# Health Care Systems Research Collaboratory Grand Rounds:

# Enhancing EHR Data for Research and Learning Healthcare – A collaborative Approach to Standards

Rachel Richesson, PhD

February 1, 2013

A Virtual Home for Knowledge about Pragmatic Clinical Trials using Health Systems: www.theresearchcollaboratory.org

The Collaboratory

# Asking Questions and Getting Help

- To enhance audio quality, all attendees have been muted.
- To ask the speaker a question, send a chat message to “Everyone.” Your question will be answered during the Q&A.
- For technical support, send a private chat message to “Technical Support.”

# Enhancing EHR Data for Research and Learning Healthcare – A collaborative Approach to Standards

HCS Research Collaboratory Grand Rounds

February 1, 2013

Rachel Richesson, PhD
Associate Professor, Duke University School of Nursing

Duke Center for Health Informatics

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# Objectives

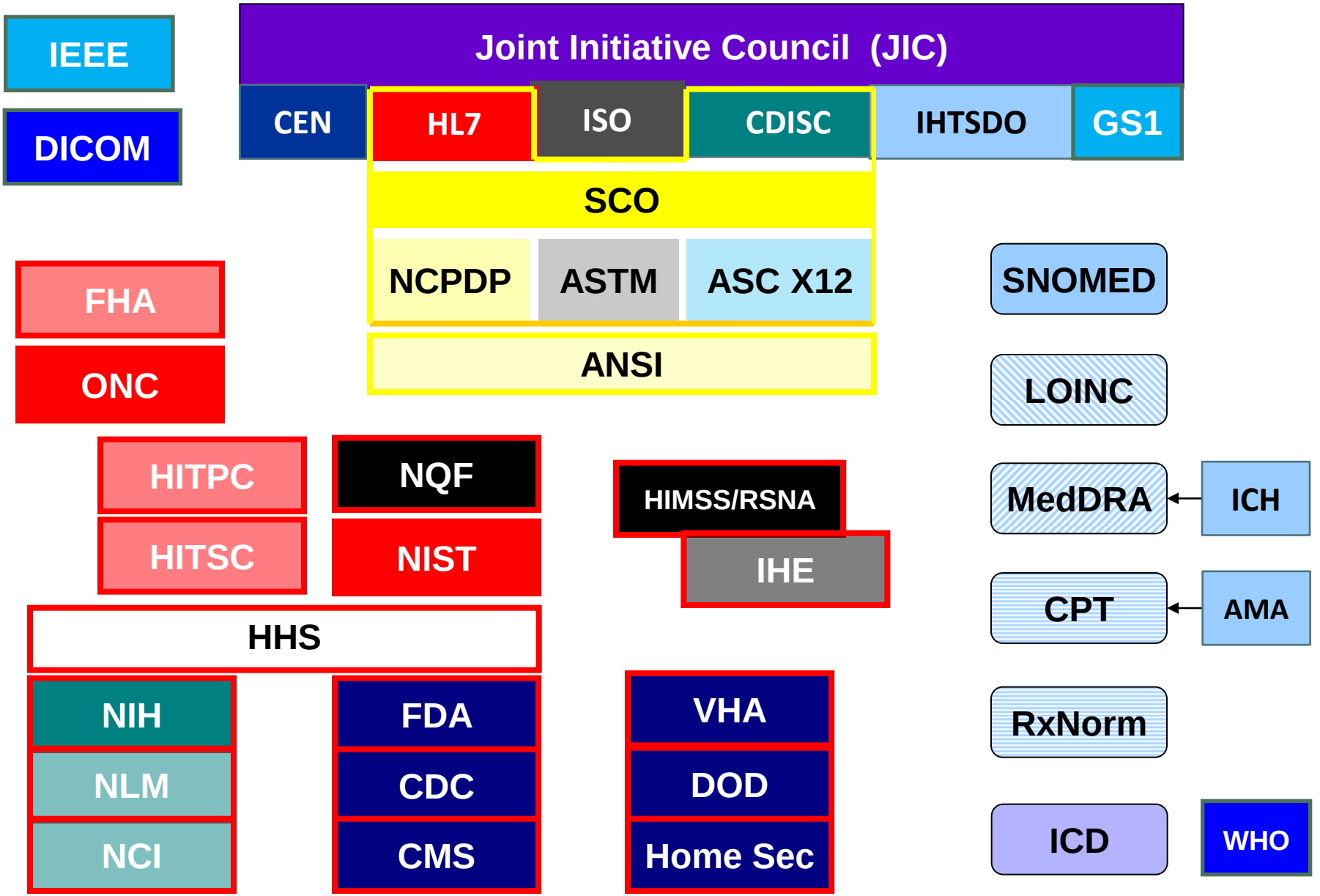
- Describe a completed demonstration for identifying disease-specific data elements in context of EHR.
- Explore how data elements might be adopted and implemented consistently into EHR projects.
  - Relationships to EHR standards (and SDOs)
  - Relationships to regulatory standards (e.g., FDA)
- Discuss strategies and drivers for enhanced and standardized EHR data collection that will support efficient, rapid, and meaningful research.
- Discuss the role of The Collaboratory in the development and use of these standards.

# Outline

- Background
  - Standards
  - CDEs
  - EHRs, Phenotypes, and the Collaboratory
- Pilot Project for multi-purpose EHR standards (diabetes)
  - Process
  - Lessons learned
- Future
- Discussion

Disclaimer: The demonstration and experience presented represent the views of the author and do not necessarily represent endorsement of any of the organizations mentioned.

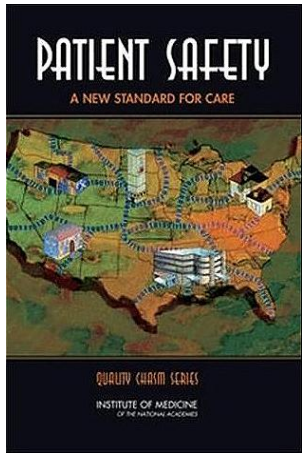
# Healthcare Standards Landscape

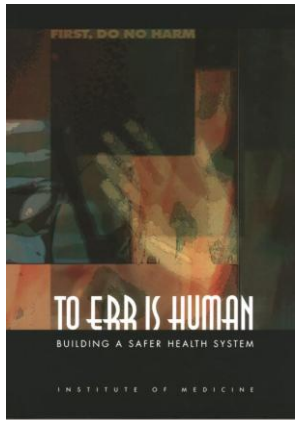


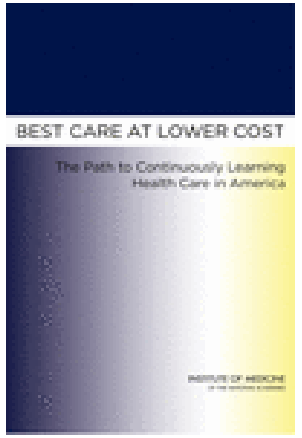

*Source: Dr. W. Ed Hammond, Duke Center for Health Informatics*

# Standards Can Improve

- Patient Safety
- Continuity of Care
- Quality Measurement
- Research (observational & interventional)
  - efficiency in implementing new studies
  - increase ability to share data
- Care Delivery
  - patient-centered care
  - learning healthcare system



# "Standards" Include:

- Messages (and underlying information models)
- Data elements
- **Values for data elements**
  - Can be part/whole of coding systems or controlled terminologies
- Mappings between different value sets
- Survey questions and responses
- Methods of data collection & data sources

Some coding systems are standardized e.g., ICD-9-CM

(For some diseases, data elements might be preferable to dx, lab, and medication codes.)

# Data Elements and CDEs

- **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)

- **Common data element (CDE)**
  - Data element represented uniformly across multiple sources or settings

# Examples of Data Elements

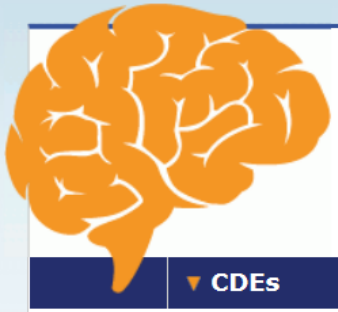
- Medication type: pills, liquid, injection
- Body surface area: _____
- Autoimmune disease diagnosis? (yes/no)
- Diabetic ketoacidosis? (yes/no)
- Foot problems? (yes/no)
- Chronic immunosuppressant use? (yes/no)
- Concomitant medications
  *"Are you currently taking steroids?; anti-infection meds; anti-hypertensive; any other prescription medication(s); non-prescription medication(s); or supplements other than insulin?"*
- Smoker? yes/no/unknown
- Smoker? current/former/never
- Tobacco use? yes; types
- Assistive devices: cane, walker, ….

# Data Elements: A Common Standards Approach

- 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
- Data Elements for Emergency Department Systems (DEEDS)

- The Joint Commission measure sets
- National quality improvement registries sponsored by clinical professional societies
  - Society for Thoracic Surgeons (STS)
  - NSQIP
  - Get with the Guidelines

- NCI - Oncology CDEs in caDSR
- NINDS - CDEs for neuroscience-related clinical research



# NINDS Common Data Elements

Harmonizing Information. Streamlining Research.



## Streamline Your Neuroscience Clinical Research using content standards that enable clinical investigators to systematically collect, analyze, and share data across the research community.

The NINDS strongly encourages researchers who receive funding from the Institute to ensure their data collection is compatible with these common data elements (CDEs). Learn more about the CDE Project.

**Launch Your Own Studies Faster**

- Case report form modules
- Standardized data element definitions
- Instrument recommendations

**Incorporate CDEs Into Systems**

- Search for current CDEs
- Download CDE metadata
- Download Case Report Forms

**Learn About the CDE Project**

- Project overview and background
- Meetings and Presentations
- Collaboration with developers around the world

**CDEs Now Available** | CDEs Under Review | CDEs in Development

- Neuromuscular Diseases *New!*
- Multiple Sclerosis *New!*
- Huntington's Disease *New!*
- Headache *New!*
- Traumatic Brain Injury (Version 2.0) *New!*
- General (CDEs that cross diseases)
- Amyotrophic Lateral Sclerosis
- Epilepsy
- Friedreich's Ataxia
- Parkinson's Disease



NINDS Common Data Elements — Harmonizing information. Streamlining research.

National Institutes of Health

USA.gov

Page last updated on Friday, January 11, 2013

# FDA/CDER Data Standards Plan

- Purpose: to support and promote development of data standards for all key data needed to make regulatory decisions.

- 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**.

FDA
Center for Drug Evaluation and Research

Data Standards Strategy

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm249979.htm

- Promote the creation and use of "disease/domain-specific data standards" consisting of:
  - Clinical concepts for a specific disease or clinical domain area
  - Associated 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

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm249979.htm

# FDA Goal (CDER)

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

- FDA will likely require submission using these standards

**Priority Disease/Domain Areas for Data Standardization**

| | | |
|---|---|---|
| **Tier 1** | | |
| Acne | Pain* | Schizophrenia |
| Alzheimer's Disease* | Parkinson's Disease* | Solid organ transplantation |
| Anti-diabetic agents* | Prevention of pregnancy | Treatment of Hepatitis C* |
| Crohn's Disease | Psoriasis | Treatment of postmenopausal osteoporosis |
| Infections of skin and/or subcutaneous tissue | QT Studies | Tuberculosis* |
| Oncology: time to efficacy event other than overall survival* | Rheumatoid arthritis | Urinary tract infections |
| **Tier 2** | | |
| Addiction | Gastroesophageal reflux disease | Pneumonia |
| Anticonvulsants | Influenza | Prevention of HIV |
| Asthma | Irritable bowel syndrome | Treatment of HIV |
| Bipolar Disorder | Lipid-altering drug groups | Treatment of overactive bladder |
| Clostridium difficile colitis | Major depressive disorder | Treatment of vasomotor symptoms due to menopause |
| Diabetic nephropathy | Objective tumor response* | Ulcerative colitis |
| **Tier 3** | | |
| Actinic keratoses | Decompensated CHF | Tinea pedis |
| Aerosolized antimicrobals for cystic fibrosis | Diagnostic radiopharmaceuticals | Tramatic brain injury |
| Atrial fibrillation | General Anxiety Disorder | Treatment of cough |
| Attention Deficit Hyperactivity Disorder | Helicobacter pylori ulcer disease | Treatment of erectile dysfunction |
| Bacterial vaginosis | Infectious diseases of the abdomen | Treatment of hepatitis B |
| Chemotherapy-induced | MRI contrast agents | |

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm269946.htm

# CDISC Therapeutic Area Projects with Initiating Organization(s)

## << 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, University of Rochester)

## << 2012 and beyond >>

- Expand TB (Gates, C-Path, Global TB Alliance, IMI Europe)
- 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)

CDISC Strength Through Collaboration

*Source: B. Kisler, CDISC; presented at AMIA CRI Summit, March 2012.*

# Interest in EHR to Support Research

- Screening and Recruitment
- Registries
- Comparative Effectiveness Studies
- Cohort Identification
- Clinical Phenotyping

# eMERGE Network

electronic medical records & genomics

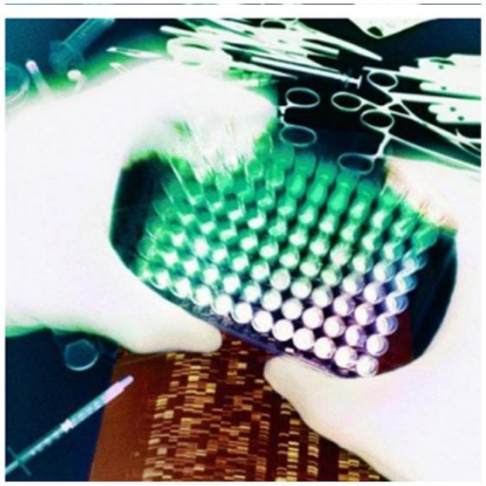
Login | Register

Home | For Researchers | Phenotypes on PheKB | eMERGE RecordCounter | News | Calendar | Contact

## The eMERGE Network

The mapping of the human genome has enabled new exploration of how genetic variations contribute to health and disease. To better realize this promise, researchers must now determine ways in which genetic make-up gives some individuals a greater chance of becoming sick with chronic conditions such as diabetes, Alzheimer's, or heart disease. The goal of gaining this knowledge is to translate it to bedside practice and ultimately improve patient care.

The Electronic Medical Records and Genomics (eMERGE) Network is a national consortium organized by NHGRI to develop, disseminate, and apply approaches to research. It combines DNA biorepositories with electronic medical record (EMR) systems for large-scale, high-throughput genetic research with the ultimate goal of returning genomic testing results to patients in a clinical care setting. The Network is currently exploring more than a dozen phenotypes (with 13 additional electronic algorithms having already been published). Various models of returning clinical results have been implemented or planned for pilot at sites across the Network. Themes of bioinformatics, genomic medicine, privacy and community engagement are of particular relevance to eMERGE.



http://emerge.mc.vanderbilt.edu/

- Children's Hospital of Pennsylvania
- Cincinnati Children's Medical Center with Boston Children's Hospital
- Geisinger Health System
- Group Health Cooperative with University of Washington
- Marshfield Clinic
- Mayo Clinic
- Mount Sinai School of Medicine
- Northwestern University
- Vanderbilt University (also home to the Coordinating Center)

# PheKB

a knowledgebase for discovering phenotypes from electronic medical records

Home | Phenotypes | Implementations | Groups | Institutions | eMERGE Network

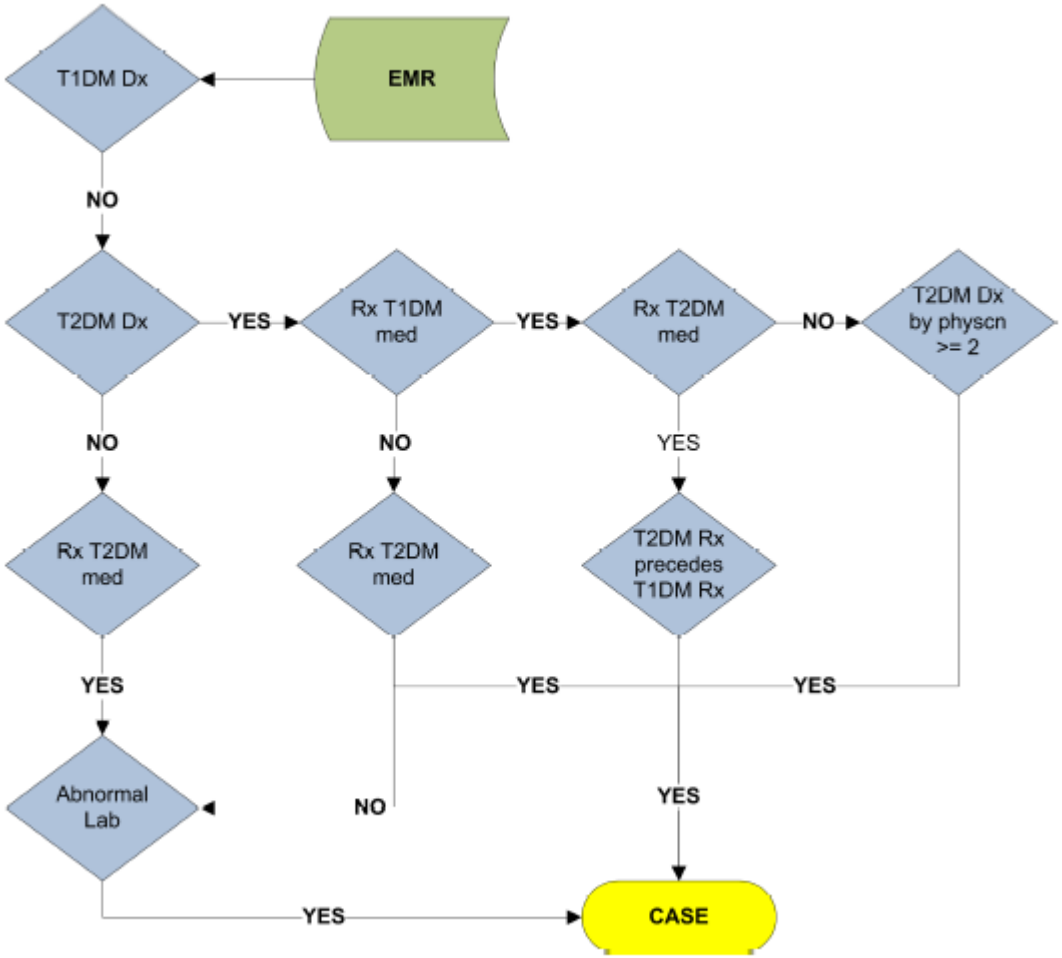
» Phenotypes

## Phenotypes

**Include Methods** | **Exclude Methods** | **Mine Only** - Any - | Apply

| Title | Groups | Institutions | Data and Methods |
|---|---|---|---|
| Type 2 Diabetes - Demonstration Project | Vanderbilt - SD/RD Group | Vanderbilt University | ICD 9 Codes, Laboratories, Medications, Natural Language Processing |
| Type 2 Diabetes Mellitus | eMERGE Phenotype WG | Northwestern University | ICD 9 Codes, Laboratories, Medications |
| White Blood Cell Indices | eMERGE Phenotype WG | Group Health Cooperative | CPT Codes, ICD 9 Codes, Laboratories, Medications |

Figure 1: Algorithm for identifying T2DM cases in the EMR



# JAMIA Call for Papers: Special Focus Issue on Electronic Health Records-Driven Phenotyping

**Guest Editors**

- Jyotishman Pathak (Mayo Clinic, Rochester, MN, USA)
- Joshua C. Denny (Vanderbilt University, Nashville, TN, USA)
- Abel N. Kho (Northwestern University, Chicago, IL, USA)

Due: March 2013

**Description of the Special Issue**

The identification of patient cohorts for clinical and genomic research is a costly and time-consuming process. This bottleneck adversely affects public health by delaying research findings, and in some cases by making research costs prohibitively high. To address this issue, the leveraging of electronic health records (EHRs) to identify patient cohorts has become an increasingly attractive option. With the rapidly growing adoption of EHR systems due to Meaningful Use, and linkage of EHRs to research biorepositories, evaluating the suitability of EHR data for clinical and translational research is becoming ever more important, with ramifications for genomic and observational research, clinical trials, healthcare delivery research and comparative effectiveness studies.


JAMIA

A scholarly journal of informatics in health and biomedicine

Electronic Health Records
**Phenotypes and Data Standards**
Patient-Reported Outcomes
Provider-Health Systems Interactions
Regulatory/Ethics
Biostatistics/Study Design
Stakeholder Engagement

# Phenotypes and Data Standards

Using EHR data for clinical research requires not only a comprehensive understanding of syntactic and semantic interoperability, but also valid approaches for identifying clinical conditions. This necessitates collaboration among clinicians, EHR experts, and informaticians in developing valid algorithms to identify clinical conditions that meet the needs of research planning and protocols. For example, a diagnosis of diabetes does not by itself indicate that a patient has been diagnosed with diabetes, but could indicate a suspicion of diabetes that must be documented to order the appropriate tests. There are many valid ways to identify such a patient—2 diagnoses separated by 3 months, a diagnosis coupled with a prescription for a diabetes medication, a diagnosis by an endocrinologist—and understanding the pros and cons of those approaches is necessary to use EHRs effectively for constructing phenotypes. We hope to accomplish the following:

- **Develop phenotype definitions**. We will work with the Demonstration Projects, the NIH, and the investigator community to identify phenotypes of interest across projects, develop a library of computable definitions and algorithms to enable phenotyping for the most common and important conditions, and develop and test phenotype algorithms that can be used within and across projects. These definitions will be based on existing literature or developed de novo in collaboration with project teams. Because computable definitions requires specificity and precision of definition, we will use standard data elements from public repositories (e.g., caDSR, USHIK) that are most likely to be collected in health care settings; i.e., those linked to standard EHR profiles and/or used for meaningful use or required reporting. Where data elements are not yet standardized, we will initiate and steward the development process through the HL7 Clinical Interoperability Council and make the data elements available in public data element registries. We will build on our experience in identifying and reviewing phenotype definitions for Mini-Sentinel, our work in EHRs to identify infectious diseases and other conditions, and the body of computable definitions currently under

**News**

Steering Committee chair Barry Coller brings a lifetime's worth of experience to the job
Jan 14, 2013

# Phenotype Core: Planned Activities

Develop library of computable definitions and algorithms to enable phenotyping for the most common and important conditions

- Synthesis from demonstration projects, others ?
- May inform EHR profiles / data collected in EHRs

- Current EHR data will be insufficient for most research needs ...

- Need enhanced, disease-specific data.
  - (Data elements!)
- Standardization across all EHRs would be ideal….

# "Diabe-DS" – Diabetes Data Strategy

- 2009 - 2011
- 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 management effort provided by AHIMA
- Pilot completed - ~~now what?~~ *What was it good for?*

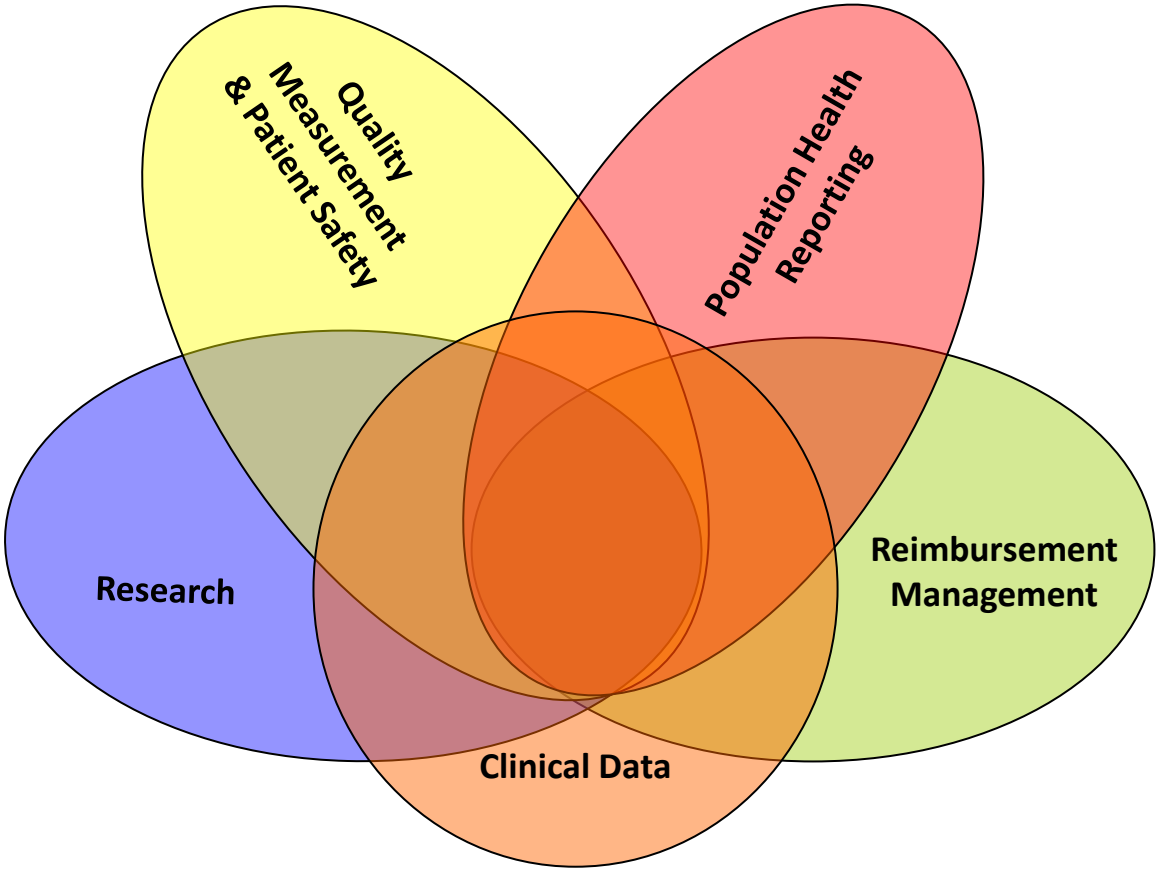
# Relevance to Collaboratory Demonstration Projects

- Diabetes as a co-morbidity
  - How can you determine through the EHR now? Is the data sufficient? Consistent? Could additional data elements better help identify and characterize diabetes as a co-morbidity?
- Enhancing data elements for other diseases of interest
  - Is current EHR data sufficient?
  - Are other data elements needed?
  - Do CDEs exist? Are they standardized? Widely used? Easy to implement? Sufficient for clinical documentation, patient care, and secondary uses?
  - **If they do not exist, how will you develop them? Can you share with others? Should you be compelled to do so?**

# 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, 2009.*

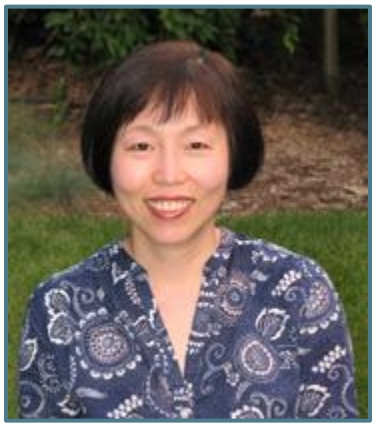
# Project Components

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.

# 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

Intern:
Yong Choi, RN, MSN



Spring, 2009

# 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

| | B | C | G | H | I | J | N | O | T |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Subject Area | Class | ITEM# | DOMAIN (Therapeutic) - First Pass Categorization of Data Elements | Sub-Domain: First Pass Categorization of Data Elements | DATA ELEMENT Name (ATTRIBUTE, Value Domain) | DEFINITION_Sept 2010 | PERMISSIBLE VALUES | Reference |
| 2 | Exam | Medical Exam Observation Name (Enum) | 45 | General Medicine | Physical Exam | Body Surface Area | The body surface area (BSA) is the measured or calculated surface of a human body, expressed in square meters. | $m^2$ | TrialNet Protocol TN05, 05Sep2008; RIT07 - Admin071006NEW |
| 3 | Exam | Medical Exam Observation Name (Enum) | 177 | General Medicine | Physical Exam | Injection Site Lipophypertrophy Indicator | Indicates whether or not the patient has lipohypertrophic of subcutaneous injection sites on inspection or palpation. | Yes; No; Unknown | USF T1D study forms (?) |
| 4 | Symptom | Symptom Type (Enum) | 183 | Endocrinology | Symptoms | Polyuria Indicator | Indicates whether or not a person releases abnormally large amounts of urine each day, also known as excessive urination. | Yes; No | http://www.nlm.nih.gov/medlineplus/ency/article/000305.htm |
| 5 | Symptom | Symptom Type (Enum) | 184 | Endocrinology | Symptoms | Polydipsia Indicator | Indicates whether or not a person is experiencing excessive thirst that lasts for long periods of time. | Yes; No | http://www.nlm.nih.gov/medlineplus/ency/article/000305.htm |
| 6 | Symptom | Symptom Type (Enum) | 185 | Endocrinology | Symptoms | Polyphagia Indicator | Indicates whether or not a person exhibits signs of excessive hunger or eating, and despite this, is still experiencing a loss in body weight. | Yes; No | http://www.nlm.nih.gov/medlineplus/ency/article/000305.htm |
| 7 | Symptom | Symptom Type (Enum) | 186 | Endocrinology | Symptoms | Unexplained Weight Loss Indicator | Indicates whether or not a person has had a reduction in body weight that occured without an obvious reason. | Yes; No | http://www.nlm.nih.gov/medlineplus/ency/article/000305.htm |
| 8 | Patient History | Medical History | 186.1 | Endocrinology | Symptoms | Yeast Infections Indicator | 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. | Yes; No; Unknown | |
| 9 | Exam | Medical Exam Evaluation Name (Enum) | 937 | General Medicine | Physical Exam | Overweight Indicator | Indicates whether the patient is overweight based upon national guidelines for body weight classification in adults using Body Mass Index (BMI). | Yes, No, Unknown | |
| 10 | Exam | Medical Exam Observation Name (Enum) | 971 | General Medicine | Physical Exam | Body weight assessment performed indicator | Indicates whether a body weight assessment was performed using the Body Mass Index in adult weight classification methodology.. | Yes; No; Unknown | |

# “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 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.

# 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 Harmonization - Example

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

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

# Detailed Mapping of Use Case to Data Requirements

| | B | C | G | H | I | J |
|---|---|---|---|---|---|---|
| 1 | Subject Area | Class | ITEM# | DOMAIN (Therapeutic) - First Pass Categorization of Data Elements | Sub-Domain: First Pass Categorization of Data Elements | DATA ELEMENT Name (ATTRIBUTE, Value Domain) |
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| 3 | Exam | Medical Exam Observation Name (Enum) | 177 | General Medicine | Physical Exam | Injection Site Lipophypertrophy Indicator |
| 4 | Symptom | Symptom Type (Enum) | 183 | Endocrinology | Symptoms | Polyuria Indicator |
| 5 | Symptom | Symptom Type (Enum) | 184 | Endocrinology | Symptoms | Polydipsia Indicator |
| 6 | Symptom | Symptom Type (Enum) | 185 | Endocrinology | Symptoms | Polyphagia Indicator |
| 7 | Symptom | Symptom Type (Enum) | 186 | Endocrinology | Symptoms | Unexplained Weight Loss Indicator |
| 8 | Patient History | Medical History | 186.1 | Endocrinology | Symptoms | Yeast Infections Indicator |
| 9 | Exam | Medical Exam Evaluation Name (Enum) | 937 | General Medicine | Physical Exam | Overweight Indicator |
| 10 | Exam | Medical Exam Observation Name (Enum) | 971 | General Medicine | Physical Exam | Body weight assessment performed indicator |

## 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 weight loss. The mother has also noticed that her daughter seems to tire easily and is more irritable than usual.

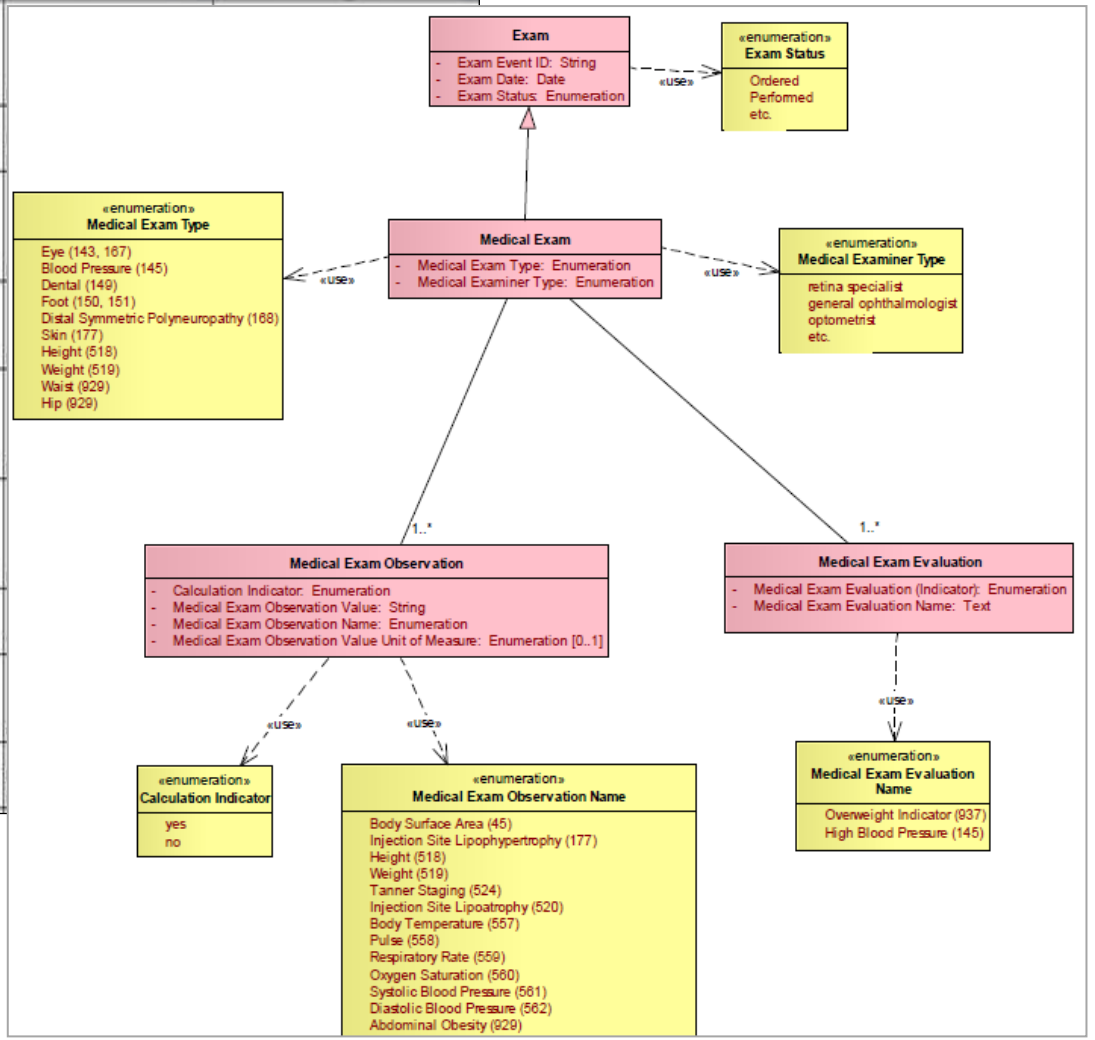
At the pediatrician's office, the pediatrician conducts an assessment which includes a limited history and physical exam. Vital signs are documented which include temperature, blood pressure, pulse rate, respiratory rate and oxygen saturation. The pediatrician documents the presence of symptoms of polydipsia 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 pediatric record, 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.

*Actors, Actions and Data Elements [Primary Care Visit]*

| Actor | Action | Data Elements |
|---|---|---|
| Mother | Take | |
| Teenager | Experience | Yeast infection indicator *[Yeast infections indicator (186.1)]* Weight loss indicator *[Unexplained weight loss indicator (186)]* Fatigue *[Fatigue (512)]* Date of birth *[Age at diagnosis of T1D (139); Date of birth (486)]* |
| Pediatrician | Conduct | Patient history *[Patient history (540)]* Physical exam *[Physical exam (539)]* Screening visit *[Type 1 diabetes presumptive diagnosis reason (4); Encounter type (203.1)]* |
| Pediatrician | Document | Polydipsia indicator *[polydipsia indicator (#184); Type 1 diabetes symptoms present indicator (700)]* |

# Modeling the Data Elements

| | B | C | G | H | I | J | N |
|---|---|---|---|---|---|---|---|
| 1 | Subject Area | Class | ITEM# | DOMAIN (Therapeutic) - First Pass Categorization of Data Elements | Sub-Domain: First Pass Categorization of Data Elements | DATA ELEMENT Name (ATTRIBUTE, Value Domain) | DEFINITION_Sept 2010 |
| 2 | Exam | Medical Exam Observation Name (Enum) | 45 | General Medicine | Physical Exam | | |
| 3 | Exam | Medical Exam Observation Name (Enum) | 177 | General Medicine | Physical Exam | | |
| 4 | Symptom | Symptom Type (Enum) | 183 | Endocrinology | Symptoms | | |
| 5 | Symptom | Symptom Type (Enum) | 184 | Endocrinology | Symptoms | | |
| 6 | Symptom | Symptom Type (Enum) | 185 | Endocrinology | Symptoms | | |
| 7 | Symptom | Symptom Type (Enum) | 186 | Endocrinology | Symptoms | | |
| 8 | Patient History | Medical History | 186.1 | Endocrinology | Symptoms | | |
| 9 | Exam | Medical Exam Evaluation Name (Enum) | 937 | General Medicine | Physical Exam | | |
| 10 | Exam | Medical Exam Observation Name (Enum) | 971 | General Medicine | Physical Exam | | |



# 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.

# 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

| | B | C | D | E | F | G | H | I | J | O |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | EHR-S FM Row # | EHR-S FM ID# | Category Name | Conformance Criteria | Subject Area | Class | Conditions | Data Element Name | Data Element Definition | Diabe-DS Data Element ID |
| 2 | 129 | DC 1.4.2.2 | Manage Medication List | The system **SHALL** display and report patient-specific medication lists. | | | | Concomitant Medication Indicator | Indicates whether or not one or more medications are being taken by or administered to the patient. | 1 |
| 3 | 130 | DC 1.4.2.3 | Manage Medication List | The system **SHALL** provide the ability to capture the details of the medication such as ordering date, dose, route, and SIG (description of the prescription, such as the quantity) when known. | | | | Diabetic Medication Dispensed Indicator | Indicates whether or not any medication was dispensed to patient for indications related to the management of Type 1 diabetes or its complications. | 209 |
| 4 | 130 | DC 1.4.2.3 | Manage Medication List | The system **SHALL** provide the ability to capture the details of the medication such as ordering date, dose, route, and SIG (description of the prescription, such as the quantity) when known. | | | | Insulin Administration Method | The route by which patient receives exogenous insulin. | 65 |
| 5 | 130 | DC 1.4.2.3 | Manage Medication List | The system **SHALL** provide the ability to capture the details of the medication such as ordering date, dose, route, and SIG (description of the prescription, such as the quantity) when known. | | | | Free Text Sig | The instructions, typically from the ordering provider, to the patient on the proper means and timing for the use of the product. This information is free-text but can also be represented as a series of Sig Components | 8.01 |
| 6 | 130 | DC 1.4.2.3 | Manage Medication List | The system **SHALL** provide the ability to capture the details of the medication such as ordering date, dose, route, and SIG (description of the prescription, such as the quantity) when known. | | | | Coded Product Name | A code describing the product from a controlled vocabulary | 8.13 |
| 7 | 130 | DC 1.4.2.3 | Manage Medication List | The system **SHALL** provide the ability to capture the details of the medication such as ordering date, dose, route, and SIG (description of the prescription, such as the quantity) when known. | | | | Coded Brand Name | A code describing the product as a branded or trademarked entity from a controlled vocabulary | 8.14 |
| 8 | 130 | DC 1.4.2.3 | Manage Medication List | The system **SHALL** provide the ability to capture the details of the medication such as ordering date, dose, route, and SIG (description of the prescription, such as the quantity) when known. | | | | Free Text Product Name | The name of the substance or product without reference to a specific vendor (e.g., generic or other non-proprietary name). If a Coded Product Name is present, this is the text associated with the coded concept | 8.15 |
| 9 | 130 | DC 1.4.2.3 | Manage Medication List | The system **SHALL** provide the ability to capture the details of the medication such as ordering date, dose, route, and SIG (description of the prescription, such as the quantity) when known. | | | | Free Text Brand Name | The branded or trademarked name of the substance or product. If a Coded Brand Name is present, this is the text associated with the coded concept | 8.16 |
| 10 | 130 | DC 1.4.2.3 | Manage Medication List | The system **SHALL** provide the ability to capture the details of the medication such as ordering date, dose, route, and SIG (description of the prescription, such as the quantity) when known. | | | | Drug Manufacturer | The manufacturer of the substance or product as ordered or supplied. The distributor may be supplied if the manufacturer is not known | 8.17 |
| 11 | 130 | DC 1.4.2.3 | Manage Medication List | The system **SHALL** provide the ability to capture the details of the medication such as ordering date, dose, route, and SIG (description of the prescription, such as the quantity) when known. | | | | Product Concentration | The amount of active ingredient, or substance of interest, in a specified product dosage unit, mass or volume. For | 8.18 |

# 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 EHR and secondary uses.
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# http://wiki.hl7.org/index.php?title=EHR_Diabetes_Data_Strategy



## EHR Diabetes Data Strategy



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

navigation
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- Permanent link

## Diabetes Data Stratagy Project

**To return to the >>** EHR Work Group Page

### Project Overview

Welcome to HL7's Diabetes Data Stratagy 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 ambul
requirements for T1D assessment so that such data can be collected once in the EHR, exchanged for continuity of care reasons, and
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

# Student practicum – Theresa Schrum, BS, RN, MSN

**Diabetes T2 Use Case**

**Part One**

Jane, a 46 year old African American female Veteran, presents to her primary care physician complaining of burning with urination, foul smelling vaginal discharge and urinary frequency. This is the fourth time in six months that Jane has been to the doctor for the same symptoms. She was treated for a bladder infection each of the previous visits. During the last clinical visit, a $HbA_{1c}$ was drawn with a result of 8.2.

Workflow:

1. *Jane phones her doctor's office, speaks to the appointment desk and makes an appointment.*
2. *Jane arrives for her appointment and checks in at the reception desk.*
3. *Receptionist asks Jane for her ID and asks her to verify her personal information and updates the medical record.*
4. *Receptionist prints an appointment sheet and places it in the nurse's bin notifying the nurse that the patient has checked in.*
5. *Jane is called back to be seen by the nurse.*
6. *Jane's weight, BP, P, R, T, and pain level are collected by the nurse as well as current symptoms.*
7. *The nurse then places the appointment sheet into the provider's bin.*
8. *The provider then retrieves the patient for the appointment.*

Dr. Case is Jane's primary care physician. After reviewing and updating Jane's history and physical exam, Dr. Case notes that Jane's blood pressure is elevated and she has had a 10 pound weight loss since her last visit a month and a half ago. Jane denies attempting to lose weight. Dr. Case observes that Jane is obese. Jane reports feeling unusually tired and irritable over the last several months. She also states that she is hungry and thirsty all the time. Dr. Case notes that Jane's mother and grandmother both have type 2 diabetes. Jane denies having anything to eat or drink since last night @ 2200. A fasting blood glucose level and $HbA_{1c}$ are collected as well as a urine specimen. Jane's blood glucose level is 183mg/dL, her $HbA_{1c}$ is 8, and her white blood cell count is elevated. Jane is given a prescription for a bladder infection. Dr. Case then discusses

*Summer 2012:*

Developed a Narrative Use Case for Collection of Clinical Data in T2DM.

Includes:

- Clinical data collection
- Telehealth / remote monitoring
- Visits over time
- Quality measurement

*Further work…*

# Student practicum – Amy Davis, BS, RN, MSN *(Fall 2012)*

## Elaborated EHR Data Elements for T2DM that Related to Quality Measures in the VA

| DATA ELEMENT Name (ATTRIBUTE, Value Domain) | DEFINITION_November2012 | PERMISSIBLE VALUES | NOTES | PERMISSIBLE VALUE DEFINITIONS | Units (Optional) | Data Type | Reference |
|---|---|---|---|---|---|---|---|
| Eye Care Specialist Provider Type | Type of specialist who performed the eye exam or who read the retinal photo or fundoscopic digital imaging | Ophthalmologist; Optometrist; Primary Care Practitioner; Other Provider; Not Applicable; Unable to Determine | For VHA retinal exam measure, diabetic retinal exam must be completed by ophthalmologist or optometrist | | | | Derived from VHA EPRP Clinical Practice Guideline and Prevention Indicators Fourth Quarter FY2012 |
| Nephropathy Diagnosis Billing Code | Documented evidence of nephropathy including diabetic nephropathy, end-stage renal disease (ESRD), chronic renal failure (CRF), chronic kidney disease (CKD), renal insufficiency, proteinuria, albuminuria, renal dysfunction, acute renal failure (ARF) | 249.4 [0-9]; 250.4 [0-3]; 271.4; 274.1; 285.21; 403; 404; 405.0-405.9; 440.1; 581.0; 581.1; 581.2; 581.3; 581.81; 581.89; 581.9; 583.81; 583; 584.5-584.9; 585; 586; 588.89; 593.70; 593.71; 593.72; 593.73; 593.9; 630-638; 639.3 | Patients with documented evidence of nephropathy do not require additional screening for renal disease. | | | | VHA EPRP Clinical Practice Guideline and Prevention Indicators Fourth Quarter FY2012 |
| Renal Transplantation Indicator | Patient who has had a renal transplant. | Yes; No; Unknown; | Patients who have had a renal transplantation not require additional nephropathy screening. | | | | VHA EPRP Clinical Practice Guideline and Prevention Exit Report Guide Fourth Quarter FY2012 |

# Project Components

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5. **Set the stage for T1D stakeholders to vet/enhance the elements to produce a true clinical T1D Domain Analysis Model.**

# 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 endeavor
- Re-think the whole concept of ‘secondary use’ of data in the context of EHRs
- Who cares? Who can promote disease-specific standards? Who can maintain them?

# Diabe-DS Acknowledgements


- Crystal Kallem (Lantana Consulting Group)
- Donald Mon (RTI International)

*Represented AHIMA at time of project.*

- Cynthia Barton, RN, MS (Duke, Oklahoma Fdn for Medical Quality)
- Patricia Van Dyke (ODS Companies)
- Luigi Sison, Donna Dulong (VA)
- Maryanne Quinn, MD (Boston Children's)
- Henry Rodriguez, MD (University of South Florida)

*Clinical experts*

- 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!)**
  **http://wiki.hl7.org/index.php?title=EHR_Diabetes_Data_Strategy**
- HL7, AHIMA

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## Clinical Interoperability Council

*Coordinates Data Element Projects*

Home | Overview | Leadership | Minutes | Documents | Listserv | Projects | Products | Reports | Cardiology *(Archived)*

### Mission

This Workgroup provides a nexus of communication and bridge to the standards development framework, organizational processes and forums for the clinical community to define content, flow and other domain requirements necessary to the development of robust health data standards. The Council provides a mechanism for clinical domains to develop common approaches to standards-related activities and form consensus on issues of interest among multiple groups.

### Charter

The Clinical Interoperability Council (CIC) will establish and support a process whereby a master set of data elements with their attributes will be defined and harmonized using a common process and a common set of attributes. The attributes will include a name (terminology), a unique and unambiguous definition, units, data type and complete value sets. The CIC will assure the decision making practices related to ensuring appropriate subject matter expertise and governance models are employed as part of the master set of data elements definition and harmonization of standards as appropriate.

CIC will support decision making practices related to clinical domain requirements developed by this committee. We will also, collaborate and offer support to other working groups when requested.

### Work Products and Contributions to HL7 Processes

The CIC will define a process by which data elements are vetted, managed and maintained. The CIC will also define requirements for tool sets to use and integrate these data elements into clinically useful applications. The vision is (1) these data elements will encompass the entire set of data elements required for all aspects of clinical care and the management of that care as defined by the community's needs; (2) only one definition per term will be permitted; and (3) no one group is likely to use all data elements, but any data elements used will come from that master set.

http://www.hl7.org/special/Committees/cic/overview.cfm

# Challenges with Standardizing Data Elements

- 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 may be copyrighted 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.
- 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.

*HL7 CIC Wisdom, compiled by Meredith Nahm.*

# What do we need?

- Process and best practices around data elements
  - Structure, attributes, value sets
  - Place to store data elements
    - caDSR, USHIK, LOINC, PhenX, NLM Value Set Center, HL7, Others?
  - Process for engaging, vetting, and updating
- Communication across communities
- Motivations for their adoption and use
- Culture change about standards
  - Re-use is good
  - Sharing is good
  - Code (pledge) about developing new data elements (?!)
  - Patience - Multi-stakeholder involvement essential

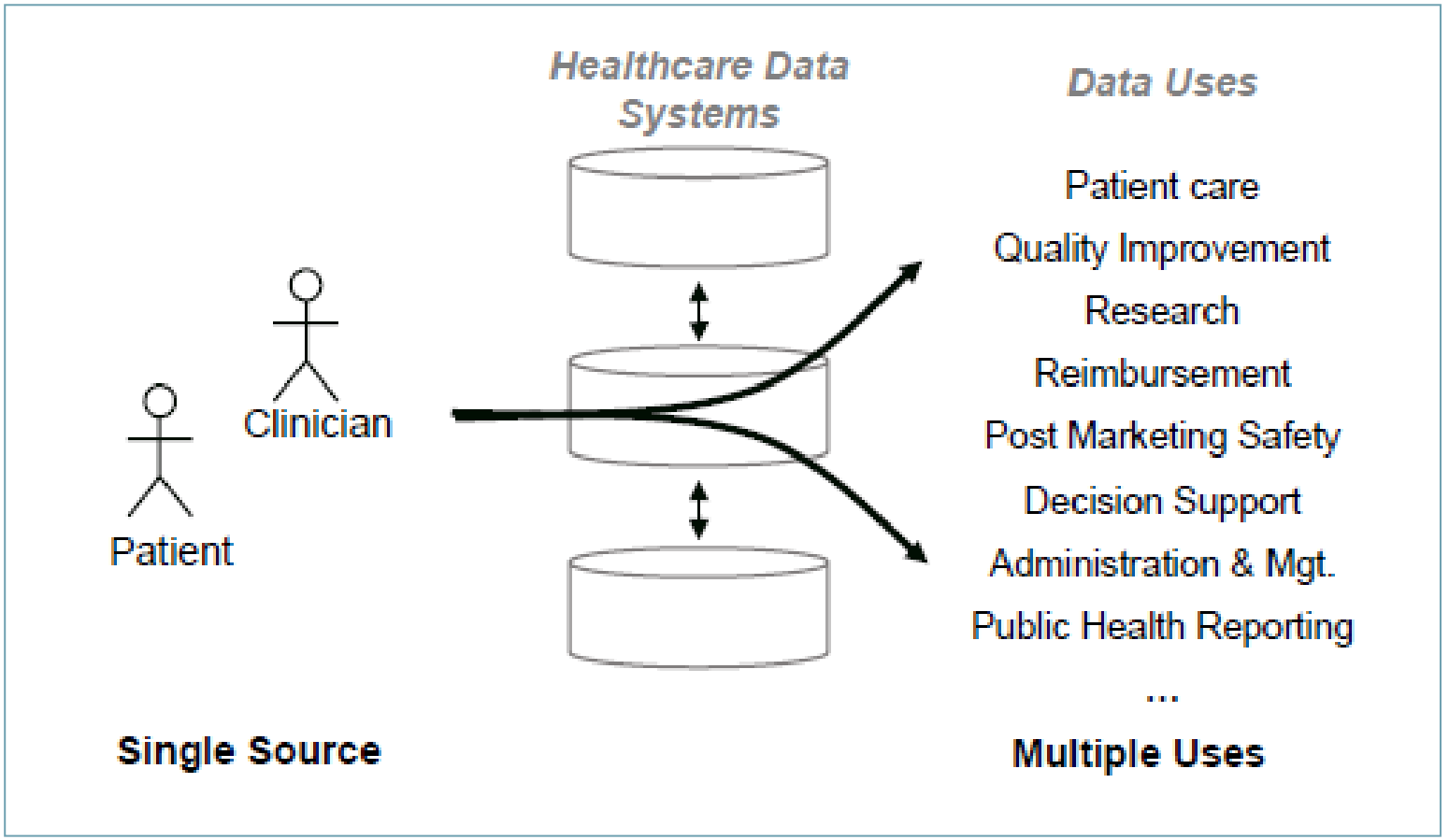
# Future….

The Collaboratory (?)

Epic™ and Vendors

Patients and Patient Advocacy Organizations

*Standard data elements*



# HCS Research Collaboratory

Clinics throughout the United States

PATIENT CARE

HEALTH CARE DELIVERY ORGANIZATIONS

RESEARCH

Leverage and expand capabilities to enable:

- Pragmatic Trials
- New Technologies