

**Adverse events following immunization associated with coronavirus disease 2019 (COVID-19) vaccines: A descriptive analysis from VigAccess**

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**Statement of the problem:** Despite the rigour of pre-marketing vaccine trials, the safety of new vaccines is not completely understood from pre-authorization clinical trial data as these trials are conducted in controlled settings different from settings of real-world use. Consequently, such data have limitations in their post-market applicability. It is therefore imperative to report Adverse Events Following Immunization (AEFI) after regulatory approval of vaccines for a better understanding of their safety profiles. This study assessed AEFIs reported on COVID-19 vaccines and determined AEFI reporting trends across all continents of the world in the World Health Organization (WHO) open access [pharmacovigilance](#) database, [VigAccess](#).

**Methodology & theoretical orientation:** The study was cross-sectional quantitative in design. VigAccess was searched on November 10, 2021 for reported adverse events following the introduction of COVID-19 vaccines. After entering the search term, “[COVID-19 vaccines](#)” in VigAccess, AEFIs associated with 9 approved brands of COVID-19 vaccines had been documented in the database. Data were captured among age groups, sex and continents of the world and analysed using Statistical Package for Social Sciences (SPSS) version 25.

**Findings:** Overall, 2,457,386 AEFIs had been reported in VigAccess at the time of the search. The top 10 commonly reported AEFI types with their percentage of the total number of AEFIs were as follows: general disorders and vaccine administrative site conditions (1,481,549, 60.1%), nervous system disorders (1,046,928, 42.6%), musculoskeletal and connective tissue disorders (704,657, 28.6%), gastrointestinal disorders (495,997, 20.2%), investigations with undesirable outcomes (341,677, 13.9%), skin and subcutaneous tissue disorders (335,932, 13.6%), respiratory, thoracic and mediastinal disorders (262,158, 10.6%), infections and infestations (180,873, 7.3%), vascular disorders (132,533, 5.3%) and injury, poisoning and procedural complications (122,519, 5%). No causal associations could be established between the vaccines and the AEFIs. It is recommended that the public accessing VigAccess data should be made aware of the fact that it is impossible to do causality assessment with data in VigAccess in order not to falsely attribute AEFIs to COVID-19 vaccines when assessing the database.