Author's response to reviews

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

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Version: 4 Date: 11 June 2013

Author's response to reviews: see over
11 June, 2013

Dear Dr Teerawattananon

RE: 5458676885421256

Thank you for reviewing the paper, “Healthcare provider knowledge, experience and challenges of reporting adverse events following immunisation: a qualitative study”

Please see the enclosed response to reviewers’ comments and the revised manuscript.

In addition to amendments in response to comments, I have also included 2 further amendments to the text in the manuscript. Both are incorporated in the Background section of the manuscript. The first provides a sentence highlighting the updated governance of vaccine safety evaluation in Australia and the second is the inclusion of a recently published study regarding healthcare provider AEFI reporting that is relevant to the literature review.

Amendments as per reviewers’ comments and edits to the text are highlighted in yellow in the revised manuscript

Thank you for considering our paper for BMC Health Services Research and hope the amendments we have incorporated into the revised paper will be accepted for publication.

Yours sincerely

Adriana Parrella
Reviewer: Sripen Tantivess

Discretionary revisions:

Comment 1: The only outstanding point is related to the workplace elements. Inserting table 3 is not relevant in this case. Please the authors consider if AEFI reporting in each study institute is influenced by peer practice of colleagues, either the same or different professional cadres, and organization’s policies/protocols for reporting (question #1 and #2 under the theme ‘Workplace’). When these guiding questions were developed, you might have assumptions that individual professionals would report AEFI if most of their colleagues carried out this activity regularly as organizational norm, and that they would do so if related policies had been well established and introduced in their hospitals or health centers. Based on the information obtained in the interviews, could you assess if these assumptions are correct or not? And, why? For instance, the lack of awareness on existing policies/protocols among some practitioners suggests that heads of their organizations might not pay serious attention to monitoring the policy implementation. From different angle, it is also possible that heads of most settings assigned nurses to be responsible for AEFI reporting, and therefore, GPs and specialist consultants in the same institute were not aware of the policies. Scrutinizing these issues will be useful, as it indicates the role of workplace factors which might be as important as individual professional factors in AEFI reporting.

Author response
The relationship between workplace factors and reporting is important to consider and perhaps was not sufficiently reported in the article. In order to further address your comment we have amended the manuscript in both results and discussion. Please see amended results that summarise participants’ response regarding discussing an AEFI (page 13) and the inclusion of workplace factors in the discussion. (pages 21 and 22.).

Finally, please note we wish to keep the table 3 inserted in previous revision as we believe it provides a clear picture of the differences in awareness across the three professional groups.

Page 13 Amendment
When describing awareness of workplace policies participants were also prompted to describe whether AEFIs were discussed during the course of their work. If an AEFI was discussed in the different workplace settings, it would usually occur informally with colleagues if a patient presented with symptoms that were unusual or serious. For example, in the hospital setting, around the time of the influenza safety signal in 2010, the ED consultants recalled informal discussions with colleagues of febrile convulsion cases presenting to the ED. The nurses would discuss cases that were “out of the norm”.
“We do discuss it between us quite a lot if you get something quite a bit different. You know such and such happened have you had that happen with yours or are you aware of that being anything? So we do usually discuss it amongst ourselves.” GP 6

“We tend to talk about things that happen. If it was something serious I think generally we would discuss those things.” GP 7

Pages 21-22, Discussion amendment

The context of the workplace setting in this study is important to consider in relation to understanding factors that might influence a health professional’s decision to report an AEFI. We did not seek information from each work setting involved as to whether in fact there was an established policy or protocol for reporting. However, from the interviews we conducted, it was apparent that reporting by immunisation nurses in local council clinics was an established norm, as a council nurse’s core work is providing immunisations to the public. Having report forms at hand, in addition to documented protocols for AEFI reporting facilitated reporting in such settings. We suggest there are three possible explanations for the variations in awareness of participants from the general practice and hospital settings (Table 3). First, it may be that there was no current policy in place. Second, if a policy existed, it had not been introduced or established effectively within the workplace. For example, in the hospital setting, the ED consultants did have access to the local Department of Health reporting form via the internal intranet, however few indicated awareness of it during interviews. This would suggest a need to ensure staff are informed and updated about accessing the reporting link. Given that the study occurred less than 12 months after the safety signal associated with the seasonal influenza vaccine and subsequent relay of public health alerts to hospitals and primary healthcare settings.
regarding the occurrence of febrile convulsions and need to report, it was surprising that there were such low levels of awareness. A third explanation for low levels of awareness amongst the GPs and ED consultants could be that reporting was not seen as a prime function of medical staff and might be delegated to nursing or administrative staff. Apart from one GP who indicated that the nurse at his practice would be responsible for reporting as part of her role in immunising patients, we did not find further evidence of this from the remaining GP interviews. In the ED setting, delegating the reporting to a registrar who was undertaking an ED rotation was described by some consultants and hence could explain their unfamiliarity with the actual processes of reporting, whether it was to local or national surveillance authorities. In this context it could be implied that reporting was not seen as a primary function of the clinician, but rather an administrative function to be performed by non-medical staff or as in the ED setting, junior medical staff.

Comment 2: Please the authors check if reference #32 is correct. It seems not relevant to the corresponding statement.

Author Response

Thank you. The reference is now #39 and amended to:

Reviewer: Greg Knowles

Minor essential revisions:

Comment 1: Contrary to author response to my comment about the spelling mistake in Table 2, Q4, now on page 28 - the word "even" appears, and i think it is meant to be "event"

Author response:

Thankyou, the spelling is corrected to “event” (please see page 30 revised manuscript)

Comment 2: page 4. "Hence, all licensed vaccines require specific pharmacovigilance plans that incorporate post-licensure passive surveillance that is “timely, efficient, sufficiently large and in place for the life of the vaccine” [10]." grammar correct - i think "is" should be "are"

Author response:

Amended to “are”. (please see page 4 revised manuscript)
Please note two further amendments detailed below we have incorporated into the Background, highlighted in yellow in the manuscript.

1. The first is the inclusion of a sentence highlighting the updated governance of vaccine safety evaluation recently introduced in Australia on page 3:

“As of 2013, in response to recommendations for an improved system of governance for safety monitoring [6], a new statutory Advisory Committee on the Safety of Vaccines (ACSOV) has been established to evaluate vaccine safety.”

2. Since submitting the manuscript to BMC Health Services Research a fourth study regarding healthcare provider AEFI reporting has been published. Please note summary of the study in the Background section of the revised manuscript on page 6.

“The fourth study is the most recent conducted to date and included family physicians, physician assistants, nurse practitioners, practice nurses and nurses working in paediatrics, family medicine and internal medicine [24]. The survey assessed demographics and professional characteristics and knowledge and attitudes toward identifying and reporting an AEFI to the Vaccine Adverse Event Reporting System (VAERS) in the United States. Although nearly three quarters of study participants were familiar with VAERS, only 14% were “very” or “extremely” familiar with the paper reporting procedure and approximately one third were not familiar when it was required to report an AEFI. Approximately 40% of all study participants had identified at least one AEFI, with only 18% indicating they had reported to VAERS. Respondents indicated they would report serious AEFI regardless of whether they were known (73%) or unknown (62%) to be associated with immunisation. Those who indicated that they were not familiar with submitting a paper report to VAERS were more likely not to report than those who were familiar with the process. Similarly,
respondents who were not at all familiar with reporting criteria to VAERS tended not to report compared with those who were familiar with the requirements.”

3. We have inserted the following three references that are relevant to previous studies of healthcare professional ADR reporting. (please see Background, pge 6)


4. Please note two additional references relevant to consumer perceptions of healthcare professional reporting. (please see Background, pge 7)
