Safety surveillance of covid-19 vaccines using large-linked database

Norazida Ab Rahman

Institute for Clinical Research, National Institutes of Health Malaysia

ABSTRACT

Summary: In the global drive to vaccinate against SARS-CoV-2, millions of people have received at least one dose of a COVID-19 vaccine. Vaccination safety is the key to the success of immunisation programs and in combating vaccine hesitancy among the public. Post-licensure safety monitoring of COVID-19 vaccines is essential to detect rare or severe vaccine-associated adverse events in the population and provide ongoing data of safety issues. Passive surveillance is the primary method most widely used to collect adverse events following immunisation (AEFI) via voluntary reporting. Monitoring through active surveillance is strongly encouraged to improve vaccine safety monitoring and provide more robust data. The SAFECOVAC project was initiated to evaluate risk of serious adverse events following COVID-19 vaccination. It leverages on the availability of nationwide COVID-19 vaccine registry, hospital admission database, and other data sources to create a large-linked database. Uniquely for Malaysia, diverse vaccine portfolio was used and we are able to compare the risk estimate for the three major vaccine types of different platform i.e., mRNA-based vaccine (BNT162b2), inactivated vaccine (CoronaVac), and adenovirus vector-based vaccine (ChAdOx1). Current data shows that safety of COVID-19 vaccine is assured and findings are fairly consistent with data from other countries.