Original Article

Teaching Pharmacovigilance to Undergraduate Students: Our Experience in Poor-Resource Setting

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Abstract

Using medicines associated with adverse drug reactions (ADRs) might cause serious health complications. The pharmacist plays a unique role in monitoring ADRs, either by themselves or with the assistance of other health-care professionals, to diminish the hazards of ADRs by distinguishing, reporting, and evaluating any proposed ADRs. To train future pharmacists who have adequate knowledge of ADRs and related aspects, it is highly recommended to introduce the WHO-ISoP pharmacovigilance (PV) in the core curriculum. In this article, we shared the suggested curriculum in Aden University. It is based on comprehensive outlines and reference books that offer a broad view of all aspects related to PV. A brief student course evaluation was carried out. Fifty students participated in the survey. Students expressed the importance of the course and indicated that they wanted to know more about the types of ADRs and common medication errors. Some of them lacked an understanding of the causal relationship between ADRs and risk assessment and not familiar with the reporting forms. They suggested for PV awareness programs for health-care staff and public. The curriculum should be tailored according to the country's needs because each country has its own medication safety issues and PV program. To reach the ultimate objective, this article reports the initiative to develop PV proficiencies in a university setting.

Keywords: *Adverse drug reactions, curriculum, pharmacovigilance, pharmacy education, Yemen*

Introduction

Most individuals are exposed to many diseases that necessitate the use of some medicines to treat them. However, using medicine associated with adverse drug reactions (ADRs) might cause serious health complications. According to a few studies, almost 5% of all acute hospitalizations are due to ADRs.[1-3] The rate of hospitalization could be reduced with ADR monitoring, the realization of the seriousness of the symptoms at the proper time, and adequate knowledge about all aspects of the incidence of these ADRs,[1,2] which emphasizes the importance of pharmacovigilance (PV). PV can be defined as "the science and actions concerning the recognition, estimation, understanding, and prevention of adverse effects or any other drug-related problem."[4] To train health professionals with PV competencies, vital aspects of PV should be involved in the educational programs of all health professionals such as doctors, pharmacists, dentists, and nurses.[5] In Yemen, PV-related topics are taught in the 4th and 5th year in the pharmacy undergraduate program. The topics are included in various courses, not in a single course.[6] The curriculum is mainly on pharmaceutical science subjects and biomedical, while lack in the area of clinical and pharmacy practice.

Importance of pharmacovigilance for pharmacy students

Pharmacists should be actively involved in the PV program and activity. Exposure on the PV aspects

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including developing the knowledge, skills, and right attitudes related to PV should start during the undergraduate level. In addition, the pharmacy colleges can develop training programs that will allow the students to be exposed with activities by the national PV center. It can be anticipated that PV teaching in the primary stage of pharmacy students' careers will help them develop information about the safety of medicines and skills for the harmless use of medicines.[7] In addition, the persistent educational campaign for health workers has proven to be efficient in achieving PV competencies.[8] The pharmacist plays a unique role in monitoring ADRs, either by themselves or with the assistance of other health-care professionals; pharmacists help to diminish the hazards of ADRs by distinguishing, reporting, and evaluating any proposed ADRs. They can also educate, recommend, and inspire medical doctors, nurses, and other health-care professionals to report ADRs.

In Yemen, there is underreporting of ADRs due to the unawareness of most health-care professionals, especially pharmacists, regarding the reporting process. Underreporting is an actual problem within PV; only 6% of all ADRs are assumed to be reported.[9] In 2011, the Supreme Board of Drugs and Medical Appliances (SBDMA) launched an official and approved ADR monitoring system, but regrettably, no ADR data were reported. In 2014, many activities were carried out such as starting the center, building the website and arranging the reporting form, and designing posters and procedures to start disseminating knowledge among the athletes (e.g. use of performance-enhancing substances), pharmacists, and consumers. In addition, Yemeni magazines printed numerous articles concerning PV.[10] Unfortunately, the heartless war in 2015 led to complete disruption of most activities, particularly with regard to the monitoring system. There should be cooperation between the SBDMA and the faculty of pharmacy to restore the activities of ADR reporting and to encourage the addition of PV to the current curriculum system, and the Medicinal Alert Center should support these activities to ensure a qualified reporting process. Recently, the head of the SBDMA directed an official message to many private and governmental universities, emphasizing the need to include the PV as a course of the study. He indicated that most university syllabuses worldwide involve PV courses due to the importance of this issue. He added that health workers are the source and developers of the medical alert and safety system, so they must have enough knowledge about the reporting of ADRs, as well as the management and observation of cases, with the help of the medical alert center.

The prevalence of pharmacists reporting ADR awareness is highly influenced by the level of knowledge and attitude regarding the importance of reporting.[11-13] There are studies that showed how reporting could be improved by education and training.[14,15] Another problem facing Yemen is that the pharmacists have less time in contact with the patients to offer the necessary and required information. The function of pharmacists has been changing from the dispensing of medicine to a more clinical role, and pharmacists in our country still have no legal rights to prescribe most of the medications. However, medicines are easily dispensed and bought by the consumers, especially from community pharmacists. For all these problems, PV should be taught to all health-care professionals. The current review focuses on the benefit of PV for pharmacy college students, particularly at Aden University. This article also included a brief evaluation, which aimed to survey students' perceptions about the course.

Pharmacovigilance curriculum for university education

The present educational program is provided by the pharmacy faculty at Aden University and includes the essential issues in terms of ADRs, although it is still limited and does not provide students with a strong basis for the clear and comprehensive knowledge of PV. In the past 20 years, the university syllabus in many countries was based on pharmaceutical chemistry and dispensing. Currently, approximately 20% of the pharmacy program is dedicated to clinical topics and approximately 10% is dedicated to social interactions and prescription management.[10,16] The theoretical aspects of PV are being taught in several developed countries, but the practical issue is absent in many low- and middle-income countries (LMICs). This might be the stumbling block in establishing a concept. To obtain a satisfactory outcome in PV issues, the experiences of developed countries in this field should be considered. For instance, the UK has attempted to introduce the yellow card scheme (the system of spontaneous reporting in the UK) into the undergraduate medical college syllabi; this system has helped improve PV outcomes in hospitals.[17] In addition, in France, the systematic gathering of ADRs over approximately 20 years has assisted in graduating a generation of physicians with full knowledge of the risks of side effects and rational drug use.[18] The situation differs in LMICs. A study in New Delhi indicated that the knowledge, attitudes, and practices (KAP) concerning ADR monitoring were similar among undergraduates and prescribers, thus it needs major improvement and development in KAP.[19]

The suggested curriculum is based on comprehensive outlines and reference books that offer a broad view of all aspects related to PV.[20-22] The curriculum should be tailored according to the country's needs because each country has its own PV program. There are key aspects stated by the WHO PV principal curriculum for university education

that are essential for the acquisition of knowledge or skills outcomes by future health professionals.[23,24] This WHO PV program focuses on the clinical aspects of PV in states that only reporting ADRs since the majority of students will be involved in clinical practice and offer patient care facilities. The main intention is to have students with high competence in dealing with the PV aspects. The curriculum should increase in complexity as the academic level increases. It should be started with an introduction to the PV concept and finished with recognizing ADRs, describing the mechanism of ADRs and recommending pharmacotherapeutic interventions.

The curriculum should involve active learning methods instead of passive ones such as case studies, problem-solving, critical thinking, simulations, and the application of activities and training at health centers, to have more effective outcomes. PV education can be added to current courses with limited time investment.

Each university should identify the current gaps in their curricula, invite PV stakeholders to educate the teaching staff, and stimulate the reporting system for ADRs. It is strongly suggested to have an ADR reporting system to provide better prevention of ADRs in health-care centers.[25] The value of the reports produced rests on the knowledge and training of the clinicians.[26] In 2011, the ADR reporting system was established by the SBDMA, although there is no authorized information or reports released by the SBDMA involving the number of ADRs that occurred and how they processed it. However, there was a mutual effort between the academics from the Faculty of Pharmacy at the University of Aden and the official SBDMA in this regard.[27]

Objectives of a pharmacovigilance teaching program

There are many important objectives in introducing PV into the academic curricula of pharmacy colleges.[28] The main intention is to focus on the patient's situation instead of drug orientation. After completion of the course, the student will be able to:

1. Improve patient safety and quality of care in relation to the use of medicines and other treatment modalities
2. Improve community health and safety, especially in relation to the use of medicines
3. Identify problems related to the use of medicines and communicate the findings in a timely manner
4. Contribute to the assessment of benefit, harm, effectiveness, and risk of medicines, leading to the prevention of harm and maximization of benefit
5. Promote the safe, rational, and more effective (including cost effective) use of medicines
6. Enhance understanding, education, and clinical training in PV and its effective communication to the public.

Content of the teaching program

The content of the current clinical pharmacy syllabus is outlined in Table 1. The teaching outlined occupies a total teaching time of 10 h/week, which is divided into theory (4 h/week), case studies (theory) (4 h/week), and hospital experience (practical) (2 h/week).

The course emphasizes an extended role of pharmacists that is patient oriented rather than drug oriented. The course is made up of four components:

1. Clinical pharmacokinetics: Practical application of pharmacokinetics in therapeutic drug monitoring and its clinical application
2. Pharmacy practice skills: Acquiring skills to enable the pharmacist to help the public optimize drug treatment by monitoring and avoid drug interactions and ADRs
3. Pharmacy practice research: Gain expertise on the evaluation of medicine through research and utilization reviews
4. Evidence-based pharmacy, evidence-based data sources, answerable clinical questions (PICO), and levels of evidence-based evaluations of medicine and research: study design, drug information systems, and writing a research project.

After completion of the course, the student is expected to be able to:

1. Monitor drug therapy for medications with a narrow therapeutic index and calculate the most important drug pharmacokinetic parameters
2. Recognize drug interactions due to pharmacokinetics and other mechanisms
3. Respond to questions regarding drug information and source evidence-based resources for drug information
4. Conduct a clinical trial and interpret the clinical outcome data
5. Predict ADRs and take action to reduce the number of ADRs that occur
6. Take a patient medical history and complete an admission record
7. Interpret laboratory clinical data
8. Conduct research and write research reports.

This syllabus contains some aspect of PV; however, the curriculum, which is based on the WHO PV guideline, aims to familiarize students who graduate from the college of pharmacy with the aspects and foundations of PV, which can be summarized in the following points [Table 2]:

1. Realizing the value of PV within the pharmacotherapy background
2. Avoiding ADRs at the proper time
3. Identifying ADRs at the time of occurrence
4. Proper ADRs management; and
5. Reporting ADRs.

Table 1: Content of the current clinical pharmacy syllabus for pharmacy undergraduate students at Aden University

Contents	Number of hours
Clinical PKs	8
An introduction to the concepts of clinical PKs and therapeutic drug monitoring	
Fundamental parameters, specifically volume of distribution, clearance, elimination rate constant (K) and half-life, with examples of most common drugs	
Pharmacokinetic calculations	
Pharmacokinetic case studies	
Pharmacokinetic interaction	
DIs	3
Definition and mechanism	
Drugs commonly involved in DIs	
People most susceptible to DIs	
The role of the pharmacist to reduce DIs	
ADRs	4
Definition, types, mechanism, and epidemiology	
Predisposing factors	
Deduction and reporting	
Presentations and discussions by students	
Case reports and cohort studies	
Case-control studies, spontaneous reporting	
Clinical laboratory data	8
Importance of reference ranges for biochemical and hematological values	
Monitoring of blood tests and their reliability	
Most common disease induced laboratory value changes	
Most common drugs and food induced laboratory value changes	
Practical experiments	
Drug information systems	8
Method of gathering and using medical and pharmaceutical information	
Type of sources for drugs and poisons (primary, secondary, etc.)	
Retrieving, analyzing, and evaluating information	
The use of computer short courses	
Understanding clinical trials	
Pharmacogenomics	3
Introduction and concept	
Human drug response	
Polymorphisms of drug metabolism	
Disease-associated polymorphisms	
Therapeutics	20
Most common cardiovascular diseases	
Most common gastrointestinal diseases	
Most common respiratory diseases	
Most common skin diseases	
Most common endocrine diseases	
Most common central nervous system diseases	
Most common urological problems	
Infectious tropical diseases in Yemen	
Case studies	8
Heart failure, myocardial infarction, and angina	
Hypertension	
Acute renal failure	
Peptic ulcer	
Epilepsy	
Hospital practice	
Attend ward rounds and/or morning meetings (if available)	
Writing medical history and understanding the terms and acronyms	
Interpret admission reports and relevance of investigation	
Study treatment protocols and report on possible contraindication, DI, and inappropriate indication	

PKs: Pharmacokinetics, DIs: Drug interaction, ADRs: Adverse drug reactions

The main objective of this program is to provide graduate students with the clinical aspects of PV. The students will be in direct contact with the patients, so they must have a comprehensive knowledge of the detailed aspects of the PV such as the safety of the prescribed drugs, possible risk factors, clinical manifestation of early symptoms, and reporting of ADR cases. The desired outcome can only be achieved by involving PV in the current curriculum at the pharmacy college.

Teaching–learning evaluation and methods

Pharmacy colleges must apply the teaching and learning method that students learn PV best. As academician, we need to use the different teaching styles that will engage and motivate the students to learn PV. The teaching methods used at Aden University can be summarized in the following points:

1. Lectures and seminars – in addition to the didactic lectures, seminars were organized occasionally on a selected PV topics
2. Hospital and primary health-care (PHC) unit experience – Students were arranged to visit the hospital and PHC settings; they learned the activities that are carried out in these institutions
3. Group work – students worked in group on a research project assigned to them
4. Assignment – this can be a paper writing on a specific PV topic.

Table 2: Outline of the main aspects and skills that form a pharmacovigilance core syllabus for university education based on the WHO pharmacovigilance curriculum

Main aspect	Knowledge	Skills	Attitude	Examples of teaching methods
Realizing the value of PV	Case study of a patient admitted to hospital due to serious ADRs	Identifying ADRs and their effect on patients	Broad-mind perspective about the consequences of drug usage in pharmacotherapy	Historical examples of ADRs Patient meeting
Avoiding the ADRs	Overall hazard factors, Specific hazard factors, Management strategies and protection information	Selecting proper drug therapy	Harmless advising/dispensing	Problem resolving simulating of a situation and participation in a role-playing exercise ADR monograph
Identifying ADRs	ADR categorization Hazard factors Confounding factors Epidemiology	Clinical analysis Causality analysis	Realization of expected and unexpected ADRs	ADR report evaluation Prescribing safety evaluation training time
Proper ADR management	ADR categorization significance Severity	Select correct activities, patients and HCP communications Reporting of ADR data	Evaluating hazard-benefit equilibrium in a specific patient	
Reporting ADRs	Boundaries of premarketing stage Significance of ADR reporting Documentation of ADRs	Distinguishing ADRs in practice Integral reporting form	Obligation for sharing (reporting) of ADRs	ADR reporting task

HCP: Healthcare professional, ADRs: Adverse drug reactions, PV: Pharmacovigilance

With regard to the contents, the theoretical part can be evaluated by means of short answer type questions and multiple-choice questions (MCQs). A group activity could be the best way to assess ADR reporting. The overall evaluation for the course could be carried out by the final written examination and assignment.

An Evaluation of the Pharmacovigilance Course among Students at Aden University

Our team conducted an evaluation of the PV course among our students at Aden University, Faculty of Pharmacy. Fifty 5th-year students participated in the survey that was conducted in December 2019. The ethics approval was obtained from the ethical committee of faculty of medicine. Verbal consent was obtained from the students. If the student responds to the evaluation, it indicates that he/she approved to participate.

The survey tool was developed from a previous literature review about the evaluation of courses; it was modified after been reviewed by two faculty members from different universities. It aimed to meet the objective of the PV course evaluation and translated to Arabic language. The content of the English version is attached in Appendix 1.

The tool was distributed to fifty students after the PV lecture, and they were given 15 min to answer the open-ended questions. The data were collected, coded, and subjected to a content analysis because the tool contained open-ended questions.

The findings indicated that most students wanted to know more about the types of ADRs, with examples and pictures of their harmful effects. In addition, students wanted to know the common medication errors in dispensing drugs because they will face all these problems in their future employment. Some students lacked an understanding of the causal relationship between ADRs and risk assessment, and some were unsure how to fill out reporting forms or did not know where these forms were available. They preferred to have the MCQs on the exam as opposed to the open-ended questions.

Students suggested training seminars to fill out reporting forms, raising awareness, and creating day-to-day awareness among health workers and the public and improving communication with the national PV center.

Most students felt the importance of their studies to raise the level of their performance and competence in the future; they were grateful and satisfied with their teachers and reported that the teaching of the course was very good.

Conclusions

Insertion of PV into the current academic syllabus is an essential aspect to ensure the safe use of medicines in poor-resource setting. The suggested curriculum has a hierarchical harmonized structure with a gradual increase in complexity. The theoretical section is reinforced by practical training. The main aim of applying the curriculum is to have a new generation of pharmacists that have enough PV knowledge and skill to be active participants in the country PV system in LMICs.

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Conflicts of interest

There are no conflicts of interest.

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Appendix

Appendix 1: An evaluation of your study of pharmacovigilance

Hopefully, it will take some time to answer the following seven questions and return the completed form to Dr. Alshakka. When giving answers to the questions, you can use the following abbreviations for the components of this course:

a) Lectures;

b) Discussion sessions;

c) Workshop;

d) Assignments;

e) Project;

f) Exam;

g) Textbooks and other educational materials.

1) What are the two most important components that draw your attention to the course on pharmacovigilance? Why?

2) What are the components of the pharmacovigilance course that has less value for your learning? Why?

3) What do you think about the form of the exam and the forms of teaching in general?

4) What is the contribution of the pharmacovigilance course to your professional competence as a future pharmacist?

5) Do you have a message to any specific member (s) of the pharmacovigilancecourse team, teaching professors, or teaching assistants?

6) Do you have any suggestions on how to make, this course better?

7) What is your comprehensive evaluation of the course? Use the following scale:

1.(Excellent); 2.(Very good); 3.(Good); 4.(Well); 5.(I don't know); 6.(Weak); 7.(Bad); 8.(Very bad)