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

Jennifer R. Popovic, DVM, MA,[1] Candace C. Fuller, PhD, MPH,[2] Caren Spencer-Smith, MIS, MT(ASCP),[3] Jason Hickok, MBA, RN,[3] Karla M. Miller, PharmD, BCPP,[3] Russell Poland, PhD,[3] Denise M. Boudreau, PhD[4]

[1] RTI International, Waltham, MA

[2] Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA

[3] Hospital Corporation of America, Nashville, TN

[4] Kaiser Permanente Washington Health Research Institute, Seattle, WA

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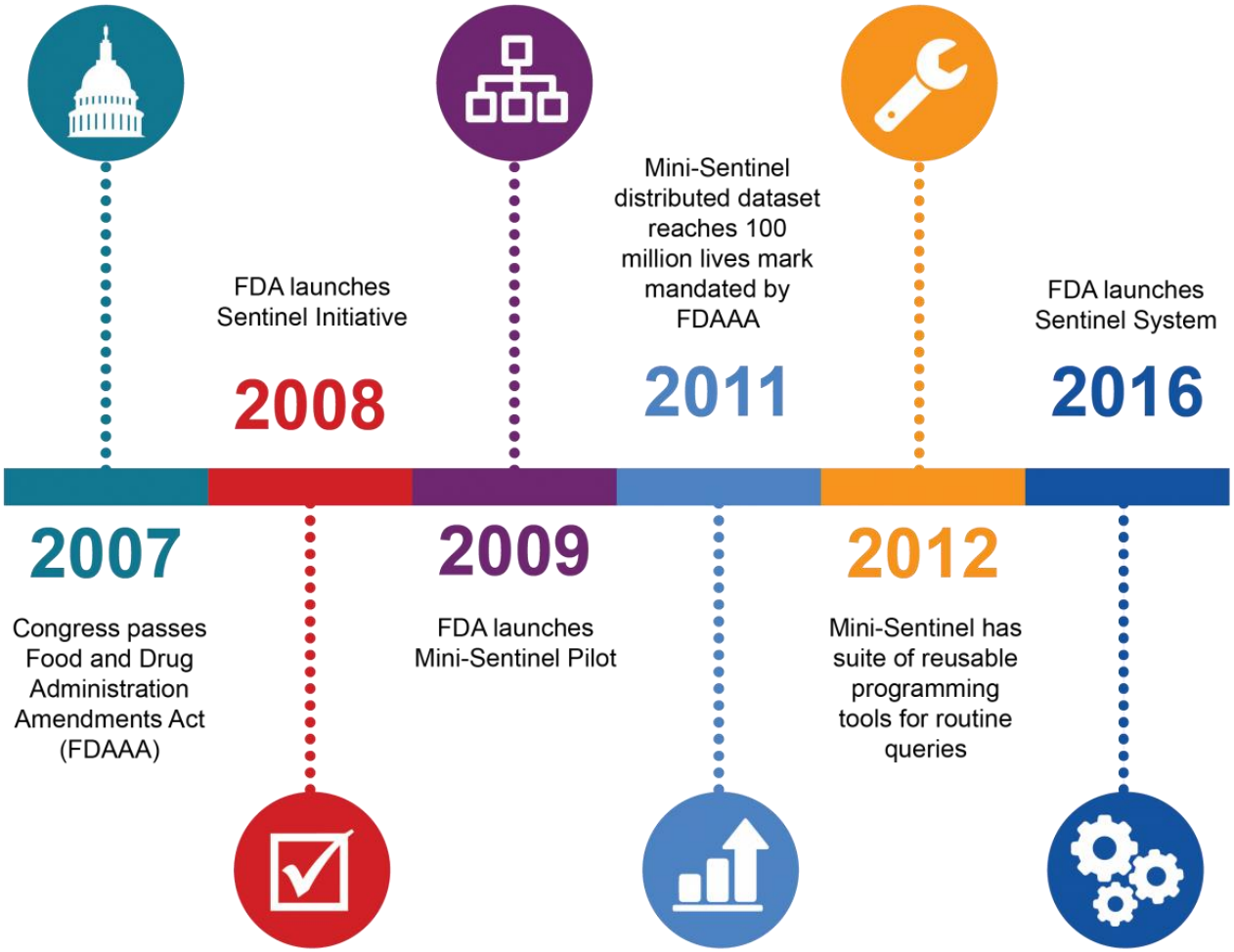
Outline

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

Sentinel Initiative



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

Field Name	Definition
PatID	Unique member identifier → **Who**
EncounterID	Unique encounter identifier
NDC	National Drug Code → **What**
RxID	Useful to map back to source data
RxADate	Administration date → **When**
RxATime	Administration time → **When**
RxRoute	Administration route → **How**
RxDose	Administration dose → **How much**
RxUOM	Administration unit of measure → **How much**

Sentinel Common Data Model: Inpatient medication use, one patient

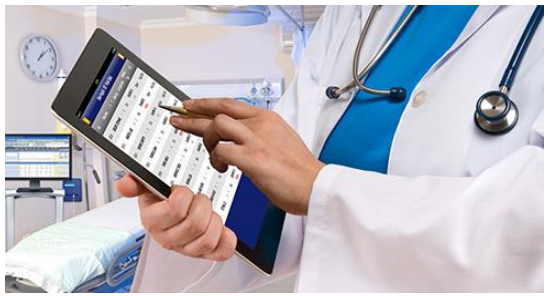
INPATIENT PHARMACY								
PATID	**ENCOUNTERID**	**NDC**	**RxID**	**RXADATE**	**RXATIME**	**RXROUTE**	**RXDOSE**	**RXUOM**
PatID1	EncID1	00409653301	RxID1	2015-03-15	10:28	IV	1000	MG
PatID1	EncID1	00409653301	RxID2	2015-03-15	14:32	IV	1000	MG
PatID1	EncID1	00409433201	RxID3	2015-03-16	15:17	IV	500	MG
PatID1	EncID2	66267011615	RxID4	2015-07-23	19:09	PO	800	MG

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

First Databank class categories	Example generic names
Anesthetics	Propofol Lidocaine HCL
Antibiotics	Piperacillin sodium/Tazobactam Vancomycin HCL
Antineoplastics	Megestrol acetate Hydroxyurea
Cardiac/Cardiovascular	Amlodipine besylate Metoprolol tartrate
CNS	Gabapentin Levetiracetam
Diagnostic	Iopamidol Iohexol
Psychotherapeutic	Alprazolam Lorazepam

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

Route	Description	Count
PO	Oral	311,664,598
IV	Intravenous	194,587,637
SUBQ	Subcutaneous	31,416,904
INH	Inhaled	18,821,402
IH	Inhaled	11,480,749
NEB	Nebulizer	10,784,936
TOPICAL	Topics	8,161,071
IM	Intramuscular	7,629,967
SQ	Subcutaneous	4,651,895
NASAL	Nasal	3,844,684

Inpatient medication use data challenges: Dose and units

NDC	GenericName	Label	Strength	RxADate	RxATime	Route	Dose	Units
00409653301	VANCOMYCIN HCL	VANCOMYCIN 1 GM VIAL	1 G	2015-03-15	10:28	IV	1000	MG
00409433201	VANCOMYCIN HCL	VANCOMYCIN 500 MG VIAL	500 MG	2015-03-15	22:17	IV	100	MLS
00409433201	VANCOMYCIN HCL	VANCOMYCIN 500 MG VIAL	500 MG	2011-10-22	9:44	IV	500	MG

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?