Comparison of Adverse Events in Pregnant Persons receiving COVID-19 and Influenza Vaccines: A Disproportionality Analysis using Combined Data from US VAERS and Eudravigilance spontaneous report databases, Drug Safety Journal

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The READUS-PV checklist

Section and topic	Item #	Checklist item	Location where item is reported
Title			
	1a	*If disproportionality analyses are a prominent component of the published study, the study should be identified as a "disproportionality analysis". The type of data and name of the database(s) should be specified.*	*Title*
	1b	*Report the name of adverse event(s) and/or drug(s) under study, when applicable.*	*Title*
Introduction			
Background	*2a*	*Describe the drug(s) and its utilization, the nature of the adverse event(s) under study and its frequency, and the existing knowledge on the drug-event combination.*	*Introduction; paragraphs: 2nd, 3rd*
	2b	*Specify the rationale for performing the analysis, e.g., as part of routine pharmacovigilance, to investigate an overall safety profile, or to assess a pre-specified hypothesis.*	*Introduction; paragraphs: 3th*
	2c	*Explain why ICSR databases and disproportionality analysis are suitable to fill the knowledge gap.*	*Introduction; paragraphs: 4th*
Objectives	*3*	*State specific objectives, identifying the adverse event(s), the drug(s), and the reference group, including any pre-specified hypothesis, if applicable.*	*Objective*

Methods			
Study design	*4a*	*Identify the study (i.e., "disproportionality analysis") and the type of data used (e.g., "individual case safety reports").*	*Table 1*
	4b	*Provide an outline of the entire study design, including primary and sensitivity analyses performed, and other designs such as case-by-case analysis or literature review.*	*Methods : study design section + Method/ Disproportionality Analysis section: 3rd paragraph*
Data description, access, and pre-processing	*5a*	*Specify the name of the database(s), the database(s) custodian, and the coverage. Specify the type/number of drugs included within the database and the thesaurus, taxonomies, or ontologies used for coding drugs and events.*	*Table 1 – Methods: 2nd, 5th and 6th paragraphs (MedDRA)*
	5b	*Specify the extraction dates and describe and justify all choices used for data pre-processing, including any data transformation or exclusion, if appropriate.*	*Methods (Selection of ICSRs related to pregnant women – figure 1 + deduplication process)*
Variables definition	*6a*	*Describe the study population, including any restriction.*	*Figure 1*
	6b	*Describe the nature and the meaning of key variables assessed in the work.*	*Key variables in Disproportionality Analysis, Merging dataset using a CDM and De-duplication along with CDM in supplementary material*
	6c	*Specify and justify any grouping of drugs or events. For drugs, specify and justify whether active ingredients/trade names/salts were considered and/or the selected role.*	*Disproportionality analysis: 1st and 2nd paragraph*
	6d	*Describe any additional data source used, the type of data, and how they interact with ICSRs.*	*EV and VAERS were described in method*
Statistical methods	*7a*	*Present any descriptive analysis performed, specifying variables investigated, statistical tests, and significance thresholds.*	*Table 2*
	7b	*Describe the measure(s) selected for the disproportionality analysis including any threshold used to identify signals of disproportionate reporting. Explain the reason for this choice if applicable.*	*Disproportionality analysis: 3rd paragraph and table 2*
	7c	*Clearly describe any sensitivity analysis and any tool to control confounding, including any restriction, subgroup, stratification, adjustment, or interaction.*	*Merging dataset using a CDM and De-duplication and Sensitivity analysis sections*
	7d	*Specify the variables and methods used for the case-by-case analysis, including any algorithm or criteria used to assess causality, if performed.*	*Merging dataset using a CDM and De-duplication section: 4rd paragraph*
	7e	*Specify any statistical methods used for other data sources.*	*Disproportionality analysis*
Results			
Participants	*8a*	*Specify the number of individual case safety reports included at each stage, including reasons for exclusion.*	*Figure 3 - flowchart*
	8b	*Provide key demographic and clinical characteristics of cases, if possible comparing cases with any appropriate reference group.*	*Table 3*
Disproportionality analysis	*9*	*Present all results including confidence intervals. Present also results of sensitivity analyses, if performed.*	*Forest plot figures for PRR and*

Case-by-case analysis	*10*	*Present the case-by-case analysis of key variables. Present the causality assessment, if applicable.*	*A the causality assessment of case-by-case analysis of SDRs and supplementary materials*
Discussion			
Key results	*11*	*Discuss key results with reference to study objectives and contextualize them within the current literature and other consulted sources. Clearly discriminate between expected reactions and emerging safety signals.*	*1st, 2nd, 4th and 5th paragraphs of Discussion section*
External validity	*12a*	*Discuss the external validity of the results to the general population.*	*4th and 5th paragraphs of Discussion section*
	12b	*Discuss the potential relevance of results in clinical practice*	*Conclusion*
	12c	*Propose further study designs if applicable*	*Conclusion*
Limitations	*13*	*Present general limitations, making clear that disproportionality analysis alone cannot prove causation or measure incidence, and specific limitations, including confounding and reporting bias and efforts to mitigate them.*	*Last paragraph of Discussion section*
Declarations			
	14a	*Provide the source of funding/sponsorship and the role of the funders/sponsors for the present study and for any original study on which the present article is based.*	*Not applicable (or UMCU ?)*
	14b	*Clearly identify potential commercial and intellectual conflicts of interest (e.g., link to any drug/event investigated, whether financial, legal action, or software used).*	*Refer to conflict of interest*
	14c	*Declare any institutional approval needed or granted in the investigation.*	*Not applicable (or UMCU ?)*
	14d	*Include a statement on data availability, code availability (including the version of the statistical software used), and protocol registration.*	*Data availability and Software session*