Advancing the Collection and Use of Patient-Reported Outcomes through Health Information Technology

FINAL REPORT

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Acknowledgements

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Executive Summary

Introduction and Background

The *Advancing the Collection and Use of Patient-Reported Outcomes through Health Information Technology* project was launched by the Office of the National Coordinator for Health Information Technology (ONC) and the Agency for Healthcare Research and Quality (AHRQ) in 2017.[1,2] This project is part of ONC's portfolio of patient-centered outcomes research (PCOR) projects funded by the PCOR Trust Fund administered by the Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE). The PCOR Trust Fund facilitates coordination of HHS projects aimed at building data capacity for PCOR, which is research "designed to produce new scientific evidence that informs and supports the healthcare decisions of patients, families, and their healthcare providers."[3] This cross-agency project focused on standardizing the collection, exchange, and integration of patient-reported outcome (PRO) data in electronic health record (EHR) systems and other health information technology (IT) solutions to support the electronic sharing of this information.[4,5]

PROs are defined as any report of the status of a patient's health condition coming directly from the patient, without interpretation of the patient's response by a clinician or anyone else.[6] To assess patient symptoms, functioning, and health-related quality of life, PRO data are often collected by questionnaires called instruments or Patient-Reported Outcome Measures (PROMs).[7,8] PROMs are designed to provide a standardized way important clinical information, such as functional status, pain levels, behavioral health risks, and therapeutic effects that generally cannot be captured with objective medical testing.

PRO data, however, are not yet routinely captured electronically or integrated into EHR systems and other health IT solutions. Prior to this project, neither standards nor guidance were available, for the collection and exchange of structured PRO data across health information technology systems. Accessing PRO data in a structured format increases its value and potential use across health systems for research, care delivery, or other purposes such as benchmarking for quality improvement. Health data standards and technology that facilitate the exchange of data such as application programming interfaces (APIs) could fill these needs to support the electronic collection, exchange, and integration of PRO data.[9]

Developing and Pilot Testing the Health Level Seven International® (HL7®) Patient-Reported Outcomes Fast Health Interoperability Resources® (FHIR®) Implementation Guide

A PRO FHIR Implementation Guide was developed during this project to establish a standardized specification, along with API guidance for collecting, exchanging, and integrating PRO data between

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[1] https://www.healthit.gov/topic/scientific-initiatives/pcor/patient-reported-outcomes-through-healthit-pro
[2] https://www.healthit.gov/techlab/ipg/node/4/submission/2541
[3] https://aspe.hhs.gov/patient-centered-outcomes-research-trust-fund-faqs
[4] Electronic health record: See glossary
[5] Patient reported outcome: See glossary
[6] https://www.fda.gov/media/77832/download
[7] Broderick JE, DeWitt EM, Rothrock N, Crane PK, Forrest CB. Advances in Patient-Reported Outcomes: The NIH PROMIS® Measures. EGEMS (Wash DC). 2013;1(1):1015. Published 2013 Aug 2. doi:10.13063/2327-9214.1015. Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4371419/
[8] Patient-Reported Outcome Measures: See glossary
[9] Application programming interface: See glossary

health IT systems in real time.[10,11]

A critical component to successful testing of the implementation guide was partnering with organizations to test the use of FHIR resources and provide constructive feedback. This helped refine the PRO FHIR Implementation Guide by identifying issues with the technical guidance and FHIR, aiding in the development of the technical approach for this project, and providing real world insights about additional considerations organizations should take into account when implementing health IT solutions that support PRO data.

Considerations for Furthering the Collection, Exchange, and Integration of Electronic PRO Data for Healthcare and PCOR

This project demonstrated the value of APIs to support collection, exchange, and integration of PRO data. This was further reinforced by the project led by partner agency AHRQ, which called innovators to leverage the PRO FHIR Implementation Guide and APIs to build better tools to facilitate PRO collection and use. In addition, the data exchange frameworks and technology tested through this project can be leveraged for a wide array of question and response workflows such as clinical quality measurement (CQM), post-acute care service instruments, and surveys for social determinants of health as long as the health measurement instruments (similar to PROMs) for these workflows are available.

However, there is further work that needs to be done to continue to steward and refine the FHIR standard and the PRO FHIR Implementation Guide; standardize health measurement instruments such as PROMs; build standardized APIs to support PRO data exchange; and provide education and outreach to providers and patients regarding the value of PROs to healthcare and research.

Conclusion

Technology and guidance now exist for the electronic, interoperable, and standardized collection, exchange, and integration of PRO data.[12,13,14] The PRO FHIR Implementation Guide has been pilot tested, vetted through Health Level 7 (HL7), and is available to organizations and researchers who are interested in implementing PRO data in real time production environments. [15] The PRO FHIR Implementation Guide is health measure instrument agnostic meaning that in addition to PROMs, it can be used to exchange a wide variety of health measure instruments. Continuing to build on the work conducted by this project can ultimately empower patients, facilitate patient-provider relationships reduce provider burden, and lead to more robust PCOR. The results of this project have shown great promise in supporting the further development of a health IT ecosystem that includes electronic PRO data.

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[10] Fast Health Interoperability Resources: See glossary
[11] Implementation Guide: See glossary
[12] Interoperability: See glossary
[13] http://hl7.org/fhir/us/patient-reported-outcomes/2019May/
[14] https://www.healthit.gov/isa/collection-and-exchange-patient-reported-outcomes
[15] Health Level Seven International: See glossary

Introduction

The Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE) administers the Patient-Centered Outcomes Research Trust Fund (PCORTF) and partners with 12 HHS agencies who lead intradepartmental projects that build data capacity and infrastructure for conducting patient-centered outcomes research (PCOR). PCOR is designed to produce new scientific evidence to inform and support healthcare decisions of patients, families, and their healthcare providers. PCOR focuses on studying the effectiveness of prevention and treatment options with consideration of the preferences, values, and questions patients face when making healthcare choices.[16] The *Advancing the Collection and Use of Patient-Reported Outcomes through Health Information Technology* project is part of a suite of groundbreaking PCOR projects managed by the Office of the National Coordinator for Health Information Technology (ONC) that address challenges faced by PCOR researchers when accessing robust health information collected and stored within electronic health record (EHR) and other health information technology (health IT) systems.[17,18,19,20]

This inter-agency project, between the Agency for Healthcare Research and Quality (AHRQ) and ONC, aimed to standardize the collection, exchange and, integration of PRO data to facilitate interoperability of patient-reported outcomes among EHRs and other health IT.[21] The United States Food and Drug Administration (FDA) defines a patient-reported outcome (PRO) as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."[22,23,24] PROs offer a complementary perspective to clinician assessments, and may provide greater insight into health status, function, symptom burden, adherence, health behaviors, and quality of life. PROs critically inform patient-centered outcomes research and support shared decision making, patient self-management, care planning, goal setting, and goal attainment. Incorporating the patient perspective can lead to better outcomes in prevention, diagnosis, treatment, and long-term care. Clinical researchers have found that including PRO data to measure outcomes has been particularly useful from identifying participants for clinical trials to studying drug efficacy and reasons for patient non-adherence.[25]

Standardizing the collection of PRO data could enable tracking outcomes across providers and health IT systems that are providing comprehensive care delivery or comparing across study populations for PCOR.[26] While there are some EHR systems that are currently able to capture some structured PRO data,

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[16] https://aspe.hhs.gov/patient-centered-outcomes-research-trust-fund

[17] https://www.healthit.gov/topic/scientific-initiatives/pcor/patient-reported-outcomes-through-healthit-pro

[18] https://www.healthit.gov/pcor

[19] Electronic health record: See glossary

[20] https://www.healthit.gov/techlab/ipg/node/4/submission/2541

[21] Interoperability: See glossary

[22] https://www.fda.gov/media/77832/download

[23] https://www.ncbi.nlm.nih.gov/books/NBK338448/

[24] Patient reported outcome: See glossary

[25] Deshpande PR, Rajan S, Sudeepthi BL, Abdul Nazir CP. Patient-reported outcomes: A new era in clinical research. Perspectives in clinical research. 2011;2(4):137–144. Published 2011 Oct 31. doi:10.4103/2229-3485.86879. Accessed at: http://www.picronline.org/article.asp?issn=2229-3485;year=2011;volume=2;issue=4;spage=137;epage=144;aulast=Deshpande

[26] Broderick JE, DeWitt EM, Rothrock N, Crane PK, Forrest CB. Advances in Patient-Reported Outcomes: The NIH PROMIS(®) Measures. EGEMS (Wash DC). 2013;1(1):1015. Published 2013 Aug 2. doi:10.13063/2327-9214.1015. Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4371419/

this information is not commonly collected at the point-of-care. Also, prior to this project, guidance regarding the use of standards for the exchange of structured PRO data was lacking. These gaps limit the ability to use PROs for research or other purposes such as benchmarking for quality improvement. The ability to exchange PRO data is one example of how to complete the feedback loops between patients, clinicians, and researchers as part of a health ecosystem that engages patients and builds the evidence base for improved health outcomes.

Project Goal

The goal of the project was to standardize the collection, exchange, and integration of PRO data which will facilitate interoperability of this data among EHR systems and other health IT solutions. This standardized integration and consistency across products is achieved by using data element and data capture standards. This approach allows PRO assessments to be readily conducted and shared regardless of the EHR or health IT solution used. Standardizing PRO data collection promotes consistency in interpretation, while also enhancing the meaning of results for patient-provider communication and fostering shared decision-making.

As part of this interagency project, ONC developed and tested the Patient-Reported Outcomes Fast Healthcare Interoperability Resources® (FHIR®) Implementation Guide (PRO FHIR Implementation Guide) in partnership with two organizations, patient-centered SCAlable National Network for Effectiveness Research (pSCANNER) and Research Action for Health Network (REACHNet).[27,28,29,30] In parallel, AHRQ worked with MedStar Health to pilot test this implementation guide and hosted a challenge competition to encourage innovators to develop user-friendly patient facing applications that collect PRO data using application programming interfaces (APIs) and FHIR.[31] This report details project activities, findings, and considerations for furthering the standardization of PRO data for healthcare and PCOR.

Background

Patients can provide insight regarding their health that an observer or technology, like devices that collect data passively, may otherwise not provide. PROs are data typically collected after or during the course of a treatment or intervention as directed by a provider or researcher. PROs can include information regarding symptoms, frequency of symptoms, severity of symptoms, the impact of disease or condition on the patient's daily life, and perception and feelings towards the disease or treatment.[32] PRO data are typically collected in a survey format, many times using validated questionnaires, to capture a patient's responses to questions. In contrast, patient-generated health data (PGHD) are health-related data that

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[27] http://hl7.org/fhir/us/patient-reported-outcomes/2019May/

[28] Fast Healthcare Interoperability Resources: See glossary

[29] Implementation Guide: See glossary

[30] https://www.healthit.gov/techlab/ipg/node/4/submission/2541

[31] Application programming interface: See glossary

[32] Deshpande PR, Rajan S, Sudeepthi BL, Abdul Nazir CP. Patient-reported outcomes: A new era in clinical research. Perspectives in clinical research. 2011;2(4):137–144. Published 2011 Oct 31. doi:10.4103/2229-3485.86879. Accessed at: http://www.picronline.org/article.asp?issn=2229-3485;year=2011;volume=2;issue=4;spage=137;epage=144;aulast=Deshpande

can include vitals such as blood pressure or heart rate.[33,34] More recently, one method for collecting PGHD is through wearable devices, such as smart watches, medical devices, or fitness devices. While PGHD can provide useful data and insights, this project focused specifically on the collection, exchange, and integration of PRO data into health IT systems.

PROs "can be measured in absolute terms (e.g., severity of a symptom, sign, or state of a disease) or as a change from a previous measure."[35] Patient-reported outcomes measures (PROMs), which are validated questionnaires, capture PRO data and translate patient-reported symptoms and responses into a numerical value for measurement and analysis.[36] There are a variety of PROMs, also called instruments, available to measure different facets of health and for a variety of health conditions. The National Institutes of Health (NIH) has established the Patient-Reported Outcomes Measurement Information System (PROMIS®), a publicly-available system of highly reliable, precise measures of patient-reported health status for physical, mental and social well-being.[37,38]

PROMs and the resulting PRO data are becoming more prevalent in cases where the quality of life plays an essential role in treatment. In oncology, PROMs have been linked to improved symptom management, enhanced quality of life, and longer survival.[39] Due to the improved outcomes, payers are encouraging providers to incorporate PROMs into the routine course of care, such as in the Medicare Comprehensive Care for Joint Replacement Model, where Medicare is incentivizing payment for collection of PRO data from patients undergoing elective hip and knee replacements at hospitals.[40,41] Not only can the use of PRO data enhance care for patients, but it also has been linked to increased physician satisfaction and reduced burnout by improving physician-patient relationships and symptom comprehension. PROs can also facilitate "conversations that may not otherwise have taken place by allowing sensitive issues to be raised

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[33] Cohen DJ, Keller SR, Hayes GR, Dorr DA, Ash JS, Sittig DF. Integrating Patient-Generated Health Data into Clinical Care Settings or Clinical Decision-Making: Lessons Learned from Project HealthDesign. JMIR human factors, 2016.3(2), e26. Published 2016 Oct 19. doi:10.2196/humanfactors.5919. Accessed at: https://www.ncbi.nlm.nih.gov/pubmed/27760726

[34] Patient-generated health data: See glossary

[35] https://www.fda.gov/media/77832/download

[36] Patient-reported outcomes measures: See glossary

[37] http://www.healthmeasures.net/explore-measurement-systems/promis

[38] Patient-Reported Outcomes Measurement Information System: See glossary

[39] Basch, Ethan. Patient-Reported Outcomes — Harnessing Patients' Voices to Improve Clinical Care. N Engl J Med. 2017.376(2). 105. Published 2017 Jan 12. doi: 10.1056/NEJMp1611252. Accessed at: https://www.nejm.org/doi/full/10.1056/NEJMp1611252

[40] Rotenstein LS, Huckman RS, Wagle NW. Making Patients and Doctors Happier — The Potential of Patient-Reported Outcomes. N Engl J Med 2017; 377:1309-1312. Published 2017 Oct 5. doi:10.1056/NEJMp1707537. Accessed at: https://catalyst.nejm.org/patients-doctors-happier-pro-collection/#references

[41] https://innovation.cms.gov/initiatives/CJR

in systematic ways," such as in cases regarding sexual dysfunction and domestic abuse. [42, 43] Another example is the use of PRO data by the FDA to better evaluate how drugs and medical devices affect how patients feel and function in their daily lives.

While there is promise in the clinical and research uses of PROMs and resulting PRO data, health systems have been slow to utilize their data due to operational barriers such as clinical workflow integration at the point-of-care and technology barriers inhibiting the consistent use of electronic PROMs and resulting data in EHRs and other health IT solutions.[22] Standards did not previously exist to support the exchange of structured PRO data across systems, limiting ability to reuse of this data for research or other purposes such as benchmarking for quality improvement. ONC engaged with the standards development organization throughout this project to ensure that the implementation guide that would be pilot tested for this project was in alignment with the development of the FHIR standard, to set it on a path for approval by Health Level Seven International® (HL7®), and eventual adoption by the health IT developer community.[44]

HL7 Standards Development

HL7 is an American National Standards Institute (ANSI) -accredited organization that host and maintain numerous electronic health data exchange and integration standards that support a variety of use cases dependent on interoperable, electronic health information transactions.

HL7 standards are developed and maintained by members of the healthcare community and include a range of healthcare applications such as EHRs, biomedical research, and security. When a particular standard is created, it must go through a series of ballots before it can be approved and accredited by HL7 and ANSI. There are four stages of ballots: 1) For Comment Only, 2) Draft Standard for Trial Use (DSTU), 3) Informative, and 4) Normative.[45] The balloting process takes place three times per year and adheres to a strict, detailed calendar of events dictated and scheduled by HL7, consisting of pre-ballot content deadlines, voting pool sign-up, voting, and publication timelines if a ballot is approved.

The FHIR Standard

FHIR is an HL7 standard envisioned to be the global standard for exchanging healthcare information electronically. Healthcare data represented in FHIR format are easily human-readable and highly structured for computational use. FHIR consists of "resources," where a single resource represents a single healthcare concept. For example, "Patient" is a FHIR resource, as is a "CarePlan," a "Questionnaire," and a "Condition." One might think of a resource as a representation of a paper form. Each form contains information (clinical, administrative, financial, etc.) for capture and sharing. Currently there are over 140 FHIR resources defined across the gamut of healthcare in FHIR Release 4 (FHIR R4).[46] The FHIR standard has evolved through several versions. The most recent version, R4, is the first version balloted that

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[42] Rotenstein LS, Huckman RS, Wagle NW. Making Patients and Doctors Happier — The Potential of Patient-Reported Outcomes. N Engl J Med 2017; 377:1309-1312. Published 2017 Oct 5. doi:10.1056/NEJMp1707537. Accessed at: https://catalyst.nejm.org/patients-doctors-happier-pro-collection/#references

[43] Deshpande PR, Rajan S, Sudeepthi BL, Abdul Nazir CP. Patient-reported outcomes: A new era in clinical research. Perspectives in clinical research. 2011;2(4):137–144. Published 2011 Oct 31. doi:10.4103/2229-3485.86879. Accessed at: http://www.picronline.org/article.asp?issn=2229-3485;year=2011;volume=2;issue=4;spage=137;epage=144;aulast=Deshpande

[44] Health Level Seven International: See glossary

[45] https://www.hl7.org/documentcenter/public/procedures/HL7Voting.pdf

[46] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=491

contains Normative resources, and was the version of FHIR that was used to develop the PRO FHIR Implementation Guide under this project.

FHIR resources attempt to model the most common attributes or healthcare data, but try not to be too prescriptive so as to preclude their use in a wide variety of domains or contexts.[47] However, in every healthcare environment there are likely data elements and other constraints that are unique to its field. For this reason, FHIR resources are designed to be easily and formally extensible from the start. For example, a resource definition, such as "Patient" may be "extended" to accommodate the need to record the concept of "consent." To fulfill this requirement, a developer may define an extension to the resource to contain the patient's consent agreement.[48] Figure 1 illustrates the basic form of the Questionnaire resource in Extensible Markup Language (XML) and includes an extension as an example.

HL7 FHIR Implementation Guides

Among the many products balloted within HL7 are implementation guides. An implementation guide is a document instructing developers on how to adhere to a particular technical standard and provides guidance regarding the best practices for building standardized systems that support interoperability. Typical items found in implementation guides are data structures; specific application programming methods for retrieving, creating, and updating data; constraint and conformant rules; and finally, general guidance and references aiding in the development of the system. Implementation guides are an important tool in supporting the implementation and adoption of standards.

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[47] Domain: See glossary
[48] https://www.hl7.org/fhir/extensibility-examples.html

```
<Questionnaire xmlns="http://hl7.org/fhir">
 <id value="3141"/>
 <url value="http://hl7.org/fhir/Questionnaire/3141"/>
 <title value="Cancer Quality Forum Questionnaire 2012"/>
 <status value="draft"/>
 <subjectType value="Patient"/>
 <date value="2012-01"/>
 <text>
  <status value="generated"/>
  <div xmlns="http://www.w3.org/1999/xhtml">
   <pre>
      1.Comorbidity?
       1.1 Cardial Comorbidity
        1.1.1 Angina?
        1.1.2 MI?
       1.2 Vascular Comorbidity?
       ...
      Histopathology
      Abdominal
        pT category?
       ...
   </pre>
  </div>
 </text>
 <item>
  <linkId value="1"/>
  <code>
   <system value="http://example.org/system/code/sections"/>
   <code value="COMORBIDITY"/>
  </code>
  <type value="group"/>
  <item>
   <linkId value="1.1"/>
   <code>
    <system value="http://example.org/system/code/questions"/>
    <code value="COMORB"/>
   </code>
   <prefix value="1"/>
   <type value="choice"/>
   <extension url="http://www.example.org/questionnaire-question-extension/order>
     <valueCode order="1"/>
   </extension>
   <answerValueSet value="http://hl7.org/fhir/ValueSet/yesnodontknow"/>
  </item>
  ...
 </item>
 ...
```

Meta Data

Human Readable Summary

Standard Data for the Resource...
Questionnaire Data:
    Questions, Answer Options, Groupings ,etc.
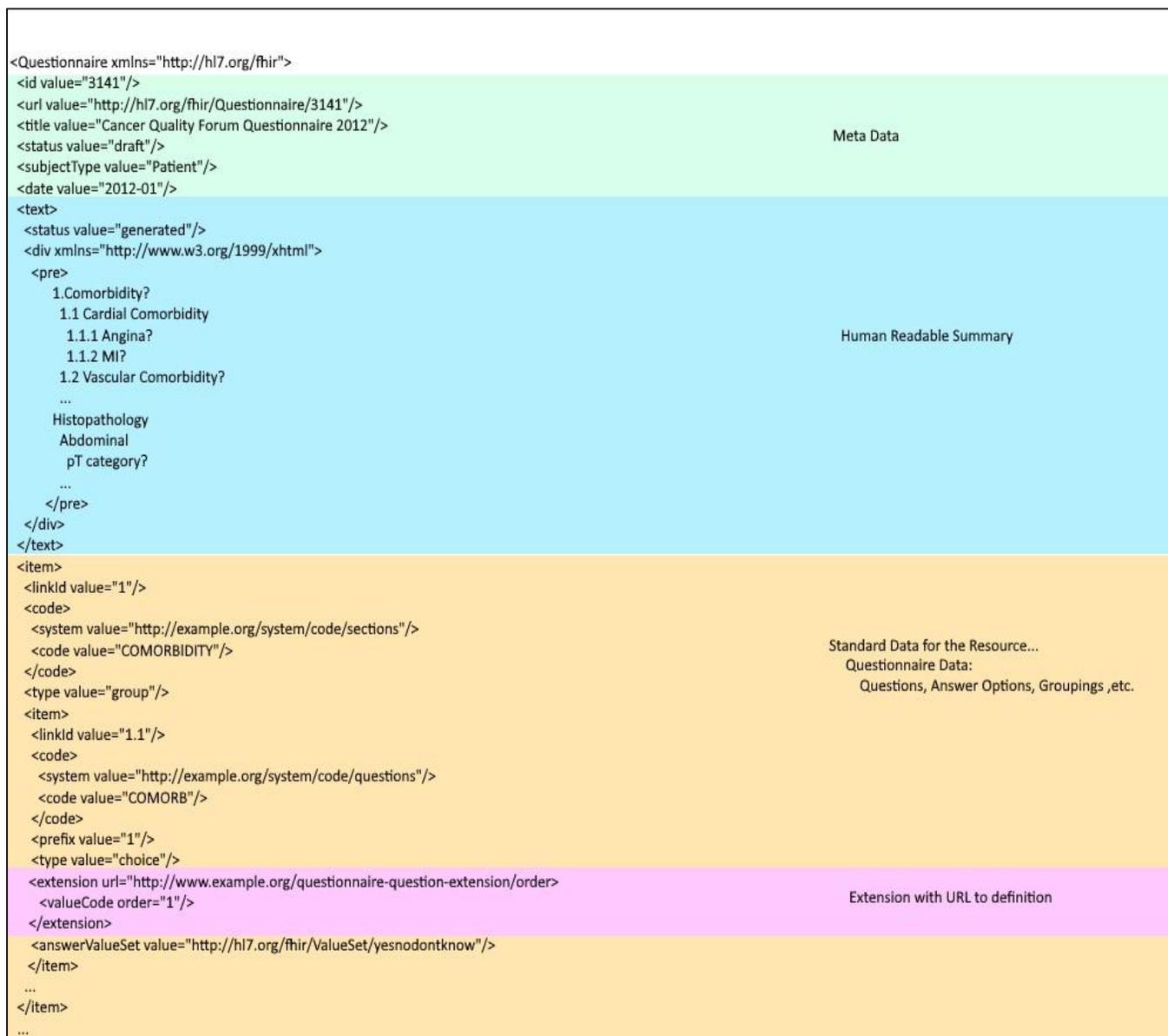
Extension with URL to definition

Figure 1: The Basic Form of a PRO FHIR Questionnaire Resource

Environmental Scan

The project undertook the following activities to achieve its goal:

- Environmental scan of the PROM and the PRO data captured by PROMs
- Development of PRO FHIR Implementation Guide specifications
- Testing of PRO FHIR Implementation Guide

An environmental scan was conducted to evaluate the current use of PROs, specifically physical function, and related technologies in clinical and research settings. This activity was also used to identify operational and technical gaps and pain points associated with supporting electronic capture and the use of PRO data within the healthcare industry and inform the next steps of the project. The environmental scan consisted of a literature review and unstructured discussions with industry stakeholders with relevant technical experience with PROMs, PRO data, and PRO software/platforms (i.e., clinicians, health IT developers, researchers, PRO software developers). The environmental scan focused on the current state of PRO data collection, technical processes, types of PRO measures, PRO data sharing, PRO platform usage, EHR integration, use of computer adaptive testing (CAT), gaps and challenges encountered, and stakeholder recommendations.[49]

Several themes emerged from the environmental scan findings that influenced subsequent project activities. First, participants reported that PROMs can have an immediate impact on provider decisions and patient care. Clinicians and researchers indicated PROMs facilitated more in-depth conversations with their patients and participants regarding quality of life symptoms. This mainly resulted from the need to explain the PROM and subsequent receipt of the collected responses. Interviewees noted that patients perceived and received improved quality of care which can result in better outcomes.

Second, participants universally described constraints to PRO data collection in the clinical and research settings. Due to significant variations in the use of PROMs and their implementation, the collection and sharing of PRO data to support patient care was difficult. In many cases, a customized third-party interface, maintained in-house, was used to collect and send the PRO data back to the clinician or researcher. This resulted in additional costs being incurred to integrate and maintain a separate health IT solution with the EHR. There were few instances where an EHR permitted write access to a record from applications that collect data from the patient portal. Organizations wanting to implement PRO workflows had to host disease or condition specific repositories. While these repositories may be available to organizations participating in multi-organizational research efforts, this type of PRO data collection would typically leverage a proprietary interface, again resulting in additional costs. Minimal integrations existed between their third-party or homegrown applications to their EHR systems.

Third, participants identified many PROMs noting differing levels of importance but were unable to identify a single PROM that should be prioritized for standardization. Further exploration discovered a majority of providers and researchers use a variety of over 300 PROMIS measures from HealthMeasures.[50]

Fourth, participants articulated that it is essential to further standardize the electronic collection, exchange, and integration of PRO data into EHRs and research data systems. The lack of common data elements representing the questions and responses (value sets) within PROMs make it challenging to integrate data into EHRs. Interviewees also noted that there is a level of complexity with PROMs that most content standards cannot currently support since some questionnaires have interwoven logic within the answer choices that are difficult to represent with current exchange standards. Interviewees also noted that real world implementation of standards is not always consistent which causes interoperability issues despite the availability of a standard.

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[49] Computer adaptive testing: See glossary
[50] www.healthmeasures.net

Lastly, participants communicated the possibility of using emerging standards to help advance the electronic capture of PRO data such as HL7 FHIR and SMART on FHIR.[51,52] Overall, they suggested that guidance paired with incentives and common metrics on universal domains could lead to more standardized reporting and greater utilization of PROs.

Other key findings that were identified describe other significant factors:

- Typically, the primary driver for collecting PRO data was to improve patient care and quality of care while the secondary driver was to conduct and support institutional research activities.
- Data collection workflows often included in-person administration of PROMs at the point-of-care using an electronic device. A second common process was administering a questionnaire through a patient portal or a web interface accessible via a link emailed to a patient.
- Most participants were supportive of CAT technology and reported the administration of these PROMs through the HealthMeasures Assessment Center. Though CAT technology is available, the implementation of the technology is limited due to the high cost when used on electronic devices.

Development and Balloting of the PRO FHIR Implementation Guide
PROM Selection
The environmental scan revealed that a variety of PROMs were in use by clinicians and researchers. Therefore, there was not one specific PROM of broad interest that surfaced as a priority for standardization in this project. Federal stakeholders at AHRQ and ONC agreed to select the CAT-enabled PROMIS Physical Function v2.0 questionnaire.[53] This alignment meant that this questionnaire would also be leveraged for the Step Up App Challenge conducted by AHRQ as part of their effort on this project.[54]

Scope
A PROM Life Cycle (Figure 3) illustration was created to depict the activities from the entire PROM workflow in the real world. The technical areas that could be considered for standardization as part of this project include:

- Creation and publishing of PROMs into a repository for use by PRO applications
- PROM administration within EHRs and other health IT systems
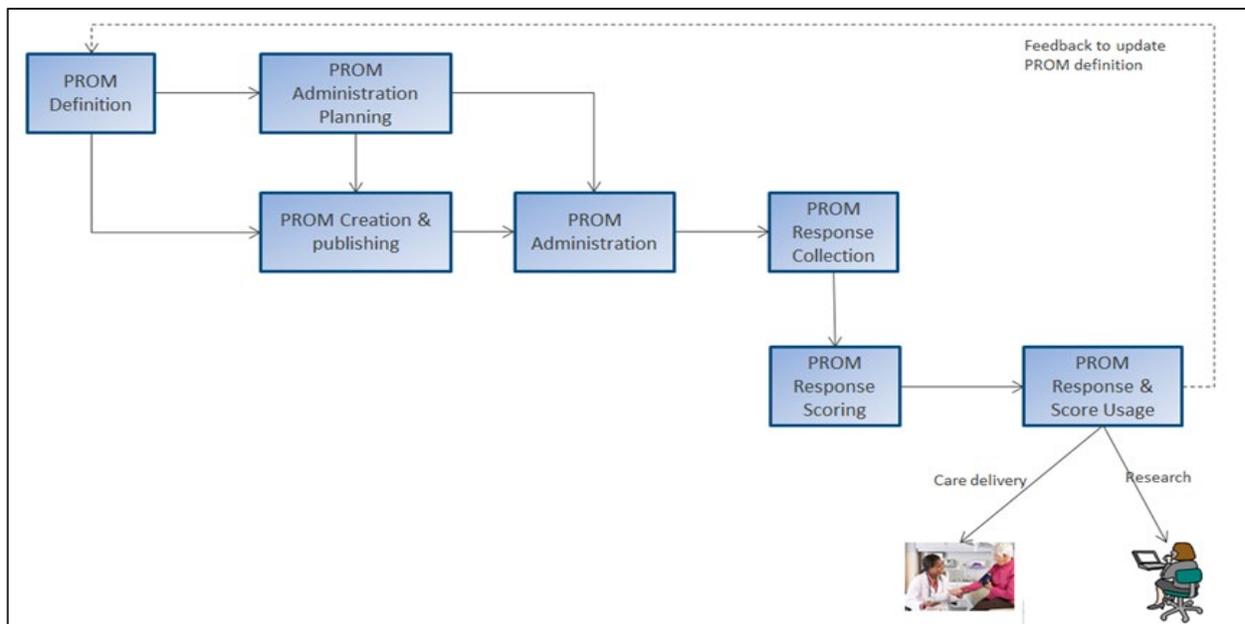- Collection and storage of PROM responses

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[51] https://smarthealthit.org/
[52] SMART on FHIR: See glossary
[53] http://www.healthmeasures.net/administrator/components/com_instruments/uploads/PROMIS%20Bank%20v2.0%20-%20Physical%20Function%20-%2011-29-2016.pdf
[54] https://www.ahrq.gov/stepupappchallenge/index.html

Figure 2: PROM Life Cycle

To fully test a PRO system, the functionality of administering PRO questionnaires had to be included in the scope of this project despite FHIR only being able to support portions of that process. FHIR resources (and profiles) are data representations. The FHIR standard does not dictate how the data in those resources are presented to a user or analyzed. While the FHIR PRO Implementation Guide provides an overview of the entire PROM life cycle, it does not provide guidance regarding the workflows related to the creation and administration of PROMs or how to score results. It provides technical guidance to enable the ability to retrieve PROMs that have been created and published, transmit them electronically, populate responses or fields, include scores, and return those results. The implementation guide provides guidance on how to interact with the external health IT systems or resources, such as the HealthMeasures Assessment Center, that provide the functionality that lies outside of the scope of the PRO FHIR Implementation Guide.

The Abstract Model (Figure 4) was developed to outline that guidance and illustrate the three data flow (DF) options and actors involved within PROM Life Cycle activities. The three main categories of actors include the 1) PRO Instrument Repository, 2) EHR or Other Health IT System, and 3) External PRO Systems. Each actor in the abstract model has specific capabilities requiring standardization. Beginning with standardization of the PROM creation and publishing process, the project drew on the knowledge and lessons learned from past ONC-led and PCORT TF supported initiatives such as Structured Data Capture (SDC). [55,56] SDC is a framework for user-friendly infrastructure that enables the use of forms and templates to capture patient-level data collected within an EHR, populate those forms, and transmit the structured data among health IT systems. SDC can be applied to retrieve existing and vetted forms, like the PROMIS Physical Function V2.0, which can in turn set a foundation for semantically consistent common data elements (CDE).[57] This supports initial interoperability and can also support consistency in interpretation,

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[55] http://hl7.org/fhir/uv/sdc/2018Sep/index.html
[56] Structured Data Capture: See glossary
[57] Common data element: See glossary

offering clarity regarding the meaning of results for patients and providers, and fostering shared decision-making. To facilitate movement of the structured data in these forms, APIs, which are defined as a set of protocols and tools for building software applications for data exchange, were identified as being beneficial for the development of future tools and resources that facilitate the collection, exchange and integration of PRO data into health IT systems. The SMART on FHIR specification was selected because it is a publicly available and free, standards-based API.[58]
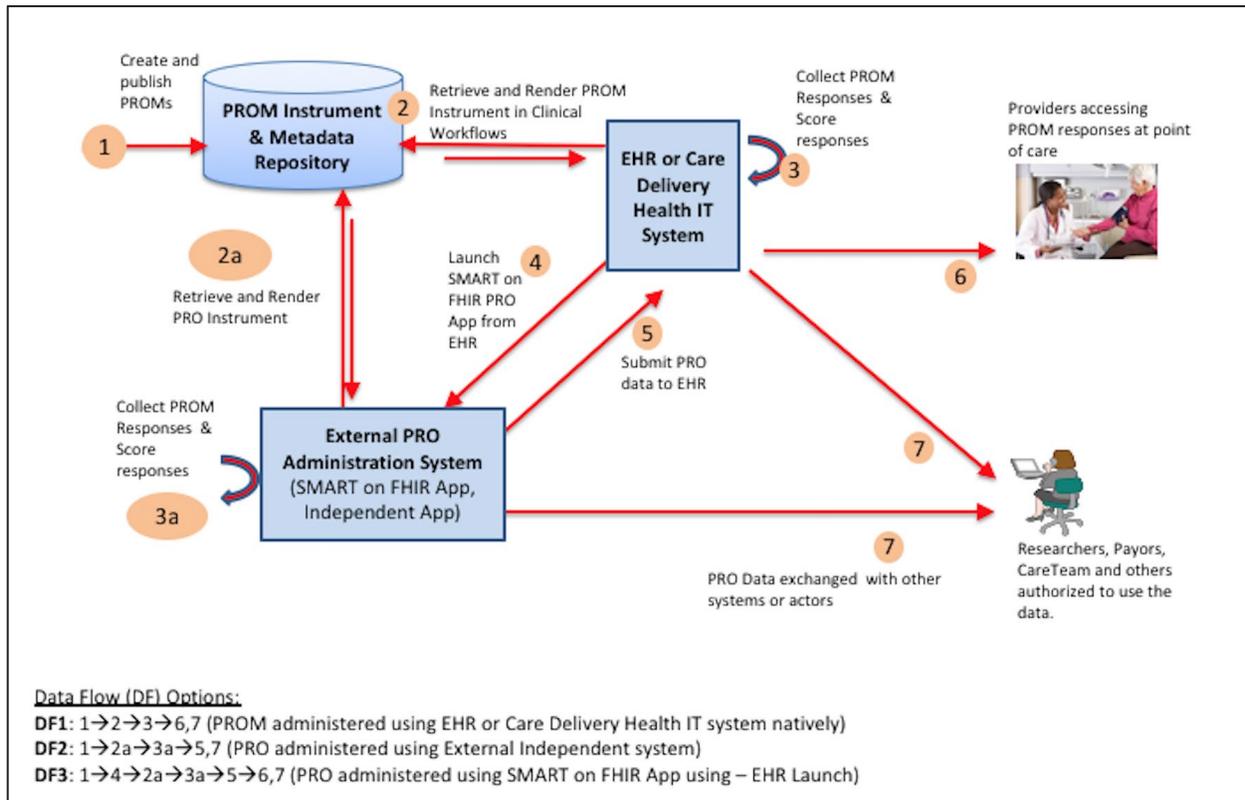

Figure 3: Abstract Model

Development

The basic building blocks of the PRO FHIR Implementation Guide were built upon the Questionnaire and QuestionnaireResponse resources as profiled in the SDC Implementation Guide. The questionnaire format used by PROMs can be mapped to the Questionnaire resource which can represent a list of questions and answer options for each question. [59] Responses to those questions can be mapped to the QuestionnaireResponse resource, which represents the results or user answers to the associated questionnaire. [60] The specifications outlined within the PRO FHIR Implementation Guide are recommended for the administration of the PROMIS Physical Function v2 Questionnaire long form using FHIR Questionnaire and QuestionnaireResponse resources as well as the short form of the questionnaire

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[58] http://docs.smarthealthit.org/authorization/
[59] http://build.fhir.org/ig/HL7/sdc/sdc-questionnaire.html
[60] http://build.fhir.org/ig/HL7/sdc/sdc-questionnaireresponse.html

via the Computer Adaptive Testing (CAT) functionality using FHIR Adaptive Questionnaire and Adaptive QuestionnaireResponse resources.

In addition to using the guidance from the SDC FHIR Implementation Guide, the PRO FHIR Implementation Guide leverages the FHIR US Core Implementation Guide and profiles.[61] Alignment with the SDC and FHIR US Core Implementation Guides limits redundancies within FHIR resources. Although these resources were nearly perfectly suited for representing PRO data, there were limitations of the standard Questionnaire and QuestionnaireResponse resources that emerged as development of the implementation guide proceeded. Extensions to these resources were required to properly represent the elements that are specific to PROs. FHIR's core architecture of resources only includes structures that will be used by the majority of implementers. The ability to add extensions in FHIR resources enables them to accurately model unique use cases. The PRO FHIR Implementation Guide encourages the use of existing resources to the fullest extent possible and limit the creation of extensions only when deemed absolutely necessary to support interoperability. The PRO FHIR Implementation Guide extends the SDC profiles as follows:

- SDC Questionnaire profile/ SDC Adaptive Questionnaire
    - Questionnaire extended with a 'Question Order' element indicating the order in which questions are presented to the user.
    - Questionnaire extended with a 'Question Type' element extending the types of questions in a Questionnaire to include multiple-choice with multiple selections enabled.
- SDC QuestionnaireResponse profile / SDC Adaptive QuestionnaireResponse
    - QuestionnaireResponse extended with a 'Score' element storing the numeric score calculated as a PRO questionnaire is administered to a patient.
    - QuestionnaireResponse extended with a 'Standard Deviation' element storing the standard deviation of the calculated questionnaire score described above.

Balloting the PRO FHIR Implementation Guide

The team worked with HL7 to ballot the PRO FHIR Implementation Guide for comments in September 2018. This occurred part way through the pilot testing cycle because it was important to demonstrate that this implementation guide was directly informed by pilot organization findings. During this process, interested stakeholders provided their feedback and comments about the PRO FHIR Implementation Guide's technical soundness. The PRO FHIR Implementation Guide version 1.0 was approved as a Standard for Trial Use (STU) through the HL7 balloting process and procedures in May 2019. In August 2019, the implementation guide was submitted for publication and will be available as an HL7 STU publication from September 2019 to September 2020.[62] The submission for trial use is normally open for one to two years and followed by one year or less for completion of the normative ballot period. With continued support from the HL7 community, the PRO FHIR Implementation Guide could go through the submission for Normative balloting in August 2020 via a process intended to validate the protocol in preparation for approval by the American National Standards Institute (ANSI) as an American National Standard. The approval process is much more rigorous and restrictive for the Normative process, with a 75 percent affirmative vote required for approval and at least 60 percent of the HL7 members in the ballot pool (i.e., work group) participation in the voting. The consensus group will require the implementation guide be

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[61] https://www.hl7.org/fhir/us/core/

maintained and stewarded to track maturity of the standard. Further information on the HL7 balloting process can be found on the HL7 FHIR website.

Pilot Testing the PRO FHIR Implementation Guide

Approach

To guide the development of the implementation guide and to ensure its reflection and applicability to real-world conditions regarding the capture, exchange, and integration of PRO data, two independent organizations were engaged to conduct pilot testing. Each pilot organization had to meet certain criteria to participate. This included having appropriate established technical and administrative infrastructure to test the technical specifications (e.g., CAT functionality) and having FHIR infrastructure in place (e.g., FHIR Server). The organizations were also experienced in the administration of PROMs and collection of resulting PRO data. Two organizations participated:

1. patient-centered SCAlable National Network for Effectiveness Research (pSCANNER) at the University of Southern California (USC) was established in April 2014 and was funded by the Patient-Centered Outcomes Research Institute (PCORI). They are a stakeholder-governed federated network utilizing a distributed, service-oriented architecture to integrate data from three existing networks covering over 24 million patients. pSCANNER is one of 11 clinical data research networks and one of the nine project sites working with Northwestern University through the Improving Patient-Reported Outcomes Data for Research Through Seamless Integration of the PROMIS Toolkit into EHR Workflows Project. pSCANNER had existing experience with the Functional Status & Global Health measurement instruments.
2. Research Action for Health Network (REACHnet) at the Louisiana Public Health Institute (LPHI) is a PCORI-funded clinical data research network (CDRN) of health systems containing clinical records for more than 5 million patients in Louisiana and Texas. Launched in March 2014, REACHnet is a partnership between the Louisiana Public Health Institute, Ochsner Health System, Partnership for Achieving Total Health (PATH), Louisiana State University, Pennington Biomedical Research Center, Tulane University, Baylor Scott & White Health, and University Medical Center. REACHnet had existing experience with the PACIC11 instrument.

The participating organizations were tasked with implementing a FHIR-based version of their current use of PROMs using guidance from the draft PRO FHIR Implementation Guide and provide feedback as it was developed. Roadblocks and other issues encountered by the pilot projects during the process advised and guided the development of the IG and are summarized in this report.

Pilot testing was divided into three development sprints as can be seen in Figure 5 conducted from February 2018 to May 2019, with each sprint lasting between three to six months in duration. Each sprint cycle consisted of the pilot organizations:

- Identifying gaps in the technical specifications of the PRO FHIR Implementation Guide and providing suggestions for improvement
- Summarizing challenges and successes related to implementing the technical specifications
- Implementing workflow and administrative process to support testing

At the end of each sprint, each organization demonstrated their progress of development and implementation within their respective ecosystems and workflows in real time. In addition to these pilot-

tests, a parallel project, sponsored by project partner AHRQ, also tested the specifications at Medstar Health and contributed their feedback to the PRO FHIR Implementation Guide. The specifications created for this project also supported an effort by AHRQ to incent the development of patient-focused applications that use APIs for PRO collection, as developers were instructed to use the PRO FHIR Implementation Guide. Based on feedback from development sprints and feedback received from AHRQ, the draft implementation guide would be updated and shared with the pilot organizations for use during the following sprint.

Sprint 1 April – July 2018	Sprint 2 July – November 2018	Sprint 3 December 2018 – May 2019
• Pilot Environment: Controlled/Sandbox • Measure: Any that are currently approved • Data does not go into EHR	• Pilot Environment: Pre-production • Measure: Physical Function v2.0 • Use EHR for data exchange if possible	• Pilot Environment: Production • Measure: Physical Function v2.0 and Pain Scale • Use EHR for data exchange if possible

Figure 4: Sprint Timelines and Targets

Pilot Project Overviews
pSCANNER
The pSCANNER development team (in a partnership between the NIH and a coalition of nine universities, led by Northwestern University) built a prototype SMART on FHIR application (EASI-PRO) to administer PROMs.[63] The software uses the Assessment Center API to access the selected PROM. Unlike REACHnet's strategy of using the Assessment Center API to retrieve and locally store PROMs within their internal FHIR server, pSCANNER's implementation consists of using the Assessment Center API in real time. This implementation demonstrated a process (Figure 6) to fetch PROMs from the Assessment Center when ordered by the clinician, and then have the response data sent to the Assessment Center where the scores are calculated and results are sent back to the clinician in real time.

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[63] https://taggs.hhs.gov/Detail/AwardDetail?arg_AwardNum=U01TR001806&arg_ProgOfficeCode=264
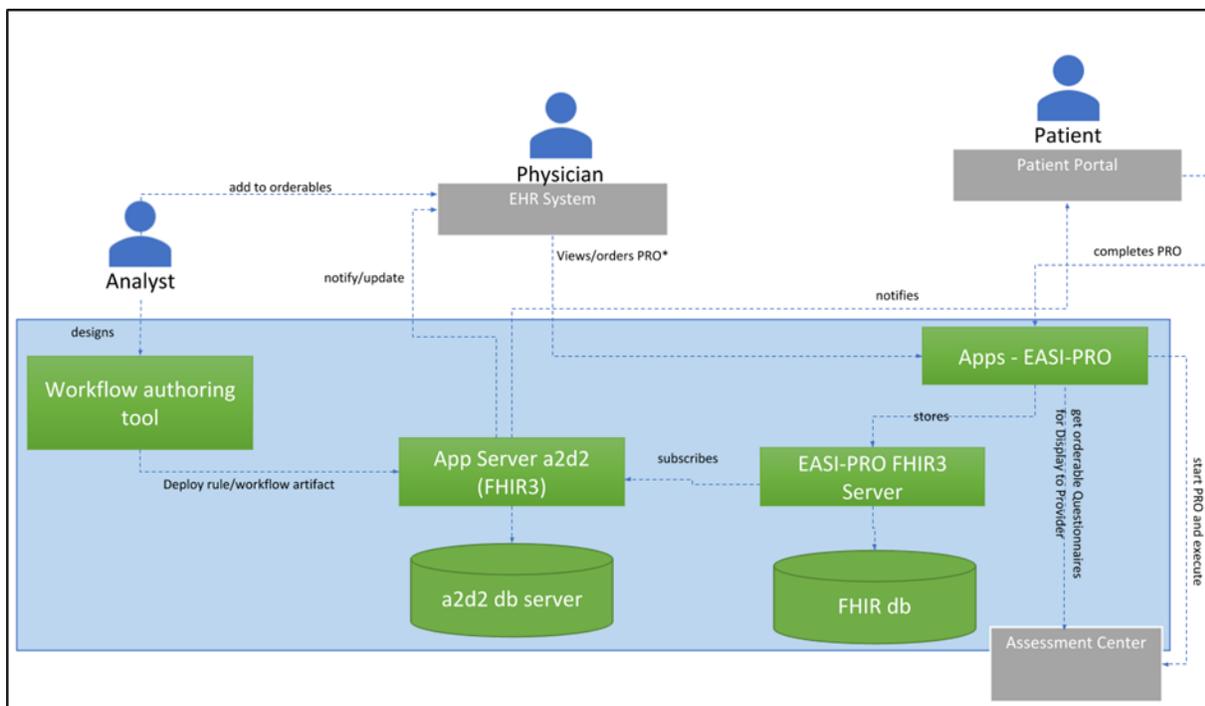
Figure 5: pSCANNER Implementation Approach

REACHnet

Figure 7 outlines REACHnet's ecosystem which leverages a tablet-based system among its clinic sites. The tablets employ a platform called 'Health in Our Hands' (HiOH) that is connected to a clinical workflow definition tool 'Command Center.' The 'Command Center' creates the workflow defined by a study coordinator using various settings in the software and determines which patient is administered a PROM via the tablet. REACHnet enhanced their system by developing and implementing a FHIR server and FHIR loader module to map PROMs sourced from the Assessment Center and Lime Survey, a custom survey generation tool, as FHIR resources and load them into a local FHIR server. The PROMs are fetched from the local FHIR server via an android OS-based app created to render and administer the PROMs to patients and collect their responses on tablets.
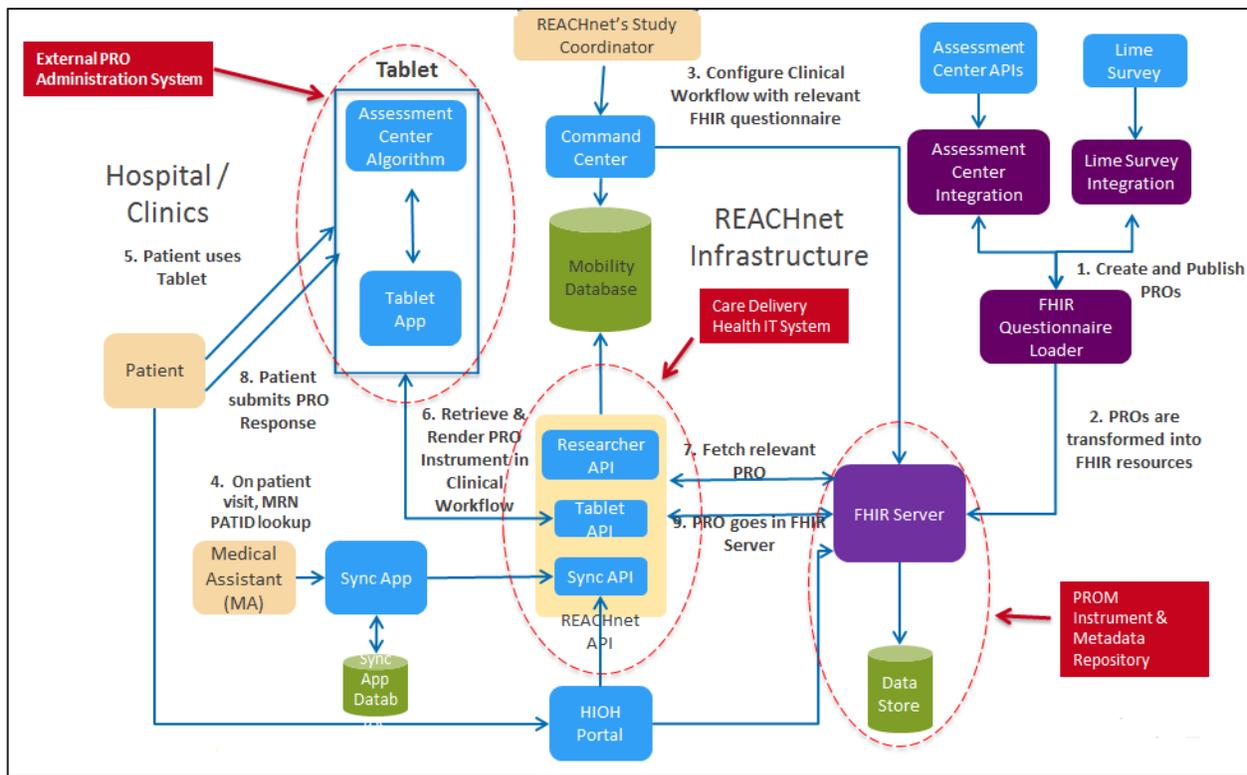
Figure 6: REACHnet Implementation Approach

Summary of Pilot Results

Pilot organizations successfully tested the ability of the technical specifications of the PRO FHIR Implementation Guide to support collection of PRO data using and exchanging PROMs although using different processes. Throughout the iterative, sprint-based approach, lessons and implementation experiences were captured as the pilot organizations expanded their capabilities to collect, exchange, and integrate PRO data in the operational and technical realms.

REACHnet leveraged their home-grown tablet-based system, called Health in Our Hands (HiOH), to administer a PROM and collect PRO data. Their pilot testing used existing workflows and their testing did not include integration with an EHR. Having separate systems for the collection of PRO data is common. REACHnet successfully demonstrated the use of standards to support current workflows. This is valuable for organizations wanting to collect PRO data but who have encountered challenges such as needing additional resources that are currently required to fully integrate third party systems with EHRs or who have a need for this type of workflow. In contrast, pSCANNER created a SMART on FHIR app that was integrated with an EHR to administer PROMs, and collect and store PRO data. This approach demonstrated how standards can be used to support the collection, exchange, and integration into the EHR, facilitating the use of PRO data for healthcare delivery. As both pilot organizations are clinical research networks, both approaches demonstrated the use FHIR to support the availability of PRO data for research.

To retrieve PROMs, both pilot organizations engaged the Assessment Center in their implementation efforts. Before this project, the Assessment Center provided PROMs represented in a proprietary data

format. In a separate effort that coincided with this project, the Assessment Center created separate FHIR-enabled endpoints in their system to return PROMs represented in FHIR Questionnaire format as outlined in the FHIR PRO FHIR Implementation Guide. This was a substantial and extremely beneficial capability taken on by the Assessment Center which further demonstrated the utility of using a standard format for the transfer of healthcare data. REACHnet determined that they would locally host the PROMs that were used for testing while pSCANNER opted to interact with the Assessment Center in real time to retrieve PROMs as needed. Since REACHnet leveraged their internal system, responses were stored within HiOH. In contrast pSCANNER received and stored responses via the EASI-PRO app. Table 1 shows a summary comparison of the pilot testing capabilities. The information regarding pilot testing conducted by MedStar Health which is included as an additional example. However, since MedStar Health's pilot project was overseen by AHRQ, the details regarding that pilot testing will be discussed in the final report produced by AHRQ.

Table 1: Comparison of Pilot Testing Capabilities

	REACHnet	pSCANNER	MedStar Health
PRO Measures (PROMs) Implemented	PACIC11 & PROMIS Physical Function v2.0	PROMIS Physical Function v2.0	PROMIS Physical Function v2.0
CAT Enabled	Yes	Yes	Yes
Capability to represent measure along with any metadata as FHIR Questionnaire	Yes	Yes	Yes
Capability to represent responses along with any metadata in FHIR Questionnaire Response	Yes	Yes	Yes
PROM Administration	Via local repository using API provided by Assessment Center	Via interaction directly with Assessment Center	Via interaction directly with Assessment Center
Trigger to administer PROMs	'Command Center' tool allows to select a cohort of patients to administer select PROMs	Clinician can order specific PROMs within EHR for a specific patient	Administration Dashboard allows staff to administer PROMs

	REACHnet	pSCANNER	MedStar Health
Method to deliver PROM	Tablet app running within their Health in Our Hands (HiOH) platform	SMART on FHIR app (EASI-PRO)	SMART on FHIR App (OBERD)
Integration with EHR	Responses stored within HiOH ecosystem	Responses delivered to CERNER via FHIR Document resource	In-situ EHR provider facing visualization

Lessons Learned from Pilot Testing

Health IT Developer Support for Integration of Clinical PRO Workflows

Although health IT developers' support for FHIR is increasing, the level of support available to participating organizations emerged as an issue during pilot testing. Moreover, the varying stages of implementation of different FHIR versions (STU 2, 3 or R4) impeded either pilot site from successfully testing in a production environment. One such example of these issues and limitations was evident with the request from clinicians to receive notifications within their EHR when PROM instruments were completed by patients. The creation of a SMART on FHIR App was based on the FHIR R4 version, but it was limited in its capabilities due to the EHR system only supporting a HL7 v2 platform. Two middleware solutions were created to support the clinician requirements as a workaround for lack of support for specific FHIR resources and issues with backwards compatibility. [64] The first converted the FHIR Communication resource for a patient message to an EHR portal message/email. The second middleware solution created a FHIR DocumentReference resource from a QuestionnaireResponse resource (which was not supported by the EHR) to trigger a rule within the EHR that sends a notification of a completed PROM. The established value of PRO data was enough to spur the pilot organizations to develop the necessary temporary solutions despite the additional time, capital, and resources.

Thoroughly Evaluate Processes and Ecosystem

Developers should thoroughly evaluate and test the ramifications of any changes being considered within their ecosystem or processes before going into production environments. These changes can include upgrading their current ecosystem or adding features for PRO administration outside of those listed in the PRO FHIR Implementation Guide. Although changes can add additional functionality, it could also result in disabling others. A thorough evaluation should include considering privacy, security, and interoperability issues. Understandably, testing a variety of processes and data flows can be challenging. Pilot test participants found that a sandbox environment can aid developers conduct data flow and API testing under various conditions to improve and understand the capabilities of the APIs and FHIR profiles.

Provider Support for the Use of PROMs

Obtaining provider participation in the collection of PRO data can be greatly increased if the PROMs can also provide information that helps them make clinical decisions (e.g., pain management for oncologists).

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[64] Middleware: See glossary

Clinical decision support can be improved by making data accessible to providers in real time. Real time data integrated within an EHR can be a valuable resource to providers in providing an impetus to collect PRO data. Increased support for PRO data availability in EHRs may better demonstrate the value of PROs via better patient care results facilitation of patient-provider relationships. Providers that see the value of PROs to their clinical practice can help champion implementation in production clinical environments.

Clinical providers have varying workflow preferences or needs. Additionally, the same PROM may be used multiple ways with some organizations using a PROM to collect pre-visit PRO data, another using the same form to collect post-visit PRO data, and a third conducting data collection at both times. This should be taken into account when considering the implementation of PROMs. For example, while the PROMIS Physical Function PROM was selected for this project, the pilot organizations noted that while testing the use of this PROM could be useful for establishing some technical infrastructure and capabilities, it was not widely used or called for by all of their providers. This can limit initial support for the implementation of PROs. Therefore, the design of the workflow in the collection of PRO data should be comprehensive and adaptable so that it can be leveraged in various clinical settings to increase the potential of adoption of PROs and satisfy the needs of a wider array of provider needs.

Patient-Reported Outcome Measure Standardization

PROMs are created by a variety of organizations (e.g., REDcap, LimeSurvey, PROMIS), each using their own architecture and formats (e.g., XML, Java, JavaScript). The absence of standardization among these organizations that create PROMs results in interoperability issues. Adoption of standards, like FHIR, among these organizations could help overcome those issues and may even increase use of PROMs. This benefit was experienced by the pilot participants when the PROMIS data elements that were mapped to FHIR data elements in the Questionnaire and QuestionnaireResponse resources became available. This allowed for any FHIR based ecosystem to administer PROMIS PROMs as well as collect and exchange the PRO data.

PROM usage is most effective when the collected data is turned into a numerical score that can be used by providers and researchers. This activity is called scoring. Scoring of a PROM can vary based on the PROM itself and the organization using the PROM. PROM administration and scoring can vary depending on the clinical workflow. Workflows can vary depending on the time the clinician prefers to administer the PRO instrument. Some providers prefer to collect pre-visit PRO data, administering the PRO instrument to a patient before their clinical visit to gather insight into the reason for their visit. Alternatively, other providers will collect post-visit PRO data to determine how a patient is feeling or performing after a procedure (e.g., total knee replacement surgery, cardiac stent). Also, the scoring can vary based on the measure as well as how different organizations use and validate the difference in outcomes pre- or post- intervention. The scores for each PROM administered is a critical part of the PRO data collection before its intended usage. The representation of the PRO scores and making these scores available in a standardized manner will help improve the overall usage of PROMs. Open source documentation and licensing of the scoring algorithms is needed to help improve the interoperable adoption of PRO systems and workflows. This activity will require multi-stakeholder collaboration, similar to measure definition activities, and will require consensus amongst subject matter experts with various PRO domains.

Considerations for Furthering the Collection, Exchange, and Integration of Electronic PRO Data for Healthcare and PCOR

Considerations for Implementing PRO Data Flows

This project highlighted how the HL7 FHIR standard can support the use of PROMs to collect, exchange, and integrate PRO data into health IT systems. The FHIR-based implementation guidance developed as part of this project proved implementable across various EHRs, applications, and workflows. The flexibility of the standard, coupled with standardized PROMs, allowed for the interoperable exchange of metadata, responses, and scores between various actors. However, it is important to note the challenges and effort required to successfully integrate PRO data into health IT systems.

For organizations building their own applications and platforms to capture and integrate electronic PRO data, there are several issues related to semantic mapping, accuracy, staff competency, infrastructure, privacy, and security that will need to be addressed. Organizations taking a different approach leveraging existing infrastructure, such as an EHR and a SMART on FHIR application face challenges of a different nature, such as EHR integration, EHR and FHIR version incompatibilities, and EHR storage capacity. In either case, privacy and security safeguards should be in place to ensure patient data is not exposed to potential threats. Each organization should review the various workflows that capture and exchange PRO data to ensure compliance with security and privacy regulations (e.g., HIPAA, NIST SP 800-53). [65] Organizations should evaluate their approach to challenges according to their existing IT infrastructure and clinical needs.

Community Coordination to Advance Collection, Exchange, and Integration of PRO Data in Healthcare and Research

The community using patient-reported outcome measures in practice is very broad and stretches across multiple facets of the healthcare community, including research, therapeutics, clinical trials, and others. Relevant subject matter experts across several domains should also be included such as oncology, behavioral health, and other domains that could benefit from access to PRO data. Additional stakeholders include federal agencies, PROM repositories, organizations that oversee quality efforts, health IT developers, patients, and many others. For example, stakeholders could focus on organizing PROMs based on the domains to which they may be relevant and sharing experiences regarding their use. By storing and categorizing PROMs in a single repository based on their clinical domains or creating a robust and accessible catalogue of PROMs, providers and researchers may find it easier to identify the PROMs available for their patients in an intuitive, organized manner. It can also help to limit redundancy by allowing providers and researchers to determine what is already available before time and resources are spent to develop, test, and validate another PRO instrument.

Stakeholders could also come together to build metadata for PROMs to further expand the interoperability of PRO data within and between provider domains. Developing standardized PROM or other health measurement instrument metadata that follows their electronic exchange and the PRO data in them can help in maintaining the integrity and fidelity of the exchanged documents. For example, metadata can include provenance information regarding the source of the PRO administration, responder data, and time of administration and completion. Maintaining provenance information may also provide important context when collecting PRO data for longitudinal research efforts where PROMs may be

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[65] https://www.healthit.gov/sites/default/files/pdf/privacy/privacy-and-security-guide.pdf

administered at multiple points during a long-term clinical intervention with multiple providers, or where multiple providers are involved in a patient's care, such as with cancer treatment.

Leveraging stakeholder expertise to further standardize aspects outside of PRO data exchange, such as data collection and integration, can yield better treatment outcomes and research findings, and enhance public health for all. Artificial intelligence (AI) and machine learning technologies rely on standardized data formats and structures, as well as a foundation in common data models, to be optimally efficient.[66] As bodies of standardized patient-reported outcomes data become available, at the micro- and macro-levels, AI-driven learning can expand by fine tuning algorithms to inform clinical decision-making support services and other outcomes-related approaches to medicine, such as the use of a specific oncological therapy based on patient-outcome feedback from a statistically significant patient pool. Applying AI and machine learning approaches to PRO data can help expedite the improvement of patient outcomes, increase public health, increase care quality, reduce physician burden, reduce hospital readmissions, and reduce risk.

Forming a nationwide PRO network to synergize efforts and standardize data and metadata for PROMs and other health measurement instruments can help advance technological implementation and expedite the standardized collection and use of PRO data in the routine course of care and health related research.

Reducing Provider Burden to Improve Patient Outcomes

Making the resulting PRO data available to patients may encourage improved response rates and data quality from patients so providers may continue to gain enhanced insight for effective, quality care. In an editorial published in 2011, the authors indicated integration of real time, electronic PRO data in EHRs would be necessary for use by clinicians.[67] The paper described ideal features an interface should include like automated reminders for patients to self-report, numeric and graphic reports for clinicians showing longitudinal trajectories of patients' symptoms, real time alerts to clinicians when concerning symptoms are reported, notifications to nonclinical staff when patients miss scheduled self-reporting appointments, and triggers for patient education. Clearly, there is room in the future for clinical decision support (CDS) expansion within the PRO FHIR Implementation Guide to accommodate these types of functionalities.[68]

CDS triggers for PROMs would not only need to be streamlined, but also effective and actionable—communicating only the information pertinent to the provider at a specific point in time to limit information overload and result in a precise action. These triggers may need to be defined on a domain by domain basis for pre- and post- administration, where triggers for oncology-based PROMs may be vastly different than those for primary care. To achieve optimal performance of CDS tools, clinician focus groups would need to be convened to understand the needs for PRO data within their specific domains and establish the required triggers for the best patient outcomes. Along with focus groups to establish requirements, providers would need to test and provide feedback for tools developed to support the collection and clinical use of PRO data in the routine course of care.

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[66] Artificial intelligence: See glossary

[67] Basch E, Abernethy, A. Supporting clinical practice decisions with real-time patient-reported outcomes. Journal of clinical oncology. Journal of Clinical Oncology. 2011.29(8) 954. Published 2011 Mar. doi: 10.1200/JCO.2010.33.2668. Accessed at: https://www.researchgate.net/profile/Ethan_Basch/publication/49799588_Supporting_Clinical_Practice_Decisions_With_Real-Time_Patient-Reported_Outcomes/links/0f317536106e0c9e76000000/Supporting-Clinical-Practice-Decisions-With-Real-Time-Patient-Reported-Outcomes.pdf

[68] Clinical decision support: See glossary

Though APIs and other apps provide mechanisms to collect and exchange data for various use cases, health IT developers may consider building functionality to support streamlined PRO data collection workflows buy building PRO data-specific modules into their systems. In this scenario, each PROM could have an associated procedure code or other mapping to facilitate CDS at the point of care, and for ease of access via standardization. This EHR-embedded functionality may potentially remove hurdles of needing to implement middleware to achieve organizational and research-oriented uses of PROs. This may also potentially mitigate issues organizations face in providing their own resources for semantic and syntactic mapping to FHIR.

Being Mindful of the Patient Burden Resulting from Data Collection

Consequently, patient burnout should also be kept in mind when implementing or designing solutions and workflows. As the use of PROMs in the routine course of care increases due to technological advances, the patient may not appreciate having to complete questionnaires before, after, and during all visits to providers, especially those who may be receiving care for a chronic illness with involvement from several specialists. Patients should participate in focus groups to determine if the interfaces support an effective patient experience, and the formats administered are broadly acceptable. Additionally, making the resulting PRO data available to patients may encourage improved response rates and data quality from patients.

Through all the potential opportunities and advancements that can be made to build upon the current capabilities within the PRO FHIR Implementation Guide, it will need to be updated and further refined to reflect the evolution of industry protocols and national priorities with regard to PRO data.

Alignment with Federal Policies and Priorities

An increase in the collection, exchange, and integration of PRO data into healthcare and research will necessitate periodic analysis to ensure that the use of this data aligns with the policies and priorities and that those align with the needs of providers, patients, and researchers. Another example is PRO data related to behavioral health that may require further analysis for adherence to 42 CFR part 2 and data segmentation regulation. Depending on the subject matter, there may be other regulations and/or policies that may need to be adhered to or updated.

Evolution of the PRO FHIR Implementation Guide Technical Capabilities

The PRO FHIR Implementation Guide that was developed for this project was submitted For Comment Only, underwent comment Reconciliation, and was submitted as a Standard for Trail Use (STU) in September 2019. The PRO FHIR Implementation Guide is instrument agnostic and can be adapted for any question and response type workflow, such as clinical quality measurement (CQM), post-acute care service instruments, and surveys for social determinants of health as long as the health measurement instruments (similar to PROMs) for these workflows are available. For example, there may be potential to build upon the PRO FHIR Implementation Guide IG and apply it to exchange quality measure information between payers and providers because this is a workflow that uses request and response types of transactions conducted for CQM reporting. Given the outcomes and lessons learned by pilot testing and the need to further mature the FHIR standard, it is clear more testing of the guidance and standards in the PRO FHIR Implementation Guide are needed. Testing it to support other potential use cases in addition to the electronic integration of PRO data into health IT systems could create a robust implementation guide and advance the maturity of FHIR. Implementation feedback from testing is critical to standards development. The PRO FHIR Implementation Guide must be maintained and stewarded to track maturity of the standard through to an ANSI Normative standard which can take

years and requires active engagement between implementers and HL7. This ongoing relationship is critical to ensure FHIR and the implementation guide are revised to reflect real-world needs and support interoperability. For example, once EHR systems have enhanced FHIR capabilities, the implementation guide may also need to be revised and expanded to support connectivity with various EHR FHIR endpoints, APIs, and applications. Another example is that with time, future stewards of this standard may consider developing a PRO data specific FHIR resource to accurately and effectively collect PRO data for analysis and examination.

This project also demonstrated the value of APIs to support collection, exchange, and integration of PRO data. Using APIs opens up opportunities for app developers to build better tools to facilitate PRO collection and use. User-friendly apps on both the patient and provider facing sides may ease the burden on clinical facilities, trials, and research sites by reducing the need to collect PRO data using paper forms or the need to build home-grown applications as was seen in this project. Advancements in the use of APIs and improved data collection and visualization apps can also open doors to integrate with other types of patient-derived data, such as from wearable devices, so providers may be able to have a more holistic patient snapshot at any given point in time.

There are other potential technologies that could be leveraged in conjunction with health data standards and health IT to contribute to additional areas such as telemedicine and home health monitoring. The abstract model in the implementation guide offers a framework for the different actors that play a role in the workflow of collecting, exchanging, and integrating PRO data. This results in a framework that offers flexibility to implementers regarding who or what the specific entity or organization is that fills each role. For example, the actor filling the role of administering a PROM may be part of a health IT solution that provide telemedicine services in the comfort of a patient's own home. This can provide important patient reported information to providers from wherever the patient may be. Additionally, patients receiving care in the home, such as for palliative care, may be able to also take PRO assessments from home to help providers keep track of the patient reported information from their patients in real time. Telemedicine and home health may benefit from implementation guidance resulting from this project to facilitate the collection of PRO data before and between virtual visits, potentially with the help of voice controlled devices. Using these types of devices to facilitate PRO data collection may reduce the reporting burden on the patient, especially if the patient has a chronic condition requiring care from multiple providers. It is important to note, however, that each PROM should be administered according to their associated protocols in the way they were intended to be used.

Conclusion

Technology and guidance now exist for the electronic, interoperable, and standardized collection, exchange, and integration of PRO data. The PRO FHIR Implementation Guide has been pilot tested, vetted through HL7, and is available to organizations and researchers who are interested in implementing use of PRO data in real time production environments. The PRO FHIR Implementation Guide is health measure instrument agnostic meaning it can be used for a wide variety of instruments. The data exchange frameworks and technology tested by this project can be leveraged for a wide array of question and response workflows. There is further work that needs to be done to continue to steward and refine the FHIR standard, standardize health measurement instruments such as PROMs, build APIs, and provide education and outreach to providers and patients. Continuing to make these strides can ultimately empower patients, facilitate patient-provider relationships reduce provider burden, and lead to more

robust patient-centered outcomes research. Overall, the results of this project have shown great promise in supporting the further development of a health IT ecosystem that includes electronic PRO data.

Glossary

Term	Definition
Application programming interfaces (API)	A system access point or library function that has a well-defined syntax and is accessible from application programs or user code to provide well-defined functionality.[69]
Artificial intelligence (AI)	Artificial intelligence (AI) is a branch of computer science dealing with the simulation of intelligent behavior in computers; the capability of a machine to imitate intelligent human behavior.[70]
Clinical decision support (CDS)	This provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and better healthcare. CDS encompasses a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools.[71]
Common data element (CDE)	A data element that is common to multiple data sets which improves data quality and promotes data sharing.[72]
Computerized adaptive testing (CAT)	Computer Adaptive Tests (CATs) are a type of measure in which the questions a person answers are tailored to that person. Each response is used to further refine a person's score.[73]
Domain	A specified sphere of activity or knowledge.
Electronic health record (EHR)	An EHR is a digital version of a patient's paper chart. EHRs are real-time, patient-centered records that make information available instantly and securely to authorized users. One of the key features of an EHR is that health information can be created and managed by authorized providers in a digital format capable of being shared with other providers across more than one healthcare organization. EHRs are built to share

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[69] https://csrc.nist.gov/glossary/term/Application-Programming-Interface
[70] https://www.merriam-webster.com/dictionary/artificial%20intelligence
[71] https://www.healthit.gov/topic/safety/clinical-decision-support
[72] "NIH Common Data Element Resource Portal", U.S. National Library of Medicine, last reviewed April 25, 2019, https://www.nlm.nih.gov/cde/.
[73] http://www.healthmeasures.net/resource-center/measurement-science/computer-adaptive-tests-cats

Term	Definition
Electronic health record (EHR) continued	information with other healthcare providers and organizations—such as laboratories, specialists, medical imaging facilities, pharmacies, emergency facilities, and school and workplace clinics—so they contain information from all clinicians involved in a patient's care.[74]
Fast Healthcare Interoperability Resources (FHIR)	Fast Healthcare Interoperability Resources is a draft standard describing data formats, elements (known as "resources"), and an API for exchanging electronic health records, created by HL7.
Health Level Seven International (HL7)	HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services. [75]
Implementation guide	A document that instructs developers on the best practices for building systems that adhere to a particular standard and establishes the standardized specification, along with API guidance, for administering, collecting, and exchanging data. [76]
Interoperability	Health information technology that enables the secure exchange of electronic health information for authorized use without special effort on the part of the user.[77] According to section 4003 of the 21st Century Cures Act, the term 'interoperability,' with respect to health information technology, means such health information technology that—"(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user"; "(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law"; and "(C) does not constitute information blocking as defined in section 3022(a)."[78]
Middleware	Middleware is software providing services and capability to applications outside of what they are typically offered within their operating system.[79]

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[74] https://www.healthit.gov/faq/what-electronic-health-record-ehr
[75] https://www.hl7.org/about/index.cfm?ref=common
[76] https://www.hl7.org/fhir/implementationguide.html
[77] U.S. Congress, House, 21st Century Cures Act, Act of 2016, HR34, 114th Congress, 1st sess., introduced in House December 13, 2016, https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf.
[78] https://www.healthit.gov/topic/interoperability
[79] https://www.redhat.com/en/topics/middleware/what-is-middleware

Term	Definition
Patient-generated health data (PGHD)	Patient-generated health data (PGHD) are health-related data created or recorded by patients to inform their self-care and understanding regarding their own health.[80]
Patient-reported outcome (PRO)	A PRO is a measurement based on a report coming directly from the patient without interpretation of the patient's response by a clinician or anyone else and pertains to the patient's health, quality of life, or functional status associated with healthcare or treatment.[81]
Patient-reported outcomes measures (PROMs)	Validated questionnaires or short forms that turn symptoms into a numerical score.
Patient-Reported Outcomes Measurement Information System (PROMIS)	PROMIS is a set of person-centered measures that evaluates and monitors physical, mental, and social health in adults and children. It can be used with the general population and with individuals living with chronic conditions.[82]
Northwestern University Assessment Center (Assessment Center)	The Assessment Center is an online data collection tool that enables researchers to create study-specific websites for capturing participant data securely. The instrument library includes self- and proxy-report short forms, computerized adaptive tests (CATs), and batteries or profiles.[83]
SMART on FHIR	SMART Health IT is an open, standards-based technology platform that enables innovators to create apps that seamlessly and securely run across the healthcare system. Using an EHR system or data warehouse that supports the SMART standard, patients, doctors, and healthcare practitioners can draw on this library of apps to improve clinical care, research, and public health. The SMART platform is composed of open standards, open source tools for developers building apps, and a publicly accessible app gallery.[84]

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[80] Cohen, D. J., Keller, S. R., Hayes, G. R., Dorr, D. A., Ash, J. S., & Sittig, D. F. (2016). Integrating Patient-Generated Health Data into Clinical Care Settings or Clinical Decision-Making: Lessons Learned from Project HealthDesign. JMIR human factors, 3(2), e26. doi:10.2196/humanfactors.5919

[81] https://www.ncbi.nlm.nih.gov/books/NBK326791/

[82] http://www.healthmeasures.net/explore-measurement-systems/promis

[83] https://www.assessmentcenter.net/

[84] https://smarthealthit.org/an-app-platform-for-healthcare/about/

Term	Definition
Structured Data Capture (SDC)	SDC is focused on the identification, testing, and validation of standards necessary to enable an EHR system to retrieve, display, and fill a structured form or template, and store/submit the completed form to an external system and/or repository. SDC was created by a previous ONC-led project that worked towards standardizing the capture and expanded use of patient-level data collected within an EHR via questionnaires and forms.[85]

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[85] https://www.healthit.gov/topic/scientific-initiatives/pcor/research-evaluation/structured-data-capture-sdc