Achieving Measurable Burden Reduction by Instantiating “Source of Truth”

Modeling a Data-Quality Specification Standard and Workflow Support for Medication Reconciliation

Phase 1: Pilot-Ready, Limited Scope
Phase 2: Prototype Build to Pilot Plan
Phase 2.1 Rescanning The Environment

An HL7 EHR Systems Standards Workgroup Initiative

January 16, 2023
Current State: Still on Pause

Keystones for next step (prototype build) remain unmet

1. Defined end-user
   a. University of Alabama-Birmingham HIV Clinic lost control of its HIT, dropped out
   b. Candidate project thru Saperi Systems changed from Q1 2023 to Q3 2023
   c. CIHC Hypertension Project (with MITRE) not looking at MedRec until Q4 ‘23 or later.

2. Resources/Funding
   a. Saperi Systems continues to build prototype on “as time/resources permit” basis
   b. CIHC funding for technology build not available at this time

Current known “best case” requires funding for 1b.
Work to Undertake Q1 and Q2 2023

1. Continue development of artifacts

2. Seek additional end-use/end-user channels
   - Leapfrog Group  https://www.leapfroggroup.org/
   - 3GPP Telecommunications SDO Consortium  https://www.3gpp.org/
   - Know others? Pass them along!
Artifacts-In-Progress

• User Scenarios representing As-Is State, To-Be State, with inventories of burdens mitigated, eliminated (stable-unchanged since 9/22)
• User Story Formalisms Framework (HL7 Use Case Format) (extended, thank you Gary and Keith)
• Usability Factors Formalisms (Failure Mode and Effects Analysis) (stable-unchanged)
• Revisions to Wireframe workflow representation (stable-unchanged)
• Incorporation of data element mapping in FHIR already done by joint HL7/NCPDP White Paper (incomplete)
• Project Plan with NCPDP Workgroup 10/14 (stable, work remains pending)
• Development of Accuracy/Authenticity “White Paper” for Data Quality Science to U.S. Law and Legal Process, ASTM E-2147(18), and FHIR 5.0, including the Joint NCPDP HL7 Initiative (incomplete)
• “Swimlane” representation of project thru prototype and pilot (incomplete)
New Events, Discussion, Questions

October 9 New York Times
Life Expectancy
Legal/Law (U.S. Domain)
Others (?)

Discussion?

Questions?
The Opposite of Clinician Burden

*Care Quality and Clinical Operations Enhancements-by-Design*

Science-Grade Clinical Care and Decision-Making

requires

Science-Grade, Trusted, Accessible, and Fit-for-Use Data

Extending CLIA’s success model to infinitely variable, unregulated EHR Systems
Initial cRML Team (alphabetical)

Samuel Almasi, D.O. (Family Practice Resident, Adventist Health (Glendale)
Gary Dickinson, HL7 EHR Systems Workgroup Co-Chair (Ind)
Reed Gelzer, MD, MPH (Trustworthy EHR, LLC)
Lisa Masson, MD, MBA (Cedars-Sinai)
Brooke Penney, MSW, LGSW, MHSI (University of Alabama-Birmingham/UAB)
Keith Salzman, MD (Ind/MHS retired)
David Schlossman, MD (Ind)
Noa Segal, PhD (Duke Human Simulation and Patient Safety Center)
James Tcheng, MD (Duke)
Lincoln Weed (Ind)

With special thanks for additional end-use requirements input from UAB’s Dr. James Willig, Alfredo Gonzales
Expanded cRML Team 2022 (alphabetical)

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Melissa Christian (UNebraska/CIHC)
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Shelly Shapiro, Executive Director, Pharmacy HIT Collaborative
Noa Segal, PhD (Duke Human Simulation and Patient Safety Center)
James Tcheng, MD (Duke)
Nancy Vega (Ind)
Lincoln Weed (Ind)
John Windle ((UNebraska/CIHC Acting Director)
Tom Windle (UNebraska/CIHC)
Project Origination

Reducing Clinician Burden

• Challenge from CMS Representatives: Practical (utility and scale) project to address documentation burden

• Convened clinician interest group, reviewed options that met “utility and scale”
As-Is State and Potentials

• EHR “Medication Lists” are inconsistent, often out of date, of uncertain origins, untrustworthy

• Extensive evidence that medication errors contribute to clinical errors, patient harms, costs

• Lost value of clinical professionals’ work and rework curating current medication information (difficult to find, undifferentiated, or lost)

• When accessible and useable, very high utility for clinical decision making

• Good starting point for incremental address of complex interoperability challenges that also cause extensive burden (ex: Problem List, integration into Problem-Oriented Health Record)
Project Objectives

A “trusted, accurate rendering of current medication list” supported by

• Initial “minimum necessary” scope as determined by clinician participants
• User-friendly, data normalizing workflow
• Creates an output that is impactful, trustworthy, and interoperable in all respects.
• Machine-verified conformant with fitness for use specifications per Data Quality Science and U.S. Domain definition of authenticity.
Phase 2: Start Points

• End-user/implementer partner (University of Alabama HIV Clinic) forced to withdraw
• Next-step research indicated that most (all?) forward paths would require a prototype
• Project leadership transferred to resource-backed management (Center for Intelligent Healthcare at University of Nebraska)
• Recruitment of a technical partner enterprise with shared mission, purpose, and production experience (Saperi Systems) for prototype development
• Establishment of baseline procedures for working with NCPDP WG 10/14 as SME on Pharmacy Data Standards
• Securing end-user/implementer partner replacement remains in-progress. Key attributes include projects with complementary baseline requirements:
  • A source-of-truth ready current medication list as (def: what is the patient actually taking now)
  • A near-term project plan, with end-use/implementation site that requires a working prototype
  • Conformance with Data Quality Science constructs including specification-defined fitness for use parameters
  • Acceptance of machine-verified specification conformance
  • Patient control of PHI sharing
Thank you

Questions, input welcome

Meetings to resume when definitive end-user/implementer re-established

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HL7 Confluence Page: (updates pending)
https://confluence.hl7.org/pages/viewpage.action?pageId=104568480#ReducingClinicianBurden(RCB)-HL7RCBProjectFocusTeam-MedicationListManagementandReconciliation
Additional Information
Aspiration: “Universal Source-of-Truth” Exchangeable Medication List

Working Model Programming

Objective: Translate the work into:

1. A “pilot-suitable” Application Programming Interface (API) supporting workflow assuring reliability in data origination, retention, and rendering (outputs) and exchange, for demonstration and further testing purposes.

2. A FHIR 4.0 Implementation Guide (Conformance testable)
   a. Data specification designed for data normalization in local and exchange environments and incorporating conformance testing
      • Local-tests conformance, similar to local laboratory data quality assurance protocols, automated
      • Exchange: Sender and receiver each assert and confirm conformance with the reference specification Standard for universal trust, similar to CLIA operations, using the ISO 21089 Record Lifecycle Event (RLE) components expressed in FHIR 4.0
      • “Source of Truth” Example NCPDP ResQ™ Project as a near-analog, supporting a single, trusted resource for pharmacy credentialing data
      • Reference specification “library” suitable for automating data object conformance testing against specifications of differing complexities.
   b. Enablement of exchange infrastructure validating conformance (yes/no acceptance or conditional acceptance, similar to CLIA for lab results.)
Phase 1 End-Points

- "Minimum necessary for utility, impact" parameters
  - Capturing initial scope inclusions, focusing on reducing burden,
  - Small scope expansion to illustrate a value-add element (MA scope of care correction)
  - Capturing “parking lot for next steps” Ex: Inpatient, Outpatient non-Rx/OTC meds)
- End-user/implementer business and clinical case representation adaptations (Thank you University of Alabama at Birmingham, HIV Clinic)
- Outreach to Federally Qualified Health Center constituencies in Alabama and Mississippi
- Outreach to Cedars-Sinai as potential end-use representative and implementer
- Basic environmental scan via participants’ experience with current systems
- User Scenarios representing As-Is State, To-Be State, with inventories of burdens mitigated, eliminated
- User Story Formalisms Framework (HL7 Use Case Format)
- Usability Factors Formalisms (Failure Mode and Effects Analysis-Thank you Dr. Noa Segal)
- Revisions to Wireframe representation
- Incorporation of data element mapping in FHIR already done by joint HL7/NCPDP White Paper
- Achieved Project status for NCPDP
Up to 70% of Patients Have Errors on Their Medication Lists

Leveraging pharmacy staff prevents harm and increases clinician time for patient care functions

Problem

- 20% of admissions are medication-related
- High risk patients have 8 errors on admission medication lists
- Only 5.3% of patients 65 year or older on >5 medications have accurate lists
- One third of inpatient orders have errors and 85% originate from the medication history
- Up to 59% of errors can cause harm
- Up to 80% of patients have at least 1 medication error at discharge

Solution

On admission, studies demonstrate increased accuracy of medication lists obtained by pharmacy staff vs usual care

- Accuracy rates: Nurses, 20%; Hospitalists, 50%; Technicians, 100%
- Nurses 14% vs pharmacy technicians 94% (p<0.0001)

At discharge, pharmacists identified errors in medication lists in 49% of patients and problems in an additional 16% vs usual care

Business Case

Cost of Harm

- Cost of adverse drug event (ADE): $2,262 - $5,790
- Increased length of stay due to ADE: 3.1 days
- Cost/readmission ~ $12,300-13,800

Benefits

- 75% reduction in ADEs
- 41 minutes of nursing time saved/patient
- Cost-effective to utilize technicians for medication histories; $830,000
- Patients have an accurate medication list upon discharge
- Reduced readmissions
- Enables clinicians to practice at the highest level of their license and training

Recommendation: For high risk patients, pharmacy will ensure the accuracy of the medication list at admission and discharge
“Improving admission medication reconciliation with pharmacists or pharmacy technicians in the emergency department: a randomised controlled trial”

Joshua M Pevnick, Caroline Nguyen, Cynthia A Jackevicius, Katherine A Palmer, Rita Shane, Galen Cook-Wiens, Andre Rogatko, Mackenzie Bear, Olga Rosen, David Seki, Brian Doyle, Anish Desai, Douglas S Bell

**Conclusions** Pharmacists and technicians reduced AMH errors and resultant AMO errors by over 80%. Future research should examine other sites and patient-centred outcomes.

Citation: Pevnick JM, Nguyen C, Jackevicius CA, et al. BMJ Qual Saf Published Online doi:10.1136/bmjqs-2017-006761

*Note: A universally applicable/common data set and workflow will facilitate, the recommended “Future research examining other sites, outcomes.”*
Incremental Lessons Reinforced

• Current systems capture useful, impactful clinical information that’s inaccessible, easier to re-do (over and over) than to find. Invested cognitive effort is substantially if not entirely lost

• “Re-work” is a huge drag on clinician uncertainty and morale, both rarely recognized or measured thus rendering these burdens partially invisible while also expanding risk

• The fact that correct information exists (ex: reconciliation notes) but un-accessed is readily discoverable and elevates institutional risk.

• **Commitment to “Closed Loop” modeling and execution is critical, effective**
  • An information requirement identified must be methodically managed to closure
  • “Truth” is dynamic, continuously maintained. Revalidation is required to assure continuous trust
  • Usability science captures these requirements, renders them actionable

• **Criticality of development of the Record Lifecycle Event (RLE) as means to represent accuracy and authenticity constructs from Data Quality Science**

• **HL7 institutional reluctance to expand its mission to include accurate data and authentic records in its “interoperability” constructs**