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Characterization of Mothers in the Sentinel Distributed Database Mother-Infant Linkage Table

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BACKGROUND

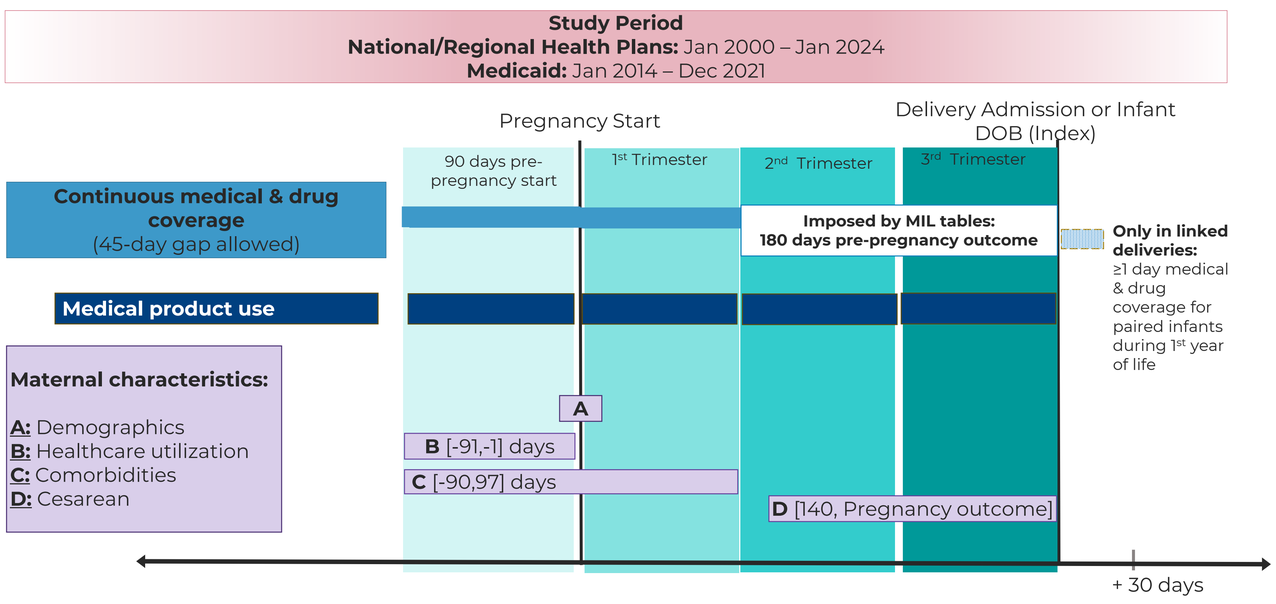
The United States (US) Food and Drug Administration's (FDA) Sentinel Distributed Database (SDD) contains claims data from various healthcare organizations, including mother-infant linked (MIL) tables, enabling studies of maternal, infant, and prenatal characteristics and drug use before, during, and after pregnancy.

OBJECTIVES

To characterize the demographics, health characteristics, and drug utilization of mothers with singleton live births (linked and unlinked to an infant record in the MIL table) and those with non-live birth outcomes identified through claims algorithms in the SDD.

METHODS

Figure 1. Study Design Diagram



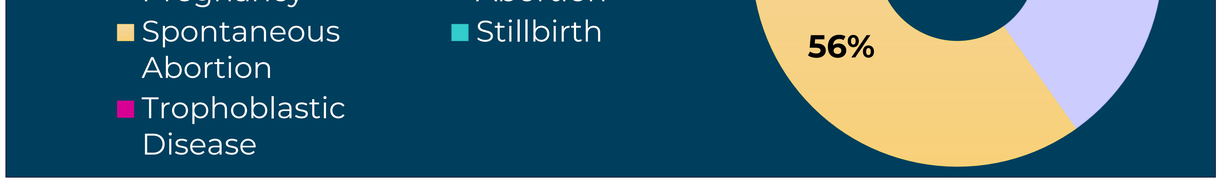
- **MIL Table:** The MIL table is part of the Sentinel Common Data Model (SCDM), providing the linkage infrastructure utilized.
- **Population:** Females aged 10–54 with continuous enrollment from 90 days pre-pregnancy through delivery. Included pregnancies with live births (linked/unlinked to infants) or non-live birth outcomes (stillbirth, trophoblastic disease, ectopic pregnancy, spontaneous or induced abortion).
- **Data:** Claims data from 2000–2024 across Medicaid and five national/regional health plans (Figure 1). Pregnancy outcomes identified using a validated algorithm; MIL tables used for mother-infant linkage for live births.
- **Analysis:** Described maternal demographics, health conditions, and medication use (including potential teratogens) from 90 days pre-pregnancy to 30 days postpartum. No formal statistical comparisons since analysis was descriptive.

RESULTS

- Of the total live birth deliveries from the MIL table, 78% were linked (5,349,432), and 22% were unlinked (1,514,740) (Figure 2).
- Non-live birth outcomes totaled 3,264,447, with spontaneous abortion being the most common (55.6%) (Figure 3).

Figure 2. Linkage rate in MIL tables in Sentinel Distributed Database (Jan 2000-Jan 2024)

Figure 3. Pregnancy Outcome in mothers with non-live births in the Sentinel Distributed Database (Jan 2000-Jan 2024)



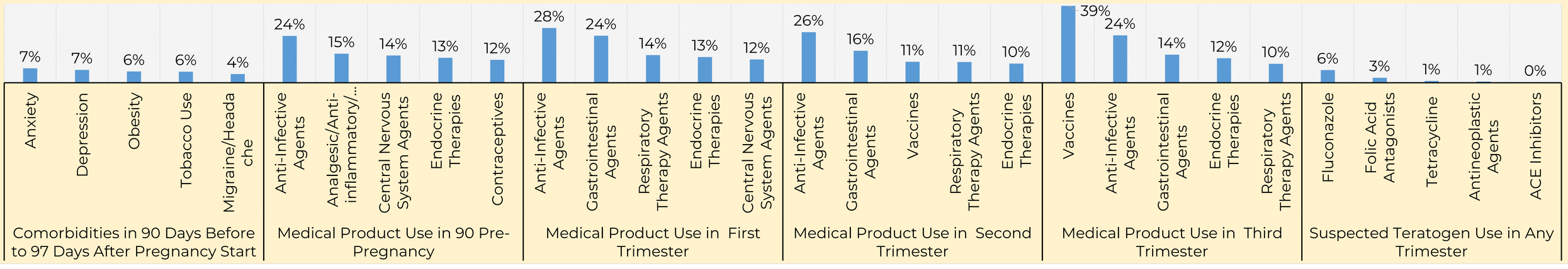
- The mean maternal age across live birth deliveries was 29 years old (standard deviation 5.6). Among these deliveries, 28% were cesarean and 10% were preterm. Also, 88% had ≥461 days of enrollment prior to the pregnancy outcome (*Table* 1).
- Among linked live birth deliveries, anxiety (7%) and depression (7%) were the most common maternal comorbidities from 90 days before to 97 days after pregnancy start (Figure 4).

Table 1. Demographics and Healthcare across live birth (linked/unlinked) and non-live birth pregnancy outcomes in the Sentinel Distributed Database (Jan 2000-Jan 2024)

	Linked Live Birth Deliveries	Unlinked Live Birth Deliveries	Non-live Birth Deliveries
Ever enrolled, N (100%)	5,349,432	1,514,740	3,264,447
Mean (SD) age at delivery	29.6 (5.2)	27.2 (6.5)	29.9 (6.5)
Known Race, %	50	50	49
Non-White Race, % of Known	36	39	45
Mothers with ≥461 Days of Enrollment Before Pregnancy Outcome, %	88	88	69
Mean (SD) annual number of ambulatory encounters	2.1 (3.7)	2.0 (4.1)	2.5 (4.3)

- During the 90 days before pregnancy, women most commonly used anti-infective agents (24%), analgesics/anti-inflammatories (15%), and central nervous system agents (14%) (Figure 4).
- Medication use shifted across pregnancy trimesters: anti-infective agents remained common throughout, peaking in the first trimester (28%) and remaining steady in the third (24%). Gastrointestinal agents were frequently used in the first (24%) and second trimesters (16%), while vaccines were the most used class in the third trimester (39%). Suspected teratogens were rarely used during pregnancy. Fluconazole, an antifungal, was the most common (6%), followed by folic acid antagonists (3%) (Figure 4).

Figure 4. Common Comorbidities (90 Days Before to 97 Days After Pregnancy Start), Most Common Medical Product Use (Pre-Pregnancy and by Trimester), and Suspected Teratogen Use (Any Trimester) in Linked Deliveries (MIL Tables, Sentinel Distributed Database)



CONCLUSION

The study characterized over 6.8 million live births and 3.2 million non-live birth outcomes among SDD enrollees, assessing real-world use of various drug classes, including suspected teratogens, across pregnancy trimesters. This data, particularly for 5.3 million deliveries linked to an infant record, provides valuable opportunities to study medication exposure and its impact on maternal, prenatal, and infant health outcomes.

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- The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the US Government.