The Office of the National Coordinator for Health Information Technology

Patient-Reported Outcomes on FHIR®

Three Real-World Implementations of the HL7® FHIR PRO Implementation Guide and Other Applications

August 15, 2019

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	ONC PRIORITIES
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 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

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[1]
  - » Relevant to clinical care and research
  - » Still not routinely available in electronic form

[1] FDA Guidance for Industry. Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. 2009. Available at: http://www.fda.gov/downloads/Drugs/Guidances/UCM193282.pdf. Accessed March 13, 2019.

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.

PRO Implementation Guide

- 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

PRO Implementation Guide Cont'd

- 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

PRO Implementation Guide Cont'd

- 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

PRO Implementation Guide Cont'd

- Last Balloted Version
  - » http://hl7.org/fhir/us/patient-reported-outcomes/2019May/
- Continuous Build Version (Updated as comments are reconciled)
  - » 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

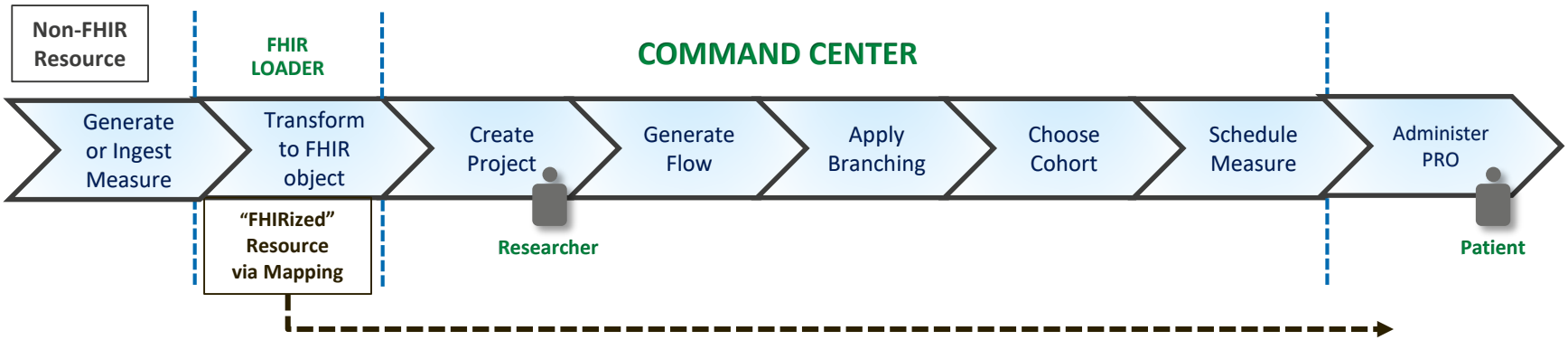
PRO IG Guided Administration of FHIR Questionnaires REACHnet

Kyle Bradford

Associate Director, Informatics

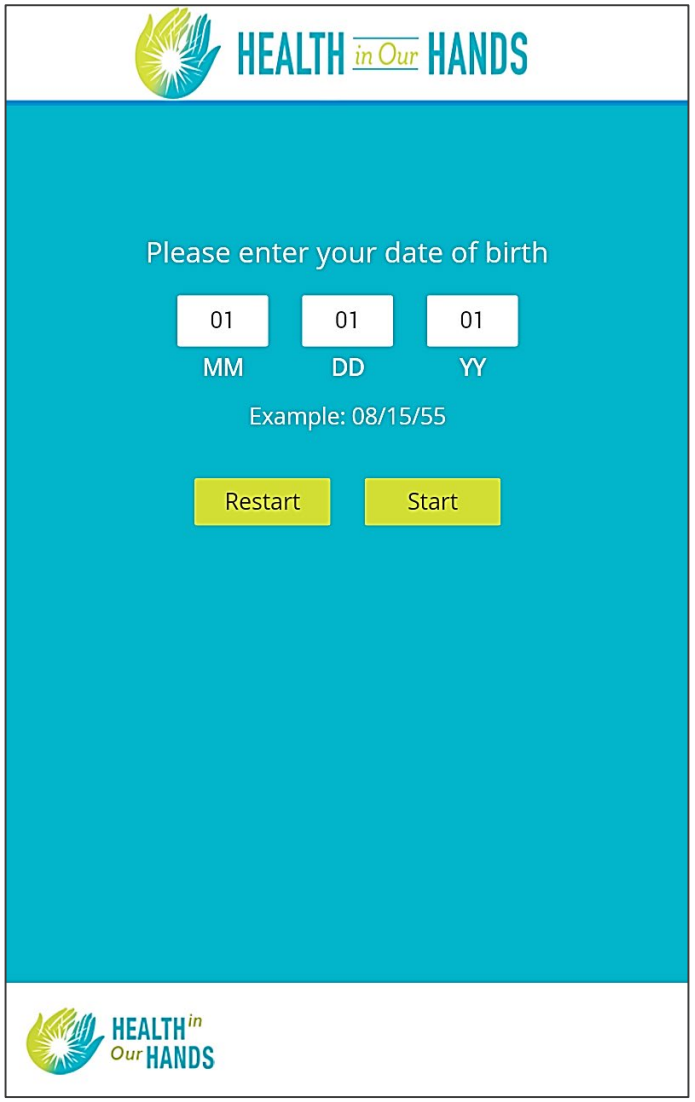
LPHI

Workflow


Non-FHIR Resource
FHIR LOADER
COMMAND CENTER
Generate or Ingest Measure
Transform to FHIR object
Create Project
Generate Flow
Apply Branching
Choose Cohort
Schedule Measure
Administer PRO
"FHIRized" Resource via Mapping
Researcher
Patient

Physical Function v2.0 Administration

Assessment Centre-Sourced Measure



TABLET DEMONSTRATION

FHIR Benefits, Use case & Future (REACHnet)

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

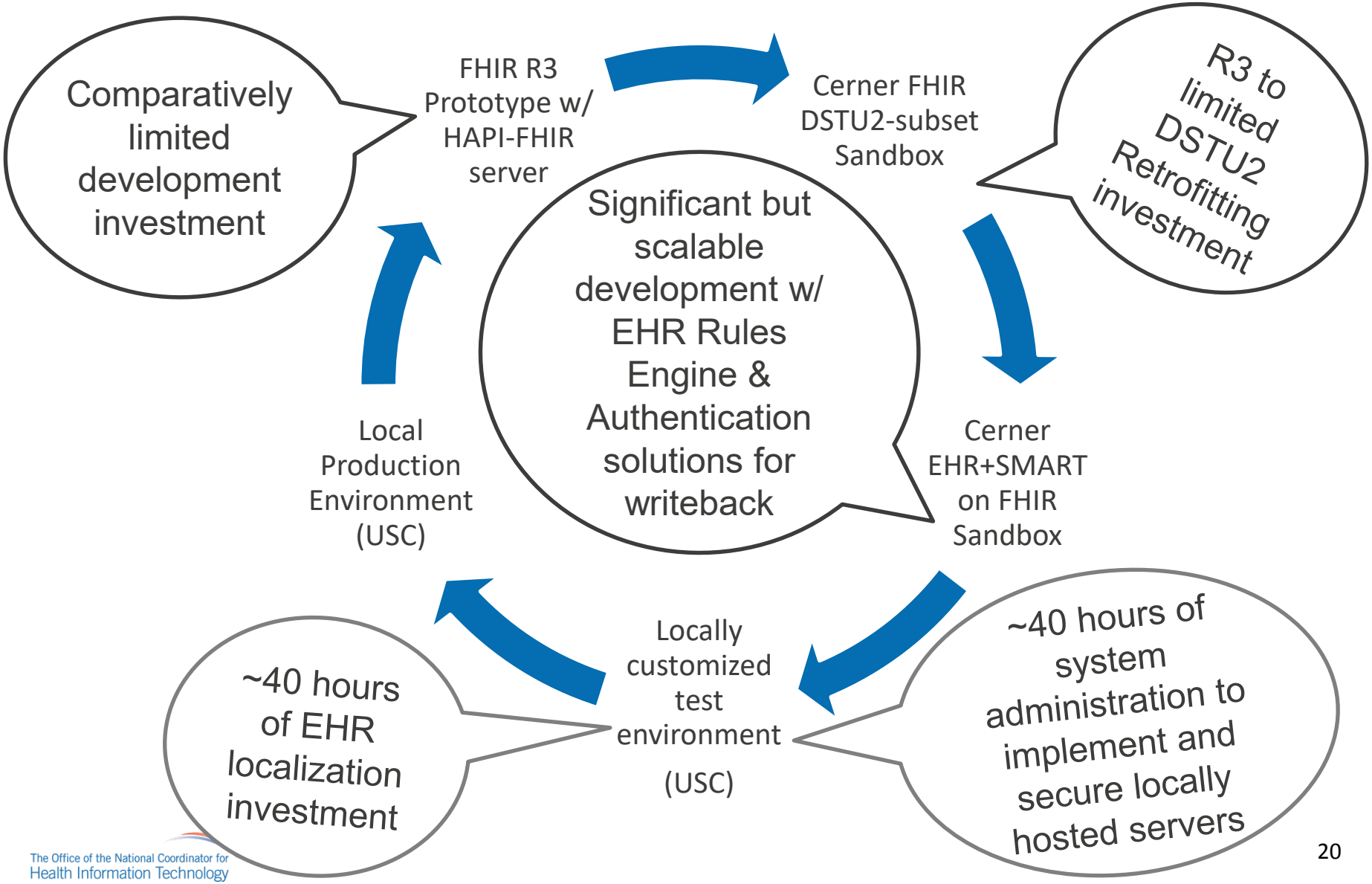
Director, Clinical Research Informatics

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

Development Strategy for SMART-on-FHIR PRO App



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

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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** (**O**utcomes **B**ased **E**lectronic **R**esearch **D**atabase)
  - Web based application currently in use in MedStar Health Orthopedics
  - PROMIS physical function measure
    - Computer Adaptive Test format

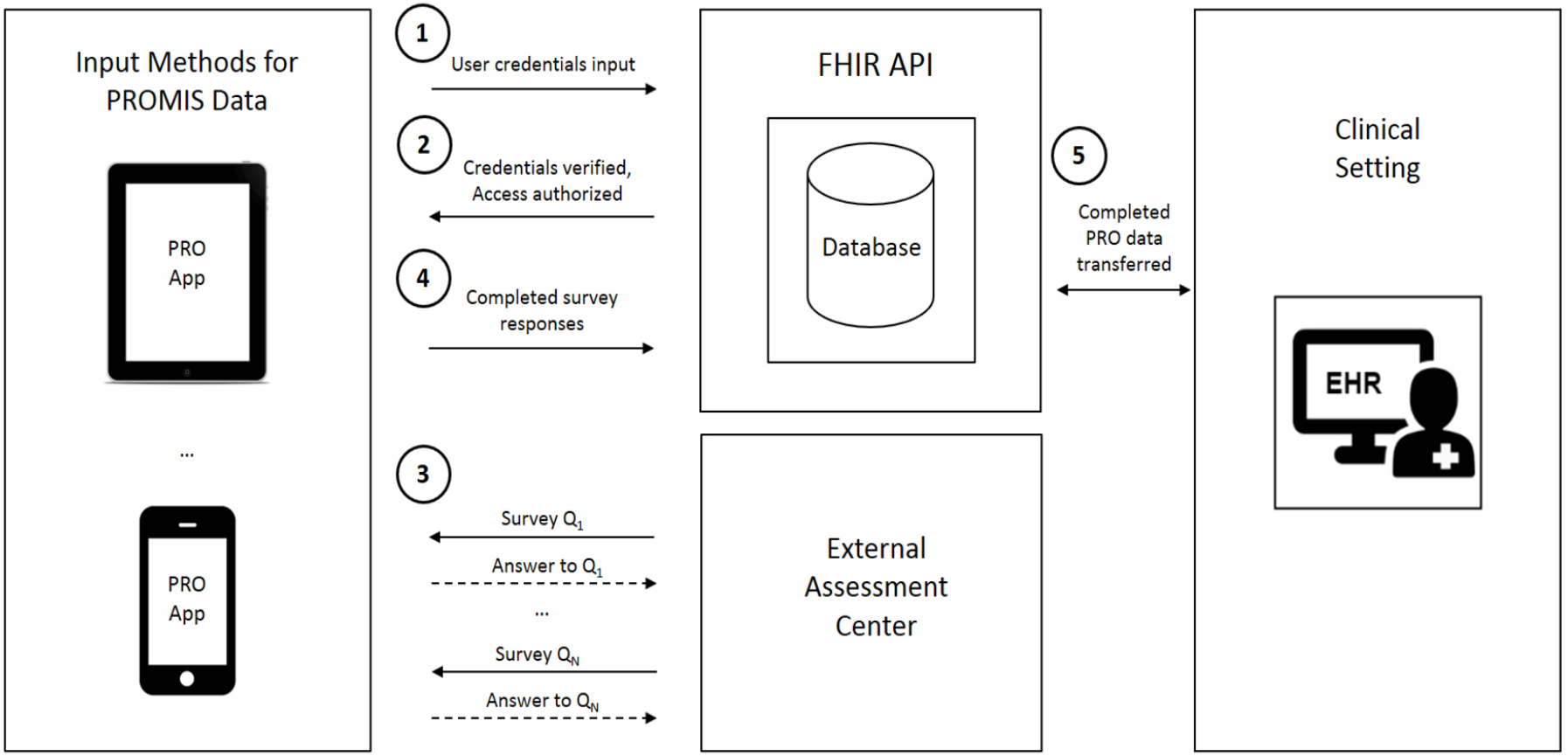
MedStar Health Pilot Testing Environment

Site Demographics					
Affiliation	Site	Practice Size	Patient Volume	Patient Demographics	EHR
MedStar	MedStar Medical Group at Adams Morgan	Providers: 2 MAs: 2 Admin: 3	30-35 per day	Age: All 35% White/Caucasian, 30% African American, 15% Latin American, 15% Asian American, 5% Other	Cerner
	MedStar Medical Group at Bethesda	Providers: 4 MAs: 3 Admin: 3	42 per day	Age: 18+ No race/ethnicity demographics	Cerner
	MedStar Medical Group Family Practice at Olney	No data	No data	No data	No data
	MedStar Medical Group at Alexandria	Providers: 2 MAs:3	32 per day	Age: All Diverse Racial/Ethnic Background	Cerner
	MedStar Medical Group at Capitol Hill	Providers: 6 MAs: 7 Admin: 8	50 per day	Age: 16+ No race/ethnicity demographics	Cerner
	MedStar Shah Medical Group, Lakeside Medical Center	Providers: 3 MAs: 1 Admin: 2	18 per day	Age: All 63% Non-Hispanic or Latino	NextGen
	MedStar Shah Medical Group, Waldorf Medical Center	Providers: 18 MAs: 5 Admin: 2	20 per day	77% Non-Hispanic or Latino	NextGen
CAPRICORN	Potomac Physicians Associates Chevy Chase	Providers: 9 PAs: 3	100 per day	Age: 16+ No race/ethnicity demographics	NextGen
	Family Medicine at Spring Valley	Providers: 10	No data	Age: 18+ 87% Not Hispanic or Latino	Cerner

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



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

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Office of the National Coordinator for Health IT

Summary of Pilot Projects

	REACHnet	pSCANNER	MedStar
PRO Measures (PROM) Implemented	PACIC11 & PROMIS Physical Function v2.0	PROMIS Physical Function v2.0	PROMIS Physical Function v2.0
CAT Enabled	Yes	Yes	Yes
Ability to represent measure and metadata as FHIR Questionnaire	Yes	Yes	Yes
Ability to represent responses and metadata in FHIR QuestionnaireResponse	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 PROM	'Command Center' tool allows patient cohort selection to administer select PROM	Clinician can order specific PRO within EHR for a specific patient	Administration Dashboard allows staff to administer PROM
Method to deliver PROM	Tablet app running within 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

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

Organization	Team Members
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
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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)

Organization	Team Members
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AHRQ	Chris Dymek, Director Division of Health Information Technology Bryan Kim, Health Scientist/Program Official Janey Hsiao, COR
MedStar Health	Deliya Wesley, MPH PhD Raj Ratwani, PhD Kate Kellogg, MD MPH Robin Littlejohn MS Alexandra Burn MS Joseph Blumenthal Shrenik Shah Shrey Mathur MS Zoe Pruitt MA Ram Dixit MS Laura Schubel Melissa Harris Vicky Parikh MD MPH

Questions and Discussion

Please submit questions via the chat feature of this webinar.

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