MedStar Health Family Medicine at Spring Valley	1	[61, 70]
G	MedStar Shah J. Patrick Jarboe Medical Center	1	[61, 70]
H	MedStar Shah at Waldorf	-	N/A
I	MedStar Shah Philip J. Bean Medical Center	-	N/A

Interviews with patients revealed several key facilitators and barriers to the implementation of PROs:

Facilitators:

1. **Usability of PRISM**
   (*Related STS dimensions: (3) human computer interface; (4) people*)

   When asked if it was easy or difficult to download and use the PRISM mobile app, 5 out of 5 (100%) patients said that it was easy to use. One patient stated, "I thought it was pretty standard. It's not that I do surveys all the time, but I use apps a lot to do things like banking or checking in for a flight- it was pretty similar." Additionally, all patients said that the app took minutes to use and expressed that they were comfortable with the process taking that amount of time.

2. **Question Applicability/Relevance**
   (*Related STS dimensions: (4) people; (5) workflow and communication*)

   Four patients were asked if the questions in the survey were applicable to them. Of these four patients, three said that the questions were applicable. One patient elaborated that the questions seemed appropriate for her age demographic, "They seemed like questions good for someone who is not young. It wasn't geared toward young, active people."

3. **Changed the Conversation**
   (*Related STS dimensions: (4) people; (5) workflow and communication*)

   Two patients expressed that the survey had a positive impact on their care because it changed the conversation that they had with their physician. One stated, "I liked when the doctor pulled it up. That was eye opening. Game changer...I would love for my doctor to know my interest in my health. It makes it a real partnership. It's not just your doctor telling you information and you listening. It makes you an active participant."

Barriers:

1. **Password and App Store Issues**
   (*Related STS dimensions: (3) human computer interface; (4) people; (6) internal organizational policies, procedures, and culture)*

   Conversely, three patients reported needing assistance in completing the process; one patient elaborated that they were confused about the necessity of creating a password. Another patient-reported that they struggled to remember their Apple ID password and had to complete the study on the researcher's phone.

2. **No Impact on Care**
   (*Related STS dimensions: (4) people; (5) workflow and communication*)

   Patients were most split on the level of impact that the survey had on their care. Three patients expressed that the survey had no impact on their care. One patient elaborated to express that the app had potential, "Everyone is asking for surveys and it becomes somewhat annoying. This was simplistic and sort of meaningless. Maybe if you stress the importance of the survey it would make people feel like they were contributing to their betterment."

Summary of Barriers and Facilitators for Implementation from the Patients' Perspective

Most eligible patients who were approached declined to participate in the study. The primary barrier to consent was the lack of a compatible phone which made it impossible for patients to download the PRISM app. Another significant barrier for patients was concern about downloading an app on their personal device or the privacy of their data. Many participants simply had no interest in participating in the study at all.

In general patients found the PRISM app itself easy to use. Patients did appear to struggle with the required process of creating a password, perhaps due to the size of the phone keyboard and small text of the password requirements. Some patients also struggled to remember their App Store ID. However, overall feedback from the interviews and SUS data suggests that the survey function of the app itself was straightforward.

Unfortunately, the context and language of some of the PROMIS survey questions presented a challenge for some participants. Three of the four patients who completed the interviews felt like they were the right audience for the questions; however, researcher's observations suggest that many people found the questions confusing or in some instances 'absurd'.

Lastly, it appears that patients had mixed feelings about the impact of the survey on their visit. Three patients interviewed expressed that they found the survey meaningless, while other (n=2) said that it helped them better participate in their own care. This suggests that the survey has merit when targeting applicable patients and used by providers in an engaging way.

Provider Level Assessments

Semi-Structured Interviews

After the completion of data collection at each site, semi-structured interviews were completed with a participating provider to understand their experience. Except for four sites, one provider from each site was interviewed. The exceptions included three sites with unavailable providers, and one site in which the provider did not have any success recruiting patients. To account for these discrepancies, we interviewed two providers from one site (Site C) and the research coordinator of the independent tier (Site G) who had a particularly unique role in the project. In total, seven interviews were conducted. Provider demographics can be found in Table 6 and the full provider interview guide can be found in Appendix I

Table 6. Provider demographics

Site ID	Site Name	# of Providers Interviewed	Specialty	Years of Practice
A	MedStar Health at Lafayette Centre	1	Internal Medicine	6
B	MedStar Medical Group Family Medicine at Fort Lincoln	0	N/A	N/A
C	Family Health Center at MedStar Franklin Square	2	Family Medicine	40
			Family Medicine	6
D	MedStar Medical Group at Bethesda	1	Internal Medicine	21
E	MedStar Medical Group Washington Primary Care Physicians	1	Internal Medicine/ Geriatrics	24
F	MedStar Health Family Medicine at Spring Valley	1	Family Medicine	15
G	MedStar Shah J. Patrick Jarboe Medical Center	1*	N/A	N/A
H	MedStar Shah at Waldorf	0	N/A	N/A
I	MedStar Shah Philip J. Bean Medical Center	0	N/A	N/A

*The site coordinator was interviewed as a replacement to the Provider. The site coordinator is not a practicing clinician with a specialty.

Interview questions for providers focused on usability and functionality of the EHR visualization, the utility of PRO measures and their impact on workflow, and patient/provider communication. Interviews were coded for consistent themes and analyzed to extract facilitators and barriers.

Facilitators:

1. **Research team presence onsite during data collection made implementation much easier** *(Related STS dimensions: (4) people; (5) workflow and communication; (6) internal organizational policies, procedures, and culture)*

   All participating providers emphasized the importance of having individuals (outside of practice staff) at the clinic devoted to data collection. A common theme was that the addition of a survey would be burdensome to the clinic staff in addition to their other tasks. As one provider stated, "Patient rooming already takes 10-15 minutes. We wouldn't want to add more for the MAs to do… 5 extra minutes for an app download and survey completion is too much."

2. **Most providers found it easy to access the data within the EHR using the reference materials when needed**
   (*Related STS dimensions: (3) human computer interface*)

   Only one provider needed assistance with accessing the visualization within the EHR. Four physicians relied on the access guides to navigate to Cerner mPages to see the patient output. One provider who participated in the first phase was able to recall the navigation and access the output without assistance.

3. **Potential for PROs to enhance care**
   (*Related STS dimensions: (4) people; (6) internal organizational policies, procedures, and culture*)

   While most participating providers did not report that the PRO measures influenced care, three providers suggested that PROs have the potential to positively impact care in some way. Specifically, one provider noted that PROs permit patients to feel like active participants in their care.

Barriers:

1. **Provider notification of survey completion**
   (*Related STS dimensions: (3) human computer interface); (4) people; (5) workflow and communication*)

   Because the app did not notify providers through the EHR that patients had completed the survey, notification of the provider was dependent on reliable and consistent communication between the relevant staff and provider within each practice. Three providers were alerted to patient PRO completion through communication with the front desk or an MA. Three providers reported missing several patient outputs because they were not informed that the patients had completed the measure. One provider stated that he needed "an indicator that there was data to review in order for [the PRO] to fit into the existing workflow."

2. **Lack of relevance or clinical utility of the data to the patient population**
   (*Related STS dimensions: (2) clinical content; (4) people; (5) workflow and communication*)

   All providers reported that the PROs did not influence the care provided to their patients. While the information was reported to have value, providers all agreed that the outcomes did not impact care. One provider stated, "[PROs] are only relevant to the extent that they have a clinical

impact. I don't know how to interpret these data." One provider emphasized the need for evidence based and actionable PRO measures in order to be effective.

3. **Timing of patient arrival and survey completion**
   (*Related STS dimensions: (4) people; (5) workflow and communication*)

   Two providers commented that the proposed workflow worked the best when patients arrived early for their appointment and had adequate time to complete the survey measure. One provider commented that the PRO workflow was acceptable if it did not delay patient visits.

Summary of Provider Interviews

Overall, providers were satisfied with the PRO workflow and data collection process. While no providers reported the output having an impact on patient care, all providers reported value in collecting and reporting on PRO measures. From these interviews, providers emphasized the importance of having support on site to facilitate data collection, ease of access within the EHR and existing workflow, and guidance for PRO interpretation and action. Future projects should attempt to anticipate these needs when implementing PRO measures within ambulatory care.

Health IT Staff Level Assessments

Semi-Structured Interviews

Upon completing of the technical implementation, we interviewed five health IT staff who were involved at various stages of this implementation. Questions related to FHIR compatibility with different EHRs, institutional requirements and policies, and the general success and pitfalls of the project. Technical experts identified a number of facilitators and barriers to the project as described below. The full Health IT interview guide can be found in Appendix J.

Facilitators:

1. **Consistent communication between teams**
   (Related STS dimensions: 4) people; 5) workflow and communication)

   Technical experts commented that it was helpful that the project teams were easily accessible and kept an open line of communication for questions and concerns. This includes promptly responding to emails and consistent meetings throughout the entire process as well as providing valuable exchanges of information throughout the process.

Barriers:

1. **Cloud-based services**
   (Related STS dimensions: 1) hardware and software computing infrastructure; 7) external rules, regulations, and pressures)

   Two cloud-based services were used during this project. Technical experts expressed that these cloud-based services proved vital in quickly scaling a HIPPA compliant solution. However, the cloud-based services also made it difficult to build a scalable platform and created unanticipated institutional hurdles down the line.

2. **Institutional hurdles**
   (Related STS dimensions: 7) external rules, regulations, and pressures)

   Technical experts argued that the project team did not anticipate the amount of time it would take to obtain institutional clearances (e.g., from the hospital system's Information Systems (IS) department). Technical members close to the IS department also reported that the project team did not provide appropriate documentation to the institution, further extending the length of the process.

Summary of Health IT Interviews

Overall, technical experts were satisfied with the interaction between project teams. They believed that the close working relationship between the teams helped to facilitate the sharing of essential information that moved the project forward. One exception was communication about institutional hurdles, which lead to choices about cloud-based services that complicated institutional barriers even further. Future projects should attempt to anticipate and understand the scalability and regulatory needs before selecting technical solutions. Additionally, knowledge of these hurdles must be disseminated early and to all key team members to facilitate effective decision making.

Section VII: Summary of Key Findings by Stakeholder Group: Clinical Implementation and App Usage

In addition to the facilitators and barriers that have been detailed in the previous sections, we identified key lessons learned from the entire implementation process. These lessons learned have direct implications for scalability of the standards and PRO technology. We outline these by stakeholder group.

Patients Using the PRO App

- In general, the PRISM app was found by patients to be usable and easy to navigate for completion of the PROMIS survey.

- Downloading from the App Store or Google Play and password issues were a common challenge for many patients attempting to engage with the app.

- Successful engagement with the PRISM app was highly dependent on patients having the appropriate technology (smartphone) and having the tools to make the technology work (e.g., a reliable cellular network or strong Wi-Fi connection).

- The PRISM app facilitated efficient survey completion (74 seconds on average) highlighting the potential for this technology to be scaled for a large battery of clinically relevant PROs.

- Successful engagement with the PRISM app in the pilot test setting was often dependent on the patient generally being in good health.

- The value proposition for patients engaging with a PRO app is critical-- patients have to perceive value in how their data will be used by their provider or impact their care. Many patients were skeptical of whether their provider was actually going to use the data they were reporting.

- Security and privacy concerns remain paramount for many patients and would likely impact their willingness to continuously use the PRISM app or similar technology.

- For many patients the language and context of PROMIS survey items were potentially confusing (i.e. “row a boat vigorously for 30-minutes”).

- The ideal timing for patients to complete their PRO survey can be highly variable and is not always optimal immediately before their appointment or in clinic.

Primary and Specialty Care Providers Using the PRO Data Provided by Patients

- Providers play a key role in patients’ willingness to use PRO apps to collect PF data as patients were more willing to use the app if they knew the provider was looking at their data.

- Surfacing PRO data via a dynamic template in the EHR proved to be a viable solution allowing providers to easily access and consume the PRO data in the EHR.

- Many provider workflows are not conducive to accessing the patient’s PRO data in the EHR prior to the patient encounter; alternate workflows need to be considered (e.g. for providers who do not review patient charts until after the encounter, or where patient volume limits this option).

- Providers expressed the need for flexibility in terms of what they could do with the PRO data (e.g., paste it in notes, save it to the chart).

- Provider notification or an EHR alert of a patient’s survey completion is needed so as not to hamper workflow and to prevent providers from missing the data.

- Despite increasing use of PROs some providers still expressed hesitation about their interpretation because it represented a patient’s perception rather than an objective physiological measure.

- Providers generally still noted they were unsure of what to do with the PF PRO data and which scores were actionable.

- Several providers in this pilot suggested limited clinical utility of PF PRO data for primary care in this context.

- Certain primary and specialty care providers may benefit more from patients using this technology than others. E.g. providers in certain specialties who routinely track and interpret these data as part of a standard periodic evaluation, or who can pair it with a targeted intervention.

Developers and Health IT Staff

- Having well laid-out standards allowed for the PRISM app to quickly and easily switch from one FHIR server to another—a process that would have been far more complicated in the absence of such standards.

- The FHIR standards enable a successful abstraction layer to bridge the mobile app and the multiple EHRs—assuming that it is supported by the vendor and site.

- While SMART on FHIR technology is generally relatively easy to implement, many health systems do not currently have the tools or technology resources on hand to support it.

- Several EHRs do not currently support the latest SMART on FHIR standards and some clinic sites may not be willing to purchase the app.

- SMART on FHIR solutions for PRO apps are only part of the solution of scaling to diverse populations where cell connectivity may be unreliable. Apps need to also support alternative architecture that does not rely on app downloads (e.g., web-based apps or embedded apps on clinic tablets).

Primary or Specialty Care Practices

- Practices most likely to adopt and implement this PRO technology would have dedicated staff to facilitate patient use and adoption, and a clear delineation of roles and responsibilities for staff supporting patients and the data collection.

- Practices with efficient communication between the different levels of clinic staff are most likely to successfully adopt this technology and integrate it with their workflow.

- Practices that see a high patient volume may experience challenges with engaging patients with this technology in clinic given the lack of resources to also provide technical assistance to patients.

- Practices are likely to adopt and sustain this technology if they also have supportive technical infrastructure (e.g., Wi-fi or connectivity).

- Providing technical assistance to practices implementing this technology may not necessarily be the key driver of adoption (fully assisted sites still had practice-specific challenges to adoption and use).

- The availability of Wi-Fi of and cellular service are critical to adopting and sustaining use of this type of technology. This can be especially challenging in hospitals in rural areas with poor cellular service, or individual practices with specific architectural or physical constraints (e.g. lead walls installed for protection from nuclear medicine).

Institutions or health systems implementing PRO technology

- Involving all system stakeholders including legal and compliance as early in the implementation process as possible is critical to successful and timely adoption of this PRO technology given the multiple policies and regulatory considerations.

- Systems should anticipate significant challenges of using cloud-based services including security assessments, HIPAA, BAAs and related internal process.

- Institutions and health systems with complex and uniform vetting processes for adopting any new technology may benefit from standardized, expedited approval processes for integrating novel patient-facing Health IT.

- Dedicated technical staff are needed regardless of the size of the implementation to ensure successful integration and adoption for different clinic workflows.

Section VIII: Discussion, Conclusions and Limitations

Discussion

Broadly, some of the findings from this pilot study highlight important barriers and facilitators for PRO implementation, some of which align with the exiting literature, and several which generate important new considerations for the potential scalability of technology-enabled PRO data collection. This pilot demonstrated that for a technical implementation of this scale, the PRO app itself was rarely the most significant challenge, rather the interplay of multiple socio-technical factors impacted the implementation. Across each pilot site several broad themes held true:

The mobile form factor is particularly amenable for patients taking surveys: In this pilot, patients clearly demonstrated that the use of mobile phones is a great way to take PRO surveys in a way that is convenient and familiar to most patients. Once able to download and access an app, patients could efficiently complete a PRO survey with their own technology. The PRO literature does not stress the clear opportunity of using a patient's own technology to gain widespread collection of PROs from patients in primary and specialty care.

The PRISM app itself was highly usable and presented limited challenges for patients once they were able to access the survey on their phones. In general, it appeared to be mostly factors outside the app that hindered survey completion, particularly considering the average survey (once accessed) was completed in 74 seconds across all users. For users of a range of technical abilities, the app presented a great user experience, however patient frustration, perceived utility, and value in the app was mostly related to factors external to the app itself. We noted the significantly lower SUS scores from patients in the pilot compared with the higher SUS scores from the initial app UX testing. A potential explanation for this is the patients in the pilot were likely reporting on usability challenges encountered during the entire process which included challenges they may have had downloading the app and setting and remembering passwords.

Technical assistance or additional staffing is a critical factor to ensure adoption for many practices: Despite the fact that on the average we obtained only 50% completion rate for the PRO survey across all sites, there were significant differences between the different tiers in terms of how many potentially eligible patients could be reached. The completion and consent rates for each tier as shown do not accurately reflect or clearly illustrate the number of patients missed because the front desk staff were overextended tending to patients, or the days the research team were unable to go to clinic because the clinics were short staffed and therefore unable to facilitate the study on those days. To that end, one of the main facilitators at the fully assisted and independent sites was the availability of a full-time study operator. This individual had the sole task of collecting data and was not overburdened by additional tasks of the clinic, such as intaking patients or answering phones. At the partially assisted tiers, where clinic staff assumed some tasks for study completion (i.e., entering information into the admin hub, sending the text, notifying the physician), they struggled to keep up with the demands of the study. This resulted in

researchers being unable to approach eligible patients or eligible patients being taken back to the exam room before their appointment. **In future implementations, it will be essential for staff workload to be appropriately addressed so that clinic staff have the appropriate resources to perform survey collection tasks.**

No amount of planning can replace testing in the 'real world' -- which is critical to successful local implementation: Despite detailed and rigorous planning, technical teams need to test this type of technology in the real world to determine what it takes for this to work "in the wild". Given the complexity of healthcare contexts, all the planning and preparation still rarely prepares you for the realities of local implementations. Many realities are simply impossible to anticipate. One interesting aspect in this pilot is that during the initial PRISM usability testing, most of the issues surfacing were due to patient's unfamiliarity with their own mobile phones. For example, even in the prototype testing, patients often did not know how to download an app or find an SMS message. Similar issues were found when PRISM was used at the clinics where most of the issues were not due to the PRISM app but were rather general technology and mobile issues (forgetting passwords, not understanding app downloading, etc.).

An abstraction layer in front of the EHR was critical to our success. Using the Hub as an abstraction layer was critical in being an adapter and bridge between all the technical and version issues that we encountered integrating with the various EHRs. A standards-based, loosely coupled architecture enables rapid reuse of existing apps and allows developers to focus on building valuable tools and not integrating them. We saw this when we transitioned PRISM from the Cerner Sandbox to the Hub, there were only a couple of issues relating to message formatting and versions which were quickly and easily solved. Unfortunately, the world isn't quite ready for this future and so having the Hub in the middle to align with the standards and abstract away EHR idiosyncrasies made development much faster.

Impact on clinical decision-making is still unclear: While assessing clinical impact and utility was not a primary goal tested in this pilot, we were able to obtain feedback and insight from participating clinicians related to how, if at all their clinical decision-making was in any way impacted. It is likely this was more a function of the study design and the use of the Physical Function PRO measure, which several clinicians noted was not the PRO they would have most liked to collect for their patients. The study was designed to assess the issues with patients providing PROs using their own mobile devices, it was not designed to measure clinical impact. Physicians did look at the PRO scores and responses from patients, but anecdotal feedback from participants suggested the Physical Function PRO was not necessarily appropriate or useful for a specific patient's condition.

In general, for this pilot key barriers arose in three areas of clinical implementation: technical and workflow integration, patient engagement (due largely to connectivity and cell service) and institutional policies. One of the most significant barriers encountered was an unanticipated delay in implementation due to unforeseen complex institutional policies and regulations we had to navigate to secure approval and clearance to integrate the PRO technology with the health institution's native information systems architecture. These policies and regulations will likely be highly variable by institution and health systems but will need to be anticipated in any implementation timeline. Technical teams should allow significant time to navigate these processes and to meet institutional requirements, particularly when new vendors are working with a system for the first time. These issues all highlight critical points at which the coordination of human and technical processes is crucial to ensure the successful use of PRO data.

Conclusion

In this pilot study we demonstrated the ability to successfully implement a newly developed SMART on FHIR PRO app (PRISM) in a variety of primary and specialty care clinics. Notably we were able to demonstrate the types of settings and system circumstances that are most conducive to this type of technical implementation, and settings where this technology is most likely to be successfully adopted. Our pilot also successfully demonstrated the model for a healthcare institution using a PRO app by leveraging the modern standards of SMART on FHIR to implement a patient-facing app and an EHR-based provider-facing app**.** Key drivers of this success included the ability to design, deploy, and maintain a loosely coupled architecture to centralize communication and decrease variability between sites and EHR implementations. Another key driver of success was the ability to engage with sites and their technical teams as early as possible to begin early testing of data connectivity as well as any limitations of the EHR's underlying capabilities to render advanced custom visualizations. Each of these key drivers to success may vary based on the team building and deploying the solution as well as the level of support from local IT teams or their EHR vendor. This study was an important step toward identifying the various system factors key to the successful implementation, adoption, scalability, and sustained use of this technology to collect Physical Function PRO data in diverse primary and specialty care settings.

With respect to technology adoption, it is important to note that even a successful implementation of a PRO data collection system does not necessarily guarantee or imply long-term or meaningful use of the data. Successful use of PROs is complex – tending to be context-dependent and strongly coupled to the existing relationships between patients and providers.

Limitations

We note some limitations specific to our pilot. First, implementation and patient and provider enrollment for this study was relatively controlled even at the independent sites. This experience is therefore likely not entirely representative of how the clinical implementation of such a PRO app would function “in the wild” and in clinics with a more typical workflow that does not include some level of intervention by a research coordinator or other facilitator of this alternate workflow. Our pilot rather serves as a proof of concept. Second, there is likely selection bias in terms of the clinics, providers, and even patients who agreed to participate in this pilot. Actual adoption by providers and practices is likely highly variable. Third, the SUS survey results from the patient’s usability assessment of the app should be interpreted with caution. Patients were often confused by the wording of some of the SUS items relative to the app. For example, the SUS items reference a “website” and patients were sometimes confused what the term referred to. In addition, patients were asked for feedback on the usability of the app but were likely providing feedback on the entire process including having to download the app and create passwords. Fourth, we only used one type of PRO (Physical Function). We expect that patients would find other surveys as easy to use but did not assess that aspect. Finally, this study only asked patients to take an initial survey in a clinic setting. It did not test how well patients could take the survey at home or as a periodically scheduled survey between office visits.

Section IX: PRISM Sustainability

The PRISM team intends to sustain the success of the PRISM app by first, releasing the PRISM as open source and secondly, we will actively build a community of like-minded researchers and clinicians interested in encouraging PRO adoption and advancing the capabilities of PRISM.

Open Source Release

The source code for the PRISM app will be released as Open Source at the conclusion of this Challenge. It will be released under the Apache 2.0 software license and will be available on the AHRQ github at https://github.com/ahrq-patient-reported-outcomes/ahrq-prism

The source code in the repository is the version of PRISM that was implemented at MedStar Health and was used in Phase 3 of AHRQ's Step-Up App Challenge. The PRISM App consists of a Frontend Hybrid mobile app built using Angular and Ionic and Backend built AWS Lambda and other services. To get up and running with the project, you will need to fully install the PRISM Backend before moving on to PRISM Frontend. There are a number of services that need to be configured in order for the app to run in your Amazon AWS environment. There are complete instructions for configuring and deploying the PRISM app available as Readme's in the github repository.

PRISM Community Development

While the PRISM app has been shown to be easy to use as part of this study, there is much that should be done to encourage the app's adoption and enhance its functionality. The PRISM team would like to build a community around the app in order to continue to develop it and make those enhancements available as open source.

Our goals for a PRISM Community in the near future are two-fold:

1) Implement PRISM in multiple clinical settings to assess its impact on collection and use of PROs as well as related patient outcomes, and clinical workflow

There are many clinical areas that can benefit from the use of PROs. One area that shows great promise is for patients who have undergone surgery. Post-operative recovery remains a difficult metric to track as it must include subjective information from the patient, and it has the potential to vary widely among patients and types of surgery. A variety of instruments are currently used to capture different aspects of the recovery process, such as physical function, pain management, opioid use, and general quality of life. They are typically measured at scheduled postoperative visits with no ability to track patients' progress in between visits or over longer periods of time. Other clinical areas of high potential use of PRISM include, but are not limited to mental health disease, cardiac rehabilitation, integrative medicine interventions, pain management interventions, cancer treatments, and cancer survivorship.

2) Develop an open-source community to support PRISM and foster adoption across healthcare organizations

The open source model has proven to be very successful for some healthcare applications. For example, projects such as i2b2 (https://www.i2b2.org/), PopMedNet (https://www.popmednet.org/) and SMART (https://smarthealthit.org/) all started as grant funded research that evolved into open source communities that were very successful in both adding capabilities and gaining widespread adoption of their projects. More recently, HL7 FHIR (https://www.hl7.org/fhir/) has used the open source model to advance the adoption of that interoperability standard across healthcare. We would like to build similar community around patient reported outcomes.

There are already a few open source apps that support the capture of patient reported outcomes, but we are aware of only one, MyStudies, that is a mobile app. In 2018, the FDA released its MyStudies app

(https://www.fda.gov/drugs/science-and-research-drugs/fdas-mystudies-application-app) for iOS and Android. And RedCap offers a freely available PRO capture solution (only for researchers), but it is not open source. PRISM offers a better approach because it is based on the newly release FHIR R4 standards which allow PRISM to capture any PRO instrument that conforms to the Structured Data Capture (SDC) standard and the data can be stored into any EHR that also supports that standard. Using PRISM and these standards means that PRO developers don't have to learn different tools to create a survey, they just need to create a SDC compatible version. And it also means that IT departments of healthcare organizations can easily integrate the data from the surveys into their EHRs using the same standard.

A number of researchers and projects have already contacted the PRISM team indicating their interest to use PRISM to capture PROs for their studies when it becomes available. We want to build a community that will be a forum for sharing, collaboration on projects, support for implementing and using the PRISM app as well as a way to continue the development of features. We envision a PRISM Community where collaborators may contribute funding from grants or contribute software developer effort to help with the design and development of additional features and capabilities. There is so much work to be done related to PROs and it is inefficient for everyone to have to "reinvent the wheel" of a patient facing PRO data capture mobile app. We want to make it easy for everyone to adopt PRISM for their research or clinical operations. We would like to invite anyone who is interested in joining the PRISM Community, please go to the community website at http://z.umn.edu/prism

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Appendix F. Readiness for Change Scores by Site

Site ID	**Site Name**	**Overall perception of e-health** (Possible score range: [24,120])	**Organizational readiness** (Possible score range: [21; 105)	**e-Health experiences in my organization** (Possible score range: [12; 60])	**Total Score** (Possible score range: [57; 285])
A	MedStar Health at Lafayette Centre	53	68	39	160
B	MedStar Medical Group Family Medicine at Fort Lincoln	53	50	22	125
C	Family Health Center at MedStar Franklin Square	55	53	32	140
D	MedStar Medical Group at Bethesda	37	43	23	103
E	MedStar Medical Group Washington Primary Care Physicians	44	55	22	121
F	MedStar Health Family Medicine at Spring Valley	66	72	38	176
G	MedStar Shah J. Patrick Jarboe Medical Center	33	27	15	75
H	MedStar Shah at Waldorf	33	27	15	75
I	MedStar Shah Philip J. Bean Medical Center	33	27	15	75

Appendix G. System Usability Scale

System Usability Survey

Please complete the survey below.

Site:	◯ MedStar Shah -- Philip J. Bean Medical Center ◯ MedStar Shah -- Waldorf ◯ MedStar Shah -- J. Patrick Jarboe Medical Center ◯ Family Medicine at MedStar Health Center at Spring Valley ◯ Medstar Franklin Square Medical Center ◯ MedStar Health at Lafayette Centre ◯ MedStar Medical Group Washington Primary Care Physicians ◯ MedStar Medical Group at Bethesda ◯ Fort Lincoln Family Medical Center
I think that I would like to use this website frequently.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
I found the website unnecessarily complex.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
I thought the website was easy to use.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
I think that I would need assistance to be able to use this website.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
I found various functions in this website were well integrated.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
I thought there was too much inconsistency in this website.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
I would imagine that most people would learn to use this website very quickly.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree

I found the website very cumbersome/awkward to use.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
I felt very confident using the website.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
I needed to learn a lot of things before I could get going with this website.	◯ Strongly Disagree ◯ Disagree ◯ Neutral ◯ Agree ◯ Strongly Agree
Please provide any comments about this website:	_____
Are you willing to participate in a 20 minute phone call with MedStar researchers about your experience with this website? If you agree to participate you will be asked for your name and phone number. MedStar researchers will call you within 24 hours to schedule a time to talk. Any information you provide in the phone call will be kept anonymous, and you will be given a $25 gift card as a thank you for your time. If you choose not to participate, no further action will be taken. This will not result in any negative consequences against you.	◯ Yes, I would like to participate in a phone call about my experience with this website. ◯ No, I would not like to participate in a phone call about my experience with this website.
Name:	_____
Phone Number:	_____

Appendix H. Patient Interview Guide

We are working on a study to learn more about your experience with the PRO app you used a few days ago. We want to get some feedback from you on the things you like and dislike, and the things that can be improved.

Office Location:	
Physician:	
Physician Specialty:	
Assigned Tier:	

Demographics Questions

1. What is your age?
    A. 18 – 30
    B. 31 – 40
    C. 41 – 50
    D. 51 – 60
    E. 61 – 70
    F. 71 – 80
    G. 81 – 90
    H. 90+
2. What is your gender?
    A. Male
    B. Female
    C. (Open field)
3. What is the highest level of education have you completed?
    A. 8th grade or less
    B. Some high school
    C. High school diploma or GED
    D. Associates degree
    E. Bachelor's degree

F. Master's degree

G. Doctoral degree

Interview Moderator Guide

App Usage

Process

1. How easy or difficult was it for you to download the PRISM mobile application?

    A. Did you have any difficulty locating the mobile application in the App Store/Google Play Store?

    B. Did you have any difficulty downloading the mobile application onto your cell phone?

    C. Did you have any difficulty registering a username/password with the PRISM App?

    D. Is there anything else you would like to share about your experience getting the app and being able to complete the survey?

2. How easy or difficult was it for you to interact with the survey?

    A. Did you have any difficulty submitting responses to the survey?

    B. Was there any confusion/uncertainty?

    C. Where you able to tell that you had successfully submitted your survey?

        i. How could you tell?

3. About how long did it take you to complete the survey?

4. Do you have any concerns about the amount of time it took you to complete the survey?

A. At any point did you need any assistance when filling out the survey?

B. (If yes) Why did you need assistance?

5. Did you feel comfortable using your personal device to complete this task?

    A. Did you use Wi-Fi or cellular data to download and complete the survey?

        i. Did you feel comfortable with this process?

6. Prior to a doctor's visit, how often would you be willing to fill out a survey using this app?

7. Thinking about the process to fill out the survey (i.e., obtain the instructions from HCP/RA upon arrival to appointment, download the application onto your phone, fill out the survey, complete second (SUS) survey, return materials to the HCP/RA before appointment), is there anything about the process that works well?

    A. Is there anything about the process that could be improved?

8. Would you prefer to fill out the PRO survey at home before you came to your appointment or at the clinic immediately before your appointment like you did [day of appointment]?

9. If you had to choose, would you prefer to fill out the PRO survey on a tablet, cell phone, or computer?

Content

10. How did you feel about the content of the survey, or what it was asking you?

A. Were the questions applicable to you?

B. Did you have any questions/confusion about the survey questions?

    1. How did you resolve your confusion?

    2. Is there any additional information/resources you believe the survey should provide to help someone resolve their confusion (e.g., help text, customer service number, etc.)?

C. Were there any questions or information missing that you would have liked to report?

11. Do you believe the survey questions (and the content they collect) are valuable for your care?

12. Did filling out the survey have any impact (good or bad) on the conversation between you and your doctor during your appointment?

A. How did the conversation change, if at all?

B. Did the survey make it easier to have any new conversation with your doctor (e.g., did the survey alert you to questions or concerns that you wanted to talk about with your doctor that you were not previously thinking about)?

Comprehension

13. Do you know why you were filling out the PRO survey?

14. Do you know what the doctor is doing with your survey information or how the information will be used?

Overall

15. Do you have any concerns about the privacy of the information that you entered into the survey?

    A. If yes, what are your concerns?

16. Is there anything else we should know about the PRO app or the process?

Appendix I. Provider Interview Guide

Thank you again for participating in our pilot. Now that all patients are enrolled we want to learn more about your experience with using the PRO data for your patients and the visualization in the EHR. We want to get some feedback from you on the things you liked and disliked, and the things that can be improved.

Office Location:	
Physician Name:	
Physician Specialty:	
Assigned Tier:	

Demographics Questions

1. What is your gender?

A. Male

B. Female

C. (Open field)

2. What is your primary specialty?
3. How many years have you been in practice, including residency?

A. <5

B. 5-10

C. 11-15

D. 16-20

E. > 21

Interview Moderator Guide

App Usage

4. Since we launched the pilot, how many times did you review PRO data?
    A. # of Patients
5. When did you typically review PRO data?
    A. Before the patient's visit

B. During the patient's visit

C. After the patient's visit

6. Are you currently using any other patient-reported outcomes (PRO) data such as these to help inform your clinical care and decisions?

    A. If YES, how does the PRO app compare to the other patient-reported measures that you use?

Training and Instruction

7. Did you receive any training or instruction for how to access the PRO outcomes?

A. If YES, was the training effective?

B. If YES, how could the training or instruction be improved?

C. If NO, do you think there training or instruction that would have helped you during the pilot?

8. Did you receive any job aids or reference materials?

    A. If YES, what did you think of these materials? Were they helpful/confusing?

    B. If NO, are there any job aids or reference materials you would have liked to have had?

Accessing Information

9. How were you alerted to the fact that a patient had sent data?

    A. How often/how many times were you alerted to the fact that a patient had sent data?

    B. Can you think of easier or more streamlined ways to be notified that a patient had sent data?

10. How did you access the PRO data in the EHR?

11. Was there any confusion/uncertainty at any point about accessing survey data?

12. Did you require assistance at any point to access the data?

    A. If YES, if you had questions who did you ask for help?

13. Did you experience any issues while trying to access or review survey data (crashing, freezing, unavailable data)?

Time and Efficiency

14. On the average about how long did it take for you to access and review the survey data?

    Do you have any concerns about the amount of time it took you to access and review patient data?

15. IF INDEPENDENT TIER:

    A. From your perspective, how well did the PRO pilot fit into the existing workflow?

        i. Did it ever interfere with the clinical workflow?

        ii. (If yes) What were the issues?

    B. Were there ever points during the PRO process in which you believe your site could have used additional support?

        i. When?

        ii. In what way?

    C. Do you believe your practice was adequately prepared to collect PRO data as instructed?

    D. Knowing what you know now, would you have done/requested anything different prior to beginning this pilot test?

16. IF PARTIAL SUPPORT TIER:

    A. From your perspective, how well did the PRO pilot fit into the existing workflow?

        i. Did it ever interfere with the clinical workflow?

        ii. (If yes) What were the issues?

i. Were there ever points during the PRO process in which you believe your site could have used additional support? When?

ii. In what way?

    B. Do you believe your practice was adequately prepared to collect PRO data as instructed?

    C. If everything was implemented for you (on the tech side), do you believe your practice has the resources and bandwidth to have (more) independently collected these PRO measures?

    D. Knowing what you know now about the project, would you have done/requested anything different prior to beginning this pilot test?

17. IF FULL SUPPORT TIER:

    A. From your perspective, how well did the PRO pilot fit into the existing workflow?

        i. Did it ever interfere with the clinical workflow?

        ii. (If yes) What were the issues?

    B. Were there ever points during the PRO process in which you believe your site could have used more or less support?

        i. When?

        ii. In what way?

    C. If everything was implemented for you (on the tech side), do you believe your practice has the resources and bandwidth to independently collect these PRO measures?

        i. What would you need to independently collect these PRO measures?

    D. Knowing what you know now about the project, would you have done/requested anything different to beginning this pilot test?

18. ALL TIERS:

    A. Thinking about the overall process of collecting data, sending it to the EHR, being notified by [notification indicated above], and viewing the data—is there anything about this process that works particularly well?

    B. Is there anything about the process that you believe could be improved?

    C. A survey like this could potentially be filled out on in the waiting room or at home before the patient's appointment. Do you have a preference for when patients complete the survey?

        i. Why do you prefer [preference]?

    D. Would you be interested in trending this data over time?

        i. If yes, how often?

Feedback

19. Did you receive any feedback from the front desk staff regarding the PRO survey process?

20. [Independent and partially supported tiers] Did you receive any feedback from the site coordinator regarding the PRO survey process?

21. Did you receive any feedback from patients regarding the PRO survey process?
22. Do you think patients understood the survey content?
23. In your opinion, what kind of impact do the PRO surveys have on the Patient experience (positive, negative, no impact)?

Content (General)

24. What are your thoughts on the content of the survey?

A. Were the questions applicable?

B. Were there any questions /data missing that you would have liked to receive?

25. How easy or difficult was it for you to understand the content/questions in the survey?
    A. If DIFFICULT, how did you resolve your confusion?
    B. If DIFFICULT, what changes would have helped you understand the survey better?

Content (Visual)

26. Is the data presented in a useful/actionable way?
27. Is there anything you would change about the way the data was presented?

Content (Usefulness)

28. From your perspective how valuable is this PRO data?
29. Did the data impact (positively or negatively) your clinical decision making?
    A. If YES, how so?
30. Did the survey have any impact (good or bad) on the conversation between you and your patient during your appointment?

Overall

31. Is there anything else we should know about the PRO app or the process?

Appendix J. Health Information Technology Professional Interview Guide

We are working on a study to learn more about your experience with implementation and integration of the PRO app. We want to get some general feedback and insight from you about the implementation process, and your overall technical perspective.

Name:	
Role:	
Office location:	
Physician(s) supported:	
Tier Allocation(s) (if applicable):	
Specialty:	

Demographics Questions

1. What is your gender?
   A. Male
   B. Female
   C. (Open field)
2. What level of education have you completed?
   A. 8th grade or less
   B. Some high school
   C. High school diploma or GED
   D. Associates degree
   E. Bachelor's degree
   F. Master's degree
   G. Doctoral degree
3. What best describes your essential job function?
   A. Application Developer
   B. Technical Team Lead
   C. Technical Operations Manager

D. Other: (enter)

4. How many years have you been in this role?

A. < 5

B. 5-10

C. 11-15

D. 16-20

E. >21

Categories of Experience

1. Please share your experience with implementation of the PRO application and its integration in to the EHR (this applies to any extent to which you were involved).

Facilitators

2. What worked well during the PRO app implementation process?

Barriers

3. What were the unanticipated challenges to implementation of the PRO application?
4. Were there any institutional barriers to integrating the PRO app to the EHR?
5. Were there any regulatory (anticipated and unanticipated) barriers to app integration?
6. Did you encounter any runtime, unexpected error or failure? If so, can you describe that? If yes, how were these problems resolved?

Support

7. Where there any unforeseen resource shortages during implementation?
8. Where there any resources that you would have liked to have but were unavailable for implementation?
9. Were you able to get support when needed? If yes, how? If no, why not?
    A. If yes, what about the support/communication with [team] worked well?
10. Did you require any external support from the EHR or application vendor?

11. Did you have proper documentation that explained the scope, purpose, and life-cycle of PRO application?

12. Did you receive adequate information about your allocated roles and responsibilities on this project?

13. Did you feel any need for further training or documentation while performing tasks related to PRO application integration or implementation?

Existing EHR System

14. Did the integration of PRO app affect functions or workflow of any other application within the EHR? If yes, please give details.

15. Did you find the PRO application launch and usage to be cohesive and inclusive to existing EHR system?

16. Is there anything in terms of UI flow which might have made PRO application look more native to the her that you worked on?

Data Storage

17. What data storage option would provide the most secure data storage in accordance with MedStar (or other) standards?

18. Did you experience any data security issues? If yes, how did you resolve the data security issues?

19. Do you have any concerns about continued maintenance of data storage and app functionality?

Other

20. Did you see any differences in terms of performance or functionality based on different settings (such as different computer, network, physical location, logged-in user) which was not expected? If yes, can you describe the differences?

21. Do you think PRO application needs a direct link within the application to end-user documentation?

Lessons Learned

22. Are there any lessons learned from implementing the PRO app?

A. If you had to implement a similar app, is there anything you would do differently?

Overall

23. Did you receive any feedback from healthcare providers about their experience with the use of the PRO app and data?

A. Did the healthcare providers experience any barriers to use?

1) Accessing patient data in the EHR

2) Incorporating the app data review in their workflow

24. Did you receive any feedback from the research/technical team throughout the integration process?

25. Are there any suggestions to increase adoption of the app?

26. Is there anything else we should know about the PRO app or the implementation /integration process?

Appendix L. Decline and Failure Codebook

Decline and Failure Codebook	
Decline	Patient level rejection to participate
Phone Issue	Reason for decline related to patient's device or technology barrier
Patient Issue	Reason for decline related to patient having personal or contextual concerns
Informed Decline	Decline occurring after a description of the research study due to general disinterest or barriers.
Immediate Decline	Decline occurring before description of the research study due to undisclosed reasons
Unable to Consent	Inability for patient to provide informed consent to participate
Workflow Breakdown	Inability to complete study due to a technological malfunction, a failed process, or other external barrier outside of staff and patient control
Failed Attempt	Inability to complete study due to a patient-level barrier such as human error or usability issue
Tech	Breakdown or failed attempt centered around a technological malfunction, connectivity error, or other error in which the used technology did not perform as expected
Patient	Breakdown or failed attempt due to human error or other person-level component
Workflow	Breakdown or failed attempt due to a process or timing issue
Staff	Breakdown or failed attempt due to an administrative issue with either the research or clinical staff