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.

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 (1/2)...