

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Improvement of Knowledge, Attitude and Perception of health care workers about ADR, a pre and post clinical pharmacists' interventional study
AUTHORS	Hosseini Khalili, Niayesh Mohebbi, Narjes Hendoiee, Abbas-Ali Keshtkar, Simin Dashti-Khavidaki

VERSION 1 - REVIEW

REVIEWER	Anne Spinewine Professor in clinical pharmacy, and head of clinical pharmacy service Université catholique de Louvain, Louvain Drug Research Institute and CHU Mont-Godinne Belgium
REVIEW RETURNED	16/09/2011

REPORTING & ETHICS	No ethics approval mentioned
GENERAL COMMENTS	<p>The paper describes a study evaluating the effect of clinical pharmacists on the knowledge, perception and attitudes of HCPs toward reporting ADRs. The topic is interesting but the quality of the paper is heavily weakened for different reasons that are explained below.</p> <p>General comments</p> <ul style="list-style-type: none"> - The written English is far from optimal, and I had to read many sentences several times to try to understand them. - It would be nice to clarify the definition of ADR that was used in the study, as there are frequent discrepancies on this. <p>Introduction</p> <ul style="list-style-type: none"> - Although I am a clinical pharmacist myself, it is rather surprising to come up with that "single" intervention to try to improve ADR reporting. Although I agree that this can be part of the work of clinical pharmacists, it is certainly not the only (and probably not the most effective) method to address the issue under

	<p>consideration. Therefore the introduction should have one paragraph to summarise the different approaches that can potentially improve the knowledge,... toward reporting ADRs</p> <p>Method</p> <ul style="list-style-type: none"> - to better understand the context and conduct of the study, several important data are lacking: <ul style="list-style-type: none"> o What kind of hospital is the Imam Khomeini Complex hospital? o The authors mention that the study was done over a one-year period, but later on they describe that the second measurement was done after three months. This contradiction should be clarified. o Some basic information should be provided relative to the questionnaire: context and results of validation; content (main sections, nb of questions); types of questions (open ended? Close?) o How were health care workers selected? At random? How many individuals from each profession were selected? How was sample size selected? o Intervention: what was the frequency and duration of workshops? Did every respondent attend? o Clinical pharmacists attended morning reports. Was this only for the purpose of the study? Did they have any other roles? Was this done as part of a broader job (eg the usual pharmaceutical care process)? <p>Results</p> <ul style="list-style-type: none"> - as stated above, it is very often difficult to clearly understand them for language reasons. One example: first sentence of the third paragraph on page 6 - in many cases it is unclear what the authors expect on answers provided to the questionnaire. For example on Table 2 “reaction is well recognized for a particular drug”; it seems that after the intervention the respondents would be more likely to report such ADRs, which in my opinion is not positive, as such events should usually not be reported to a pharmacovigilance center (unless the ADR is very severe or occurs in a “new” population, but this is not specified in the question). - Same comment for 1st paragraph on p7: did the authors expect an increase for all items?
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	<p>Discussion</p> <ul style="list-style-type: none"> - The authors link the intervention to the causes of under-reporting (p8). It should be specified that the intervention addressed several but certainly not all the causes of under-reporting. - Many important limitations are not discussed: study performed in one hospital; evaluation performed short term; it would be interesting to provide the data on the ADRs reported by HCPs over the next 1 or 2 years (likely to have decreased after the end of the intervention; other weaknesses addressed above. - Previous studies evaluating the effect of approaches to increase reporting are not discussed, while this seems essential to put the results into pers
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REVIEWER	<p>Nour Chachaty, MD, MSc, CPHQ Lecturer, Faculty of Medicine, Aleppo, Syria No competing interests.</p>
REVIEW RETURNED	16/09/2011

THE STUDY	<ul style="list-style-type: none"> - Define terms such as participants' "perception", "attitude", and "idea" about reporting ADRs. - The sample size is a little too small to allow for aggregation of results. - Could the presence of a pharmacist among participants have biased the results? What about the seniority of participants? Were any of them leaders at the hospitals? - How was the study population/sample selected? How long was the period of exposure to intervention? What was the interval between pre- and post-tests? - The text needs to be edited - The most important point is that studying perceptions of healthcare workers about reporting ADRs should always take into account the culture of safety in the organization. Refer to the work of AHRQ in this area.
RESULTS & CONCLUSIONS	<p>The analysis could benefit from an effort to identify associations between participants' perceptions and their characteristics (by discipline; level of seniority, age in the organization, etc).</p>

VERSION 1 – AUTHOR RESPONSE

Dear Editor of BMJ Open

Thank you for sending the valuable reviewers comments. I have read them and have included in the main text of the manuscript.

-English writing of the manuscript have been tried to improve.

-Limitations of the study were added to the article summary section.

-Authorship criteria were edited.

Reviewer 1:

- English writing of the manuscript have been tried to improve.
- WHO definition of ADR was added to the method section.
- Different approaches that may improve KAP about ADR were added to the introduction section.
- The hospital was defined.
- This is right. Total duration of the study (coordination with the hospital manager and health care workers, wards, preparation of the material for educational program, gathering information about ADR and IPC in Iran, doing interventions and analysis and reporting) have been done during one year period.
- We have used a previously validate questionnaire from the literature (Reference 1). Information about number of questions in each section and type of questions was added to the method of the manuscript.
- Information about selected sample was provided in the method section.
- Information about education course was added in the method section.
- Attending in the morning report is a part of broader job of the clinical pharmacists in our hospital and during study period we focused on the ADR reporting system on the sections.
- Result section was revised.
- Discussion section was revised.

Reviewer 2:

- Perception and attitude were defined in the method section.
- Information about participants was added.
- Information about sample size and interventions were added in the method section.
- Our study's statistical consultant recommend that the study sample size was not enough for further analysis such as correlation between perception and level of seniority, age category of participants and so on.

VERSION 2 - REVIEW

REVIEWER	No competing interests Nour Chachaty Lecturer Aleppo Faculty of Medicine Syria
REVIEW RETURNED	11/10/2011

The reviewer filled out the checklist but did not comment further.