Agenda

• Introduction by the Office of the National Coordinator for Health Information Technology (ONC)
  » Patient-Centered Outcomes Research (PCOR)
  » What are Patient-Reported Outcomes (PROs)?
  » Project Overview

• HL7 ® FHIR® PRO Implementation Guide Overview

• Pilot Demonstrations and an Introduction by the Agency for Healthcare Research and Quality (AHRQ)

• Questions and Discussion*

*Please send all questions via the chat feature of this webinar.
ONC Mission and Priorities

**FEDERAL HEALTH IT MISSION**

Improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

**ONC PRIORITIES**

ONC will work to make health information more accessible, decrease the documentation burden, and support EHR usability under 21st Century Cures and MACRA.
At the Intersection Between Research and Care Delivery

- Develop and evaluate ONC’s scientific efforts and activities
- Recommend scientific policy to the National Coordinator
- Promoting activities that **spur innovation**, support patient-centered outcomes research, and **advance precision medicine**
- [https://www.healthit.gov/topic/scientific-initiatives](https://www.healthit.gov/topic/scientific-initiatives)
Patient-Centered Outcomes Research (PCOR)

- Produce new scientific evidence that informs and supports the health care decisions of patients, families, and their health care providers.

- Through Assistant Secretary for Planning and Evaluation (ASPE) and the Patient-Centered Outcomes Research Trust Fund (PCORTF) support intradepartmental projects that build data capacity for PCOR.
Patient-Reported Outcomes (PROs)

- Any information providing the status of a patient’s health outcome which comes directly from the patient without interpretation of that patient’s response by a clinician or anyone else
  - Relevant to clinical care and research
  - Still not routinely available in electronic form

Patient-Reported Outcomes through Health IT

- Identify barriers related to electronic capture of PROs
- Develop technical specifications to improve electronic capture of PROs
- Test the technical specifications in clinical settings using electronic health record systems and/or applications
- Communicate challenges and successes related to implementing the technical specifications
- Identify gaps in technical specifications / suggest improvements
Health Level Seven International (HL7®)
Fast Healthcare Interoperability Resources (FHIR®)
PRO Implementation Guide Overview

Nageshwara ‘Dragon’ Bashyam
Drajer, Inc.
• An Implementation Guide is an artifact that contains
  » Background and Workflow descriptions for a use case
  » Identifies interactions that can be standardized and their benefits
  » Specifies how a standard (e.g. HL7 FHIR) can be used to standardize interactions
    – What Resources are to be used?
    – What profiles, valuesets and vocabularies should be used?
    – What are the security considerations for implementation?
  » Provides Requirements for implementers of various sub-systems
  » Provides guidance for implementation
  » Provides examples for implementers
• Provides an overview of PRO Measure Lifecycle

• Identifies interactions that can be standardized using HL7 FHIR
  » PROs using Adaptive Questionnaires
  » PROs using Fixed Questionnaires

• Identifies how to use FHIR to
  » Collect PRO data through a stand-alone app (not tethered to an EHR)
  » Collect PRO data through a SMART on FHIR App (tethered to an EHR)

• Provides Implementation Guidance on how to implement the various actors for PRO

• Has gone through multiple cycles of balloting and resolution through HL7
Summary

- PRO IG is built on Structured Data Capture IG
  - Reuses the overall SDC framework for Questionnaires
- PRO IG can be used by EHRs to implement PRO capabilities
- PRO IG can be used by stand-alone apps for PRO data collection
- PRO IG can be used by SMART on FHIR Apps to implement PRO capabilities

PRO IG can be used for

- Different type of PRO instruments (Fixed vs Adaptive Questionnaires)
- Different Domains by disease or condition
- Patient Surveys (PROs for follow ups and random surveys)
- PROs for registries and other structured data collection apps
• Last Balloted Version

• Continuous Build Version (Updated as comments are reconciled)
  » [http://build.fhir.org/ig/HL7/patient-reported-outcomes/](http://build.fhir.org/ig/HL7/patient-reported-outcomes/)
Pilot Organizations

- Research Action for Health Network (REACHnet) at the Louisiana Public Health Institute (LPHI)
- Patient-centered SCAlable National Network for Effectiveness Research (pSCANNER) at the University of Southern California (USC)
- MedStar Health
PRO IG Guided Administration of FHIR Questionnaires
REACHnet

Kyle Bradford
Associate Director, Informatics
LPHI
Workflow

Non-FHIR Resource
Generate or Ingest Measure
Transform to FHIR object

COMMAND CENTER
Create Project
Generate Flow
Apply Branching
Choose Cohort
Schedule Measure

Administer PRO

"FHIRized" Resource via Mapping

Researcher

Patient

Generate or Ingest Measure
"FHIRized" Resource via Mapping

FHIR LOADER

The Office of the National Coordinator for Health Information Technology
Physical Function v2.0 Administration
Assessment Centre-Sourced Measure

Please enter your date of birth

01 01 01
MM DD YY

Example: 08/15/55

Restart  Start
Benefits:
• Enables interoperability
• Expands the scope of available measures
• Streamlines Questionnaire Resource DB management
• Easily understandable by technically adept personnel

Use cases:
• Identification of patients for clinical interventions
• Data collection for research studies
• Useful as a quality of service assessment tool via the Patient Satisfaction Survey

Future:
• Patient recruitment to the HiOH registry via an Out of Clinic (OOC) web application
• Patients to be assigned cohorts and assigned workflows.
• Patient responses to be persisted as FHIR objects.
Integrating Patient-Reported Outcomes Into EHR Workflows

Daniella Meeker, PhD
Director, Clinical Research Informatics
University of Southern California
The EASI-PRO Collaboration

• **EASI-PRO system**
  » Patient reported outcomes workflow
  » To be piloted at USC
  » Integrates with Cerner and Epic
  » Leverages the PROMIS® Assessment Center API originally developed by NIH
  » 150 *validated PROs*

• **EASI-PRO funded by**
  » U01TR001806 from NCATS
  » PI: Justin Starren, MD, PhD, FACMI
  » Northwestern University
Comparatively limited development investment

Significant but scalable development w/ EHR Rules Engine & Authentication solutions for writeback

Local Production Environment (USC)

Locally customized test environment (USC)

~40 hours of EHR localization investment

~40 hours of system administration to implement and secure locally hosted servers

FHIR R3 Prototype w/ HAPI-FHIR server

Cerner FHIR DSTU2-subset Sandbox

R3 to limited DSTU2 Retrofitting investment

Cerner EHR+SMART on FHIR Sandbox
EASI-PRO Patient and Provider Applications

**Patient-Facing FHIR Application**
- Present PRO ordered by provider in patient portal
- Administer interactive PRO using Adaptive Questionnaire Server*
- Score PRO*
- Post PRO Questionnaire Responses and Score

**Clinician Facing FHIR Application**
- Recommend PROs using CDS
- Present Orderable PROs by retrieving from Questionnaire Server*
- Post Order as task to patient portal
- Notify Patient

*Conducted by the PROMIS Assessment Center*
Current State

• Evaluated ONC Implementation Guide
• Addressing gaps in Cerner integration and localization for USC deployment
• Addressing Cerner security criteria to deploy in Cerner’s application marketplace
• Cataloging additional requirements from users
  » Portal integration for parent proxy PROs
  » SMS conversion for users with limited internet access
  » Conversion of reports to discrete data elements that are fully integrated into
  » Pending Cerner support for Questionnaire and Questionnaire Response
Lessons Learned

• Multi-party, multi-state PRO interactions are more complex to integrate into EHRs

• Clinician requirements are based on EHR user experience for other clinical transactions (e.g. labs)

• Publicly available FHIR sandboxes speed development but do not reflect real-world EHRs

• ~40 hours of effort for EHR builder to integrate with local clinical workflow and rules
AHRQ Step Up App Challenge: Advancing Care Through Patient Self-Assessments

Chris Dymek, EdD
Director, Health IT Division
Agency for Healthcare Research and Quality
AHRQ Responsibilities

• Overall project management
• Collaboration with other Federal partners
• Development and testing of:
  » Apps (new and existing) that incorporate the HL7 FHIR PRO Implementation Guide. The new app was produced via the AHRQ Step Up App Challenge Competition.
    – Apps can administer the PROMIS physical function measures via computer adapted test (CAT)
  » Technical infrastructure to integrate PRO data with EHR systems for clinical care and research
    – Use a FHIR server to enable real-time data integration with different EHR systems
MedStar Health PRO Pilot Project
funded by AHRQ HHSP2332015000221

Deliya Wesley, PhD
MedStar Pilot Co-PI | Research Scientist
MedStar Health Research Institute
Assistant Professor
Georgetown University School of Medicine

Joseph Blumenthal
MedStar Pilot Technical Lead
Senior Clinical Informatics Researcher and Developer
MedStar National Center for Human Factors in Healthcare
Project Goals

- Test using Fast Healthcare Interoperability Resources (FHIR), technical specifications for PRO app development, implementation, and effective use of the resulting PRO data

- Rigorously evaluate the implementation and use of FHIR based PRO app, by end users in ambulatory care settings
MedStar Health Pilot Test

- Apply FHIR technical specifications to existing app and implement at nine primary and specialty care practices in Washington, DC area

- Modified healthcare system PRO app
  - **OBERD** (Outcomes Based Electronic Research Database)
  - Web based application currently in use in MedStar Health Orthopedics
  - PROMIS physical function measure
    - Computer Adaptive Test format
<table>
<thead>
<tr>
<th>Affiliation</th>
<th>Site</th>
<th>Practice Size</th>
<th>Patient Volume</th>
<th>Patient Demographics</th>
<th>EHR</th>
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<tr>
<td><strong>MedStar</strong></td>
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<tr>
<td>MedStar Medical Group at Adams Morgan</td>
<td>MedStar Medical Group at Adams Morgan</td>
<td>Providers: 2</td>
<td>30-35 per day</td>
<td>Age: All 35% White/Caucasian, 30% African American, 15% Latin American, 15% Asian American, 5% Other</td>
<td>Cerner</td>
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<td></td>
<td>MedStar Medical Group at Bethesda</td>
<td>Providers: 4</td>
<td>42 per day</td>
<td>Age: 18+ No race/ethnicity demographics</td>
<td>Cerner</td>
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<td>MedStar Medical Group Family Practice at Olney</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
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<td></td>
<td>MedStar Medical Group at Alexandria</td>
<td>Providers: 2</td>
<td>32 per day</td>
<td>Age: All Diverse Racial/Ethnic Background</td>
<td>Cerner</td>
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<tr>
<td></td>
<td>MedStar Medical Group at Capitol Hill</td>
<td>Providers: 6</td>
<td>50 per day</td>
<td>Age: 16+ No race/ethnicity demographics</td>
<td>Cerner</td>
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<tr>
<td>MedStar Shah Medical Group, Lakeside Medical Center</td>
<td>MedStar Shah Medical Group, Lakeside Medical Center</td>
<td>Providers: 3</td>
<td>18 per day</td>
<td>Age: All 63% Non-Hispanic or Latino</td>
<td>NextGen</td>
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<td></td>
<td>MedStar Shah Medical Group, Waldorf Medical Center</td>
<td>Providers: 18</td>
<td>20 per day</td>
<td>77% Non-Hispanic or Latino</td>
<td>NextGen</td>
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<td><strong>CAPRICORN</strong></td>
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<td>Potomac Physicians Associates Chevy Chase</td>
<td>Potomac Physicians Associates Chevy Chase</td>
<td>Providers: 9</td>
<td>100 per day</td>
<td>Age: 16+ No race/ethnicity demographics</td>
<td>NextGen</td>
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<tr>
<td>Family Medicine at Spring Valley</td>
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<td>Providers: 10</td>
<td>No data</td>
<td>Age: 18+ 87% Not Hispanic or Latino</td>
<td>Cerner</td>
</tr>
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Provider Facing Visualization Implementation

• Build of an integration testing application used across all EHRs

• Implementation spanned 3 distinct health systems’ EHRs
  » Differences in build of same EHR
PRO Architecture

Input Methods for PROMIS Data

1. User credentials input
2. Credentials verified, Access authorized
3. Survey Q_i, Answer to Q_i
4. Completed survey responses

FHIR API

5. Completed PRO data transferred

External Assessment Center

Clinical Setting

PRO App

PRO App

The Office of the National Coordinator for Health Information Technology
FHIR Implementation Guide: Strengths

- Strong guidance on both high level and details for implementation
- Clearly defines required and optional resources
- Provides crisp examples of FHIR API calls
- This served as a “true” IG to hand off to vendor
FHIR Implementation Guide: Opportunities

- Only updates would be suggested
- Provide a link to Northwestern’s SMART on FHIR sandbox
- Outline the process for building a “distributor”
Future Directions: SMART on FHIR

• Potential for extending beyond pilot

• Active EHR builds of CDS systems to support workflow and enhance safety
  » Provider Workflow CDS
  » CDS Hooks for cardiac risk
Concluding Remarks and Acknowledgements

Stephanie Garcia
ONC PCOR Program Manager
Chief Scientist Division
Office of the National Coordinator for Health IT
## Summary of Pilot Projects

<table>
<thead>
<tr>
<th></th>
<th>REACHnet</th>
<th>pSCANNER</th>
<th>MedStar</th>
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<tbody>
<tr>
<td><strong>PRO Measures (PROM) Implemented</strong></td>
<td>PACIC11 &amp; PROMIS Physical Function v2.0</td>
<td>PROMIS Physical Function v2.0</td>
<td>PROMIS Physical Function v2.0</td>
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<tr>
<td><strong>CAT Enabled</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td><strong>Ability to represent measure and metadata as FHIR Questionnaire</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Ability to represent responses and metadata in FHIR QuestionnaireResponse</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td><strong>PROM Administration</strong></td>
<td>Via local repository using API provided by Assessment Center</td>
<td>Via interaction directly with Assessment Center</td>
<td>Via interaction directly with Assessment Center</td>
</tr>
<tr>
<td><strong>Trigger to administer PROM</strong></td>
<td>‘Command Center’ tool allows patient cohort selection to administer select PROM</td>
<td>Clinician can order specific PRO within EHR for a specific patient</td>
<td>Administration Dashboard allows staff to administer PROM</td>
</tr>
<tr>
<td><strong>Method to deliver PROM</strong></td>
<td>Tablet app running within Health in Our Hands (HiOH) platform</td>
<td>SMART on FHIR app (EASI-PRO)</td>
<td>SMART on FHIR App (OBERD)</td>
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<tr>
<td><strong>Integration with EHR</strong></td>
<td>Responses stored within HiOH ecosystem</td>
<td>Responses delivered to CERNER via FHIR Document resource</td>
<td>In-situ EHR provider facing visualization</td>
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Other Potential Applications of the HL7 FHIR PRO IG

- Aggregated PRO data for multi-state/multi-organizational use
- Patient recruitment for clinical trials based on organizational or aggregated PRO data
- Support for research studies (outcomes-based, epidemiological, etc.) using organizational or aggregated PRO data
- Quality of Service Assessments via patient satisfaction surveys
- Quality Measure Development for measures consisting of multiple PROMs (e.g. – eCQM CMS 90v9 – Functional Status Assessments for Congestive Heart Failure)
- Long-Term Post-Acute Care Assessment Instrument Administration and Response Generation (e.g. – CMS Data Element Library, supporting the Improving Medicare Post-Acute Care Transformation (IMPACT) Act)
- Support for other non-PRO clinical assessments
PRO FHIR Testing and Next Steps

• AHRQ and MedStar to continue pilot testing

• Continue HL7 collaboration and update the FHIR technical specification
  » Publish the Standard for Trial Use for public consumption and feedback in September 2019
  » Continue expanding standard to incorporate other developments in health IT, including CDS Hooks and SMARTonFHIR

• Discuss lessons learned and next steps in a final white paper published by ONC

• American Medical Informatics Conference November 2019
# Acknowledgements – ONC PRO Project

<table>
<thead>
<tr>
<th>Organization</th>
<th>Team Members</th>
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</table>
| **ONC**               | Dr. Teresa Zayas-Cabán  
                        Stephanie Garcia                                                      |
| **ESAC, Inc.**        | Sweta Ladwa, Program/Project Manager  
                        Dan Donahue, Technical SME  
                        Abdullah Rafiqi, Pilot Lead  
                        Christina Nguyen, Communications Lead  
                        Holly Stone, Project Coordinator  
                        Rachael Rohan, Project Analyst |
| **Drajer, Inc.**      | Nageshwara 'Dragon' Bashyam, Lead Architect and Technical SME               |
| **REACHnet – LPHI**   | Thomas Carton, PI REACHnet & Chief Data Officer  
                        Beth Nauman, Director Health Services Research  
                        Eliel Oliveira, Director Research Data Infrastructure (Dell Medical School)  
                        Kyle Bradford, Associate Director Informatics  
                        Sylvester Tumusiime, Informatics Project Coordinator |
| **Persistent Systems**| Amandeep Kaur  
                        Ashmeet Chhabra  
                        Chetan Goyal  
                        Chandrakant Talele  
                        Manisha More  
                        Piyush Bhalerao  
                        Pooja Kengale  
                        Prachi Sharma, Project Manager  
                        Sundeep Ganguly |
| **pSCANNER – USC**    | Daniella Meeker, Director of Clinical Research Informatics  
                        Dr. Aziz Boxwala, President (Elimu Informatics)  
                        Gayathri Nagaraj, Research Programmer  
                        Nick McKenzie (Cerner)  
                        Yami Messer | Geoff Gordon (Cerner Integration UAB) |
### Acknowledgements (Continued)

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<tr>
<td><strong>Northwestern University</strong></td>
<td>Michael Bass, PROMIS Assessment Center Principal Architect/Programmer</td>
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<tr>
<td><strong>AHRQ</strong></td>
<td>Chris Dymek, Director Division of Health Information Technology</td>
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<td></td>
<td>Bryan Kim, Health Scientist/Program Official</td>
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<td>Janey Hsiao, COR</td>
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<td><strong>MedStar Health</strong></td>
<td>Deliya Wesley, MPH PhD</td>
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<td></td>
<td>Raj Ratwani, PhD</td>
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<td>Kate Kellogg, MD MPH</td>
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<td>Robin Littlejohn MS</td>
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<td>Alexandra Burn MS</td>
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<td>Joseph Blumenthal</td>
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<td>Shrenik Shah</td>
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<td>Shrey Mathur MS</td>
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<td>Zoe Pruitt MA</td>
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<td>Ram Dixit MS</td>
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<td>Laura Schubel</td>
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<td>Melissa Harris</td>
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<td>Vicky Parikh MD MPH</td>
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Questions and Discussion

Please submit questions via the chat feature of this webinar.
CONTACT INFORMATION

Stephanie Garcia, MPH

Stephanie.Garcia@hhs.gov

www.healthit.gov/pcor