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OBJECTIVES

- To evaluate a cohort of pediatric patients with evidence of hypertension via clinical, EHR-based data and compare to evidence derived from claims-based information within the FDA's Sentinel Initiative
- To characterize vital signs data (systolic and diastolic blood pressure (BP), height) among a pediatric population to report on suitability as a Real-World Data source for pediatric hypertensive patients

 Table 1. Concurrence between Claims and Clinical Definitions of Hypertension and
 Elevated BP

		Claims Definitions	
Clinical Definitions		Hypertension Definition 1	No Hypertension Definition 1
	Hypertensive Blood Pressure	1,506 (0.3%)	508,901 (99.7%)
		Hypertension Definition 2	No Hypertension Definition 2
	Hypertensive Blood Pressure	2,995 (0.6%)	507,412 (99.4%)
		Elevated Blood Pressure	No Elevated Blood Pressure
	Elevated Blood Pressure	1,643 (0.3%)	512,249 (99.7%)

BACKGROUND

- In 2017 the American Academy of Pediatrics (AAP) issued new clinical guidelines for the definition of pediatric hypertension **Figure 1. Sentinel Common Data**
- In 2019, we estimated rates of pediatric hypertension using claims diagnosis codes. Low prevalence estimates suggested a potential for under-coding of pediatric hypertension using claims data
- Sentinel Common Data Model • The includes Lab Result and Vital Signs Clinical Data tables populated with EHR. The Vital Signs table is populated by Data Partners representing seven Integrated Delivery Sites (IDS) and was leveraged for this study

Clinical Data				
Lab Result	Vital Signs			
Patient ID	Patient ID			
Result & Specimen Collection Dates	Measurement Date & Time			
Test Type, Immediacy & Location	Height & Weight			
Logical Observation	Diastolic & Systolic BP			
Identifiers Names and Codes (LOINC®)	Tobacco Use & Type			
Etc.	Etc.			

Model's Clinical Data Tables

METHODS

• We identified patients aged 3-17 years with blood pressure (BP) measures between January 1, 2006 and December 31, 2018

Table 2. Demographic and Vital Characteristics of Patients with BP Measures

	All Patients (N=1,659,773)	Patients with Any Elevated or Hypertensive BP Measure (N=1,024,299)	Patients with Only Normotensive Measures (N=502,992)
Episodes, n	10,021,452	1,024,299	502,992
Age (years), mean	11.2	10.1	9.7
3-5 years, %	18.4%	31.5%	34.8%
6-11 years, %	32.7%	27.3%	26.9%
12-17 years, %	48.9%	41.2%	38.3%
Height (inches), mean	56.8	54.4	53.0
Blood Pressure Measurements			
Diastolic (mmHg), mean	62.8	68.9	58.5
Systolic (mmHg), mean	106.6	115.7	98.6

- Valid BP measures were defined as same-day systolic and diastolic BP with a height within 6 months and classified as normal, elevated, or hypertensive according to AAP percentiles. Biologically implausible values were removed
- Among patients with high BP (either elevated or hypertensive) measures, we assessed concurrence against the following claims-based definitions for elevated or hypertensive BP in the year after the clinical measure:

Elevated BP: diagnosis code for elevated BP without diagnosis of hypertension

Hypertension Definition 1: one inpatient or two outpatient diagnosis codes for hypertension

Hypertension Definition 2: any hypertension diagnosis code

- We also examined:
- Demographic and average vital measure value on day of BP measure
- Pre-existing conditions in the year prior to BP measure, including presence of body mass index (BMI) diagnosis codes
- Presence of additional valid BP measures in the 6 months, one year, and entire enrollment history following BP measure

RESULTS

• We identified 1,659,773 patients in the Sentinel Network with a BP measure, with

Female, %	49.4%	45.1%	58.1%
Race			
White	45.1%	45.6%	44.8%
Black	10.4%	11.2%	8.9%
Asian	16.2%	16.0%	16.8%
Other	28.3%	27.2%	29.5%

Figure 2. Breakdown of BMI diagnosis codes among Patients with BP Measures



6.0 average BP measures per patient

- Of these patients, 61.7% (n=1,024,299) had an elevated or hypertensive BP measure at some point during the query period; 30.3% (n=502,992) of patients had no evidence of any elevated or hypertensive BP measures at any point in their enrollment history
- 35% (n=364,093) of patients with an elevated or hypertensive BP measure never had a subsequent normotensive measure in their enrollment history
- Of patients with an elevated or hypertensive BP measure, over 75% (n=771,268) had two or more additional measures in their enrollment history
- Patients with high BP were older and more likely to be male compared to those with exclusively normotensive BP (see Table 2)
- Among patients with any elevated or hypertensive BP measures, concurrence with their respective claims-based definitions was poor (see Table 1)

ACKNOWLEDGEMENTS/DISCLOSURES

CONCLUSIONS

- Poor concurrence between claims and clinical definitions of hypertension suggest studies relying exclusively on claims could under-capture patients' hypertension status
- Incorporation of EHR data in future studies where pediatric hypertension is an important outcome or comorbidity could improve specificity

LIMITATIONS

- We only used a single blood pressure measure for the identification of hypertensive patients while the complete AAP algorithm requires multiple measures. Future work should assess concurrence between claims and EHR definitions of pediatric hypertension when applying the complete EHR definition
- The views expressed in this presentation represent those of the presenters and do not necessarily represent the official views of the U.S. FDA.
- This project was supported by Task Order 75F40119F19001 under Master Agreement 75F40119D10037 from the US Food and Drug Administration (FDA).
- Many thanks are due to Data Partners who provided data used in the analysis
- The authors have no conflicts of interest to disclose