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Spotlight: Sentinel Initiates a New Project to Leverage Medicaid Data

Sentinel is excited to announce a new project funded by the Assistant Secretary for Planning and Evaluation (ASPE) called [Making Medicaid Data More Accessible Through Common Data Models and FHIR APIs](#). This project evaluates the feasibility of implementing Fast Healthcare Interoperability Resources (FHIR) APIs (Application Programming Interfaces) to link T-MSIS data with electronic health record (EHR) data. This is a joint agency project involving the Food and Drug Administration (FDA) and the National Institutes of Health/ National Library of Medicine (NIH/NLM) that expands data infrastructure by converting Medicaid and Children's Health Insurance Program (CHIP) data into the Observational Medical Outcomes Partnership (OMOP) and Sentinel Common Data Models (SCDM).



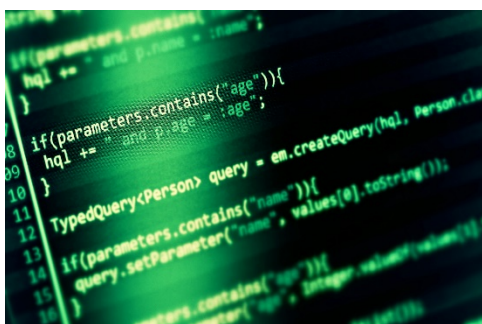
With an estimated 40-50% of pregnant patients covered by Medicaid insurance, we expect the addition of Medicaid data to the Sentinel System will create the largest network of both commercially and publicly insured pregnant patients that can be linked to their infants. Sentinel will engage in maternal health-focused demonstration projects under ASPE funding with a joint working group of the above-mentioned federal agencies, in addition to the Centers for Disease Control and Prevention (CDC) and the Health

Resources and Services Administration (HRSA). Sentinel has invited participation of a Technical Expert Panel to provide guidance for these projects.

FACT OR MYTH?

Sentinel is assessing the feasibility of linking Transformed Medicaid Statistical Information System (T-MSIS) data with electronic health record (EHR) data. [Click here](#) to find the answer.

Sentinel Highlights: Advancing Scalable Natural Language Processing Approaches for Unstructured Electronic Health Record Data



In the decade since the launch of Mini-Sentinel, the biomedical research community has demonstrated the benefits of marshalling unstructured clinical data to better understand disease etiology and improve care delivery. Often referred to as precision phenotyping, advanced analytic methods are being applied to structured and unstructured EHR data to characterize the timing, severity, and complexity of patients' health conditions. This prior work to characterize patients' health conditions suggests that harnessing ubiquitous, unstructured EHR data is beneficial for generating information on populations, exposures, health outcomes

of interest, and covariates, which can help achieve Sentinel's medical product safety surveillance objectives, in general, and surveillance efforts in response to the COVID-19 pandemic, in particular.

In response to the pandemic, the FDA Sentinel System has focused on addressing the following questions:

- How can the Sentinel System be optimally utilized to conduct post-market surveillance on the safety and effectiveness of COVID-19 treatments?
- Which health outcomes of interest of COVID-19 disease, and COVID-19 treatments, merit close monitoring using the Sentinel system?
- What outcomes must be measured to assess treatment effectiveness?
- Which covariates and comorbid conditions must be measured to enhance inference based on observational studies?
- Which of these outcomes and covariates can be better, or solely, captured from unstructured EHR data?
- How can unstructured EHR data be leveraged to answer important questions about the pandemic?
- How can FDA utilize the Sentinel System to prepare for the next pandemic?

Methods that are developed through the demonstration project will help advance medical product surveillance through the following objectives:

- **Objective 1:** Identify Study Populations – in addition to using structured diagnosis codes and laboratory results, we will develop methods and algorithms to identify relevant COVID-19-positive patient populations from unstructured EHR data.
- **Objective 2:** Extract Select Clinical Features – to address Sentinel Active Risk Identification and Analysis (ARIA) sufficiency needs and demonstrate the viability of this approach, we will develop methods and algorithms to capture a select subset of COVID-19-relevant clinical features (exposures, health outcomes of interest (HOIs), and covariates) from unstructured EHR data sources.
- **Objective 3:** Evaluation – to assess the benefits of utilizing unstructured data, we will compare results of using structured data only versus structured + unstructured data for identifying study

populations and capturing sample features in each ARIA category (population, exposure, outcome, covariates).

Engage with the Sentinel Community

The 2022 Sentinel Innovation and Methods Seminar Series

The Sentinel Innovation and Methods Seminar Series features presentations by leading experts and innovators on topics related to the work of the Innovation Center (IC) and the Sentinel Operations Center (SOC). The Seminar Series utilizes emerging technologies such as feature engineering, natural language processing, advanced analytics, and data interoperability to improve Sentinel's capabilities.

Past Seminars:

- [Do All Roads Lead to FHIR? Imagining FHIR as a Meta-Common Data Model for Research](#)
- [An Introduction to Negative Control and Proximal Causal Learning](#)
- [Synthetic Data to Support Reproducible Clinical Research: Opportunities and Challenges](#)
- [Inverse Probability of Exposure and Censoring Weights for Marginal Structural Models](#)

Upcoming Seminar:

The following seminar will occur on Monday, March 28, 2022 at 12:00pm EST:

REGISTER:

Data Leakage Due to Care Provided Outside of the Study Electronic Health Record System: Potential Biases and Solutions

Visit the [Sentinel Meetings, Workshops, & Trainings page](#) to view past seminars, webinars, and workshops and to register for upcoming events in 2022.

2022 Community Building and Outreach Center Webinar Series

On January 19, 2022, the Sentinel Community Building and Outreach Center (CBOC) hosted a webinar on how Health Advocates can use publicly available resources on the Sentinel website. The webinar provided an overview of the Sentinel System, explained how the Sentinel System protects health data, and how to navigate the [Sentinel website](#). The webinar reviewed how to find recent publications, presentations, reports of drug safety assessments, and training and workshop materials. The goal of this webinar is to enhance Health Advocates' awareness and understanding of Sentinel. Please click the link below to access the webinar recording.

WATCH:

An Overview of the Sentinel Website for Health Advocates Webinar

New Analytic Packages, Methods, Tools and Reports

Methods Projects:

- [Data Quality Review and Characterization Programs](#)

The SOC created a set of data quality review and characterization programs to ensure that the Sentinel Distributed Database (SDD) meets reasonable standards for data transformation consistency and quality and that the SDD data meets expectations needed for a distributed health data network.

- [Development and Illustration of a Framework for Conducting Nonrandomized Studies of Medication Safety and Effectiveness Using Healthcare Databases](#)

This project will develop a causal inference framework for safety and effectiveness evaluations of medical products that leverage claims data alone or in combination with EHR data.

Tools:

- [Routine Querying System](#)
- [Sentinel Routine Querying System Reporting Tool](#)

Reports:

- [Bleeding Events and Venous Thromboembolism \(VTE\) following Enoxaparin Use: A Descriptive Analysis](#)
- [Tofacitinib, Disease-Modifying Anti-Rheumatic Drugs \(DMARDs\) and Tumor Necrosis Factor Inhibitors \(TNFi\) Use: A Descriptive Analysis](#)
- [N-nitrosodimethylamine \(NDMA\)-Contaminated and Non-NDMA-Contaminated Valsartan Use: A Descriptive Analysis](#)
- [Prenatal Tests & Stillbirth](#)
- [Duration of Follow Up for New Molecular Entities Approved in 2019: A Descriptive Analysis](#)
- [Duration of Follow Up for New Molecular Entities Approved in 2017: An Updated Descriptive Analysis](#)
- [Zoloft \(Sertraline\) & Intentional Self-Harm and Hospitalized Depression](#)
- [Intentional Self-Harm and Hospitalized Depression Following Sertraline Use: A Propensity Score Matched Analysis](#)
- [Intentional Self-Harm and Hospitalized Depression Following Sertraline Use: A Propensity Score Matched Analysis \(A Follow-up to a Previous Analysis\)](#)
- [Hospitalized Depression Algorithm Defined in "Intentional Self-Harm and Hospitalized Depression Following Sertraline Use: A Propensity Score Matched Analysis"](#)
- [Intentional Self-Harm Algorithm Defined in "Intentional Self-Harm and Hospitalized Depression Following Sertraline Use: A Propensity Score Matched Analysis"](#)
- [A Comparison of Race and Ethnicity in COVID-19 Testing, Hospitalization, and Mortality](#)

Recent Publications and Presentations

- [Major Moments in the Development of Sentinel](#)
- [Utility of Fertility Procedures and Prenatal Tests to Estimate Gestational Age for Live-births and Stillbirths in Electronic Health Plan Databases](#)
- [Real-World Data: Data Networks, Standardization, and Federated Analysis](#)

- [Broadening the Reach of the FDA Sentinel System: A Roadmap for Integrating Electronic Health Record Data in a Causal Analysis Framework](#)
- [FDA Labeling Change: Oral Methotrexate and Wrong Frequency Dosing Errors](#)
- [Validation of Diagnosis Codes to Identify Hospitalized COVID-19 Patients in Health Care Claims Data](#)

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