'Background' adverse event study will inform global COVID vaccine safety monitoring

June 22 2021

Credit: Pixabay/CC0 Public Domain

COVID vaccine surveillance efforts are a global priority, but safety monitoring for vaccines should not reflect a single population. The largest, most extensive international study of the background rates of

adverse events of special interest (AESI) that are being tracked in vaccine surveillance efforts show that adverse event rates vary substantially by age, sex, and method of data capture.

Led by researchers at Oxford University, Columbia University, Erasmus MC, UCLA, and Janssen, an international team of collaborators from the Observational Health Data Sciences and Informatics (OHDSI) network provided a timely reference of the background rates of AESIs in a new study published June 14 in *The BMJ*.

The researchers found significant differences in the observed rates of AESIs based on the age groups and sex of more than 126 million people across four continents and 13 databases. Differences were also observed among people within databases.

"We knew regulators would be monitoring a long list of events for the surveillance of COVID vaccines safety," said co-senior author Dani Prieto-Alhambra MD MSc Ph.D., Professor of Pharmacoepidemiology at the University of Oxford. "To do this, they need robust estimates of the background rates of these events in historical data. These results can be used as benchmark for the monitoring of these potential safety events and for any upcoming COVID-19 vaccines."

There were 15 prespecified adverse events studied, matching those being monitored by the U.S. Food and Drug Administration and similar to those used by other regulatory agencies, including heart attack, stroke, and blood clotting. Incidence rates were classified by age groups and gender across the databases, though the outcomes of those groups vary by database.

"We found significant heterogeneity in background rates between age and sex," said co-lead author Xintong Li, DPhil candidate and Clarendon scholar at the University of Oxford. "If we compare these rates

regardless of age or sex group, we may either find a false signal or neglect a real safety signal while monitoring vaccine surveillance.

"The observed and expected rates comparison should also be conducted within the same health database whenever possible," Li added. "While we understand that is not possible for all surveillance systems or vaccine safety studies, choosing a similar population and stratifying or standardizing by age and sex is highly recommended."

Heart attack, for example, was observed as a very rare (