Standardizing Clinical Data Elements to Support Regulatory Review of Marketed Therapeutics

Rachel Richesson, PhD -- Duke University School of Nursing, DCHI
W. Ed Hammond, PhD -- Duke Center for Health Informatics (DCHI)
Bron Kisler -- Clinical Data Interchange Standards Consortium (CDISC)
Meredith Nahm, PhD -- Duke Center for Health Informatics (DCHI)
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 (ISO 11179-3)

• **Clinical data element** – data element used in context for patient care

• **Common data element** – data element represented uniformly across multiple sources or settings
Motivation

• Although safety data are relatively well-defined and standardized through CDISC SDTM,

• Efficacy data, *i.e.*, the trial endpoints are not.

*Problems:*

– Finding the data in the submission
– Understanding precise definitions and measurement method/s for comparability to similar endpoints from other trials
– Inability to pool data across trials for secondary uses important to public health, *e.g.*, ISS/ISE, class effect analysis, detection of rare safety signals, combination with post market data for safety surveillance, ...
Early Data Element Standardization

Commonalities
• standardize or in some way define data elements for a disease, disorder or clinical specialty/domain area.
• focused on an intended data use, i.e., a clinical trial, registry, performance measures
• majority were initiated by government agencies, thus, the data elements publically available.

Examples
• Uniform Hospital Discharge Data Set (UHDDS) for billing,
• Surveillance Epidemiology and End Results (SEER),
• Birth defects & Death registries,
• Implant, Immunization, & Trauma registries,
• UNOS Organ transplant,
• The Joint Commission measure sets,
• National quality improvement registries sponsored by clinical professional societies
  – Society for Thoracic Surgeons (STS)
  – NSQIP
  – Get with the Guidelines, ...
  – CDEs for neuroscience-related clinical research²
  – Oncology CDEs in caDSR³
  – traumatic brain injury and psychological health⁴
  – posttraumatic stress disorder (PTSD)⁵
  – potentially adverse psychological health outcomes from the stress of military operations⁶
  – Data Elements for Emergency Department Systems (DEEDS)⁷
FDA Solution (interpretation)

• Promote creation and use of “disease/domain-specific data standards”

• These consist of
  – Clinical concepts for a specific disease or clinical domain area.
  – Their relationships
  – Associated standard terminology (including standard value sets)

“Ideally, data requirements for multiple use cases (e.g. healthcare, clinical research, public health reporting, regulatory review) are used to create a “superset” data standard that can support multiple uses of the data. This harmonization can help break down the information silos that adversely impact assessments across a medical product’s lifecycle.” - FDA data standards web page
FDA/CDER Data Standards Plan

- Current version: 1.1  December 15, 2010
- Issued by: FDA/CDER Office of Planning and Informatics
- Purpose: to support and promote development of data standards for all key data needed to make regulatory decisions.
- Program objectives:
  - Ensure that useful, publicly-available data standards exist;
  - Ensure that there is a well-defined standards adoption process in place;
  - Ensure that regulatory data is submitted according to those standards; and
  - Ensure that regulatory review processes can fully leverage the standardized data.

Known Challenges with Standardizing DEs:

- Some domains have well-defined “de facto standard”, others do not.
- There is a difference between standardizing data elements (atoms) and endpoint definitions (molecules).
- Standard terminology is required but may be copyrighted, not yet exist, or change over time.
- Each domain needs an authoritative steward who keeps clinical definition and technical data standards up to date with new science.
- Work of standardizing clinical definitions and technical specifications requires a measure of expert consensus and manual human labor.
  - Both require time and effort.
- Curation / maintenance / hosting require resources, yet standards need to be publically available at low or no cost.
- The time period between when standards are available and when software fully supports and leverages them will be painful.
Thoughts

• Standardizing data elements to support regulatory review of marketed products is under way.
• There are several approaches and no one method is clear.
• Demands are great; work is hard.
• Process is important.
• Big picture.....
Panel Presentations

• Regulated research, CDISC & FDA perspectives (Bron Kisler)

• Data element identification, HL7 perspectives (W. Ed Hammond)

• Diabetes data element case study (Rachel Richesson)
Therapeutic Area Data Standards: Expanding Innovative Collaborations

Bron W. Kisler
CDISC VP, Strategic Initiatives

AMIA CRI Summit
San Francisco, March 2012
The Genesis

• 2006-2008: US National Institutes of Health grants awarded to Duke University; partnered with CDISC and HL7

• Working with clinicians, focus on repeatable development methodology

• Leverage existing CDISC & HL7 processes to ensure jointly approved standard

• **Pulmonary TB**: 139 TB data elements with clinical definitions; standard TB data collection modules; implementations (industry, US CDC)

• **Acute Coronary Syndrome (ACS)**: 25 data elements with clinical definitions agreed to by clinical professional societies, regulators, industry
**FDA Goal (CDER)**

Standardize **efficacy** data elements in 57 therapeutic areas in the next 7 years

- FDA will likely require submission using these standards
- Currently in draft recommendations for enhancements in PDUFA V
- Proposed guidance to industry → Final Guidance

### Priority Disease/Domain Areas for Data Standardization

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<thead>
<tr>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
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<tr>
<td>Acne</td>
<td>Gastroesophageal reflux disease</td>
<td>Actinic keratoses</td>
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<tr>
<td>Alzheimer’s Disease*</td>
<td>Influenza</td>
<td>Aerosolized antimicrobials for cystic fibrosis</td>
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<tr>
<td>Anti-diabetic agents*</td>
<td>Irritable bowel syndrome</td>
<td>Atrial fibrillation</td>
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<td>Crohn’s Disease</td>
<td>Lipid-altering drug groups</td>
<td>Attention Deficit Hyperactivity Disorder</td>
</tr>
<tr>
<td>Infections of skin and/or subcutaneous tissue</td>
<td>Major depressive disorder</td>
<td>Bacterial vaginosis</td>
</tr>
<tr>
<td>Oncology: time to efficacy event other than overall survival*</td>
<td>Objective tumor response*</td>
<td>Chemotherapy-induced</td>
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<td>Rheumatoid arthritis</td>
<td>Ulcerative colitis</td>
<td>Chemo therapy-induced</td>
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<td>Schizophrenia</td>
<td>Pneumonia</td>
<td>Pain*</td>
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<td>Solid organ transplantation</td>
<td>Prevention of HIV</td>
<td>Parkinson’s Disease*</td>
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<td>Treatment of Hepatitis C*</td>
<td>Treatment of HIV</td>
<td>Prevention of pregnancy</td>
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<td>Treatment of postmenopausal osteoporosis</td>
<td>Treatment of overactive bladder</td>
<td>Psoriasis</td>
</tr>
<tr>
<td>Tuberculosis*</td>
<td>Treatment of vasomotor symptoms due to menopause</td>
<td></td>
</tr>
</tbody>
</table>

FDA Goal: Reduce Time to Access and Analyze Data to Increase Time for Review

Source: Theresa Mullen, PhD, FDA CDER Associate Director
FDA R24 Funding Efficacy Data Standardization Work

• FDA PAR-11-209 R24 – small awards of 1-year duration; 6-month grant submission cycles
  ▪ 1R24FD004271-01 (Duke) Schizophrenia and Cardiovascular Imaging
  ▪ R24 FD004273-01 (CDISC) Hepatitis-C / Virology

• Critical Path Institute (C-Path) projects thru FDA-C-Path MoU and CDISC Partnership

• Great area for CTSA involvement, so that standards will support research funded by NIH Institutes and Centers!

CDISC Therapeutic Area Projects with Initiating Organization(s)

<< Through 2011 >>
- Tuberculosis (NIH, Duke)
- Acute Coronary Syndrome (NIH, Duke)
- Cardiovascular Disease (FDA, ACC, Duke)
- Polycystic Kidney Disease (PKD Foundation, C-Path)
- Alzheimer’s (C-Path)
- Parkinson’s Disease (NINDS, C-Path)
- Tumor Response (NCI, FDA)
- Other: Pain & Analgesics (FDA, U. of Rochester, FDA)

- Other Neurological Disorders (NINDS) such as TBI
- Oncology common across all cancers (NCI)
- Diabetes (FDA, HL7 CIC)
- Hepatitis-C / Virology (FDA)
- Vaccine Safety (IMI Europe)
- Schizophrenia (FDA, Duke, HL7 CIC)
- Other: Medical Devices and Imaging (NCI, FDA)

<< 2012 and beyond >>
- Expand TB (Gates, C-Path, Global TB Alliance, IMI Europe)
- Other Neurological Disorders (NINDS)
“Standards for Patients” through the eyes of a practicing physician
PKD Clinical Use Case

Desired future endpoint

Current endpoint

Concentrating defect, Hypertension, Proteinuria

Pain, Hematuria, Stones, Infections

Source: Dr. Ron Perrone PKD Foundation & Tufts Univ.
PKD Project Aims

• Develop standard clinical data elements and definitions that are specific to PKD to enable the remapping of retrospective data and collecting prospective data in a standard format

• Develop the PKD standard with clinical (and standards) experts and obtain broad consensus through CDISC public comment; ensure input from both FDA and EMA

• Create a new database of aggregated data from existing multiple, longitudinal, and well-characterized research registries maintained over decades by leading academic institutions in PKD clinical investigation

• The disease models will be used as evidence in a formal application to the FDA and the EMA for qualification of Total Kidney Volume as a biomarker “fit for use” in evaluating the efficacy of new therapies and treatments for PKD

Source: Dr. Ron Perrone PKD Foundation & Tufts Univ.
The Patient Ultimately Benefits

• Our goal is to gain scientific consensus that TKV is the most sensitive and specific measure to predict progression of ADPKD including progressive loss of GFR, clinical outcomes, and the development of ESRD.

• Successful completion of this project will allow formal application to the FDA and the EMA for qualification of TKV as a biomarker “fit for use” in evaluating the efficacy of new therapies and treatments for ADPKD.

• Adoption of such a biomarker will speed the development of clinical therapies to slow or stop the progression of ADPKD.

Source: Dr. Ron Perrone PKD Foundation & Tufts Univ.
COALITION AGAINST MAJOR DISEASES
Public Announcement June 11, 2010

PUBLIC RELEASE OF ALZHEIMER’S CLINICAL TRIAL DATA BY PHARMACEUTICAL RESEARCHERS
First Combined Pharmaceutical Trial Data on Neuro-degenerative Diseases;
Shared Resource from Unique Public-Private Partnership Will Help Accelerate Alzheimer’s, Parkinson’s, and Other Brain Disease Research

Washington, DC – A new database of more than 4,000 Alzheimer’s disease patients who have participated in 11 industry-sponsored clinical trials will be released today by the Coalition Against Major Diseases (CAMD). This is the first database of combined clinical trials to be openly shared by pharmaceutical companies and made available to qualified researchers around the world.
CAMD Data Repository for Alzheimer’s Disease

- CAMD Goal – identify biomarkers to id patients very early in their disease
- Using CDISC standards, remapped and pooled data from 22 clinical trials; >6,000 patients
- Database open to qualified researchers; currently >200 in 35 countries

The CAMD database is currently composed of the placebo arm data from clinical trials conducted by the member companies. These trials include drugs on the market or at different stages of development including termination.
Tuberculosis: Global Public Health Imperative

Credit: James Nachtwey

Credit: CDC Public Health Image Library
TB: Global Unmet Medical Need

TB Prevalence, Burden and Impact

- **TB kills 3,800 people every day and 1 person every 25 seconds**
- 2 billion people or *approximately* 1/3 of the world’s population is infected with TB
- 9.4 million new cases annually
- TB is the leading cause of death amongst people with HIV/AIDS

**Cases of MDR and XDR-TB are increasing**
TB: Global Unmet Medical Need

Treatment for active, drug sensitive TB consists of 4 (first line) medicines

- WHO requires the use of combination therapies to prevent resistance
- Require prolonged treatment (6-9months) and follow-up (2-years)
- Existing treatments nearly 5 decades old
- Not compatible with many HIV therapies
- Have significant drug interactions and adverse effects

New drug development tools are urgently needed
CPTTR Alliance: Critical Path to TB Drug Regimens

A collaboration to accelerate the development of new, safe, and highly effective regimens for TB by enabling early testing of drug combinations.
CPTR Goal

TB Data Standards are Key
Enhancing CDISC standards
CDISC Therapeutic Area Standards

Protocol
Form Setup & Config
Data Capture
Data Mgmt
Analysis
Submission and/or Reporting
Review

Protocol → CDASH → SDTM and ADaM

Therapeutic Data Elements (TB, Cardiology, Oncology, Neurological Disorders, Diabetes, PKD)

Controlled Terminology
What are the standards products?

1. **Standard clinical data element names, valid values and definitions (aka CDEs)**

1. Annotated sample CRFs

1. SDTM and CDASH domains with groupings for data collection and regulatory submission

1. Controlled Terminology / Coded Concepts

1. Therapeutic Area-specific User Guide

1. Clinical Domain Models
Critical Terminology Services

CDISC

TA Standards
SDTM, CDASH, SEND

TA Standards; CTR
SPL, RPS, ICSR

NCI Thesaurus

NCI Thesaurus

EVS

ENTERPRISE VOCABULARY SERVICES

NATIONAL INSTITUTES OF HEALTH

NCI

NATIONAL CANCER INSTITUTE
In Conclusion

• Many new Therapeutic Area projects (need for new standards) coming online from many directions; upfront and agreed project scoping is critical
• Improve project “air traffic control” between key driving organizations and geographic regions US (FDA, NIH), Europe (IMI, EC), Asia (Japan, China)
• Ensure positive standards experience for clinicians and researchers; encourage volunteerism
• Patient-focused projects reduce silos / walls
• Need central electronic standards library to publish and align CDEs, terminology, and information models (e.g. NCI caDSR)
Groundbreaking Advances

“The adoption of standards and common data elements across diseases is groundbreaking, promotes cross-disease analysis, and provides a rich source of information to be mined by researchers around the world.”

Barbara M. Alving, M.D., Acting Director, NCRR

NIH Launches Clinical Studies Nationwide to Investigate Rare Diseases
$71 Million Effort to Address Neglected Conditions (Friday, May 5, 2006)
The CDISC vision is to inform patient care & safety through higher quality medical research.
Clinical Interoperability Council (CIC)

Data Element Standardization Process and Products

William Ed Hammond, PhD
Director, Duke Center for Health Informatics
Director, Applied Informatics Research, DHTS
Professor of Community and Family Medicine
Professor Emeritus of Biomedical Engineering
Adjunct Professor, Fuqua School of Business

Meredith Nahm, PhD
Assoc. Director, Clinical Research Informatics
Duke Translational Medicine Institute
Assoc. Director, Academic Programs
Duke Center for Health Informatics
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Health Level Seven

• Formed in 1987
• ANSI accredited Standards Developing Organization
• International – 40 member countries
• Joint activities with other SDOs including ISO, CEN, CDISC, IHE, ASTM, NCPDP, X12, others
HL7

• First standard was motivated for enabling the creation of “best of breed” Hospital Information Systems. That series of messaging standards is known as version 2.n and is used by over 90% of hospitals in the U.S.

• Later developed many other standards based on an explicit information model (RIM) known as v3 standards

• These standards include the Clinical Data Architecture, EHR Functional Model, InfoButton and others
Clinical Activities in HL7

- Patient Care
- Pediatrics
- Cardiology
- Anesthesiology
Clinical Interoperability Council

• Purpose was to provide a process by which HL7 could engage the clinical community without turning them off with too many technical terms and acronyms

• Problem – how do we then communicate
Paths of communication

- Story boards
- Use cases
- Activity Diagrams
- Domain Analysis Models
- Data Models
- Profiles
- Implementation Guides
The Philosophy

Developing data element standards with healthcare and secondary data use stakeholders will enable standards that work for care AND also support secondary data uses such as research, performance measurement, quality improvement, and public health reporting.
Method

1. Standardize at source → healthcare
   - Data element as unit of exchange
   - Specificity sufficient for semantic interoperability
   - Work within HL7
   - Clinical definitions from Authoritative Clinical Professional Society(ies)

2. Include all Stakeholders
   - Research representation → CDISC
   - Public Health representation → CDC standards
   - Quality Imp. → Clinical Professional Societies
   - Healthcare representation → HL7
What Does the CIC Do

• Standardization of data elements for a particular set of activities

• Domain Analysis Model Artifacts produced:
  – Use cases and patient scenarios
  – Data elements and clinical definitions
  – Domain UML Class model
  – Domain UML Activity diagram

• Optional / other inclusions
  – Data collection form/screen mock-ups
  – Secondary use representation(s)
Early and Continuing CIC Infrastructure Work

• Data element standardization **process**
  – Artifacts required for balloting DAMs
  – Data element harmonization
  – Articulation with other HL7 Working Groups for technical specification development
  – Project management & reporting
  – Ballot publication

• Evaluation/Adoption of **tooling** for standardization process and making data elements publically available

• **Outreach** to Clinical Professional Societies
Therapeutic Area Projects

- Cardiology
  - Acute Coronary Syndromes (ACS)
  - Cardiovascular Imaging
- Tuberculosis
- Anesthesia
- Pre-hospital Emergency Care (EMS)
- Diabetes (pilot)
- Trauma registration
- Schizophrenia
Progress

• Cardiology
  – R1 May 2008 – 24 data elements
  – CDISC SDTM representation underway

• Tuberculosis
  – R1 Sept 2008 – 139 data elements
  – CDISC SDTM representation release for public comment expected April 2012

• EMS
  – DAM Sept 2010
  – CDA R2 May 2011

• Anesthesiology
  – Preoperative DAM Sept 2011

• Diabetes pilot completed 2011

• Schizophrenia - ballot expected June 2012
DATA

• Why
• What
• How
• When
• Where
Key Philosophy:

- Authoritative clinical professional societies define the data elements
  - e.g., cardiology definitions came from and are stewarded by American Heart Association (AHA) and American College of Cardiology (ACC)
- Identification and engagement of Clinical Professional Societies is critical.
- CIC harmonizes & represents the definitions for computational use.
Membership

- DAMs and similar standards are available without charge from HL7.
- HL7 is creating a new type of membership for clinical professionals ($100/year) to engage that community.
- HL7 is moving in many new directions and creating new standards that more strongly relate to the bioinformatics, clinical research informatics, and patient care informatics.
Thank you!
Diabe-DS

Defining Common Data Elements to Support Clinical Care and Secondary Use

Rachel Richesson, PhD
AMIA Clinical Research Informatics Summit
San Francisco
March 22, 2012
Sponsors / History

- Started in 2009
- Volunteer multi-disciplinary effort
- HL7 sponsored
  - EHR Working group (primary sponsor)
  - Clinical Interoperability Council (co-sponsor)
  - Patient Care Workgroup (co-sponsor)
  - RCRIM (co-sponsor)
  - Interoperability Workgroup (co-sponsor)
- Project Mgt effort provided by AHIMA
- Pilot completed at end of 2011 – next steps?
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.
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

- **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
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.
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, & lessons learned for subsequent projects.

5. Set the stage for T1D stakeholders to vet/enhance the elements to produce a true clinical T1D DAM.
Sampling of Data Elements

- Hunted and gathered
  - Research forms
  - Practice guidelines
  - Quality measures
  - Expert interviews
  - Two outpatient diabetic clinic information systems
  - The Netherlands
  - Canada

- Public health
Data Element Spreadsheet

- 230+ data elements specific to our objective
  - Excluded areas of obvious overlap with other standards (e.g., DCMs, Clinical LOINC)
- 75+ additional data elements reserved for phase 2

<table>
<thead>
<tr>
<th>Subject Area</th>
<th>Class</th>
<th>ITEM#</th>
<th>DOMAIN (Therapeutic) - First Pass Categorization of Data Elements</th>
<th>SUB DOMAIN: First Pass Categorization of Data Elements</th>
<th>DATA ELEMENT Name</th>
<th>ATTRIBUTE, Value Domain</th>
<th>DEFINITION, Sept 2010</th>
<th>PERMISSIBLE VALUES</th>
<th>Reference</th>
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<td>Medical Exam Observation Name (Enum)</td>
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<td>General Medicine</td>
<td>Physical Exam</td>
<td>Body Surface Area</td>
<td>The body surface area (BSA) is the measured or calculated surface of a human body, expressed in square meters.</td>
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<td>-</td>
<td>-</td>
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<td>Indicates whether or not the patient has lipohypertrophy of subcutaneous injection sites on inspection or palpation.</td>
<td>Yes, No, Unknown</td>
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<td>Symptoms</td>
<td>Polyuria Indicator</td>
<td>Indicates whether or not a person releases abnormally large amounts of urine each day, also known as excessive urination.</td>
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<td>Symptoms</td>
<td>Polydipsia Indicator</td>
<td>Indicates whether or not a person is experiencing excessive thirst that lasts for long periods of time.</td>
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<td>Symptom</td>
<td>Symptom Type (Enum)</td>
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<td>Endocrinology</td>
<td>Symptoms</td>
<td>Polyphagia Indicator</td>
<td>Indicates whether or not a person exhibits signs of excessive hunger or eating, and despite this, is still experiencing a loss in body weight.</td>
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<td>Endocrinology</td>
<td>Symptoms</td>
<td>Unexplained Weight Loss Indicator</td>
<td>Indicates whether or not a person has had a reduction in body weight without an obvious reason.</td>
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<td>Symptom Type (Enum)</td>
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<td>Endocrinology</td>
<td>Symptoms</td>
<td>Yeast Infections Indicator</td>
<td>Indicates whether or not a person has had one or more yeast infections in the vaginal or groin area, or oral thrush, in the past 4 weeks.</td>
<td>Yes, No, Unknown</td>
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<td>Medical History</td>
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<td>Endocrinology</td>
<td>Symptoms</td>
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<tr>
<td>Exam</td>
<td>Medical Exam Evaluation Name (Enum)</td>
<td>937</td>
<td>General Medicine</td>
<td>Physical Exam</td>
<td>Overweight Indicator</td>
<td>Indicates whether the patient is overweight based upon national guidelines for body weight classification in adults using Body Mass Index (BMI).</td>
<td>Yes, No, Unknown</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
“Data Cleaning”

- Naming conventions for data elements
  - E.g., Hypoglycemia
    ---Versus---
  - Hypoglycemia indicator
  - Hypoglycemia symptom
  - Hypoglycemia onset date

- Value set ‘quality’ (comprehensive, exhaustive, exclusive)

- Definition clarification
Project Components

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.
Analysis of Data Elements

- Organized by conceptual groups
- Resolution of similar elements
- Annotated by relationship to EHR standards
- Classified as “atomic” or “derived” elements
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

<table>
<thead>
<tr>
<th>Research Element</th>
<th>Quality Meas. Element</th>
<th>Netherlands Element</th>
<th>Atomic Elements</th>
</tr>
</thead>
</table>
| 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 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)
Data Element Example

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

- Could be derived from data in EHR
- Could harmonize these types of variants:
  - Top down: consensus of foot problem among secondary use communities.
  - Bottom-up data examination. Is there a data-driven method to define the most important data elements?
Use Cases

1. Patient presents in ambulatory clinic, diagnosed with Type 1 diabetes
2. Followed by endocrinologist through several visits
3. Seen by diabetic educator
4. Enrolled in research study
5. Data aggregated for quality measures
6. Public health use case (added later)
### Detailed Mapping of Use Case to Data Requirements

#### Diabetes Data Strategy Use Case

**Draft – Updated May 13, 2011**

**Initial Presentation to Primary Care Provider (Pediatrician)**

Mother takes her 16 year old daughter, Sweet Sally Teenager, to the family pediatrician after the daughter has experienced recurrent vaginal yeast infections for which she has used over the counter Vagisil. She has also had an unintentional 15 lb weightloss. The mother has also noticed that her daughter seems to tire easily and is more irritable than usual.

At the pediatrician’s office, the pediatrician conducts an assessment which includes a limited history and physical exam. Vital signs are documented which include temperature, blood pressure, pulse rate, respiratory rate and oxygen saturation. The pediatrician documents the presence of symptoms of polydipsia and polyuria. The pediatrician documents the results of a capillary non-fasting glucose (finger stick blood glucose), which although not diagnostic, is 200 milligrams per deciliter (mg/dL). He also documents the results of a urine test strip which shows large glucose as well as trace to small ketones. The pediatrician, who has had a lot of experience with diabetes in children, refers Sweet Sally to an outpatient pediatric endocrinology clinic which is part of a large, highly integrated health system. The pediatrician, including the family history, Sally’s history of childhood illnesses/viruses, problem list, physical exam findings, diagnosis list, medication and allergy lists, narrative records and lab results, are forwarded to the outpatient endocrinology office.

<table>
<thead>
<tr>
<th>Actors, Actions and Data Elements (Primary Care Visit)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mother</strong></td>
</tr>
<tr>
<td>Teenager</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Actor</strong></th>
<th><strong>Action</strong></th>
<th><strong>Data Elements</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pediatrician</strong></td>
<td>Conduct</td>
<td>Patient history [Patient history (540)]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Physical exam [Physical exam (539)]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Screening visit [Type 1 diabetes presumptive diagnosis reason (4); Encounter type (203.1)]</td>
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<tr>
<td><strong>Pediatrician</strong></td>
<td>Document</td>
<td>Polydipsia indicator [Polydipsia indicator (#164); Type 1 diabetes symptoms present indicator (700)]</td>
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</tbody>
</table>
Data Modeling

- Modeling the data elements
  - Creates a graphical depiction of data elements
  - Helps identify atomic data elements and relationship to reuse elements
  - Demonstrates how patterns can be identified in support of future large scale harmonization efforts
  - Leveraging existing standards (e.g., HITSP C154, FIM, BRIDG, etc.)
Modeling the Data Elements
Project Components

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.
Data Mapping to EHR-S FM

- Mapped data elements to the EHR-S FM
- Prototype to test the feasibility and support future information model/data profile development

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
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<tbody>
<tr>
<td>1</td>
<td>119</td>
<td>DC 1.4.2.2</td>
<td>Manage Medication List</td>
<td>The system SHALL display and report patients specific medication lists.</td>
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<td>Manage Medication List</td>
<td>The system SHALL provide the ability to capture the details of the medication such as ordering date, dose, route, and S(cription of the prescription, such as the quantity) when known.</td>
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<td></td>
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<td>Data Element Name</td>
<td>Product Concentration</td>
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</tbody>
</table>
Data Mapping to EHR-S FM

• Ambiguities in EHR-S FM Conformance Criteria
  • Manage Patient History (DC 1.2.1): The system SHALL provide the ability to capture, update and present current patient history including pertinent positive and negative elements, and information on clinicians involved.
    • What are the positive and negative elements?
    • What kind of information about clinicians?
  • Manage Patient History (DC 1.2.4): The system SHALL capture the complaint, presenting problem or other reason(s) for the visit or encounter.
    • Does this include symptoms?

• Ambiguities in data element definitions
  • Some instances may require additional information on context (med ordered versus administered, etc.)
Project Components

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.
Project overview
Projects notes
Use cases
Data element spreadsheets
Domain models
White paper
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
Project Components

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.

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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.
Successes

• Lots of interest in the project
• Engaging a very diverse group of volunteers – various perspectives and skill sets, including clinicians
• Identifying some gaps in existing standards
• Process supports a patient-centric view
• Compiled a large set of T1D data elements
• Identified opportunities to tie data elements and data use requirements to EHR system functions
• Documented the process, procedures, & lessons learned

• Have some artifacts to share... free...
(Hopeful) Next Steps...

- Tie into FDA-sponsored legacy data element projects
- Expand to link with HL7 initiatives
  - Formal HL7 DAM
  - Canonical Pedigree Project
  - CDS
- Formally engage various T1D experts and stakeholders
  - professional societies to endorse EHR standard elements (which also support data reuse)
  - Expand to type 2 diabetes (?)
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- Crystal Kallem (Lantana Consulting Group)
- Donald Mon (RTI International)
- Cynthia Barton, RN, MS (Duke, Oklahoma Fdn for Medical Quality)
- Patricia Van Dyke (ODS Companies)
- Luigi Sison, Donna Dulong (VA)
- Maryanne Quinn (Boston Children’s)
- William Goossen, PhD, RN (Results4Care)
- Wendy Huang (Canada Health Infoway)
- Pat Gunther, Yong Choi, Meredith Nahm (Duke)
- Scott Bolte (GE)
- Many other domain and technical experts (See wiki!)
  
- HL7, AHIMA
EHR Diabetes Data Strategy

Diabetes Data Strategy Project

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 aims to define requirements for T1D assessment so that such data can be collected once in the EHR, exchanged for continuity of care reasons, and shared among providers. This project is an instantiation of the 'collect once, repurpose many times' principle.

Project Leaders

Crystal Kallem
American Health Information Management Association (AHIMA)
Phone: 312-233-1537

Rachel Richesson
University of South Florida (USF)

Don Mon

Questions or Comments: Rachel.Richesson@duke.edu
Further reading....

- Diabe-DS Project White Paper!!

- Diabe-DS project overview: