Utility of Common Data Models for EHR and Registry Data Integration: Use in Automated Surveillance

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Outline

• Overview of Observational Medical Outcomes Partnership (OMOP) CDM (including Medical Devices)

• National VINCI VA Roadmap for Transformation of EHR and Registry data to OMOP CDM for use in operations and research

• Example of How Automated Surveillance Applications can Leverage Structured Medical Device Data
Common Data Models

- Allows transformation of multiple data sources into a harmonized representation that supports the same analysis to be conducted across multiple sites.

- Can help promote transparency and reproducibility in methods and analysis.

- Data quality assessments are critical in any multi-site CDM with documentation variation across sites.
Clinical Data Research Networks

- NHGRI eMERGE (I2B2 data model, 9 sites)

- NCATS Clinical Translational Science Award (CTSA: I2B2 data model, 62 sites)

- PCORI CDRN (PCORNet CDM, 11 Sites, 3 have OMOP as primary CDM)

- FDA Mini-Sentinel (Mini-Sentinel CDM, 17 Sites)

Data Updated 02/23/2015 - Sites counted if data partner
OMOP CDM v5

3.6 DEVICE_EXPOSURE

Devices are physical objects or instruments that are used to diagnose, prevent, or treat disease, and in contrast to drugs do not achieve their purposes through chemical action. The terms "device" and "medical supply" are used interchangeably. Devices could be simple medical supplies such as elastic bandages, examination gloves or hand-held surgical instruments, but also complex machines such as implantable pacemakers, pulse generators, HIV diagnostic tests, automated external defibrillators or hip replacement kits.

<table>
<thead>
<tr>
<th>Field</th>
<th>Required</th>
<th>Type</th>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>device_exposure_id</td>
<td>Yes</td>
<td>integer</td>
<td></td>
<td>A system-generated unique identifier for each device exposure.</td>
</tr>
<tr>
<td>person_id</td>
<td>Yes</td>
<td>integer</td>
<td></td>
<td>A foreign key identifier to the person who is subjected to the procedure.</td>
</tr>
<tr>
<td>unique_device_id</td>
<td>No</td>
<td>varchar(50)</td>
<td></td>
<td>The entire UDI or equivalent.</td>
</tr>
<tr>
<td>device_concept_id</td>
<td>Yes</td>
<td>integer</td>
<td>GUID, HGPCS, SNOMED</td>
<td>Only the DI portion of the UDI would be captured as a Concept in the vocabulary.</td>
</tr>
<tr>
<td>device_source_concept_id</td>
<td>Yes</td>
<td>integer</td>
<td></td>
<td>The concept representing the code used in the source.</td>
</tr>
<tr>
<td>device_type_concept_id</td>
<td>Yes</td>
<td>integer</td>
<td></td>
<td>Provenance for the data, e.g. procedure device, from registry, etc.</td>
</tr>
<tr>
<td>device_exposure_start_date</td>
<td>Yes</td>
<td>date</td>
<td></td>
<td>The date the device or supply was applied or used.</td>
</tr>
<tr>
<td>device_exposure_end_date</td>
<td>No</td>
<td>date</td>
<td></td>
<td>The date the device or supply was removed from use.</td>
</tr>
<tr>
<td>associated_procedure_id</td>
<td>No</td>
<td>integer</td>
<td></td>
<td>This is the procedure the device was used in if known.</td>
</tr>
<tr>
<td>associated_provider_id</td>
<td>No</td>
<td>integer</td>
<td></td>
<td>A foreign key to the provider in the provider table who was responsible for using the device.</td>
</tr>
</tbody>
</table>

3.6.1 CONVENTIONS

- Valid Device Concepts belong to the "Device" domain.
- The distinction between devices or supplies and procedures are sometimes blurry, but the former are physical objects while the latter are actions, often to apply a device or supply.
- For medical devices that are regulated by the FDA, a Unique Device Identification (UDI) is required and available in the data source recorded in the unified_device_id field.
- The DI portion of that UDI is used to define concepts in the CONCEPT table. However, devices are also defined based on other source vocabularies, like HGPCS.
- The Visit during which the device was used is recorded through a reference to the VISIT_OCCURRENCE table. This information is not always available.
- The Provider exposing the patient to the device is recorded through a reference to the PROVIDER table. This information is not always available.
- The Relevant Condition Concept is defined as the condition that is associated with the use of the device. This can be the indication, or the condition to be diagnosed or ruled out. Note that the Relevant Condition Concept ID is not a foreign key to an actual CONDITION_OCCURRENCE record, but to a Condition Concept in the Vocabulary. This information is not typically available.

## Example Table

### OMOP v5 Medical Devices

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Device Table Values</th>
<th>Mapped Table</th>
<th>Mapped Table column</th>
<th>Derived Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>device_exposure_id</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>person_id</td>
<td>32345</td>
<td>Person</td>
<td>person_id</td>
<td>&lt;name not stored&gt;</td>
</tr>
<tr>
<td>unique_device_id</td>
<td>00884838035683</td>
<td>FDA GUDID Map</td>
<td>PI</td>
<td>TAXUS Express2 Paclitaxel-Eluting Coronary Stent</td>
</tr>
<tr>
<td>device_concept_id</td>
<td>346239844</td>
<td>OMOP CONCEPT Table</td>
<td>concept_id</td>
<td>TAXUS Express2 Paclitaxel-Eluting Coronary Stent</td>
</tr>
<tr>
<td>device_type_concept_id</td>
<td>38000290</td>
<td>OMOP CONCEPT Table</td>
<td>concept_id</td>
<td>HPCPS Procedure Code</td>
</tr>
<tr>
<td>device_exposure_start_date</td>
<td>1/1/2013</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>device_exposure_end_date</td>
<td>NULL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>associated_procedure_id</td>
<td>1354355</td>
<td>Procedure Occurrence</td>
<td>concept_id</td>
<td>Cardiac Catheterization</td>
</tr>
<tr>
<td>associated_provider_id</td>
<td>34234</td>
<td>Provider</td>
<td>provider_id</td>
<td>&lt;name not stored&gt;</td>
</tr>
<tr>
<td>visit_occurrence_id</td>
<td>23434513</td>
<td>Visit Occurrence</td>
<td>visit_occurrence_id</td>
<td>Acute Inpatient Stay</td>
</tr>
<tr>
<td>relevant_condition_concept_id</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>device_source_value</td>
<td>TAXUS Express2 Paclitaxel-Eluting Coronary Stent</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
VINCI (Veterans Affairs) Strategic Roadmap

**Structured Patient Data**
- Demographics
- Billing Data
- Medications
- Medical Devices
- Laboratory Data

- Patients: 16,927,344
- Meds: 4,067,736,484
- All Devices: ~4,100,000
- Surgical Implants: ~2,200,000
- Labs: 6,642,418,408

**Clinical Registries**
- Cardiac Catheterization
- Pacemaker Implantation
- Surgical Procedures
- Others

**Common Data Model**

**Natural Language Processing**

**Patient Free Text**
- Problem List
- Radiology Reports
- Pathology Reports
- Clinical Progress Notes
- Discharge Summaries

- Text Notes: ~2,000,000,000

**Claims Data**
- CMS Medicare
- CMS Medicaid
- CMS USRDS
- 3rd Party Payors

- CMS VA Patients: ~5,100,000
Automated Surveillance Tools & Applications

• Lahey Clinic Foundation, Veterans Affairs, and the FDA are funding development of an open-source automated monitoring platform for safety surveillance or quality monitoring purposes

  • Open Source: components to be interoperable and expandable by user community
  • Observational Medical Outcomes Partnership (OMOP) Common Data Model Compliant for wider source data compatibility
  • Distributed through:
    – NLM National Center for Biomedical Computing (NCBC)
    – In the future, within the OHDSI tool development community

Automated Surveillance Tools & Applications

  – DELTA: Data Extraction and Longitudinal Time Analysis
  – OCEANS: Observational Cohort Event and Analysis Notification System
  – OMOP CDM Analytic Data Set Builder
Example: NCDR CathPCI DELTA Pilot

- DELTA system: flexible active surveillance software suite, supporting real-time prospective safety analyses.

- Implemented within NCDR in Q2 2013.
  - Secure IT infrastructure, all data stays within NCDR firewall.

- Primary Analyses:
  - Vascular complications with Mynx Vascular Closure Device [Safety Concern]
  - Safety of Thrombectomy devices used during PCI. [Negative Control]

- Propensity matched, with sensitivity analyses triggered if alert fires.
A total of 120,000 procedures in which the Mynx VCD was used were identified from the 1.6 million PCI records. The propensity matched analysis of the Mynx VCD, as compared with other VCD devices, demonstrated a 1.7 fold increased risk of Any Vascular Complication, with alerts triggered during the second quarter of data analysis.

Primary endpoint: Over 43,000 uses of the Export aspiration catheter were identified. Propensity Matched Analysis of the incidence of *any major adverse cardiac event* following use of Export versus other aspiration thrombectomy catheters showed no evidence of a safety signal.
Conclusions

• In order to leverage medical devices fully, electronic health records will need to store medical device data in structured tables with careful mapping to controlled vocabularies and GUDID.

• For downstream use of medical devices, common data models are highly useful to be able to leverage a large user community of tool builders and allow analyses to be run in different health care systems with the same code and automated applications.
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  - Daniella Meeker, Phd (USC)
  - Henry Sessamanga, MD (Lahey)

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