Sentinel System Overview

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Sentinel is:

• FDA’s medical product safety surveillance system created in response to a Congressional mandate
• Primarily electronic healthcare and administrative claims data
• Based on a distributed data network and a common data model
History of the 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 Uses Secondary Data

- Patient interaction with the U.S. healthcare system generates data
- Why is data collected?
  - Payment/billing
  - Document clinical care
  - Physician decision support
  - Recordkeeping
  - Registries
- Data provide rich source of information for patient safety evaluations
Data is Collected for Several Purposes

Administrative Data
• Collected for transactional recordkeeping, reimbursement

Clinical Data
• Collected to document elements of clinical care and support physician decision-making

Registries
• Collected to provide information on a specific population of interest
Sentinel Captures Billions of Encounters with the Healthcare System

- Populations with well-defined person-time for which most medically-attended events are known
- 223 million members*, 2000-2016
  - 178 million members* with medical and pharmacy benefits
- 43 million people currently accruing new data
- 425 million person-years of observation time

*Counts distinct “PatID” values in the database, 2000-2016
Common Data Model

• A common data “language” across different health system data sources that allows for aggregation of large amounts of data

• Patient data stay secure because the source information stays at the health care system in the Sentinel Distributed Database
Sentinel Distributed Database Ensures Data Security
Scientific Partners Bring Expertise

Lead – HPHC Institute

Data and scientific partners

Scientific partners
Data Partners Respond to Queries

- aetna
- OPTUM
- Health care systems research network
- HealthCore
- Anthem
- HCA
- MASSACHUSETTS
- VANDERBILT SCHOOL OF MEDICINE
- HUMANA
- Kaiser Permanente
- Harvard Pilgrim HealthCare
Why Is Sentinel Important?

• Sentinel generates real-world evidence to support regulatory actions aimed at protecting the public’s health

• This evidence helps inform healthcare provider decision-making for patients
What kinds of questions can Sentinel answer?

• Number of tablets of X dispensed to outpatients in 2015?
• Fraction of patients who filled a prescription for X who also filled a prescription for Y?
• Risk of a problem among patients dispensed both drug X and drug Y compared to patients dispensed drug X and drug Z?
Sentinel Webpage:
www.sentinelinitiative.org
How is FDA Using Sentinel?

How ARIA Analyses Have Been Used by FDA

This page summarizes how select analyses conducted in Sentinel’s Active Risk Identification and Analysis (ARIA) system have been used by FDA. ARIA can contribute to FDA’s regulatory process in a variety of ways, such as contributing evidence to support a label change, respond to a Citizens Petition, or become part of an Advisory Committee deliberation. Information from ARIA can also provide evidence that alleviates concerns about a particular safety issue and might lead FDA to determine that no regulatory action is necessary based on the available information.

Each ARIA analysis listed below contributed in some material way to inform an important regulatory discussion or action. FDA makes decisions about drug safety issues based upon the totality of evidence. The listing of an ARIA analysis in the table means that Sentinel’s ARIA system was one important source of evidence considered.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Outcome Assessed</th>
<th>ARIA Analysis</th>
<th>Regulatory Determination / Use</th>
<th>Date Posted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keppra (levetiracetam)</td>
<td>Anaphylaxis and angioedema</td>
<td>Level 1</td>
<td>Drug Safety Label Change, Warnings and Precautions</td>
<td>11/30/2017</td>
</tr>
</tbody>
</table>

https://www.sentinelinitiative.org/drugs/how-aria-analyses-have-been-used-fda
What Can Patients Do?

• Patients can engage with FDA’s Sentinel System by:
  – Talking with their healthcare providers and insurance plans about the Sentinel System to build awareness
  – Visiting our website for news and updates
  – Attending Sentinel’s public workshops and meetings
2018 Sentinel Initiative Annual Public Workshop

February 7, 2018 - 9:00 am
Hyatt Regency Bethesda
1 Bethesda Metro Center
Bethesda, MD 20814

Description
This annual workshop serves as a forum to bring together leading experts and interested stakeholders to discuss the ongoing development of the Sentinel Initiative. The Food and Drug Administration inaugural 2015 workshop highlighted challenges and

Speakers
Dr. Gerald Dal Pan, Director of the Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research

Summary: The Sentinel System

- Sentinel is FDA’s national medical product monitoring system
- Uses a common data model and a distributed database
- Generates evidence to inform clinical decision-making
- Multiple ways to stay informed and active
  - Sentinel website: https://www.sentinelinitiative.org/
Thank you!

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