Curating inpatient medication use data from a hospital network electronic medication administration record (eMAR) system: Lessons from the Sentinel System about expanding drug safety surveillance

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Outline

- Sentinel Initiative
  - Background
  - Sentinel Common Data Model
- Electronic Medication Administration Record (eMAR) systems
- Inpatient medication use data captured for Sentinel
Sentinel Initiative

2007
Congress passes Food and Drug Administration Amendments Act (FDAAA)

2008
FDA launches Sentinel Initiative

2009
FDA launches Mini-Sentinel Pilot

2011
Mini-Sentinel distributed dataset reaches 100 million lives mark mandated by FDAAA

2012
Mini-Sentinel has suite of reusable programming tools for routine queries

2016
FDA launches Sentinel System
# Sentinel Common Data Model: Overview

## Enrollment
- **Person ID**
- Enrollment start & end dates
- Drug coverage
- Medical coverage
- Medical record availability

## Demographic
- **Person ID**
- Birth date
- Sex
- ZIP code

## Dispensing
- **Person ID**
- Dispensing date
- National drug code (NDC)
- Days supply
- Amount dispensed

## Encounter
- **Person ID**
- Service date(s)
- Encounter ID
- Encounter type & provider
- Facility

## Diagnosis
- **Person ID**
- Service date(s)
- Encounter ID
- Encounter type & provider
- Diagnosis code & type
- Principal discharge diagnosis

## Procedure
- **Person ID**
- Service date(s)
- Encounter ID
- Encounter type & provider
- Procedure code & type

## Lab Result
- **Person ID**
- Result and specimen collection dates
- Test type, immediacy & location
- Logical Observation Identifiers Names and Codes (LOINC®)
- Test result & unit

## Vital Signs
- **Person ID**
- Measurement date and time
- Height and weight
- Diastolic & systolic BP
- Tobacco use & type

## Inpatient Pharmacy
- **Person ID**
- Administration date and time
- Encounter ID
- National Drug Code (NDC)
- Route
- Dose

## Inpatient Transfusion
- **Person ID**
- Blood product code and type
- Encounter ID
- Blood type
- Administration start and end dates and times

## Death
- **Person ID**
- Death date
- Source
- Confidence

## Cause of Death
- **Person ID**
- Cause of death
- Source
- Confidence
## Sentinel Common Data Model: Inpatient medication use

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>PatID</td>
<td>Unique member identifier</td>
</tr>
<tr>
<td>EncounterID</td>
<td>Unique encounter identifier</td>
</tr>
<tr>
<td>NDC</td>
<td>National Drug Code</td>
</tr>
<tr>
<td>RxID</td>
<td>Useful to map back to source data</td>
</tr>
<tr>
<td>RxADate</td>
<td>Administration date</td>
</tr>
<tr>
<td>RxATime</td>
<td>Administration time</td>
</tr>
<tr>
<td>RxRoute</td>
<td>Administration route</td>
</tr>
<tr>
<td>RxDose</td>
<td>Administration dose</td>
</tr>
<tr>
<td>RxUOM</td>
<td>Administration unit of measure</td>
</tr>
</tbody>
</table>

**Who**: PatID, EncounterID

**What**: NDC, RxID

**When**: RxADate, RxATime, RxRoute

**How**: RxDose

**How much**: RxUOM
Sentinel Common Data Model: Inpatient medication use, one patient

<table>
<thead>
<tr>
<th>PATID</th>
<th>ENCOUNTERID</th>
<th>NDC</th>
<th>RxID</th>
<th>RXDATE</th>
<th>RXTIME</th>
<th>RXROUTE</th>
<th>RXDOSE</th>
<th>RXUOM</th>
</tr>
</thead>
<tbody>
<tr>
<td>PatID1</td>
<td>EncID1</td>
<td>00409653301</td>
<td>RxID1</td>
<td>2015-03-15</td>
<td>10:28</td>
<td>IV</td>
<td>1000</td>
<td>MG</td>
</tr>
<tr>
<td>PatID1</td>
<td>EncID1</td>
<td>00409653301</td>
<td>RxID2</td>
<td>2015-03-15</td>
<td>14:32</td>
<td>IV</td>
<td>1000</td>
<td>MG</td>
</tr>
<tr>
<td>PatID1</td>
<td>EncID1</td>
<td>00409433201</td>
<td>RxID3</td>
<td>2015-03-16</td>
<td>15:17</td>
<td>IV</td>
<td>500</td>
<td>MG</td>
</tr>
<tr>
<td>PatID1</td>
<td>EncID2</td>
<td>66267011615</td>
<td>RxID4</td>
<td>2015-07-23</td>
<td>19:09</td>
<td>PO</td>
<td>800</td>
<td>MG</td>
</tr>
</tbody>
</table>
Electronic Medication Administration Record (eMAR) systems

- “Rights” of medication administration
  - the right patient,
  - the right drug,
  - the right dose,
  - the right route, and
  - the right time

- Documentation

- Checks and balances for medication safety
eMAR system: Workflow overview

Prescribe → Dispense → Administer
Inpatient medication use for Sentinel: By the numbers

- July 2011 to May 2015
- 166 unique facilities/hospitals
- 51 million encounters
- 657 million medication administrations
Inpatient medication use for Sentinel: Completeness/characterization

- Very little missing data
  - 1.5% of administrations are missing NDC value
  - Less than .5% missing across all other fields

- Administration dates match with encounter dates well
  - 99.9% of administration dates fall within observed encounter dates.

- Administration times are valid timestamps
Inpatient medication use for Sentinel: Medication class categories and names

<table>
<thead>
<tr>
<th>First Databank class categories</th>
<th>Example generic names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthetics</td>
<td>Propofol</td>
</tr>
<tr>
<td></td>
<td>Lidocaine HCL</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>Piperacillin sodium/Tazobactam</td>
</tr>
<tr>
<td></td>
<td>Vancomycin HCL</td>
</tr>
<tr>
<td>Antineoplastics</td>
<td>Megestrol acetate</td>
</tr>
<tr>
<td></td>
<td>Hydroxyurea</td>
</tr>
<tr>
<td>Cardiac/Cardiovascular</td>
<td>Amlodipine besylate</td>
</tr>
<tr>
<td></td>
<td>Metoprolol tartrate</td>
</tr>
<tr>
<td>CNS</td>
<td>Gabapentin</td>
</tr>
<tr>
<td></td>
<td>Levetiracetam</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>Iopamidol</td>
</tr>
<tr>
<td></td>
<td>Iohexol</td>
</tr>
<tr>
<td>Psychotherapeutic</td>
<td>Alprazolam</td>
</tr>
<tr>
<td></td>
<td>Lorazepam</td>
</tr>
</tbody>
</table>
Inpatient medication use data challenges:

Routes

- Over 900 routes of administration identified in preliminary data checking activities
  - Top 10 routes account for >90% of dispensings

<table>
<thead>
<tr>
<th>Route</th>
<th>Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO</td>
<td>Oral</td>
<td>311,664,598</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
<td>194,587,637</td>
</tr>
<tr>
<td>SUBQ</td>
<td>Subcutaneous</td>
<td>31,416,904</td>
</tr>
<tr>
<td>INH</td>
<td>Inhaled</td>
<td>18,821,402</td>
</tr>
<tr>
<td>IH</td>
<td>Inhaled</td>
<td>11,480,749</td>
</tr>
<tr>
<td>NEB</td>
<td>Nebulizer</td>
<td>10,784,936</td>
</tr>
<tr>
<td>TOPICAL</td>
<td>Topics</td>
<td>8,161,071</td>
</tr>
<tr>
<td>IM</td>
<td>Intramuscular</td>
<td>7,629,967</td>
</tr>
<tr>
<td>SQ</td>
<td>Subcutaneous</td>
<td>4,651,895</td>
</tr>
<tr>
<td>NASAL</td>
<td>Nasal</td>
<td>3,844,684</td>
</tr>
</tbody>
</table>
Inpatient medication use data challenges: Dose and units

<table>
<thead>
<tr>
<th>NDC</th>
<th>GenericName</th>
<th>Label</th>
<th>Strength</th>
<th>RxADate</th>
<th>RxATime</th>
<th>Route</th>
<th>Dose</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>00409653301</td>
<td>VANCOMYCIN HCL</td>
<td>VANCOMYCIN 1 GM VIAL</td>
<td>1 G</td>
<td>2015-03-15</td>
<td>10:28</td>
<td>IV</td>
<td>1000</td>
<td>MG</td>
</tr>
<tr>
<td>00409433201</td>
<td>VANCOMYCIN HCL</td>
<td>VANCOMYCIN 500 MG VIAL</td>
<td>500 MG</td>
<td>2015-03-15</td>
<td>22:17</td>
<td>IV</td>
<td>100</td>
<td>MLS</td>
</tr>
<tr>
<td>00409433201</td>
<td>VANCOMYCIN HCL</td>
<td>VANCOMYCIN 500 MG VIAL</td>
<td>500 MG</td>
<td>2011-10-22</td>
<td>9:44</td>
<td>IV</td>
<td>500</td>
<td>MG</td>
</tr>
</tbody>
</table>
Inpatient medication use: Limitations

- Intra-operatively administered medications are not currently captured via barcode-scanning eMAR processes,
  - Pre- and post-op captured, but not meds administered during surgery
- Multiple-medication IV-administered preparations are also not currently represented.
  - Total parenteral nutrition
  - Other multiple-medication preparations
- NDCs captured for Sentinel may not always represent the product manufacturer
Inpatient medication use: Conclusions

- Inpatient pharmacy data provide new Sentinel safety surveillance opportunities
- Additional data standardization will enhance abilities to answer safety questions
- Data partner involvement is critical to understand and enhance source data capture processes to address safety questions
Questions?
Extras
Distributed data network: Definition

- A database for which **no central repository of data exists**
- Data reside **behind the firewalls** of each data partner site
- Data in the network are therefore ‘distributed’ due to the lack of centrality
Sentinel Initiative: A unique distributed data network

- First distributed data network for which dedicated funding was allocated to a central Coordinating Center specifically for the purpose of designing, building, maintaining and expanding systems and analytic infrastructure
- The only distributed data network that is an integral part of a Federal regulatory agency’s regulatory activities
Distributed data network: Guiding principles

- Data partner sites:
  - Maintain control over their data
  - Have standardized their data to a common data model (CDM)
  - Refresh their CDM-formatted data on a regular schedule

- Programming code gets distributed to data partner sites for them to execute locally

- Following execution of programming code, data partners return results to coordinating center

- Coordinating center to build the infrastructure and governance needed to maintain high-quality data and processes
Benefits of a distributed data network

- Address data partners’ concerns over data security, patient privacy and proprietary interests
- Achieve greater statistical power due to larger numbers of observations
- Offer alternative ways to study:
  - Rare outcomes
  - Uptake or usage of new drugs or therapies
  - Diverse populations of individuals
- Encourage the development of novel analytic and statistical methods that do not rely solely on the use of patient-level data
- Challenge programmers to approach projects with the intention of building reusable, flexible and scalable programs for infrastructure purposes
Critical questions for extracting data from EHR into analysis-ready form for secondary use

- Are the data elements needed captured in the data ecosystem?
- Are they recorded/captured in a systematic, consistent way
  - Within facilities?
  - Across facilities?
  - By clinical staff within facilities?
  - By clinical staff across facilities?
- Are they collected/input/stored in structured, semi-structured or unstructured/free-text form?
- Are there existing allowable values
  - If no, can values be categorized without specific clinical knowledge/expertise into allowable values or categories?