ICD-9-CM to MedDRA Mapping – How Well Do the Two Terminologies Correlate

Anna Zhao-Wong, MD, PhD
Deputy Director
MedDRA MSSO

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Background

• ICD-9-CM: The International Classification of Diseases, Ninth Revision, Clinical Modification

• MedDRA: Medical Dictionary for Regulatory Activities

Background (cont)

• ICD-9-CM
  – US-based
  – Insurance claim, health outcome
  – Insurance company, healthcare provider, research institute
  – Morbidity and mortality statistics, epidemiology study
  – Three-level hierarchy
  – ~17,000 terms

• MedDRA
  – Global: Canada, EU, Japan, US, Australia…
  – Regulatory reporting
  – Pharma company, CRO, regulator, research institute
  – Drug safety surveillance, signal detection, indication, labeling…
  – Five-level hierarchy
  – ~70,000 terms
Background (cont)

ICD-9-CM

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>ICD-10-CM Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart failure</td>
<td>428</td>
</tr>
<tr>
<td>Congestive heart failure, unspecified</td>
<td>428.1</td>
</tr>
<tr>
<td>Left heart failure</td>
<td>428.2</td>
</tr>
<tr>
<td>Systolic heart failure</td>
<td>428.3</td>
</tr>
<tr>
<td>Unspecified systolic heart failure</td>
<td>428.39</td>
</tr>
<tr>
<td>Acute systolic heart failure</td>
<td>428.32</td>
</tr>
<tr>
<td>Chronic systolic heart failure</td>
<td>428.22</td>
</tr>
<tr>
<td>Acute on chronic systolic heart failure</td>
<td>428.23</td>
</tr>
<tr>
<td>Diastolic heart failure</td>
<td>428.4</td>
</tr>
<tr>
<td>Unspecified diastolic heart failure</td>
<td>428.49</td>
</tr>
<tr>
<td>Acute diastolic heart failure</td>
<td>428.11</td>
</tr>
<tr>
<td>Chronic diastolic heart failure</td>
<td>428.13</td>
</tr>
<tr>
<td>Acute on chronic diastolic heart failure</td>
<td>428.14</td>
</tr>
<tr>
<td>Combined systolic and diastolic heart failure</td>
<td>428.8</td>
</tr>
<tr>
<td>Unspecified combined systolic and diastolic heart failure</td>
<td>428.89</td>
</tr>
<tr>
<td>Acute combined systolic and diastolic heart failure</td>
<td>428.45</td>
</tr>
<tr>
<td>Chronic combined systolic and diastolic heart failure</td>
<td>428.44</td>
</tr>
<tr>
<td>Heart failure, unspecified</td>
<td>428.9</td>
</tr>
</tbody>
</table>

MedDRA

Health Related Metadata

Patient Outcome databases (EHR, insurance)
(Coded in ICD, SNOMED, CPT...)

Drug Safety Databases (FDA AERS, Eudravigilance, Cananda Vigilance, Pharma companies)
(Coded in MedDRA)

Epidemiology study

Safety Signal Detection
Safety surveillance
Metadata – Cross Reference

- Patient Outcome databases (EHR, insurance)
  (Coded in ICD, SNOMED, CPT…)
- Drug Safety Databases (FDA AERS, Eudravigilance, Cananda Vigilance, Pharma companies)
  (Coded in MedDRA)
- Epidemiology study
- Safety Signal Detection
  Safety surveillance

Metadata – Cross Reference (cont)

- Mapping – provide a bridge to cross walk from one terminology to another
- How well does a mapping work?
  (Level of interoperability)
- Area of interest: ICD-9-CM to MedDRA mapping
Source Data

- Observational Medical Outcomes Partnership (OMOP)
  - To research methods that are feasible and useful to analyze existing healthcare databases to identify and evaluate safety and benefit issues of drugs already on the market
- Source
  - Preliminary mapping from OMOP database v2.0
    - At MedDRA Preferred Term (~18,000) level (v12.0)
    - ~10% ICD-9-CM terms were not included in the mapping

Mapping Methodology

- Method of mapping
  - Microsoft Access queries and manual mapping
    - At MedDRA Lowest Level Term (~67,000) level
    - All ICD-9-CM terms (3, 4, 5-digit)
  - Review and verify by qualified personnel (medical and MedDRA knowledge)
    - ICH MedDRA Term Selection: Points To Consider Guide
ICD-9-CM to MedDRA Mapping (cont)

• To measure how well the match is
  – Each pair of ICD-9-CM term and MedDRA LLT is categorized
    • Complete confidence (perfect match): the concept of ICD-9-CM term is accurately represented by the mapped LLT
    • Relative confidence (No loss of information): the concept of ICD-9-CM term is covered by the mapped LLT with slightly broader scope.

ICD-9-CM to MedDRA Mapping (cont)

• To measure how well the match is
  – Each pair of ICD-9-CM term and MedDRA LLT is categorized
    • Caution (partial match): In most cases, the ICD-9-CM term contains multiple concepts and the mapped LLT represents one of the concepts
    • Out of (MedDRA) scope
Outcome

- ICD-9-CM Disease and Injury Codes (codes 001 to 999)
  - 17 Chapters based on disease, disorder, and injury
    - Chapter 1: Infectious and parasitic diseases
    - Chapter 9: Diseases of the digestive system
    - Chapter 14: Congenital anomalies
    - Chapter 17: Injury and Poisoning
  - Similar to MedDRA anatomical, physiological, and etiological based System Organ Classes (SOCs)

Outcome (cont)

- ICD-9-CM Disease and Injury Codes

<table>
<thead>
<tr>
<th></th>
<th>Disease and Injury (all levels)</th>
<th>%</th>
<th>3-digit Disease and Injury</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete confidence</td>
<td>12503</td>
<td>87%</td>
<td>905</td>
<td>98%</td>
</tr>
<tr>
<td>Relative confidence</td>
<td>996</td>
<td>7%</td>
<td>11</td>
<td>1%</td>
</tr>
<tr>
<td>Caution</td>
<td>883</td>
<td>6%</td>
<td>11</td>
<td>1%</td>
</tr>
<tr>
<td>Out of scope</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>
Outcome (cont)

• ICD-9-CM E and V Codes: Supplementary Classification for
  – Factors Influencing Health Status and Contact with Health Services (codes V01-V89)
    • “Assault by shotgun”
  – External Causes of Injury and Poisoning (codes E800-E999)
    • “Family disruption”
• Mainly equivalent to MedDRA SOC Social circumstances

<table>
<thead>
<tr>
<th></th>
<th>E code</th>
<th>%</th>
<th>V code</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete confidence</td>
<td>18</td>
<td>1%</td>
<td>181</td>
<td>15%</td>
</tr>
<tr>
<td>Relative confidence</td>
<td>335</td>
<td>26%</td>
<td>10</td>
<td>1%</td>
</tr>
<tr>
<td>Caution</td>
<td>904</td>
<td>71%</td>
<td>975</td>
<td>79%</td>
</tr>
<tr>
<td>Out of scope</td>
<td>14</td>
<td>1%</td>
<td>74</td>
<td>6%</td>
</tr>
</tbody>
</table>
Summary

- Mapping direction: ICD-9-CM --> MedDRA
- Disease and Injury Codes
  - Two terminologies correlate well
    - All levels: 94% complete or relative confidence
    - Three-digit level: 99% complete or relative confidence
      - Level for data aggregation and analysis
- E Codes and V Codes
  - Not all in the scope of MedDRA
  - Different granularities – majority in “Caution” category
ICD-10 to MedDRA Mapping

• Use case identification
  – From ICD-10 to MedDRA
    • Drug safety analysis using EMR data
    • Epidemiology study
  – From MedDRA to ICD-10
    • Healthcare cost analysis using clinical trial data
    • Epidemiology study

ICD-10 to MedDRA Mapping (cont)

• Mapping feasibility study
  – ICD-10 core
  – Country modification
    • US modification: ICD-10-CM
    • German modification: ICD-10-GM
    • Australia modification: ICD-10-AM
    • Canadian modification
    • Thailand modification
  – ICD-10 core level
    • 3-character
    • 4-character
  – Invite feedback of interested parties
Thank you!

Questions?