The ICD-10 Transition...
Implications for Pragmatic Trials

NIH Health Care Systems Research Collaboratory
Grand Rounds
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Outline

- Pragmatic Trials and phenotypes
- ICD-10 background
- Mapping and tools
  - Preliminary translation of selected phenotype definitions using GEMS
- Implication for research
- Recommendations
- Discussion
Pragmatic Trials

• Studies sampling from and embedded within the context of healthcare delivery systems

• Use electronic health record systems and data
  – Cohort identification, sampling, recruitment
  – Randomization, workflow cues
  – Use of clinical data for study
  – De novo data collection
Clinical Phenotype Definitions

• Specifications for identifying patients or populations with a given characteristic or condition of interest from EHRs using data that are routinely collected in EHRs or ancillary data sources.

• Include widely adopted coding systems
  – ICD-9-CM
  – CPT
  – SNOMED CT
  – LOINC
  – RxNorm
  – NDC
Example phenotype definition

Diabetes defined as\(^1\):

- one inpatient discharge diagnosis (ICD-9-CM 250.x, 357.2, 366.41, 362.01-362.07)

or any combination of two of the following events occurring within 24 months of each other:

- A1C > 6.5% (48 mmol/mol)
- fasting plasma glucose ≥ 126 mg/dl (7.0 mmol/L)
- random plasma glucose ≥ 200 mg/dl (11.1 mmol/L)
- 2-h 75-g OGTT ≥ 200 mg/dl
- outpatient diagnosis code (same codes as inpatient)
- anti-hyperglycemic medication dispense (see details below)
- NDC in associated list
- ...etc., etc...

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Lots of phenotypes

• >75 phenotype/cohorte definitions
  – 32 ICD-9 exclusive

• 30 public (92 private)
  – 79-96% phenotypes use ICD-9
  – Zero ICD-9 exclusive
Demonstration Projects

The Research Collaboratory is designed in part to support the design and rapid execution of several Pragmatic Clinical Trial Demonstration research partnerships. The data, tools, and resources produced by the Demonstration Projects will be made available to the greater research supports the development of exploratory or innovative research activities, and a UH3 award provides support for the second phase of research.

## Projects

<table>
<thead>
<tr>
<th>Title</th>
<th>Investigator</th>
<th>Collaboratory Affiliation</th>
<th>Name</th>
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<tr>
<td>UH3 Project: Time to Reduce Mortality in End-Stage Renal Disease (TiME)</td>
<td>Dember, Laura</td>
<td>University of Pennsylvania</td>
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<td>UH3 Project: Suicide Prevention Outreach Trial (SPOT)</td>
<td>Simon, Gregory</td>
<td>Group Health Cooperative; Group Health Research Institute</td>
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<td>UH3 Project: Strategies and Opportunities to Stop Colorectal Cancer (STOP CRC)</td>
<td>Coronado, Gloria</td>
<td>Kaiser Foundation Research Institute</td>
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<td>UH3 Project: Lumbar Image Reporting with Epidemiology (LIRE)</td>
<td>Jarvik, Jeffrey</td>
<td>University of Washington</td>
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<td>UH3 Project: Collaborative Care for Chronic Pain in Primary Care (PPACT)</td>
<td>DeBar, Lynn</td>
<td>Kaiser Foundation</td>
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<td>UH3 Project: Active Bathing to Eliminate (ABATE) Infection</td>
<td>Huang, Susan</td>
<td>University of California, Irvine</td>
<td>ABATE</td>
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<td>UH2 Project: Pragmatic Trial of Video Education in Nursing Homes (PROVEN)</td>
<td>Mor, Vincent; Volandes, Angelo; Mitchell, Susan</td>
<td>Brown University School of Medicine</td>
<td>PROVEN</td>
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<td>UH2 Project: Improving Chronic Disease Management with Pieces (ICD-Pieces)</td>
<td>Vazquez, Miguel</td>
<td>UT Southwestern Medical Center</td>
<td>ICD-Pieces</td>
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<td>UH2 Project: A Policy-Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity (Trauma Survivors Outcomes and Support [TSOS])</td>
<td>Zatzick, Douglas</td>
<td>University of Washington</td>
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<td>UH2 Project: A Blood Pressure Medication Timing Study (BPMedTime)</td>
<td>Rosenthal, Gary</td>
<td>University of Iowa</td>
<td>BPMedTime</td>
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</table>
Use Cases for Clinical Phenotypes

- Estimating numbers of patients potentially eligible for a proposed trial (study feasibility).
- Identifying patients for recruitment into prospective trials.
- Describing patient cohorts for analysis of existing data for comparative effectiveness or health services research.
- Presenting baseline characteristics or conditions to describe research populations.
- Presenting primary outcomes to test the trial hypothesis.
- The implementation of supportive tools for providers that are embedded within EHR systems and clinical workflows.
Source: http://blog.ivman.com/y2k-bug-in-retrospect/
DECEMBER 31, 1999
11:59 PM

JANUARY 1, 2000
12:01 AM

October 1, 2015

Source: http://blog.ivman.com/y2k-bug-in-retrospect/
Use of ICD-9-CM in the US

• CM – “clinical modification” based on the international ICD to give more detailed codes

• ICD-9-CM has been used in the US since 1979 (4 years after the international version) for:
  – Classification of morbidity and mortality (mortality reporting changed to ICD-10 since 1999)
  – Reimbursement (since 1983)
  – Analysis of healthcare delivery and cost
  – Epidemiological and clinical research
Long road to change

- ICD-9-CM became more and more out-dated, and there is no way to add new codes because of its rigid code structure
- 2008 – CMS issued NPRM proposing 2011 date
- 2009 – CMS final rule with deadline Oct 2013
- 2012 – postponed to Oct 2014
- 2014 – Congress passed law to delay ICD-10-CM for at least one year, CMS set new date to Oct 2015
I9-10 differences - Codes

• Codes look different:
  – Lymphocytopenia
    • ICD-9-CM: 288.51
    • ICD-10-CM: D72.810
  – First digit of an ICD-10-CM code is always alphabetic
    • Some ICD-9-CM codes also start with a letter (E and V codes)
    • No ‘code collision’ – no code is valid in both I9 and I10
  – A valid ICD-10-CM code (leaf code) has between 3 to 7 digits
    • 3-digit (< 1%)
    • 4-digit (8%)
    • 5-digit (9%)
    • 6-digit (13%)
    • 7-digit (70%)
I9-10 differences - Size

• Total number of valid codes:
  – ICD-9-CM: 14,567
  – ICD-10-CM: 69,823

• The jump in size is not uniform across chapters
Reasons for increase in size

• New codes for
  – New diseases
  – Uncommon diseases
  – Subtypes of diseases

• Additional details (combinatorial explosion) e.g.
  Fractures:
  – Laterality: left, right, unspecified, bilateral
  – Episode of care: initial encounter, subsequent encounter, sequela
  – Type of fracture: closed, open (Gustilo classification type I, II, IIIA, IIIB, IIIC)
  – Healing status: routine, delayed, nonunion, malunion
Fracture neck of femur

• ICD-9-CM:
  – 820.8 Unspecified part of neck of femur, closed
  – 820.9 Unspecified part of neck of femur, open

• ICD-10-CM (48 codes):
  
  S72.001 Fracture of unspecified part of neck or right femur
  - S72.001A..... initial encounter for closed fracture
  - S72.001B..... initial encounter for open fracture type I or II
  - S72.001C..... initial encounter for open fracture type IIIA, IIIB, or IIIC
  - S72.001D..... subsequent encounter for closed fracture with routine healing
  - S72.001E..... subsequent encounter for open fracture type I or II with routine healing
  - S72.001F..... subsequent encounter for open fracture type IIIA, IIIB, or IIIC with routine healing
  - S72.001G..... subsequent encounter for closed fracture with delayed healing
  - S72.001H..... subsequent encounter for open fracture type I or II with delayed healing
  - S72.001I..... subsequent encounter for open fracture type IIIA, IIIB, or IIIC with delayed healing
  - S72.001J..... subsequent encounter for closed fracture with nonunion
  - S72.001K..... subsequent encounter for open fracture type I or II with nonunion
  - S72.001M..... subsequent encounter for open fracture type IIIA, IIIB, or IIIC with nonunion
  - S72.001N..... subsequent encounter for open fracture type IIIA, IIIB, or IIIC with nonunion

Laterality
Fracture type
Episode of care
Healing
Chorioamnionitis

- ICD-9-CM: 762.7 Chorioamnionitis
- ICD-10-CM: (28 codes)

041.121 Chorioamnionitis, first trimester
  - 041.1210 …… not applicable or unspecified
  - 041.1211 …… fetus 1
  - 041.1212 …… fetus 2
  - 041.1213 …… fetus 3
  - 041.1214 …… fetus 4
  - 041.1215 …… fetus 5
  - 041.1219 …… other fetus

041.122 Chorioamnionitis, second trimester
  - 041.1220 …… not applicable or unspecified
  - 041.1221 …… fetus 1
  - 041.1222 …… fetus 2
  - ……
I9-10 differences: Organization

• Chapter structure largely preserved
• Sense organs separated from nervous system disorders, creating 2 new chapters:
  – Eye and Adnexa
  – Ear and Mastoid Process
• Major reorganization of some chapters e.g.
  – Mental and Behavioral Disorders
  – Diseases of the Skin and Subcutaneous Tissues
• Some diseases moved chapters e.g.
  – Gout moved from Endocrine, Nutritional and Metabolic Diseases to Musculoskeletal Diseases
I9-10 differences: Semantic

• More subtle changes e.g.,
  – Acute myocardial infarction
    • ICD-9-CM: within 8 weeks of onset
    • ICD-10-CM: within 4 weeks of onset
  – Cutoff for abortion vs. fetal death
    • ICD-9-CM: 22 weeks
    • ICD-10-CM: 20 weeks
  – Tuberculosis
    • Method of diagnosis (bacteriological or histological) no longer specified
  – Diabetes
    • No longer distinguished as controlled or uncontrolled
  – Asthma
    • No longer classified as intrinsic or extrinsic
I9-10 code sets transition

• Cohort definitions coded in ICD-9-CM will have to be transitioned to ICD-10-CM

• Resources to ease the burden
  – General Equivalence Maps (GEM)
  – Quality measure value sets
  – SNOMED CT
General Equivalence Maps

• Published by CMS and CDC
• Provide linkages between
  – ICD-9-CM and ICD-10-CM
  – ICD-9-CM volume III (procedures) and ICD-10-PCS
• Forward (9 to 10) and backward (10 to 9) maps
  – Independent maps, not mirror images
  – Different coverage of ICD-9-CM and ICD-10-CM
  – Partial overlap in the mappings
<table>
<thead>
<tr>
<th>Description</th>
<th>Forward GEM</th>
<th>Backward GEM</th>
<th>Common to both GEMs</th>
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<tbody>
<tr>
<td>Unique ICD-9-CM codes* (% of ICD-9-CM)</td>
<td>13,409 (92.0%)</td>
<td>10,949 (75.0%)</td>
<td>10,880 (74.7%)</td>
</tr>
<tr>
<td>Unique ICD-10-CM codes* (% of ICD-10-CM)</td>
<td>16,614 (23.8%)</td>
<td>69,154 (99.0%)</td>
<td>16,614 (23.8%)</td>
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<tr>
<td>Unique ICD-9-CM/ICD-10-CM code pairs</td>
<td>23,330</td>
<td>78,034</td>
<td>18,484</td>
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</table>

* Not including codes with no maps

Comparison of forward and backward GEMs
Using the GEMs in code set translation

• Study using 32 ICD-9-CM code sets (clinical phenotypes) from 3 pragmatic trials:
  – Collaborative Care for Chronic Pain in Primary Care (PPACT)
  – Strategies and Opportunities to Stop Colorectal Cancer in Priority Populations (STOP CRC)
  – A Pragmatic Trial of Population-Based Programs to Prevent Suicide Attempt
• Code sets with 3 – 161 (median=4) ICD-9-CM codes, altogether 536 unique codes
• Compared 4 mapping methods using the GEMs
The mapping methods

• 4 progressively more aggressive methods to identify ICD-10-CM targets for an ICD-9-CM code:
  1. Simple forward map – forward GEM only
  2. Forward backward map – 1. + backward GEM
  3. Secondary map – 2. + map targets identified by secondary ICD-9-CM codes
  4. Tertiary map – 3. + map targets identified by tertiary ICD-9-CM codes
Targets identified for each source code by the 4 mapping methods

<table>
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<tr>
<th>Source code</th>
<th>SFM</th>
<th>FBM</th>
<th>SM</th>
<th>TM</th>
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<td>W</td>
<td>W, X</td>
<td>W, X, Y</td>
<td>W, X, Y, Z</td>
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<tr>
<td>B</td>
<td>-</td>
<td>X, Y</td>
<td>W, X, Y, Z</td>
<td>W, X, Y, Z</td>
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<tr>
<td>C</td>
<td>Z</td>
<td>Y, Z</td>
<td>X, Y, Z</td>
<td>W, X, Y, Z</td>
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</table>
Study methodology

• Generate ICD-10-CM code sets for each of the 32 ICD-9-CM code sets using each mapping method
• Generated code sets reviewed by clinical experts for validity
• Recall, precision and F-score for each mapping method
Summary of results

• Must use both forward and backward GEMs
• More aggressive methods can identify valid ICD-10-CM targets that are indirectly related to an ICD-9-CM code, but precision is reduced. Choice of method will depend on use case.
• Works better for well-defined conditions (e.g. colorectal cancer) than vaguely-defined conditions (e.g. chronic pain)
• Not fully-automated translation – manual validation still required
Electronic clinical quality measurement

• Meaningful Use requires EHRs to demonstrate electronic submission of data for some clinical quality measures

• Quality measure value sets:
  – Code sets from standard terminologies used to identify patients with certain characteristics
  – Very similar in function to cohort definition code sets in clinical studies
  – Available from NLM’s VSAC website
Welcome to the NLM Value Set Authority Center (VSAC)

For VSAC announcements, please subscribe to the VSAC Updates listserv.

The Value Set Authority Center (VSAC) is provided by the National Library of Medicine (NLM), in collaboration with the Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services.

The VSAC provides downloadable access to all official versions of vocabulary value sets contained in the 2014 Clinical Quality Measures (CQMs). Each value set consists of the numerical values (codes) and human-readable names (terms), drawn from standard vocabularies such as SNOMED CT®, RxNorm, LOINC and ICD-10-CM, which are used to define clinical concepts used in clinical quality measures (e.g., patients with diabetes, clinical visit).

The content of the VSAC will gradually expand to incorporate value sets for other use cases, as well as for new measures and updates to existing measures.

Viewing or downloading value sets requires a free Unified Medical Language System® Metathesaurus License, due to usage restrictions on some of the codes included in the value sets.

The Data Element Catalog contains the complete list of 2014 CQMs and value set names.

https://vsac.nlm.nih.gov/
<table>
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<th>Name</th>
<th>Type</th>
<th>Code System</th>
<th>Steward</th>
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<td>Grouping</td>
<td>SNOMEDCT</td>
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</table>
Re-using quality measure value sets

• Many value sets are already defined in multiple terminologies
  – 267 value sets with ICD-9-CM code sets
  – 259 (97%) also have ICD-10-CM code sets
  – 253 (95%) also have ICD-10-CM and SNOMED CT code sets

• Some value sets are exact matches of cohort definitions (e.g., “malignant neoplasm of colon” value set and “colon cancer” phenotype code set)

• Finding matching value sets
  – May be difficult to browse through 800+ value sets
  – Can compute some similarity score between the ICD-9-CM code sets for phenotype definition and quality measurement e.g., Jaccard similarity coefficient = size of intersection / size of union
SNOMED CT

- Most comprehensive, multilingual clinical terminology in the world
- Used in > 50 countries
- Meaningful Use requires use of SNOMED CT in the EHR for problem lists, procedures etc.
- SNOMED CT is better than ICD for clinical data capture because:
  - Better content coverage
  - Clinically oriented
  - Flexible data entry and retrieval
<table>
<thead>
<tr>
<th>SNOMED CT</th>
<th>ICD-9-CM</th>
<th>ICD-10-CM</th>
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<tbody>
<tr>
<td>Congenital skin anomalies</td>
<td>205573006 Focal dermal hypoplasia</td>
<td>757.39 Other specified congenital anomalies of</td>
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<tr>
<td></td>
<td>79468000 Familial benign pemphigus</td>
<td>skin</td>
</tr>
<tr>
<td></td>
<td>5132005 Keratosis pilaris</td>
<td>Q82.8 Other specified congenital malformations</td>
</tr>
<tr>
<td></td>
<td>... <em>(total 21 codes)</em></td>
<td>of skin</td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td>Acidosis</td>
<td>59455009 Metabolic acidosis</td>
<td>276.2 Acidosis</td>
</tr>
<tr>
<td></td>
<td>12326000 Respiratory acidosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>91273001 Lactic acidosis</td>
<td></td>
</tr>
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<td>Brachial plexus disorders</td>
<td>72893007 Brachial neuritis</td>
<td>353.0 Brachial plexus lesions</td>
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<tr>
<td></td>
<td>278065000 Pancoast's syndrome</td>
<td></td>
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<td></td>
<td>78141002 Erb-Duchenne paralysis</td>
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Role of SNOMED CT

• Can help to map from ICD-9-CM to ICD-10-CM
  – 2 maps available:
    • SNOMED CT to ICD-9-CM (IHTSDO)
    • SNOMED CT to ICD-10-CM (NLM)
  – Possible to do sequential mapping from ICD-9-CM to ICD-10-CM through SNOMED CT

• Use SNOMED CT directly in cohort definitions
  – SNOMED CT codes will become more ubiquitous in EHR
  – More granular concepts → fine-tuning of definitions
  – Many quality measure value sets are already defined in SNOMED CT
Implications for Pragmatic Trials

• The same system, organizational, and cultural changes that drive variation of ICD-9 coding will also impact ICD-10 coding
• There are various tools and approaches to mapping between ICD-9 and ICD-10
• There can be variation by organization and system on how these maps are used
• More problematic in different medical specialties
• Many “convoluted” relationships (Boyd et al., 2015)
planning  data collection  analysis & dissemination

planning  data collection  analysis & dissemination
Timing of ICD-10 Transition Relative to Pragmatic Trials

• Before trial data collection (i.e., study begins after Oct 1, 2015)
  – Can use ICD-10, but cannot re-use past tools
    i.e., Must build (and validate) new ICD-10 queries based on ICD-9
  – Historical data in ICD-9 (medical history) might be problematic

• After trial begins (i.e., study began before Oct 1, 2015)
  – ICD-10-based definitions might change the characteristics of the study population (sampling bias, ascertainment bias) or the depth/accuracy of data collection (measurement bias)

• In both cases, researchers might have data in both ICD-9 and ICD-10
• To compare, need to pick one coding system (ICD-9 or 10) or a reference standard (e.g., SNOMED CT)
The Ultimate Challenge: Assessing the Semantic **Equivalence** of Phenotype Definitions

**Phenotype definition (ICD-9-CM)**

**Phenotype definition (ICD-10-CM)**

“true” population with condition

“true” population with condition
Assessing Data Quality for Healthcare Systems Data Used in Clinical Research (Version 1.0)

An NIH Health Care Systems Research Collaboratory Phenotypes, Data Standards, and Data Quality Core White Paper

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• Completeness
• Accuracy
• Consistency
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3-23-2015

Transparent Reporting of Data Quality in Distributed Data Networks

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Reporting recommendations related to Data processing/provenance:

- Mappings from original values to standardized values
  
  - “Documentation of how original data values were transformed to the target .. format.”
  
  - “Documentation should list source values and describe the logic or mappings used to transform original source to required target values.”
Recommendations

• Examine phenotype definitions to assess reliance on ICD-9
• Consider the phenotype definition as a “unit” or value set, and compare semantic equivalence of the set
• Consider different mapping approaches for automatic translation
• Examine research needs and nature of condition
• Be prepared to report methods for mapping
• Be prepared to validate locally
• Implement data quality assessment recommendations
Conclusion

• ICD 10 will enable researchers to make more targeted data queries and potential have more detailed data for patient risks or outcomes.

• ICD-10 transition will differentially threaten the research integrity and required resources for various types of studies.

• Studies where data collection includes the ICD-10 implementation date (October 1, 2015), researchers need to be cognizant of implications of the mapping relationships.
Acknowledgments

• **Study presented here is under review with eGEMS:** “Preparing for the ICD-10-CM Transition: Automated Methods for Translating ICD Codes in Clinical Phenotype Definitions and Quality Measure Value Sets.” (Submitted July 2015)
  
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  – Duke Center for Predictive Medicine and Ben Neely, MS
DISCUSSION
Research Concerns

- Performance
- Reproducibility
- Consistency

- Identify and eliminate potential bias

- Goal: at the point of randomization: a) the 2 groups have equal risk of having the outcome of interest; and b) the 2 groups are very well characterized at the point of the start of the trial.
Dataset with ICD-9 codes + Dataset with ICD-10 codes = Merged Dataset w/ one coding system:

<table>
<thead>
<tr>
<th>ICD-9-CM</th>
<th>ICD-10-CM</th>
<th>SNOMED-CT</th>
<th>others...</th>
</tr>
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<tbody>
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<td>others...</td>
</tr>
</tbody>
</table>

**ICD-9-CM**

- Cardiac anomalies (ICD-9-CM codes 746.0-746.9)
- Congenital anomalies of the cardiovascular system (746.0-746.9)
- Congenital anomalies of the heart (746.0-746.9)
- Congenital anomalies of the aorta (746.0-746.9)
- Congenital anomalies of the pulmonary arteries (746.0-746.9)
- Congenital anomalies of the atria (746.0-746.9)
- Congenital anomalies of the coronary arteries (746.0-746.9)
- Congenital anomalies of the great arteries (746.0-746.9)
- Congenital anomalies of the ductus arteriosus (746.0-746.9)
- Congenital anomalies of the aortic valve (746.0-746.9)
- Congenital anomalies of the mitral valve (746.0-746.9)
- Congenital anomalies of the tricuspid valve (746.0-746.9)
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ICD-10 Issues by Use Cases

• Estimating numbers of patients potentially eligible for a proposed trial (study feasibility).

Possible Impact: low; research planning is a one-time activity. In the past it was done with ICD-9, but now can be done with ICD-10.

Activities: ICD-9 based phenotypes will need to be converted to ICD-10.
ICD-10 Issues by Use Cases

• Identifying patients for recruitment into prospective trials.  
  ~cohort identification

• **Possible Impact:** High. If the study recruitment occurs before and after Oct. 1, 2015, then there is a danger that those recruited after the transition are *not* the same as those before.

• Could lead to sampling bias if there are differences (including certainty of disease and severity of conditions) between patients recruited early versus late in study.

• **Activities:** ICD-9 Based phenotypes need to be converted to ICD-10 – and clinically validated.
ICD-10 Issues by Use Cases

• Describing patient cohorts for analysis of existing data for comparative effectiveness or health services research.

Possible Impact: Moderate. If the data analyzed in the study was collected from health systems before and after Oct. 1, 2015, then there might be a systematic bias.

Activities: ICD-9 Based phenotypes need to be converted to ICD-10 – and clinically validated. Data quality assessment recommendations can be applied.
ICD-10 Issues by Use Cases

• Presenting baseline characteristics or conditions to describe research populations by demographics, clinical features, and co-morbidities for clinical trials.

Possible Impact: High. If the study recruitment occurs before and after Oct. 1, 2015, then there is a danger that those recruited after the transition are not the same as those before. Could lead to sampling bias if there are differences (including certainty of disease and severity of conditions) between patients recruited early versus late in study.

Activities: ICD-9 Based phenotypes need to be converted to ICD-10 – and clinically validated.
ICD-10 Issues by Use Cases

• Presenting primary outcomes to test the trial hypothesis.
• The implementation of supportive tools for providers that are embedded in EHR systems and clinical workflows.

Possible Impact: High. If the study outcomes are assessed for some patients before and some after Oct. 1, 2015, then there could be differences (including certainty of disease and severity of conditions) between patients assessed early versus late in study.

Activities: ICD-9 Based phenotypes need to be converted to ICD-10. Aggressive (iterative) mapping processes appropriate. New ICD-10 groups must be clinically validated. Data quality assessment recommendations can be applied.
## Dimensions of Quality

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Conceptual definition</th>
<th>Operational examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completeness</td>
<td>Presence of the necessary data</td>
<td>Presence of necessary data elements, percent of missing values for a data element, percent of records with sufficient data to calculate a required variable (e.g., an outcome)</td>
</tr>
<tr>
<td>Accuracy</td>
<td>Closeness of agreement between a data value and the true value*</td>
<td>Percent of data values found to be in error based on a gold standard, percent of physically implausible values, percent of data values that do not conform to range expectations</td>
</tr>
<tr>
<td>Consistency</td>
<td>Relevant uniformity in data across clinical investigation sites, facilities, departments, units within a facility, providers, or other assessors</td>
<td>Comparable proportions of relevant diagnoses across sites, comparable proportions of documented order fulfillment (e.g., returned procedure report for ordered diagnostic tests)</td>
</tr>
</tbody>
</table>