Diabetes Data Strategy Project ('Diabe-DS')

Overview and Status Update

January 2010

Objectives

- Understand the purpose and scope of the Diabe-DS proof-of-concept project
- Review the status of project work completed to date
- Discuss next steps

HL7 Workgroup Sponsors

- EHR Workgroup (primary sponsor)
- Clinical Interoperability Council (co-sponsor)
- Patient Care Workgroup (co-sponsor)
- RCRIM (co-sponsor)
- Interoperability Workgroup (co-sponsor)

A Collaborative Team Effort

Project Facilitators

Don Mon
Rachel Richesson
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Project Team Members

Pat Gunter
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Gary Dickinson
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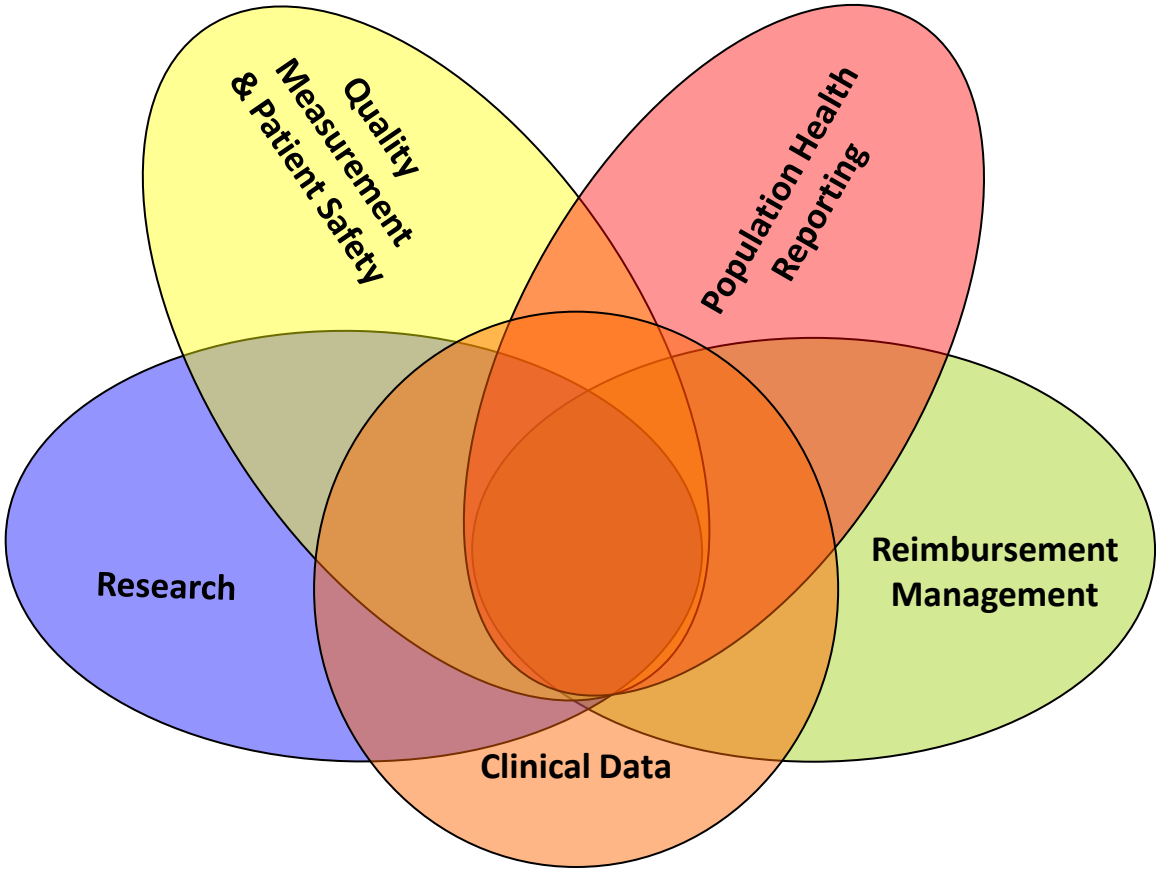
Stakeholders

- EHR vendors
- EHR users/clinicians (specifically those caring for kids/diabetics)
- Secondary data users (research, quality, etc.)
- Standards groups looking at methods for domain-specific data standards
- Professional groups (ADA, clinical societies, etc.)

Uses of Data Have Significant Overlap

Premise of project:

- Develop a process to identify a common set of data elements in the center of overlap for a given clinical domain/ therapeutic/disease area.
- Establish the framework to repeat the process in other domains.



Graphic by Don Mon, 5-2009

Project Goals

1. Develop a small set of data elements for the outpatient diagnosis of Type 1 Diabetes(T1D) that overlap* between electronic health record (EHR) and some secondary uses – like research and quality monitoring.
2. Look at how elements can be harmonized to support the "collect once, use many" paradigm.
3. Tie data elements and data use requirements to EHR system functions
4. Document the process, procedures, & lessons learned for subsequent projects.
5. Set the stage for T1D stakeholders to vet/enhance the elements to produce a true clinical T1D DAM.

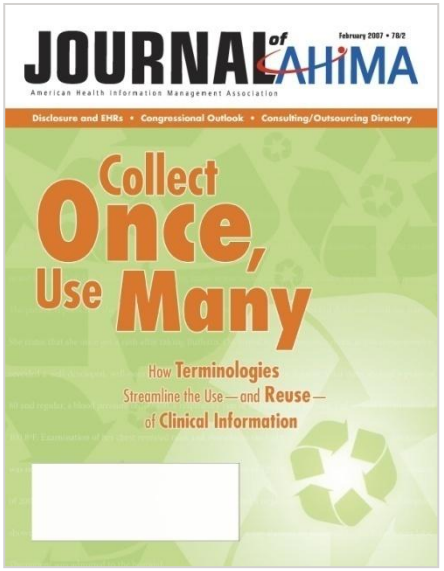
* Because the goal was to pick research measures that were likely to have related content in the EHR, we did not produce a comprehensive set of research data elements for T1D.

Related Industry Initiatives

- HITSP Clinical Research and Quality Use Case interoperability specifications and corresponding data dictionary (C154)
- HL7 Clinical Interoperability Council (CIC)
- CDISC clinical domain initiatives, SHARE, BRIDG
- NQF Quality Data Set / HL7 Health Quality Measure Format (HQMF)
- Detailed Clinical Models (DCM)
- Clinical Information Interchange Collaborative (CIIC)
- ASPIRE
- CDS Consortium

Collect Once, Repurpose Many Times

- Data in EHR now
  - Can be used in its native form
  - Data must be transformed either in, or outside of, EHR
- Data is not in EHR now, but can be
  - Can be used in its native form
  - Data must be transformed either in, or outside of, EHR
  - Data is in EHR now, has clinical, but no secondary data, use (not repurposed)
- Data has secondary, but no clinical use
  - Need not be in EHR
  - Must be collected outside of EHR



Granularity of data is important

Adds no data collection burden to physician, but data can still be collected in re-engineered work flow

Slide by Don Mon, 5-2009

Definitions

- **Data element** – a unit of data for which the definition, identification, representation and permissible values are specified by means of a set of attributes[(1)]
- **Reuse data element** - a unique concept defined for a particular secondary data use (e.g., quality reporting, research, population health, etc.)
- **Atomic data element** - the lowest level data point in which a concept can be collapsed
- **Common data element** –data element represented uniformly and has value across multiple domains

[(1)] ISO 11179-3

Data Sample and Analysis

- Methods for sample
  - List of important elements gathered from research forms, practice guidelines, quality measures, expert interviews, and two outpatient diabetic clinic information systems
  - Sample is an important, but not exhaustive or representative, list of data elements
- Analysis of Elements
  - Organized by conceptual groups
  - Mapping of like/similar elements
  - Examined and annotated by relationship to EHR standards

Data Element Annotation

1. Data is in EHR now
   - secondary data is native to EHR and format compatible
   - secondary data can be derived from EHR data
2. Data is not in EHR now, but can be (i.e., has clinical and secondary value)
3. Data has secondary, but no clinical use (out of scope; must be collected outside of EHR)
4. Data is in EHR now, has clinical, but no secondary use (out of scope; not repurposed)

ATOMIC DATA ELEMENT IN EHR? (yes, should be, no)	DIRECT or DERIVED

Data Element Example: In EHR Now

Research Element	Quality Meas. Element	Netherlands Element	Atomic Elements
Most Recent HbA1c Value	HbA1c Result	glyHb / HbA1c Value	• result date/time • result type (coded) • result value – **result units** • result status • result reference range

- Some atomic elements are in the EHR now, providing ability to derive data for reuse
- Some atomics elements are missing or not implemented consistently (e.g., lab result units are sometimes incorporated as part of the "result value" and sometimes stored as a separate element)

ATOMIC DATA ELEMENTS IN EHR? (yes, should be, no)	DIRECT or DERIVED
Yes	Direct

Data Element Example

Source	Data Elements	Definitions
Research	Foot problem indicator (yes/no)	Indicates of a person has exhibited signs of foot problems, i.e., infections, that are related to their diabetes.
Quality	Foot examination	Exam conducted
Quality	Foot care	Skin lesion monitoring ordered
Quality	Foot ulcer prevention	Evaluation for proper footwear and sizing
Netherlands	Foot examination	

- Could be derived from data in EHR
- There is no consensus of foot problem among secondary use communities. Need scientific analysis of problem so that we can make a recommendation of the 80% of foot problems that matter.
- Requires a bottom-up data examination. We have n# clinical trials and n# of quality reports that are analyzing foot problems/care/prevention. There should be a way that we can come up with a data-driven method to define the most important data elements.

Data Element Example

- Diabetes Management Method
  - The type of management of a patient's diabetes. Patients with T1D may be managed by insulin, oral hypoglycemic (e.g., metformin), diet, and exercise.
  - Permissible values: Diet/exercise only; pills; insulin
- Can this be derived from EHR?

HL7 Diabetes Data Strategy

- Collaboration between HL7 EHR and Patient Care WGs, Clinical Interoperability Council and others
- Agreed Project Scope specifies EHR Interoperability Use Case Templates (as employed in ONC/AHIC Use Case analysis) in parallel with HL7's DAM, DIM approach
- Status: Use Case Templates and examples offered to Diabetes Team and discussed on several Team calls
- Next: Build Out Use Case Scenarios, Events and Actions in Template, associating Data (elements, templates) with each (Action)
- Leads: Don Mon, PhD (EHR WG), William Goosen, MD (Patient Care WG), Crystal Kallem (Clinical Interoperability Council)
- EHR Interop Lead: Gary Dickinson

Challenges

- Many related projects and stakeholders. Had to cooperate/harmonize/leverage related work where possible while keeping focus.
- How important is a use-case to therapeutic-area data standards? How important are Activity Diagrams and what are we diagramming?
- Data elements will change/evolve over time. Need mechanism/tools to facilitate versioning, communication, harmonization, maintenance and updates.
  - Metadata repository
- If/how to vet data elements?

Challenges (cont.)

- Clearly, there will be overlap across domains and projects, hence…
  - Where do transformations of EHR data take place? Do we then need to clarify use cases better?
- Lack of heuristics to organize groups of data elements (e.g., demographic, lab tests, etc.)
  - Inspired by CDISC (CDASH & SDTM) domains, but could use terminology for this.
- Need for consistency /best practice for naming variables/questions/data elements
  - Same with characteristics of good definitions

Lessons Learned

- Re-think the whole concept of ‘secondary use’ of data in the context of EHRs
  - Secondary uses influence the features and content of EHRs – almost become a primary motivating force in EHR standards . In other words, perhaps research and quality do not have to be opportunistic about data but can help define the data to be captured at the point of care.
- There is still a lot of variation within research data elements
  - Example: the check box list/value list for element "diabetes related conditions" could vary between researchers and over time.

Project Status

Project Task/Deliverable	Projected Timeframe	Status
Review the DAMs (existing data sets) from USF and The Netherlands. Select a common set of T1D diabetes assessment data elements to be used in this project.	April 2009	Taken longer than anticipated; nearly complete
Map the DAMs and protocol eligibility requirements for the small set of data elements identified in #1 above to specific functions in the EHR-S FM and the Child Health and Clinical Research Functional Profiles.	April 2009	Mapping reuse elements to atomic elements; mapping to EHR-S FM functions/profiles yet to be completed
Discuss work in progress at the Bridging the Chasm (CIIC) meeting, if the opportunity arises.	April 2009	The CIIC has not convened. Monitoring the status of CIIC activities and will engage when there is opportunity.
Develop a DCM or use an existing series of DCMs (from The Netherlands) and tie them to the DAMs and the EHR-S FM and Child Health and Clinical Research Functional Profiles.	May-Aug 2009	Evaluating this component and available volunteers.
In parallel, perform steps #2 and #4 above using the Interoperability and Lifecycle Models with the EHR-S FM and Child Health and Clinical Research Functional Profiles.	May-Aug 2009	Drafting some examples
Assess the process, methodology, and outcome and determine whether to move forward with the next step.	September 2009	Work underway. To be completed in 2010.

Next Steps – 2010

- Update project deliverables/timelines
- Complete prototype analysis
- Assess the process, methodology, and outcome
- Summarize/publish prototype results
- Determine how to advance/expand the work
- Seek funding
- Formally engage various T1D experts and stakeholders
  - Coordinate with CIC, CIIC and Child Health WG to engage with professional groups (e.g., ADA, endocrinology, pediatrics) to endorse EHR standard elements (which also support data reuse)