Making an Impact on Interoperability: High Impact Pilots (HIP) and Standards Exploration Awards (SEA) Cooperative Agreement Program

Mera Choi, Director, Standards Initiatives Division, ONC
Caroline Coy, Senior Program Analyst, ONC

12/1/2017
HIP/SEA Program Objectives

• Focus on addressing interoperability through implementation of Technology Solutions

• Support increased use of health information technology solutions

• Incentivize use of standards from the Interoperability Standards Advisory (ISA) and newly emerging standards

• Lessons learned, and evidence generated, by these Cooperative Agreements will help advance industry understanding of health IT’s potential
<table>
<thead>
<tr>
<th>Awardee</th>
<th>Priority Category/ Subcategory</th>
<th>Impact Dimensions</th>
<th>Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Health Collaborative</td>
<td>(3) Care Coordination</td>
<td>1) Safety</td>
<td>ADT, CCD, IHE</td>
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<td></td>
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<td>2) Privacy and Security</td>
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<td>2) Practice Efficiency</td>
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<td>3) Interoperable Exchange</td>
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<td>RxREVU Inc.</td>
<td>(1) Comprehensive Medication Management</td>
<td>1) Clinical Quality</td>
<td>FHIR</td>
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<td>(i) Price Transparency at the Point of Care</td>
<td>2) Cost Efficiency</td>
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<td>3) Interoperable Exchange</td>
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<td>University of Utah</td>
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<td>1) Clinical Quality</td>
<td>SMART on FHIR</td>
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<td></td>
<td>(ii) Close-Loop (surgical) Referrals</td>
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<td>3) Practice Efficiency</td>
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## Standards Exploration Awards (SEA)

<table>
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<th>Awardee</th>
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<th>Impact Dimensions</th>
<th>Standards</th>
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<td>1) Interoperable Exchange</td>
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<tr>
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<td>1) Cost Efficiency</td>
<td>RFD and FHIR</td>
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<td>Sysbiochem</td>
<td>(4) Self-Identified - Genomics</td>
<td>1) Clinical Quality</td>
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<td></td>
<td>2) Interoperable Exchange</td>
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Presenters

• Deven Atnoor, Chief Technology Officer, Sysbiochem
• Rick Geimer, Chief Innovation Officer, Lantana Consulting Group
• Keith Marsolo, Associate Professor, Division of Biomedical Informatics, Cincinnati Children’s Hospital Medical Center
SEA-ONC Award

FHIR®-based Predictive Analytics: A Breast Cancer Pilot

Sysbiochem, LLC
Date: Dec 1, 2017
• Project Overview
  • Objectives and Goals
  • Planned tasks and Deliverables
• Product Presentation
  • Rationale
  • Status and Achievements
  • Lessons Learnt
  • Post Grant Activities
• Q&A
The combination of detailed family health history, medical history, clinical evaluation, and genomic sequencing, could shed more light on accurate disease risk prediction, diagnosis, with more informed treatment recommendations and better patient outcomes.
Value of Family History in Clinical Care

Current Data Flow (at best)

Patient enters data into Tablet PC

HL7 V3 → FHIR Genomics

Risk Engine

Patient Education

Reviews Intuitive Report & suggested management

Genetic Testing

Family history remains the best and least expensive genetic ‘test’ currently available for clinical use.

A major effort will entail developing tools to collect this information –

1. In a standardized format,
2. Store it in the patient’s electronic health record,
3. Apply risk assessment, and
4. Develop messages to clinicians that may alter patient care based on the information obtained.

Courtesy: Dr. Kevin Hughes, MGH
• Build a minimal viable product for FamilyMemberHistory (FHx) FHIR harmonization and return of validated analytics w/ message intact.
  • To provide merged risk assessment mappings with FHIR message – standardized and unified by working with the appropriate workgroups
  • Merging genetic test data to FHx message
  • Build a module that will merge FHIR messages from various sources to create the standard FHx message
  • Create a web-service for getting risk propensities for the patient.
Project Deliverables

- Standards for CDS analytics (FHIR/HL7)
  - Interoperable Message: Provide cancer risk assessment mappings for integration into any third party system

- Standards Harmonization: Validate Family Member History tools to support the round-trip payload for CDS. (including genomic test observations)

- Provide beta demonstration tool for vendors and hospitals to integrate analytics for use by providers
Goals

- Build a common/Harmonized FHIR based FamilyMemberHistory profile
- Build a round-trip application
  - Submit FHIR based message to HughesRiskApp
    - By translating the message that application understands
  - Return risk profile
    - By translating the message into FHIR based message
  - Consume the message for display to clinician
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<tr>
<td>Age</td>
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<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Alive or dead</td>
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</tr>
<tr>
<td>HL7 Fx Structure – relationship</td>
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</tr>
<tr>
<td>Identical Twins</td>
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</tr>
<tr>
<td>Race / ethnicity</td>
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<table>
<thead>
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<tbody>
<tr>
<td>Age of onset</td>
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<tr>
<td>Ovarian Cancer</td>
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<tr>
<td>Breast Cancer</td>
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<td>Oophorectomy</td>
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<tr>
<td>Mastectomy</td>
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<table>
<thead>
<tr>
<th>Genetic Observation</th>
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<tbody>
<tr>
<td>Code</td>
<td></td>
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<tr>
<td>Category</td>
<td></td>
</tr>
<tr>
<td>Interpretation</td>
<td></td>
</tr>
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</table>
FHIR resources profiles and extensions

Resource

* FamilyMemberHistory

* Observation

Profile and extensions

* FamilyMemberHistory-Genetic profile
* family-member-history-genetics-parent extension
* family-member-history-genetics-observation extension
Achievements

- Harmonized FHIR based FamilyMemberHistory with RiskAssessment
- Built a web-service to consume the FHIR message
  - Return FHIR response including RiskAssessment
- Successfully transmitted message from IMH
- Building a harness to submit large datasets from IMH
* Interoperable Exchange
  * Process the data through interoperable FHIR enabled pipeline, and return the results back
  * Track the number of FHIR messages being translated via the application interface

<table>
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<tr>
<th>Interoperable exchange</th>
<th>Q1 Actual</th>
<th>Q2 Actual</th>
<th>Q2 Actual</th>
<th>Q4 Actual</th>
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<tr>
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<td>Original</td>
<td>Updated</td>
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<tr>
<td>Q1 Target</td>
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<td>0</td>
<td>0</td>
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<td>Q2 Target</td>
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<td>Q3 Target</td>
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<td>1000</td>
<td>3000</td>
<td></td>
</tr>
<tr>
<td>Q4 Target</td>
<td>0</td>
<td>1990</td>
<td></td>
<td>30</td>
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<tr>
<td>Total</td>
<td>3000</td>
<td>0</td>
<td>10</td>
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Family Member History Summary Status

- Extension added to FMH – Genetic parent
- Extension Genetic Observation
  - [http://hl7.org/fhir/StructureDefinition/family-member-history-genetics-observation](http://hl7.org/fhir/StructureDefinition/family-member-history-genetics-observation)
- Mapping between Risk V3 and Risk Assessment FHIR
  - [https://www.hl7.org/fhir/riskassessment.html](https://www.hl7.org/fhir/riskassessment.html)

- US realm based profile – Family Member History
  - Containing race and ethnicity
    - [https://www.hl7.org/fhir/extension-us-core-race.html](https://www.hl7.org/fhir/extension-us-core-race.html)
    - [https://www.hl7.org/fhir/extension-us-core-ethnicity.html](https://www.hl7.org/fhir/extension-us-core-ethnicity.html)
Lessons Learnt

- Resource Availability
- Infrastructure Constraints
Post grant activities

- Universal Adapter
- Wider Web service availability
- SMART app
Thank you.

Questions?

Made possible by an SEA grant from ONC (Grant Number: 90AX0011/01-00)
ONC-HIP: PHARMACIST CARE PLAN (PHCP)

ONC Annual Meeting

Rick Geimer
Lantana Consulting Group
ONC High Impact Pilot Grant

- Awarded to Lantana Consulting Group
- Collaborators:
  - Community Care of North Carolina (CCNC)
  - PioneerRx
  - QS/1
Project Objectives

1. **Improve practice efficiency by**
   - Eliminating duplication of effort by pharmacists
   - Supporting pharmacists to focus on patients at high risk for negative outcomes and developing care plans incorporating CMRs for those patients

2. **Improve clinical quality by**
   - Enhancing free-text narratives with structured data
   - Sharing structured data from patient interactions between providers, pharmacist and payers

3. **Support interoperable exchange by enabling CCNC to**
   - Receive PhCPs from pharmacy management systems
   - Validate against the specification
**Phases of the Project**

**Phase 1:** Project Launch, Standards Development, and Training

**Phase 2:** Initial Implementation, Refinement, and Testing

**Phase 3:** Full Implementation and Data Collection

**Phase 4:** Data Analysis and Reporting
Three key tools placed into the public domain:

• CDA (Clinical Document Architecture) and FHIR® (Fast Health Interoperable Resources) implementation guides (IGs) for PhCPs
• A library of bi-directional transformations converting PhCP FHIR to and from PhCP CDA
• PhCP FHIR and PhCP CDA training for implementers delivered in person and materials delivered to ONC
Dual CDA/FHIR IGs

- First dual CDA/FHIR IG development project
- Included CDA and FHIR examples
- Demonstrated a viable pathway for CDA/FHIR integration and transition planning
CDA <--> FHIR Transforms

- Open Source
- Targets the PhCP document type, but extendable to others
- Bi-Directional
  - **FHIR to CDA**: Comply with existing C-CDA standards while moving early to FHIR
  - **CDA to FHIR**: Load FHIR systems and servers with C-CDA data
ClinFHIR Resource Graph
Pharmacy Management Vendor Training

Training plan:
• 3 days for CDA/FHIR training
• 1 week virtual Connectathon

Initial target: 2 vendors
Final trained: 22 vendors
Implementation of the standard, improved:

- **Practice efficiency** (objective #1)
  - Reducing redundant manual data entry
  - Increasing time for patient engagement with pharmacist

- **Clinical quality** (objective #2)
  - Increasing structured data capture, supporting automated clinical quality measurement
  - Speeding data sharing (pharmacies $\rightarrow$ CCNC), supporting reporting

- **Interoperability** (objective #3)
  - Delivering standard-based structured and coded reports
  - Validation, conversion (CDA to FHIR) done by CCNC
Clinical Quality—structured data capture, supporting automated clinical quality measurement

• Assessed PhCP data for calculating three pharmacy-based measures:
  - Percent of Antihypertensive Drug Users Adherent to Antihypertensive Therapy
  - Percent of Antihyperlipidemic Therapy Users Adherent to Antihyperlipidemic Therapy
  - Percent of Patients Adherent to Multiple Chronic Medications

• Found that PhCP specifications and submitted files contained all data elements required to calculate these measures
Interest in the standard grew substantially during the pilot.

- At start of pilot, only 2 pharmacy management vendors involved
- By the end of pilot, trained 20 more organizations

The standard will be reviewed by a larger audience as both specifications move through the HL7 ballot process, opening an opportunity for nationwide adoption.
Cincinnati Children’s Hospital Medical Center
Standards Exploration Award Project Summary

ONC Annual Meeting

Keith Marsolo, PhD
Associate Professor
Division of Biomedical Informatics
Cincinnati Children’s Hospital Medical Center
December 1, 2017
Cincinnati Children’s Hospital Medical Center (CCHMC) – FY16 numbers

- 629 inpatient beds
- 1.3M patient encounters
- 15K+ employees
- $200M in research grants & contracts (3rd in pediatrics)

- Informatics / Information Technology support
  - Operations – Department of Information Services (IS)
  - Research – Division of Biomedical Informatics (BMI)
CCHMC Biomedical Informatics Data Services

- Service areas
  - Research data warehouse & Honest Broker service
  - Support for distributed research networks
  - Infrastructure & standards to support learning health systems
  - Integration with the electronic health record (EHR) to support quality improvement (QI) & research

- Structure
  - ~25 staff, mix of application & database developers, project management
  - Led by staff director & faculty advisor (Marsolo)

- Project is a collaboration between BMI & Information Services
Motivation

• Learning health system
  • Data captured in EHR supports clinical care, QI & research
  • Supports learning cycle – knowledge to practice & practice to knowledge

• Reusing data from the EHR – typical workflows:

  - Data entered into EHR (structured field or note)
  - EHR Reporting Database / Warehouse
  - Custom program developed to extract data
  - Chart abstraction onto paper form
  - Data uploaded to external repository
  - Double-data entry into Case Report Form(s) (CRFs)

• Challenge with option #2 – process to develop/deploy standardized data collection forms within the EHR at scale is cumbersome
Other alternatives

- Capture data in EHR -> pre-populate eCRF -> coordinator completes remaining fields

- Potential benefits
  - Save time on chart abstraction
  - No need for EHR-specific form (eventually)

- Potential drawbacks
  - Resources need to configure & maintain new interfaces are unknown
Proposed project

• Description
  • Collect data on time required to complete eCRFs using double-data entry compared to eCRFs launched from the EHR with pre-populated fields
  • Test using ongoing pragmatic clinical trial, CCHMC as testbed

• Interoperability need(s):
  • Leveraging the EHR and other health information technology (HIT) systems to integrate healthcare and clinical research
  • Pre-population of research CRFs from EHRs

• Priority category – Self-identified

• Impact Dimensions – Cost Efficiency
  • Metric – time to complete form; time spent on chart abstraction
Relevant standards

- Retrieve Form for Data Capture (RFD)
  - Retrieve Form
  - Display & complete Form
  - Return data to requesting application

- Fast Healthcare Interoperability Resource (FHIR)
  - Application Programming Interface (API)-like approach to healthcare data
  - Web service-based requests for common data elements

- SMART on FHIR
  - Authentication & authorization – OpenID and OAuth2

- Structured Data Capture
  - Successor to RFD
  - May eventually allow external form to write to EHR & to external repository
  - Very early in adoption

Data entered into EHR

EHR Reporting Database / Warehouse

External data repository
Trial information

• Clinical Outcomes of Methotrexate Binary treatment with INfliximab or adalimumab in practicE (COMBINE)
  • Funded by the Patient-Centered Outcomes Research Institute (PCORI)
  • Compare outcomes of patients with Crohn’s Disease who receive anti-tumor necrosis factor (anti-TNF) medications with those that receive anti-TNFs and low-dose methotrexate

• Patients recruited from centers in the ImproveCareNow (ICN) Network
  • 106-center quality improvement & research network focused on pediatric Inflammatory Bowel Disease

• Trial data are collected in a module of the ICN registry
  • Screening / randomization + follow-up study visits (every ~10-13 weeks)
  • Currently have 102 patients randomized across 25 sites
High-level project tasks

• Determine optimal placement in EHR for “button” (hyperlink) to launch registry

• Develop extensions to allow registry to be called from the hyperlink

• Reconfigure the registry to minimize extraneous display content

• Configure web services to allow EHR data to pre-populate the CRF

• Allow research coordinator to log in to the registry using EHR credentials
Project workflow

*Mockup. Unable to share full EHR screenshot publicly.
**Project workflow (2)**

*Mockup. Unable to share full EHR screenshot publicly.*

![EHR Mockup](image-url)
Project workflow (3)
Results

- Deployed technology solution ~1 month ahead of schedule (early June 2017)

- Collected data on study visits pre-deployment (CCHMC & 2 other COMBINE sites) & post-deployment (CCHMC)
  - Slower-than-expected-recruitment limited # of visits
  - Initial findings: decrease in abstraction time (~10 minutes); slight increase in data entry time (~1.5 minutes) – may artifact from low number of visits or potentially for time spent validating pre-populated data

### Pre-deployment

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<tr>
<th>Site</th>
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<th>Data entry</th>
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</tr>
<tr>
<td>Site Y</td>
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<tr>
<td>Site Y</td>
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<td>Site Y</td>
<td>30</td>
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**Average (minutes)** 25 5

* Numbers reported appear to combine abstraction & data entry into a single value; subsequently removed from analysis

### Post-deployment

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<tr>
<th>Site</th>
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</tr>
<tr>
<td>CCHMC</td>
<td>8</td>
<td>8</td>
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**Average (minutes)** 15 6.6
Key findings / Lessons learned

• Time savings limited by number of CRF elements captured discretely in EHR
  • COMBINE study visit CRF only had a handful of applicable variables (weight, labs)

• Initial sequencing of events posed a challenge (e.g., tried to request access to web service first)
  • Bring all functions together first – make sure everyone understands hand-offs and sequencing
  • Frequent huddle to ensure that progress continues

• Process for deploying & enabling access to FHIR resources is not well-defined
  • Frequent contact with vendor to understand all the steps
  • FHIR standard does not reflect the way data have been captured over time – will need to validate each variable for time range in question

• OpenID not completely supported by EHR vendor
  • Vendor-specific workaround exists, but was not well-documented
  • Suggested as area for vendor improvement in documentation & training
Acknowledgements

• Project team
  • Keith Marsolo
  • Dan Jeffers
  • Billy Shuman
  • Jeremy Nix
  • Ron Bryson
  • Katie Lake
  • Jareen Meinzen-Derr

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  • Kevin Leaton
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  • Pushya Ramaswamy
  • Wayne Geers
  • Megan Bachman
  • Nicole Slonaker
  • Steve Metz

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  • PCS-1406-18643 (PCORI)
  • CCHMC

For more information, please contact:
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Questions?