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ORIGINAL ARTICLE

Education Sessions For Pharmacy Students On Pharmacovigilance: A Preliminary Study

SUBISH P*,**,***, MOHAMED IZHAM MI****, MISHRA P*,**, SHANKAR PR****, ALAM K*,**

ABSTRACT

Introduction: In Nepal, there are no mandatory clinical trials for new products. Drugs are approved based on the data from developed countries. Manipal Teaching Hospital is one of the pioneers in establishing the Pharmacovigilance program in Nepal. For the past three years, the students of Pokhara University visit the Pharmacovigilance center, Drug information center and the Hospital Pharmacy of MTH for a 15 days training program. In the year 2007, the students were also trained in pharmacovigilance.

Objectives: To study the demographical details of the students who participated in the pharmacovigilance training and to obtain student feedback regarding the sessions.

Methodology: The session module was activity based and emphasized the following four areas: sketching out the current National Pharmacovigilance programme, designing an adverse drug reaction reporting form, carrying out the causality assessment and severity assessment. The feedback of the students on the training module was evaluated using the specially designed feedback form.

Results: Altogether, thirty students [males 18 (60%) and females 12 (40%)] were present and all of them participated in the study. The Mean ± SD overall feedback score was 81.5 ± 4.4 (maximum possible score was 100). In general, male students had a higher score (82.29 ± 4.88) than females (80.33 ± 3.75).

Conclusion: Overall, the students liked the session and were interested in having similar sessions in the future. This module can be taken as a model for other researchers who would like to carry out educational sessions in pharmacovigilance for pharmacy students.

Key Words: Education, Nepal, Pharmacy students, Pharmacovigilance.

*Department of Pharmacology
*** Department of Hospital and Clinical Pharmacy
Manipal College of Medical Sciences/ Manipal Teaching Hospital
Phulbari-11, Pokhara, Nepal.
***Discipline of Social and Administrative Pharmacy
School of Pharmaceutical Sciences
Universiti Sains Malaysia, 11800 Penang, Malaysia.
****Department of Clinical Pharmacology
KIST Medical College, Imadol
Lalitpur, Nepal.
Corresponding Author:
P. Subish M.Pharm
Assistant Professor
Department of Hospital and Clinical Pharmacy/ Pharmacology
Manipal Teaching Hospital/ Manipal College of Medical Sciences
Pokhara, Nepal.
Phone: +977 61 526416 Extn: 130/221
Email:subishpalaian@yahoo.co.in,
subishpalaian@gmail.com

Introduction

It is a well known phenomenon that new drugs are marketed widely and are often withdrawn from the market due to the Adverse Drug Reactions (ADRs) which occur once they are used by a larger population than that covered in the clinical trials [1]. Modern pharmacists

consider Pharmaceutical care as their focus and play an important role in patient care [2]. Ensuring the safe use of drugs is a combined responsibility of the healthcare team that includes Doctors, Nurses, Pharmacists and other supporting staff. One of the most importance means of ensuring drug safety is by reporting ADRs by healthcare professionals. Pharmacists being more knowledgeable in drug related aspects, have an important role in ensuring drug safety. The involvement of pharmacists in pharmacovigilance programs is considered to be vital [3],[4],[5]. However, contrary to their important role, studies from developed countries have acknowledged either a poor knowledge [6] or less experience among pharmacists regarding ADR reporting [7]. Researchers suggest the need for education for the pharmacists on Pharmacovigilance [8]. One of the better ways to do this is by providing education when they are still students. The education provided for the Pharmacy students, even in developed countries like the United Kingdom, was found to be inadequate. A study found that both medicine and pharmacy courses differed substantially in teaching about the Yellow Card Scheme (the scheme for spontaneous ADR reporting in UK) and ADRs. There is scope for increased involvement of the Medicines and Healthcare products Regulatory Agency in undergraduate education [9].

In Nepal, there are no mandatory clinical trials for new products and drugs are approved, based on the data from developed countries. This eliminates the possibility of knowing the risks involved in the Nepalese population. Recently, Pharmacovigilance programs have been started in Nepal [10]. Manipal Teaching Hospital is one of the pioneers in establishing the Pharmacovigilance program in Nepal and the members of the Department of Hospital and Clinical Pharmacy and Pharmacology were actively involved in establishing the program [10]. The members have already carried out Pharmacovigilance sessions for undergraduate MBBS students [11],[12]. However, such an initiative was not carried out for the Pharmacy students. Pokhara University runs a four year B.Pharm course. For the past three years, the students of Pokhara University visit the Pharmacovigilance center, Drug information center and the Hospital Pharmacy of MTH for a 15 days training program. The students had their training during the month of June 2007. During that time, the members of the Pharmacovigilance center conducted a voluntary Pharmacovigilance training module for the Pokhara University Final year Pharmacy students. The present study was conducted with the following objectives.

1. To study the demographic details of the students who participated in the pharmacovigilance training,

2. To study the student feedback regarding the sessions, and

3. To compare the scores of the students based on their demographic status.

Materials and Methods:

For the past three years, the final year B. Pharm students were trained in various aspects of Hospital and Clinical Pharmacy at the Manipal Teaching Hospital (MTH). The total training period of 15 days is divided into small slots of 2-3 days at the Drug Information center, Pharmacovigilance Center, Inpatient Pharmacy, Outpatient Pharmacy, Bulk Pharmacy and the Medication Counseling center. Besides running the hospital pharmacy, the Department of Hospital and Clinical Pharmacy, with the help of the Department of Pharmacology, also runs a medication counseling center, a drug information center and a pharmacovigilance center. The Pharmacovigilance activities have been going on since September 2004 and now MTH is the regional Pharmacovigilance Center for ADR monitoring for the Western region of Nepal.

During the 15 days training program, the students were also provided training in Pharmacovigilance. The module was activity based and focused on the following four areas: sketching out the current National Pharmacovigilance programme, designing an adverse drug reaction reporting form and carrying out causality assessment and severity

assessment of ADRs. Students were divided into groups of five students each. The details are listed below.

Part I: Sketching out the current National Pharmacovigilance programme: The students were asked to sketch out the National Pharmacovigilance programme of Nepal.

Part II: Designing an adverse drug reaction reporting form: Students were encouraged to design an ADR reporting form by themselves. They were instructed that the form should be brief, concise and should have all the essential information required for an ADR reporting form.

Part III: Carrying out the causality assessment: Students were asked to carryout the causality assessment of four ADRs that were reported to the Phamacovigilance center. Naranjo algorithm [13] was provided to the students to carry out the causality assessment.

Part IV: Carrying out the severity assessment: Students were also asked to carry out the severity assessment of four ADRs that were reported to our PV center. Modified Hartwig and Siegel scale [14] was provided to the students to carry out the severity assessment. These four ADRs were the same as those used for causality assessment.

The feedback of the students on the training module was evaluated using the specially designed feedback form [Table/Fig 1].

(Table/Fig 1) Questionnaire used to elicit student response about the sessions

Learning sessions on pharmacovigilance – Student feedback

Sex: Nationality: Course: Method of financing:

Semester: Urban/Rural:

For the following statements score using the following key (1 = strongly disagree with the statement, 2= disagree with the statement, 3= neutral, 4= agree with the statement, 5= strongly agrees with the statement.) Use whole numbers only.

1. The sessions made me aware of the concept of Pharmacovigilance.
2. Pharmacovigilance is very much essential to developing countries like Nepal.
3. Averse drug reactions are one of the major causes for death in the world
4. Herbal drugs also carry equal risk of causing adverse drug reactions as that of modern medicines
5. Pharmacovigilance program in Nepal is successful
6. The ADR reporting form should be in a single page
7. Pharmacovigilance should be made mandatory in Nepal
8. Pharmacovigilance should be incorporated in the curriculum of Doctors and Pharmacists
9. The pharmaceutical industry should report adverse drug reactions
10. This session may be useful for me in my job
11. Hospital drug and therapeutics committee should be a part of the Pharmacovigilance program
12. Causality assessment is an important step in Pharmacovigilance
13. Severity assessment is not an important step in Pharmacovigilance
14. A good number of adverse drug reactions can be prevented if appropriate measures are taken
15. Patients should not be allowed to report adverse drug reactions
16. Dosage adjustment is an important strategy to prevent the occurrence of adverse drug reactions
17. The session was informative and interesting.
18. The facilitators performed their roles effectively.
19. I would like to pursue my career in Pharmacovigilance
20. I would welcome similar sessions in the future.

Any other comments (Please use back of the sheet)

Results

Altogether, thirty students were present and all of them participated in the study. The demographical characteristics of the students are listed in (Table/Fig 2) .

(Table/Fig 2) Demographic characteristics of the students

Characteristics		Number	Percentage
Sex	Male	18	60
	Female	12	40
Place	Urban	21	70
	Rural	6	20
	Not mentioned	3	10
Nationality	Nepali	30	100
	Non-Nepali	0	0
Method of financing	Scholarship	0	0
	Self	25	83
	Not mentioned	5	17

Student Feedback on the Sessions

The median scores of the individual statements are listed in (Table/Fig 3). The Mean ± SD overall score was 81.5 ± 4.4 (maximum possible score was 100). We also compared the scores with the demographical status of the respondents and the details are listed in [Table/Fig 4].

(Table/Fig 3)Median scores of individual statements

S. No.	Median score (Inter quartile range)
1	5 (4-5)
2	4 (4-5)
3	4 (3-4)
4	3.5 (2-4)
5	2 (2-3)
6	3 (2-4)
7	4 (2-4)
8	5 (4-5)
9	5 (4-5)
10	5 (4-5)
11	4 (3-5)
12	5 (4-5)
13	5 (4-5)
14	4.5 (4-5)
15	5 (5-5)
16	4 (4-5)
17	5 (4-5)
18	4 (4-5)
19	4 (3-4)
20	5 (4.75-5)

Note: The questions 13 and 15 were reversed and hence were reversely scored

(Table/Fig 4) Mean scores as per the demographic characteristics of the students

Characteristics		Mean ± SD
Sex	Male	82.29 ± 4.88
	Female	80.33 ± 3.75
Place	Urban	80.66 ± 4.56
	Rural	82.17 3.49
	Data unavailable	86 ± 2

Discussion

Pharmacovigilance, previously more often referred to as adverse drug monitoring or drug surveillance is now regarded as the quality control system of the society regarding the use of medicines. Its broader aim is to check if medicines fulfill their intended role in alleviating human suffering and reducing disease related economic loss, with the best acceptable safety in use. The ultimate aim of pharmacovigilance is to attain the safe and rational use of medicines, once they are released for general use in the society. A very important outcome of pharmacovigilance is the prevention of patients being affected unnecessarily by the negative consequences of pharmacotherapy [15]. In order to protect consumers from the negative consequences of drug therapy, the healthcare professionals including the Pharmacists should be aware of the concept of pharmacovigilance. Data from Nepal clearly suggest vast amount of irrational use of medicines. Some examples of the irrational use of drugs still in evidence in Nepal are: polypharmacy, use of expired drugs, the irrational fixed dose combination of drugs and overuse of antibiotics, vitamins / herbal remedies, brand prescribing, retail shop prescribing and unethical dispensing. Such irrational practices, combined with lack of patient information on proper handling and use of drugs, can lead to wastage of medicine as well as other serious consequences like adverse drug reactions and drug interactions [16]. In Nepal, retail pharmacists are considered as the first point of contact for healthcare problems. However, they are often less qualified and do not have adequate sources of information and knowledge about drug related matters.

Moreover, in Nepal the pharmacy curriculum is more 'product oriented' and there is less emphasis on Social Pharmacy, Pharmacoepidemiology and other aspects of medicine use. The curriculum prepares the students for a job in the pharmaceutical industry than for a job in a Hospital or as a Community Pharmacist [17],[18].

We included four areas in our Pharmacovigilance training module. The first area, 'Sketching out the current National Pharmacovigilance programme' is very essential for the students. The students should know about the ongoing Pharmacovigilance program in Nepal. They were able to sketch out the current pharmacovigilance program. They also emphasized the need for more regional centers and peripheral centers. As of now, in Nepal there is a national centre and four regional centers.

The second area, 'Designing an adverse drug reaction reporting form' was well received by the students. The student designed forms had all the essential features like patient demography, drug history and drugs responsible for the ADR, contact details of the reporter, etc. In a previous session conducted for medical students, the students were creative and enjoyed the sessions [12]. Similarly, the present study also clearly reflects that students liked the sessions.

The third area, 'Carrying out the causality assessment' using the standard method, is one of the best ways to establish the causal relationship between the drug and the effect. The Naranjo algorithm is used widely in carrying out the causality assessment of ADRs. It is based on the score calculated on the basis of the points given for each of the ten questions that comprise the table. The maximum possible score was 13. If the score was 9 or greater than 9, then the adverse reaction was categorized as 'definitely' caused by the particular drug. A score of 5-8 was categorized as 'probably' caused by the drug, while a score of 1-4 was categorized as 'possibly' caused by the drug.

The fourth area, 'Carrying out the severity assessment' is an important step in Pharmacovigilance. In order to take appropriate initiatives towards management of the ADR, it is necessary to study the severity of the ADRs. Hartwig scale is widely used for the purpose. This scale categorizes the reported adverse drug reactions into different levels as mild, moderate or severe, based on the treatment and whether or not hospitalization was required for the management of the ADRs.

The feedback of the students was positive. The students agreed that the sessions made them aware of the concept of Pharmacovigilance. With regards to the success of the current Pahrmacovigilance program in Nepal, they had a negative response. This response suggests the students' concern regarding the program. One of the most striking findings was that the students wanted Pharmacovigilance to be incorporated in their curriculum.

While going through the feedback forms, we got some interesting responses from the student participants. One of the female respondents wrote, '*The session was entirely new and helpful for me. It has made me feel aware of my responsibility as a Pharmacist in some way*'. Another female respondent wrote, '*This type of session must be given to the first semester students of B.Pharm and also to the general public*.' A male student wrote, '*The information obtained during the session was very informative. Pharmacovigilance was quite a new term for me. So, it was informative for me'*.

Limitations

Our study had a few limitations. It was a preliminary study and included only 30 students. Moreover, only one batch of students was included in the training program. We also did not evaluate the improvement of knowledge of the students regarding Pharmacovigilance, following the training program.

Practice Implications

To the best of our knowledge, the present study is one of the first to introduce activity-based learning of pharmacovigilance to pharmacy students in South Asia. Pharmacovigilance is an important area of practice for pharmacists. We hope our experience will be of interest to researchers and teachers from South Asia and other developing regions.

Conclusion

The study was successful in evaluating the students' feedback on the educational sessions about pharmacovigilance. Overall, students liked the session and were interested in having similar sessions in the future. In a country like Nepal, where Pharmacy students are not taught much about the negative consequences of drug therapy, this study gains attention. This module can be taken as a model for other researchers who are willing to carry out educational sessions for pharmacovigilance for pharmacy students.

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