

# **Characterizing Pediatric Members** in the Sentinel Distributed Database

Ashley I. Michnick<sup>1</sup>, Kimberly Barrett<sup>1</sup>, Cifty Brisbane<sup>1</sup>, Samuel McGown<sup>1</sup>, Sampada Nandyala<sup>1</sup>, Emmanuel Ojol, Bahareh Rasoulil, Katherine E. Round<sup>1</sup>, Samantha J. Smith<sup>1</sup>, José J. Hernández-Muñoz<sup>2</sup>

<sup>1</sup>Department of Population Medicine, Harvard Pilgrim Health Care Institute and Harvard Medical School, Boston, MA <sup>2</sup>Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, United States Food and Drug Administration, Silver Spring, MD

Presented at the *International Society for Pharmacoepidemiology 40th Annual Meeting* (Berlin, Germany; 24-28 August 2024)



- BACKGROUND
- Real-world data (**RWD**) may improve medication safety studies in the pediatric population
- Sentinel System maintains the distributed database (SDD) at

Data Partners which provides access to high-quality RWD

as well as scientific and technical expertise.

#### **METHODS**

**<u>Population</u>**: SDD members aged **o through 21 years** during their first year

in each age group (first-year point prevalence) from 2000-2023

- **Neonates & Infants**: 0 28 days & 29 days 23 months;
- **Younger & Older Children**: 2 5 & 6 11 years;
- **Early & Late Adolescents:** 12 17 & 18 21 years
- Required  $\geq 1$  day of both medical and prescription drug coverage
- SDD primarily contains administrative claims data; ~1.1 billion person-years, including more than 300 million from Medicaid

#### **OBJECTIVE**



enrollment, Describe demographics, health and characteristics among pediatric members in the SDD

- Programmed using Cohort Identification and Descriptive Analysis module, version 12.1.2
- **<u>Outcomes</u>**: Demographics, enrollment, health conditions, healthcare utilization intensity, prescription medication use
- Statistical Analysis: descriptive statistics (mean/standard deviation or count/percentage)
  - No formal statistical comparisons since analysis was descriptive

#### RESULTS

- Total volume of pediatric enrollees in the SDD from 2000-2023 ranged from about 16 to about 46 million, depending on age group
- Minimal before 2006; highest in 2014-2019
- Composition of pediatric members by age group relatively constant over time (~20:40:40%) neonates/infants : children : adolescents)



• Late adolescents have least; older children have most continuous enrollment (median [IQR] 432 [214 – 1,004] versus 708 [320 – 1,455] days)

#### Table 1. Demographics and Healthcare Utilization **Among Pediatric Members in the Sentinel Distributed Database**

	Neonates	Infants	Young children	Older children	Early adolescents	Late adolescents
Ever enrolled, N (100%)	16,569,023	27,569,755	36,832,277	46,661,705	45,354,705	35,499,458
Known Race, %	35.6	35.3	36.3	35.7	34.2	30.0
Non-White Race, % of Known	41.3	41.4	41.3	41.2	41.1	40.7
Female, %	48.8	48.8	48.8	48.8	49.0	51.2
Mean (SD) annual number of:						
Ambulatory encounters	2.3 (1.7)	7.6 (8.0)	5.3 (10.7)	4.9 (10.1)	5.1 (10.0)	4.2 (8.5)
Dispensed prescriptions	0.1 (0.4)	3.4 (7.4)	2.9 (6.0)	3.2 (7.2)	3.7 (8.5)	4.1 (8.6)
Dispensed drug classes	0.1 (0.4)	2.0 (2.5)	1.7 (2.3)	1.5 (2.2)	1.6 (2.4)	1.8 (2.7)

- Healthcare utilization peaks in infancy, led by ambulatory office visits
- Most common of assessed health conditions was allergies (11.9-17.3% of infants and children; 6.2-9.3% of adolescents)
- Mental health conditions outpace respiratory and infectious disease conditions during adolescent years
- Prescription medication use parallels health conditions



### CONCLUSION

• This characterization of pediatric members in the SDD shows consistency with other national estimates, enhancing the Sentinel System's utility in future pediatric medical product safety assessments.

## ACKNOWLEDGEMENTS

- Supported by Task Order 75F40123F19009 under Master Agreement 75F40119D10037 from the U.S. Food and Drug Administration (FDA). The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement by, the U.S. FDA, HHS, or Government.
- The authors have no conflicts of interest to disclose. Some co-authors are employed at organizations which conduct work for government and private organizations, including pharmaceutical companies.



