Reviewer’s report

Title: Healthcare provider knowledge, experience and challenges of reporting adverse events following immunisation: a qualitative study

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Reviewer: Sripen Tantivess

Reviewer’s report:

This paper examines provider factors of reporting adverse events following immunisation (AEFI), which is an important issue in the health service systems worldwide. The main objective posed by the authors is relevant in the context where vaccine safety is among key concerns of policymakers, health professionals and parents. However, I would like to suggest revisions as followed:

Major compulsory revisions:

(1) It is unclear how the interview themes were identified and guiding questions were formulated, given that there is no information on related literature, theories and conceptual framework for this research. The basic steps of conducting research, namely reviewing literature, identifying relevant theories or models, and devising a conceptual framework is the most critical point, as these shapes further steps of study including development of interview questions, data collection, and writing results and discussion. At least, literature review on the factors determining AEFI reporting among health workers in other settings should be carried out in order to identify knowledge gap and proper research questions. The sentence commencing ‘It is likely that in healthcare provider AEFI knowledge of reporting and practice …’ (page 4, last paragraph) is fine in arguing that ‘knowledge of reporting’ should be explored in this study. In the same vein, more research articles, grey literature and/or theories/models in respective disciplines should be reviewed to justify other issues addressed in the interview questions.

(2) Most part of the Conclusion should be moved to the Discussion section. Please the authors make sure that the Conclusion is drawn on the key findings, without extended discussion.

Discretionary revisions:

(3) Although the intervention of focus is immunisation, and the authors claim that this is the first qualitative paper on provider awareness and experience on reporting AEFI, relevant lessons can be drawn from existing studies in adjacent area, i.e., health workers reporting adverse drug reactions (ADR). Discussion on the similarity and difference between the factors determining underreport of AEFI and ADR would be useful, because some strategies to address these factors and target groups are common, and responsible by the same authorities, such as hospitals, professional associations, education institutes, and local and national
governments. Moreover, in particular jurisdictions, integration of measures for improving the AEFI and ADR surveillance systems might be more efficient than introducing these measures separately.

(4) While the interview questions include two workplace elements, namely discussing AEFI with colleagues and policy/protocol for reporting AEFI, these issues are not well discussed in the Results and Discussion section of the paper. It would be useful for the readers if they could understand how and to what extent organizational environment shapes awareness and practice of health professions, as those who are expected to report AEFI do not work in vacuum. Peer opinion/practice and policy of the workplace might have a role in the issues under investigation. The assertion about workplace protocol for reporting AEFI is fine, and it would be great if the authors could add some information on the main policy regarding AEFI surveillance and its implementation in the study settings. In future study, administrators or managers of particular workplaces should be interviewed as key informants. Apart from obtaining the information from administrators’ perspectives, this would be beneficial for triangulation purpose. Note that quality assurance approach for data collection and interpretation is not discussed in this paper.

(5) Please the authors provide the justification for the argument, ‘It is likely that a single pathway for AEFI reporting will be less confusing for healthcare providers rather than the existing system which provides choice between reporting to …’. Do you think the existence of these two pathways really makes healthcare providers confused so that they do not report AEFI? Is there any difference in reporting AEFI through these two pathways, for example, the procedures, requirements, and report forms? If not, why is it so confusing?

(6) The findings and recommendations will be useful in informing development of effective strategies to enhance the current passive reporting system, especially in the study settings. In this paper, recommended strategies to increase AEFI reporting are presented in different paragraphs, alongside discussion on corresponding findings. At the same time, the last paragraph illustrates that ‘A number of recommendations made in the national review of Australian AEFI surveillance, if implemented, should strengthen vaccine safety surveillance in Australia and reduce barriers to AEFI reporting.’ The authors should clearly elaborate what these recommendations are, and if they are confirmed in this study.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
I declare that I have no competing interests.