

Incidence Rates for an Extensive List of Adverse Events of Special Interest in the Pre-COVID-19 and Active COVID-19 Eras: A Comprehensive Source for Representative Historical Background Rates in the US General Population

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POSTER **EPH209**
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BACKGROUND

- Historical background rates for Adverse Events of Special Interest (AESIs) are important for vaccine impact assessment and safety monitoring.
- A source covering a comprehensive list of AESIs from the general population is needed to provide representative historical incidence rates on AESIs, in addition to evaluating the impact of the COVID-19 vaccination/pandemic on the incidence rates of AESIs.

OBJECTIVES

- To support vaccine safety surveillance, this study used administrative claims data to estimate background incidence rates of AESIs in the United States (US) in the **Pre-COVID-19 era** and prior to vaccine availability in the active COVID-19 era (**Pre-Vaccine COVID-19 era**).

METHODS

- The incidence rates of 43 AESIs were assessed in a cohort study of the US general population using patient-level claims data.

Database:

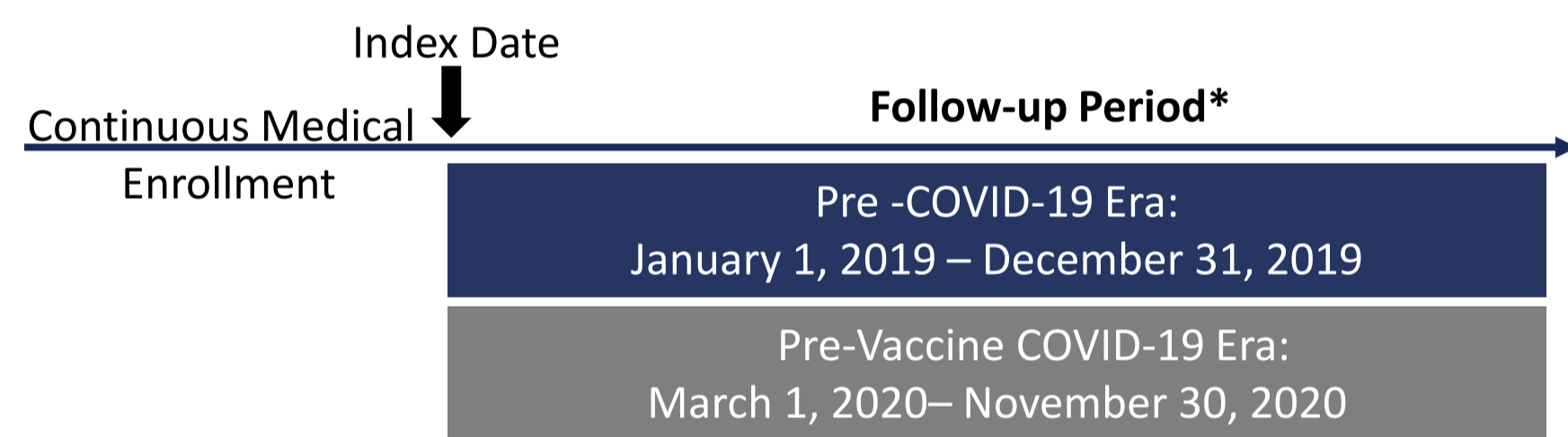
- Retrospective observational cohort study utilized secondary, de-identified individual-level medical and pharmacy claims data from HealthVerity for individuals insured under commercial, Medicare, or Medicaid plans, and/or served by providers participating in several large US medical and pharmacy insurance claims submission systems.

- Individuals were identified from the HealthVerity Private Source 20 closed claims database, which is representative of the age and sex distribution of adults and children in the US census.

Study Design:

- Inclusion Criteria:** Continuous medical and pharmacy claims enrollment (with < 32 days of gap allowed) during the 365 days prior to and on the index date.

- Exclusion Criteria:** Occurrence of the particular AESI during the baseline period.



- *Follow-Up Period:** began on the index date for all AESIs. Individuals were followed for a minimum of one day or until the earliest of: occurrence of the AESI being evaluated, disenrollment, end of the study period, or death.

- Outcomes and Analyses:** incidence rates of AESIs per 100,000 person-years and associated 95% confidence intervals (CIs) were calculated within each of the study periods using a Poisson distribution.

- Compared to incidence rates of the same AESIs examined by the FDA BEST Initiative during the same Pre-COVID-19 era

RESULTS

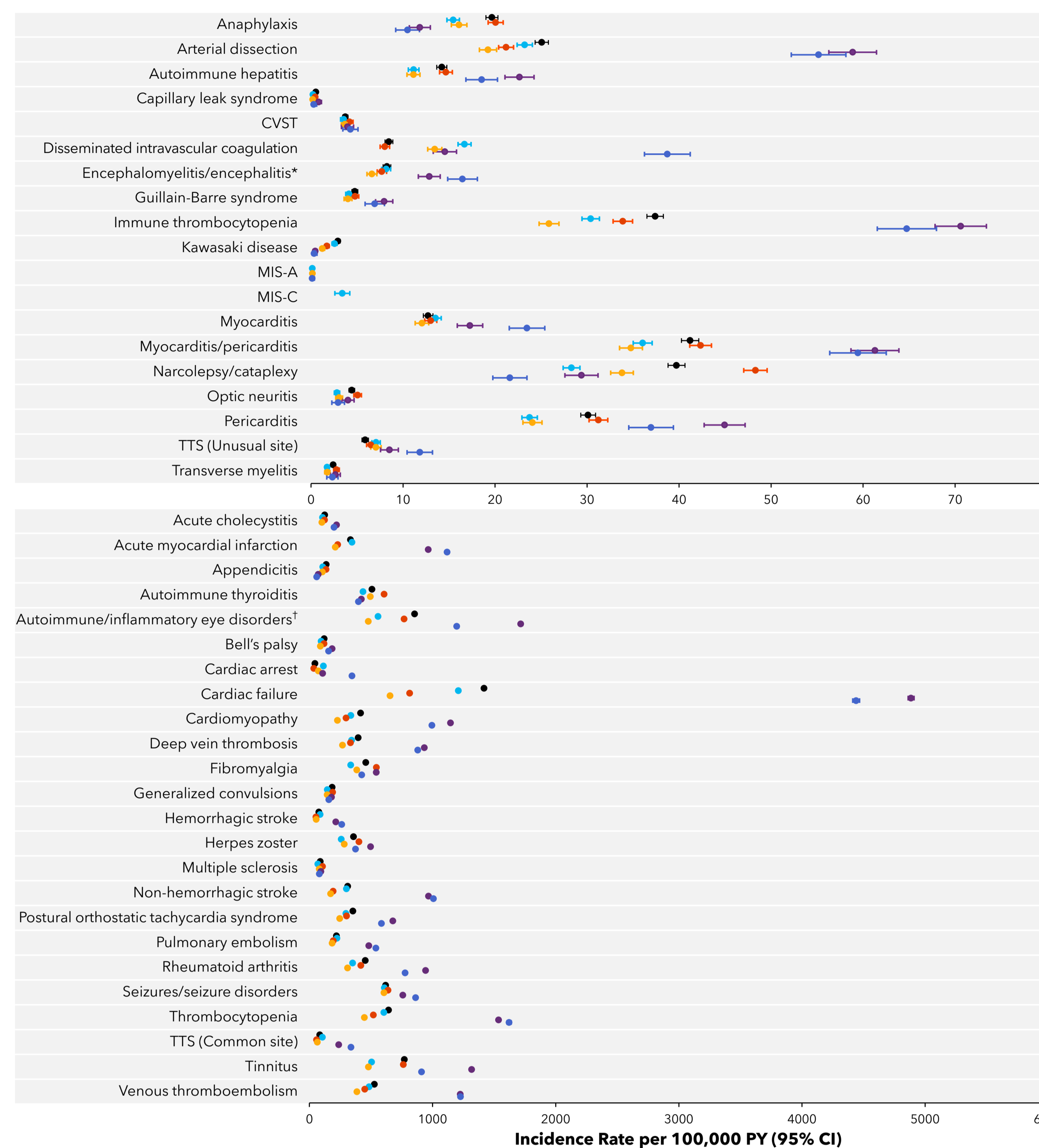
Table 1. Demographic Characteristics of Individuals Included in the Study

	Pre-COVID-19 Era (N= 19,950,199)	Pre-Vaccine COVID-19 Era (N= 19,602,060)
Age		
Median [IQR]	43.0 [24.0, 60.0]	43.0 [25.0, 60.0]
Sex; n (%)		
Male	9,427,177 (47.3%)	9,253,909 (47.2%)
Female	10,523,021 (52.7%)	10,348,151 (52.8%)
Region; n (%)		
Northeast	3,434,922 (17.2%)	3,495,626 (17.8%)
Midwest	4,456,910 (22.3%)	4,424,011 (22.6%)
South	7,612,169 (38.2%)	7,550,298 (38.5%)
West	4,362,332 (21.9%)	4,042,084 (20.6%)
Other/Missing	83,866 (0.4%)	90,041 (0.5%)
Insurance Plan Type; n (%)		
Commercial Only	10,019,370 (50.2%)	9,978,398 (50.9%)
Medicare Advantage Only	2,232,247 (11.2%)	2,165,225 (11.0%)
Medicaid Only	7,025,619 (35.2%)	7,192,807 (36.7%)
Commercial and Medicare Advantage	73,469 (0.4%)	654 (0.0%)
Commercial and Medicaid	111,294 (0.6%)	5,044 (0.0%)
Medicaid and Medicare Advantage	40,873 (0.2%)	557 (0.0%)
Plan Type Unknown	447,268 (2.2%)	259,375 (1.3%)

RESULTS (continued)

Figure 1. Incidence Rates of AESIs for the Overall Population and in Young vs Older Adult Age Group

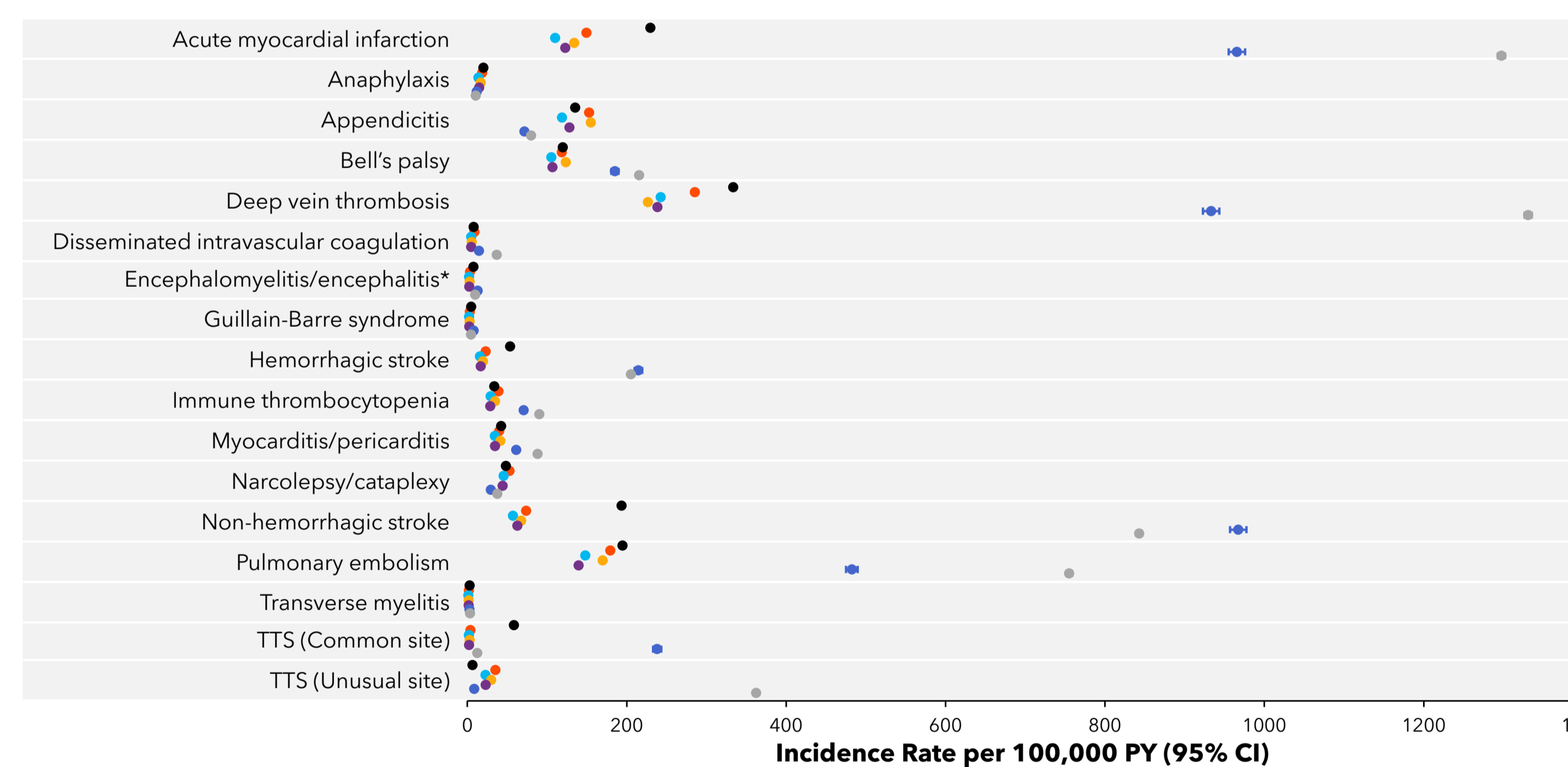
- Pre-COVID-19 Era - Overall
- Pre-COVID-19 Era - Age 18-64 Years
- Pre-COVID-19 Era - Age 65+ Years
- Pre-Vaccine COVID-19 Era - Overall
- Pre-Vaccine COVID-19 Era - Age 18-64 Years
- Pre-Vaccine COVID-19 Era - Age 65+ Years



CVST, Cerebral venous sinus thrombosis; MIS-A, multisystem inflammatory syndrome in adults; MIS-C, multisystem inflammatory syndrome in children; TTS, Thrombosis with thrombocytopenia syndrome. *Encephalomyelitis/encephalitis, including acute disseminated encephalomyelitis. †Autoimmune/inflammatory eye disorders, including uveitis.

Figure 2. Incidence Rates of AESIs in the Same Pre-COVID-19 Era as Reported from Different Databases

- Current Study - Age 18-64 Years
- MarketScan - Age 18-64 Years
- HealthCore - Age 18-64 Years
- Current Study - Age 65+ Years
- BHI - Age 18-64 Years
- Optum - Age 18-64 Years
- Medicare - Age 65+ Years



TTS, Thrombosis with thrombocytopenia syndrome. *Encephalomyelitis/encephalitis, including acute disseminated encephalomyelitis.

CONCLUSIONS

- This study features the largest number of AESIs examined in a representative population of the US general population.
- Differences in incidence rates of some AESIs between the Pre-COVID-19 era and Pre-Vaccine COVID-19 era were observed.
- This may reflect the impact of the pandemic on AESI occurrence, changes to healthcare utilization during the pandemic, or both.
- The incidence rates of some AESIs have substantial differences between age categories.
- Different datasets (HealthVerity and those included in the FDA BEST initiative) reported different incidence rates on the same AESIs, reflecting differences in the study populations.
- Background rates from populations eligible to receive a vaccine are ideal for the safety assessment of that vaccine.

ACKNOWLEDGEMENTS

This work was sponsored by Novavax Inc. C. Wang, J. Fix and T.C. Mast are employees and shareholders of Novavax Inc. J. Citronberg, S. Reynolds, I. Estevez, R. Sajedian and U. Dave are employees of Aetion Inc. Third-party figure design and medical writing support was provided by Heather Hartley-Thorne and Allison Saviano (Sephirus Communications, Inc.) and Karlena Dill (Pickled Prose LLC), respectively, and paid for by Novavax Inc.