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SHORT REPORT

Assessment of an educational module on Pharmacovigilance among hospital pharmacists in United Arab Emirates: A pilot study

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Abstract

Background: Pilot research was conducted to assess the feasibility of a pharmacovigilance educational module for hospital pharmacists in the United Arab Emirates. **Methods:** A four-hour education module was held at a private hospital in Dubai. A pre-educational module survey assessed the knowledge, attitude, practice, barriers, and suggestions that could improve adverse drug reaction (ADR) reporting. The module was formulated using Miller's pyramid as a framework, and it covered an introduction to pharmacovigilance, how to report ADRs and practical aspects. Pre- and post-educational module surveys were used to compare and assess the impact of the educational module. **Results:** The results showed that the primary hurdle preventing pharmacists from practising this approach is a lack of knowledge of the ADR reporting process, which was improved drastically by the educational module with positive feedback. **Conclusion:** The findings showed that this module has the potential to be incorporated into ongoing pharmacy professional development initiatives.

Introduction

Reporting any adverse drug reactions (ADRs) associated with medication use is important to ensure patient safety, which is the goal of pharmacovigilance (PV) (Ahmad *et al.,* 2013; Qing-ping *et al.,* 2014). Healthcare providers, including pharmacists, play a vital role in patient safety (Jeetu *et al.,* 2010). Published studies showed good knowledge and low attitudes toward PV among pharmacists in the United Arab Emirates (UAE) (AlWorafi *et al.,* 2021). On the other hand, other studies found that although pharmacists have a good level of knowledge and attitudes, under-reporting exists due to barriers like the lack of awareness about the ADR reporting process and worry about the repercussions of reporting from their organisations (Sridhar *et al.,* 2012). Furthermore, a literature review revealed no structured educational module was delivered to hospital pharmacists in the UAE, even though practising pharmacists in the UAE come from various educational backgrounds (Irujo *et al.,* 2007; Necho & Worku, 2014).

This pilot study set out to determine whether it would be feasible to teach hospital pharmacists PV. It also evaluated the module's contents, including the participants' knowledge and attitudes regarding ADRs reporting before and after the intervention, the practice of PV in hospitals, the factors that encourage and hinder reporting, the time needed to deliver the module, and participant feedback.

Methods

Study settings and participants

The pilot study was conducted for four hours at a private hospital in Dubai. Ethical approval was obtained from the Ajman University Research Ethics Committee (Approval Reference number: P-H-F-7-Jan), Dubai

Scientific Research Ethics Committee (Approval Reference number: DSREC-SR-03/2022_02), and Universiti Sains Malaysia Research Ethics Committee (Approval Reference number: USM/JEPeM/22070495). The study included the consent of three enrolled clinical pharmacists.

Development of educational module

A PV educational module was developed based on the findings from the national survey conducted by the researchers earlier. (Shanableh *et al.,* 2023). The module was designed to be delivered in four stages:

Stage 1: Didactic session: Pharmacovigilance seminar covering introduction to PV, how to report ADRs,

Stage 2: Hands-on session: Filling out the ADR reporting form and UAE ministry Mobile application for ADR reporting and obtaining feedback.

Stage 3: Reinforcement of stages 2 and 3 through WhatsApp.

Stage 4: Post-intervention: Assessment of the impact of the module on the participants. Thank you note was provided to them after the study was completed.

Results

Feasibility of delivering the education module

The findings indicated the educational module's success, confirming its suitability for integration into the proposed main study, which will be conducted after considering the pilot study findings. Additionally, the module's design and content were aligned with the participants' needs and abilities.

The time required to deliver the module

The session lasted four hours continuously to deliver the module and conduct some activities related to the PV and ADRs reporting process.

Evaluation of the contents included in the module

The results, including the knowledge and attitudes regarding ADRs reporting before and after intervention, the practice and the factors that could hinder and encourage PV, are presented in Table I. For knowledge assessment, four out of nine questions showed an improvement after completing the program; the other five had the information already and answered correctly in the pre-and post-intervention survey. Defining ADRs, case analysis, location of the international centre of ADR reporting, and the availability of WHO databases are among those which have been improved by the session. Among the three participants, attitude did not seem to change after implementing the education module. Two out of the three participants seemed unwilling to discuss ADR reporting with their managers (Table I). They all agreed before and after the session that ADR reporting should not be compulsory for pharmacists. Their disagreement on "*Reporting of ADRs is important to show patients that their concerns are taken seriously*" has not changed after the session.

Table I: Knowledge, attitude, practice, barriers and factors that could enhance ADR reporting (n=3)

Questions/Statements	Median (IQR) scores	
	Pre-intervention	Post-intervention
Knowledge assessment		
1. What is the best definition of Pharmacovigilance?	2 (2-2)	2 (2-2)
2. Which of the following defines an Adverse Drug Reaction correctly?	1 (1-1)	2 (2-2)
3. The need for hospitalisation is required as early as the appearance of:	1 (1-1)	1 (1-1)
4. Seventy-year-old man is taking Amiodarone for cardiac arrhythmia, and he developed Heart block as a side effect. Which of the following matches the type of adverse drug reaction in this patient?	1 (1-1)	1 (1-1)
5. Fifteen-year-old boy was given injection of Benzylpenicillin for rheumatic heart disease prophylaxis and developed anaphylaxis as a side effect. Which of the following matches the type of adverse drug reaction in this patient?	1 (1-1)	2 (1-1)
6. A side effect is classified as acute, when it is occurred:	2 (1-1)	2 (1-1)
7. The international center for Adverse Drug Reaction (ADR) monitoring is located in:	1 (1-1)	2 (2-2)
8. Which of the following tool is most commonly used to establish the causality of an Adverse Drug Reaction (ADR)?	2 (2-2)	2 (2-2)
9. Which of the following is the "*WHO online databases*" for reporting Adverse Drug Reactions (ADRs)?	2 (1-1)	2 (2-2)
Total Scores	**13/18**	**16/18**

Questions/Statements	Median (IQR) scores	
	Pre-intervention	Post-intervention
Attitude assessment		
1. I am willing to spend enough time to discuss patient adverse drug reaction (ADR) on regular basis with my manager	4 (1-1)	4 (1-1)
2. There should be an incentive for pharmacists who are reporting ADR	4 (1-1)	4 (1-1)
3. Patient should NOT allow to report ADR (Scoring for item 3 is reversed, as the statement was negatively worded.)	4 (3-3)	4 (3-3)
4. I believe that ADR reporting should be made mandatory for practicing pharmacists	5 (4-4)	5 (4-4)
5. It is important to report ADRs in order to answer the questions that may arise in my practice	5 (4-4)	5 (2-2)
6. Reporting of ADRs is important to show patients that their concerns are taken seriously.	5 (4-4)	5 (4-4)
Total scores	**27/30**	**28/30**
Practice assessment*		
1. Have you observed any Adverse Drug Reactions in your practice in the past one year?	1 (1-1)	-
2. Have you ever reported any Adverse Drug Reactions in the past one year?	1 (1-1)	-
3. Does your workplace provide information regarding the procedure of reporting Adverse Drug Reactions?	2 (2-2)	-
4. Did you take any training in Adverse Drug Reactions reporting at your work place?	1 (1-1)	-
5. Does your workplace encourage you to report an Adverse Drug Reaction?	2 (2-2)	-
6. Is Adverse Drug Reaction reporting mandatory at your current work place?	2 (2-2)	-
Total scores	**9/12**	
Barriers that prevent ADR reporting*		
1. It is not a part of pharmacist's job	1 (1-1)	-
2. Lack of awareness about the reporting process	4 (4-4)	-
3. All serious ADRs are already detected before registration of drug	3 (2-2)	-
4. Fear of consequences after reporting (i.e. legal actions or reduced patient's confidence)	4 (3-3)	-
5. Lack of awareness of the existence of a national ADR reporting system	4 (4-4)	-
6. Pharmacovigilance topic not included in pharmacy curriculum	2 (1-1)	-
7. Lack of proper training on ADR reporting	4 (3-3)	-
8. Difficulty in deciding whether ADR had occurred or not	3 (2-2)	-
Total scores	**26/40**	
Factors that could enhance ADR*		
1. There should be incentives for the pharmacist who perform the reporting	5 (4-4)	-
2. Availability of ADR reporting center in each hospital will enhance PV activity	5 (4-4)	-
3. Direct ADR reporting by patients to national PV center	5 (4-4)	-
4. Proper training regarding the procedure of reporting ADRs will encourage reporting by pharmacists	5 (4-4)	-
5. Legal protection should be provided to the pharmacists by their workplace or by the relevant authority if they have dispensed the medication causing ADR	5 (4-4)	-
6. Continuous education and workshops for pharmacists	5 (4-4)	-
7. Encourage all health professionals to report	5 (4-4)	-
8. Ease of access to ADR forms	5 (4-4)	-
9. Using information technology in facilitating ADR reporting in the country	5 (4-4)	-
10. PV should be taught in the pharmacy curriculum	5 (4-4)	-
11. Difficult to decide whether or not an ADR has occurred	5 (4-4)	-
Total scores	**54/55**	

IQR, Interquartile range;.*Post-intervention assessments did not incorporate evaluations of practice, barrier responses, and factors that could enhance ADR reporting, as the time gap was too short to observe significant changes in these fields

Assessment of participants' feedback on the module

The feedback on the session was satisfactory, with one comment of it being long (Table II). All participants agreed that the program made them aware of PV and its importance. They all agreed that the program is well organised, informative, interesting, and helps career development. They welcomed future follow-ups and/or sessions to improve their ADR reporting outcomes.

Table II: Participants' feedback on the pharmacovigilance educational module (n = 3)

Statement	Median (IQR) Score
The session made me aware of the concept of pharmacovigilance.	3 (3-3)
ADR reporting by pharmacist should be made compulsory in UAE	3 (3-3)
The content of the session was well structured	3 (3-3)
The case studies used in the session were informative	3 (3-3)
This session may be useful for me in my current career	3 (3-3)
The session was informative and interesting.	3 (3-3)
The duration of the session was appropriate	2 (1-1)
I would welcome follow up sessions with the instructor	3 (3-3)
I would welcome similar sessions in the future	3 (3-3)
The case studies used in the session were interesting	3 (3-3)

Discussion

Researchers across different countries have found that offering healthcare providers a targeted education and training program on ADR reporting enhances both the frequency and quality of ADR reporting by changing their understanding and perspective on PV efforts (Shuval *et al.,* 2007; Elkalmi *et al.,* 2011; Farha *et al.,* 2018, Muro *et al.,* 2023).

The study results indicated the feasibility of developing and implementing a pharmacist-oriented PV education module to enhance ADR reporting. The findings revealed a positive impact of education on pharmacists' knowledge of PV. This outcome aligns with a study conducted in Jordan in 2016, where the healthcare providers' knowledge of PV improved post-education intervention (Farha *et al.,* 2018). However, in contrast with a study conducted in Kuwait in 2017, most pharmacists demonstrated a solid understanding of the terms' definitions and intended use of the module (Alsaleh *et al.,* 2017). Although this pilot study did not evaluate the module's impact on practice, assessment is planned in the main study.

Based on participants' feedback, the authors recommend making a few changes to the education module, such as reducing the duration by summarising the historical part and introduction, retaining only one example of product withdrawal from the market, and encouraging pharmacists to work collaboratively on various activities.

Conclusion

The education module was successful in achieving the objectives and liked by the participants. Participants commented on the length of the module, which will be considered while implementing the full-scale research. Upon successful implementation, this module will be incorporated into the continuing professional development of pharmacists.

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