

A Strategy for Defining Common Data  
Elements to Support  
Clinical Care and Secondary Use in  
Clinical Research

*the “Diabe-DS” project*

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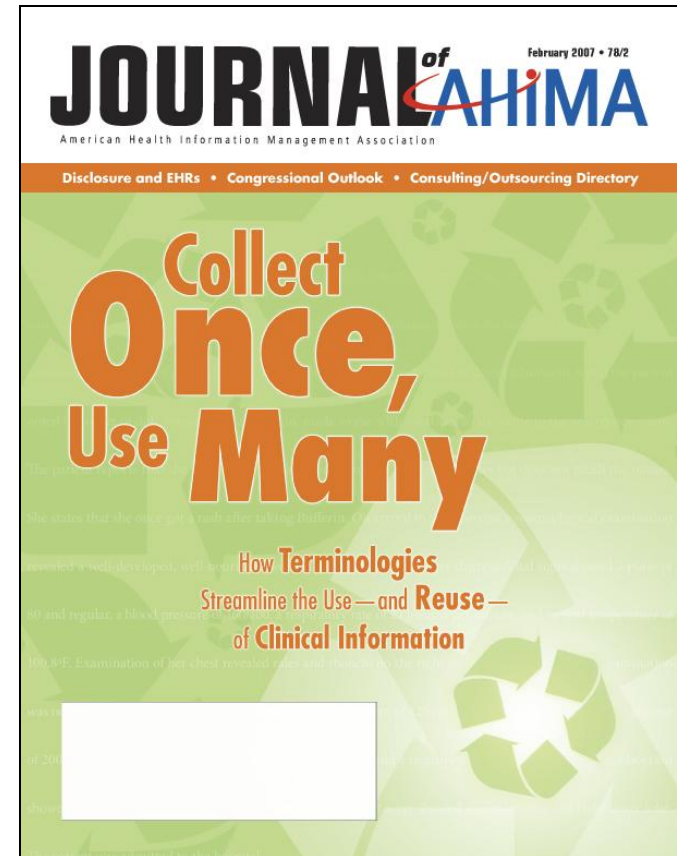
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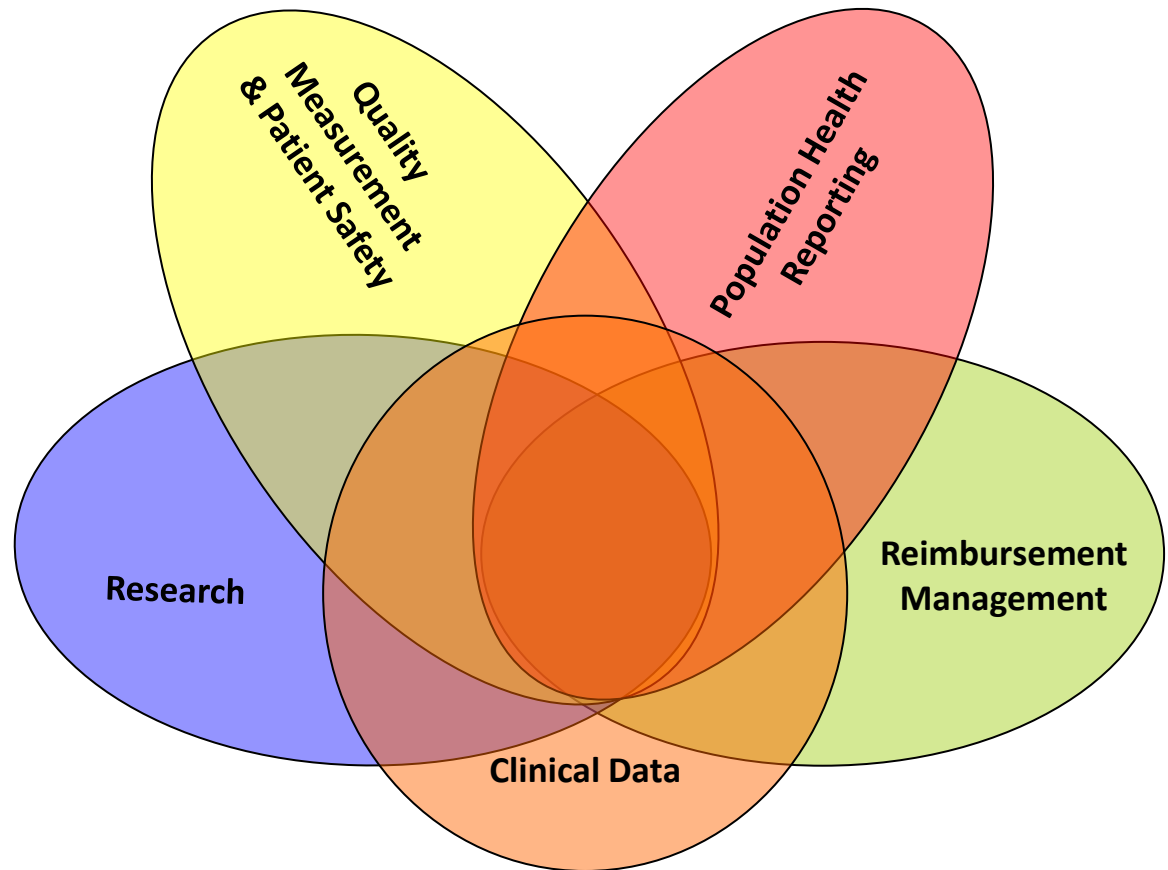
To ease secondary data collection and reporting requirements by collecting data once and repurposing many times.



# 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.



# Stakeholders

- Secondary data users
  - research
  - quality
  - population health
- Standards groups looking at methods for domain-specific data standards
- Professional societies and disease-specific organizations
- EHR developers
- EHR users/clinicians

# Diabe-DS Objectives

- Prototype a method for defining common data elements for a disease-specific domain.
- Identify methodological and process issues that must be resolved before the “collect once, reuse many” paradigm can be replicated across other domains.

# 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<sup>(1)</sup>
- **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

<sup>(1)</sup> ISO 11179-3

# Project Components

1. Develop a small set of data elements for the outpatient diagnosis of Type 1 Diabetes(T1D) that overlap\* between EHR and secondary uses.
2. Explore 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, and lessons learned for subsequent projects.
5. Set the stage for T1D stakeholders to vet/enhance the elements to produce a true clinical T1D Domain Analysis Model.



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# Sampling of Data Elements

- Hunted and gathered
  - research forms
  - practice guidelines
  - quality measures
  - expert interviews
  - two outpatient diabetic clinic information systems
- Added elements from national efforts in The Netherlands and Canada
- Filtered by “they-are-in or could/should be” in EHR
- Result: Sample is an important list of data elements, but not exhaustive or representative

# “Data Cleaning”

- Naming conventions for data elements
  - E.g., Hypoglycemia
    - Versus---
    - Hypoglycemia indicator
    - Hypoglycemia symptom
    - Hypoglycemia onset date
- Value set ‘quality’ (comprehensive, exhaustive, exclusive)
- Definitions

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# Analysis of Data Elements

- Organized by conceptual groups
- Resolution of similar elements
- Annotated by relationship to EHR standards

# Data Element Example

- Diabetes Management Method
  - Definition: “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?

# Data Element Example

Research Element	Quality Meas. Element	Netherlands Element	Atomic Elements
Most Recent HbA1c Value	HbA1c Result	glyHb / HbA1c Value	<ul style="list-style-type: none"> <li>• result date/time</li> <li>• result type (coded)</li> <li>• result value                             <ul style="list-style-type: none"> <li>– <b>result units</b></li> </ul> </li> <li>• result status</li> <li>• result reference range</li> </ul>

- Some atomic elements are in the EHR now, providing ability to derive data for reuse
- Some atomic 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 if 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.
- Requires a bottom-up data examination. Can come up with a data-driven method to define the most important data elements?



# 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**

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# Relate Data Elements to EHR Standards

- Build Use-case for secondary data uses – eligibility screening (in progress)
- Mapping reuse elements to atomic elements
- Develop a DCM or use an existing series of DCMs (from The Netherlands) and tie them to the data elements.
- Map the data elements and protocol eligibility requirements to specific functions in the EHR-S Functional Model and the Child Health and Clinical Research Functional Profiles.
- Assess the process, methodology, and outcome and determine whether to move forward with the next step.





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# Challenges

- Many stakeholders
- Overlap across domains and projects
- How important is a use-case to therapeutic-area data standards? How generalizable and abstract does it need to be?
  - 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 (SDTM) domains
- Need for consistency /best practice for naming
  - Same with characteristics of good definitions

# Challenges (cont.)

- If/how to vet data elements?
- Data elements will change/evolve over time. Need mechanism/tools to facilitate versioning, communication, harmonization, maintenance and updates.
  - Metadata repository



# Lessons Learned

- There is still a lot of variation within research, quality, and clinical data elements
- Harmonizing secondary use data elements is complicated
- Multi-disciplinary
- Re-think the whole concept of 'secondary use' of data in the context of EHRs
  - Secondary uses influence the features and content of EHRs

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# Related Initiatives

- HITSP Clinical Research and Quality Use Case interoperability specifications and corresponding data dictionary (C154)
  - Lots of HITSP items like Form standard, ... (listed in clinical research use case..)
- HL7 Clinical Interoperability Council
- CDISC clinical domain initiatives, CSHARE
- NQF Quality Data Set / HL7 Health Quality Measure Format (HQMF)
- Detailed Clinical Models (DCM)
- Clinical Information Interchange Collaborative (CIIC)
- ASPIRE
- CDS Consortium
- AHIMA/ Bridging the Chasm Meeting

# A Collaborative Team Effort

## Project Facilitators

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## Diabetes Data Strategy Project

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### Project Overview

Welcome to HL7's Diabetes Data Strategy Project wiki page!

This project is focused on the minimum data set and data standards in EHR systems for Type 1 diabetes (T1D) assessment in ambulatory care settings. The project is an instantiation of the 'collect once, repurpose many times' principle.

### Project Leaders

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