

BACKGROUND

The U.S. Food and Drug Administration's Sentinel Distributed Database (SDD) includes a Mother-Infant Linkage (MIL) table, allowing assessment of prenatal, mother, and infant characteristics.

OBJECTIVES

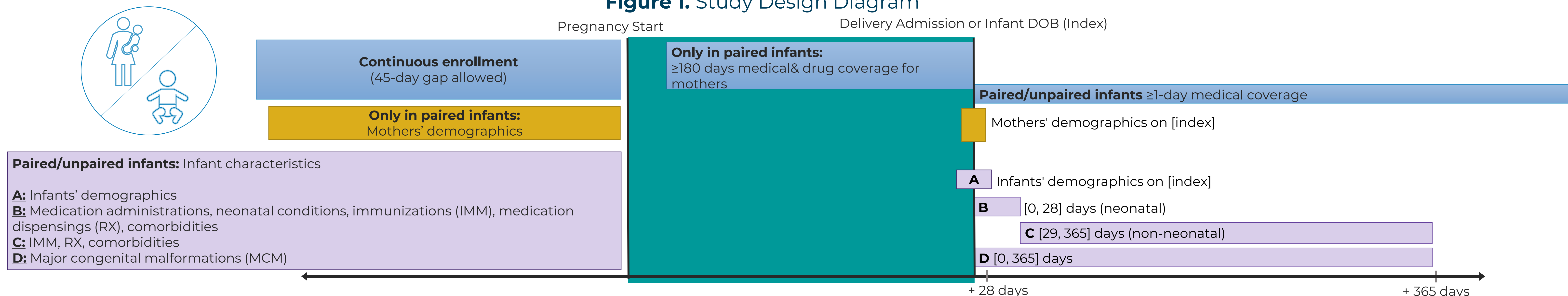
This study aims to characterize demographics, enrollment, medication use, immunizations, health conditions, and major congenital malformations (MCMs) of infants in the SDD MIL table, comparing infants paired to a mother to those not in such a pair.

METHODS

- Population:** Infants (0-365 day-old) in the MIL table of the SDD paired to a mother via a live-birth delivery in the MIL table, or infants without paired mothers in the MIL table from 2000 to 2022.
- Data:** Medicaid and four commercial health plans (56% from Medicaid)

- Analysis:** No formal statistical comparisons since analysis was descriptive. For paired infants, health characteristics were described by searching both mother's and infant's records and infant's records alone.

Figure 1. Study Design Diagram

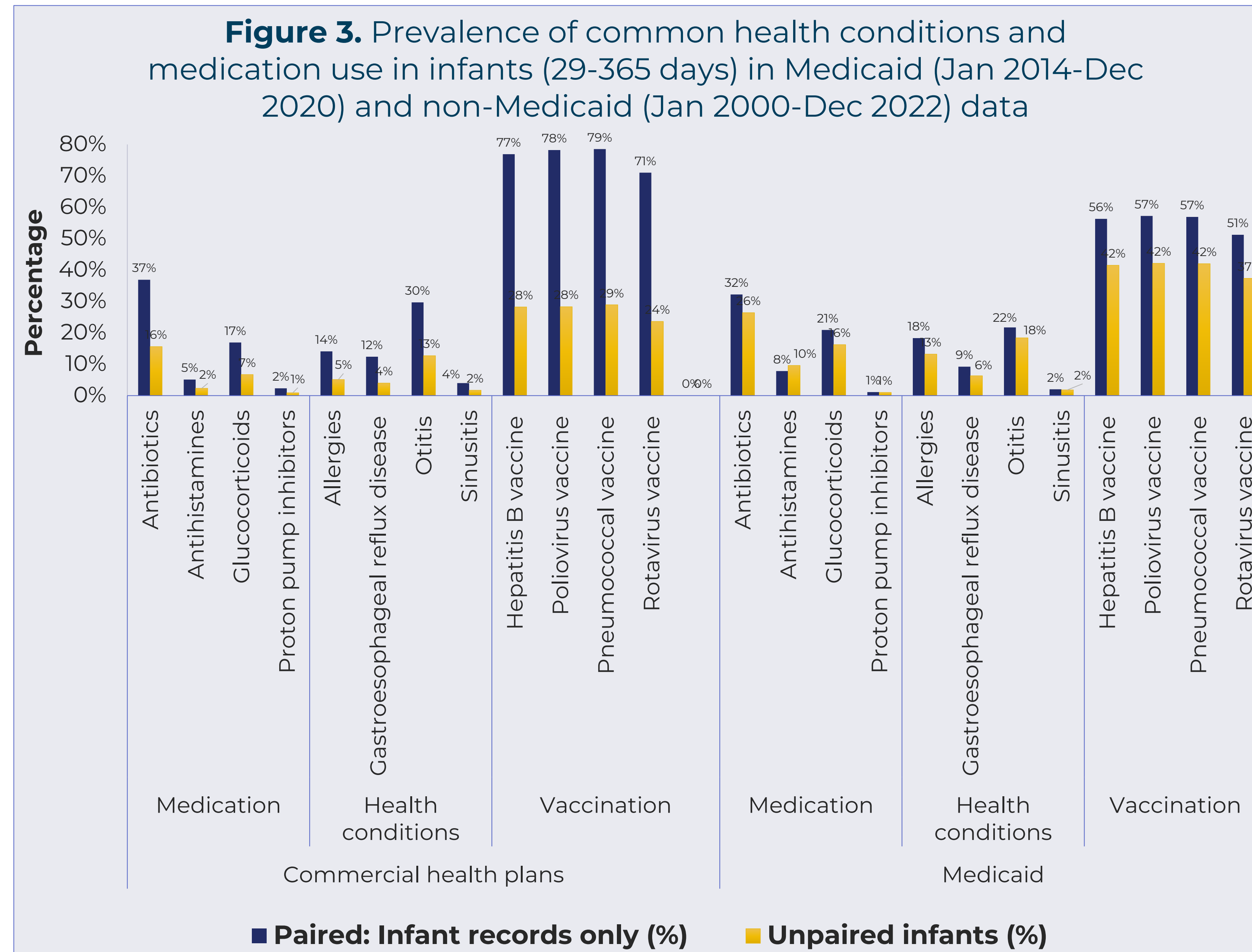
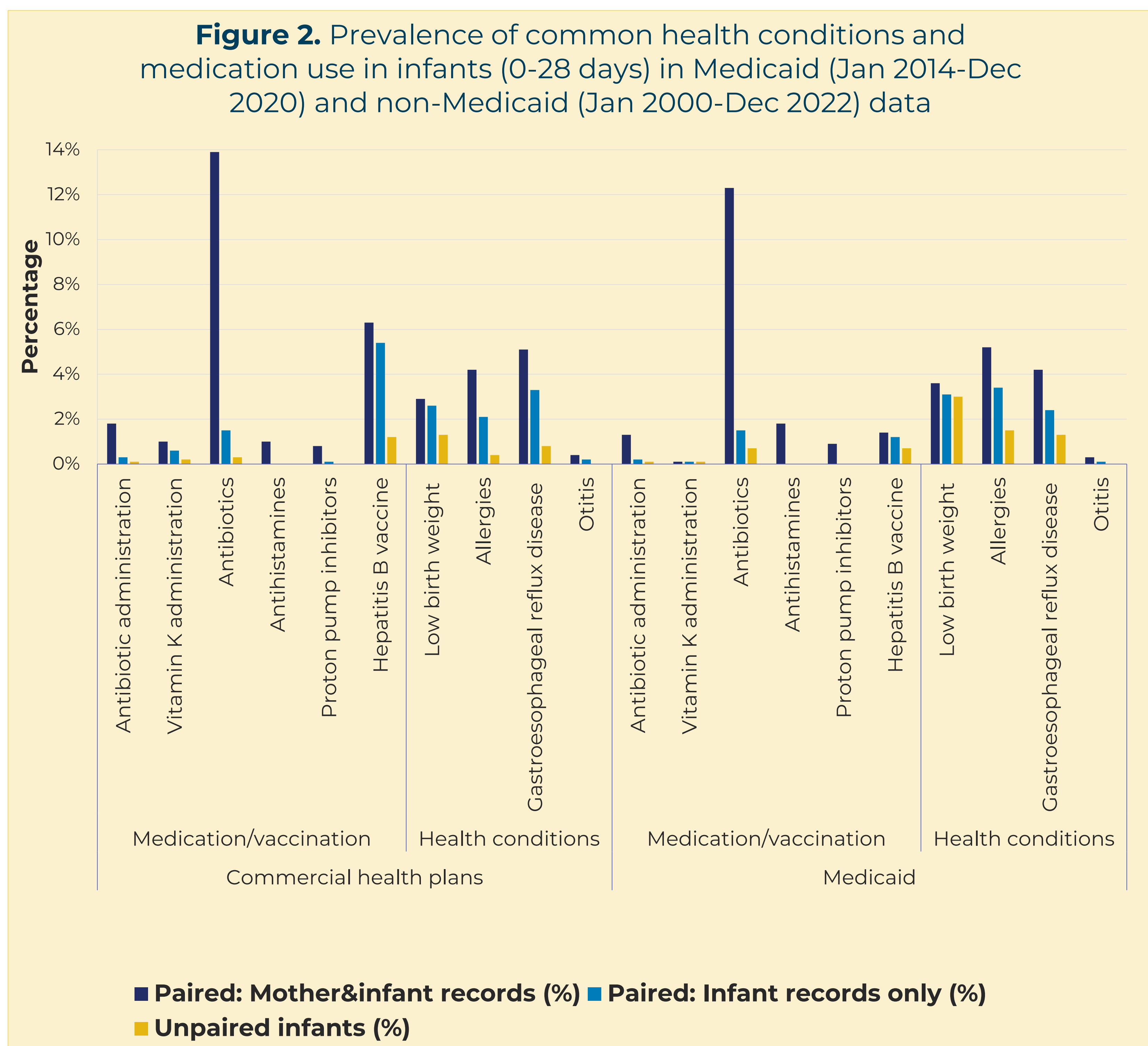


RESULTS

- 51% of 22,820,930 infants in the SDD MIL data are male, with 44% having over two year of continuous enrollment
- 12,735,673 infants were in Medicaid's MIL tables (16% mother-infant pairs)
- Of 10,085,257 infants in non-Medicaid MIL tables, 33% were paired infants
- 90% of infants in a pair were from singleton deliveries

Table 1. Characteristics of paired/unpaired infants in Medicaid (Jan 2014-Dec 2020) and commercial health plans (Jan 2000-Dec 2022) MIL tables

	Medicaid		Commercial health plans	
	Paired	Unpaired	Paired	Unpaired
Number of infants	2,088,630	10,647,043	3,344,534	6,740,723
% male	51	51	51	51
% known race	55	50	13	6
% known ethnicity	72	74	9	4
% >2 years continuous enrollment	41	45	46	41
mothers mean age at delivery (years)	27	N/A	31	N/A
% mothers with <391 days pre-delivery coverage	15	N/A	11	N/A



- In Medicaid data using only infant records, common conditions were allergies (3.4% paired, 1.5% unpaired) and low birth weight (LBW) (3.1% paired, 3% unpaired). Non-Medicaid data showed higher rates of gastroesophageal reflux disease (GERD) (3.3% vs. 0.8%) and LBW (2.6% vs. 1.3%).
- For paired neonates, the prevalence of conditions like LBW was higher in both Medicaid (3.1% vs. 3%) and non-Medicaid (2.6% vs. 1.3%) data when using both mothers' and infants' records, rather than just infants' records.

- Allergies, GERD, otitis, and sinusitis were more prevalent in infants with paired and unpaired mothers after the first month
- Medicaid infants had lower evidence of immunization rates than non-Medicaid infants
- Prevalence of major congenital malformations (MCMs) in the first year was similar in both Medicaid and non-Medicaid data, regardless of pairing

CONCLUSION

The study utilized the U.S. FDA's SDD MIL table to analyze data from over 22 million infants born between 2000 and 2022. About 23.8% of infants come from mother-infant pairs. Key findings include differences in health conditions between paired and unpaired infants within the first 28 days of life, more pronounced health differences after the neonatal period, and variations in health characteristics between Medicaid and non-Medicaid data. Using both mothers' and infants' records improved data capture for certain factors, but there are possibilities of misclassification.

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- B. Rasouli, A. Martinez, KE. Round, K. Nagavedu, S. Alam, and S. McGown are employees at Harvard Pilgrim Health Care Institute, which conducts work for government and private organizations, including pharmaceutical companies.
- 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.