Original Article

Development of pharmacovigilance training module for community pharmacists in Nepal: A focus group study

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ABSTRACT

Objective: We assessed the feedback from community pharmacists on training sessions on adverse drug reaction (ADR) reporting provided by the regional pharmacovigilance center. In addition, we examined the relationship between feedback scores and demographic characteristics of the community pharmacists.

Methods: The training on ADR reporting was divided into three sessions. Each session lasted for 1–2 h duration, spanning over 6 months. A questionnaire was provided to obtain feedback on the training sessions. The questionnaire had a total of twenty questions on a 5-point Likert scale (maximum possible total score could be 100). The feedback scores obtained were compared with a demographic profile. Mann–Whitney U-test was used for comparing the scores of the subgroups with "two groups" and Kruskal–Wallis test for the subgroups with more than two groups. $P < 0.05$ was considered statistically significant.

Results: Most of the pharmacists participated were male ($n = 18$), aged between 31 and 40 years ($n = 14$), with educational qualifications of community medical assistant ($n = 12$) and length of experience in community pharmacy between 1 and 5 years ($n = 14$). The overall median (interquartile range) of the responses was 79 (73.5–81.0); the maximum possible score was 100. There was no association between the total scores and gender, age, educational qualifications, and length of experience in the community pharmacy.

Conclusions: The feedback revealed that participants find the training sessions were useful and they were interested in future sessions. Educational interventions can play an important role in improving ADR reporting.

Key words: Adverse drug reaction reporting, community pharmacists, Nepal, pharmacovigilance

INTRODUCTION

Adverse drug reactions (ADRs) are one of the major problems associated with medication. ADRs are known to have a significant impact on the morbidity, mortality pattern, and are attributed to huge economic impact.[1-3] The World Health Organization (WHO) defines an ADR as a response to a drug which is

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noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function.[4] Monitoring the ADRs is considered a better strategy for early detection of uncommon ADRs and thus preventing it could benefit a major patient population.

Being an important member of health-care team, community pharmacists can also play an important role in ADR reporting.[5] However, in contrary to their role, the involvement of community pharmacists in pharmacovigilance programs is very low. A study from Iran found that 29% of the practicing pharmacists were not aware of the Iranian Pharmacovigilance Center. More than half of the pharmacists felt that ADR reporting should be voluntary while 26% felt it was a professional obligation. The study concluded that in Iran, pharmacists have little knowledge regarding the operation, purposes, and usefulness of ADR spontaneous reporting system.[6] Another study from Turkey reported that only 17.2% of the pharmacists had any knowledge about "pharmacovigilance" and only 7% actually reported an ADR to the National Pharmacovigilance Center. Authors concluded that Turkish community pharmacists have poor knowledge about pharmacovigilance.[7]

Nepal is a developing country in South Asia with multiple drug-use problems.[8] Initially, there was no ADR monitoring program in the country. In the year 2004, the Department of Drug Administration (DDA), the National Drug Regulatory Authority, took initiatives in establishing a pharmacovigilance program.[9] At present, Nepal is a member of the WHO ADR monitoring program.[10] Till date, there are four regional pharmacovigilance centers that report ADRs to the National Pharmacovigilance Center located at the DDA. The current national pharmacovigilance program is hospital centered and, thus, do not focus on ADRs occurring in the community settings. In Nepal, retail drug outlets outnumber health posts and health centers by a ratio of 4:1 and private drug sellers often offer the only access to modern medicines for much of the population. It is found that drug retailers are very often the first and the only source of health care outside the home and frequently serve as the public's first point of contact with the health-care system.[11] Due to various reasons, the qualified doctors refuse to set up their practice in rural Nepal. Hence, the role of community pharmacists in health-care system is very important.

To overcome this gap, the regional pharmacovigilance center at Western Nepal decided to establish a community-based pharmacovigilance program. The regional pharmacovigilance center at Western Nepal is the pioneer in initiating the concept of pharmacovigilance in Nepal. This manuscript describes the feedback of the community pharmacists who attended the training program and was conducted with the objectives of evaluating the community pharmacists' feedback regarding the training sessions on ADR reporting and to compare the feedback scores of the community pharmacists based on their demographic status.

METHODS

Study design

A focus group study to obtain feedback from the community pharmacists regarding the training program on ADR reporting.

Study subjects

Thirty community pharmacy practitioners were selected for the training. The selection was based on their willingness to participate and their prior knowledge on medicine safety. Their knowledge on medicine safety was initially evaluated using a self-developed KAP questionnaire and is beyond the scope of this study.

Intervention

The training was divided into three sessions. Each session lasted for 1–2 h duration. Group I was the pilot group pharmacists (n = 6) who received the three sessions of training in 2 months (during March to May, 2008) and Groups II (n = 10), III (n = 8), and IV (n = 6) received three training sessions spread over a period of 6 months (0, 30, and 90 days) during June–November, 2008. The contents of the training sessions are presented in Table 1.

Feedback of the participants

On completing all the three training sessions, the pharmacists from the regional pharmacovigilance center visited them at their community pharmacies and collected their feedback through the feedback questionnaire [Appendix 1]. The questionnaire has a total of twenty questions. The scoring was done as following key (1 = strongly disagree 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree). Participants were asked to use only whole numbers. The questions 7, 13, and 17 were reversed and hence scored accordingly.

Table 1: Contents of the training sessions

Session I
Initially, a brief introduction about the objectives of the training program was given. Following this, a brief "overview of the pharmacovigilance program in Nepal" was discussed. Then, the community pharmacy practitioners were asked about their experiences regarding ADRs. Each candidate answered according to his/her experience
During the training period, candidates were found to be aware of abuse and misuse of drugs. Several queries related to drug use and ADRs were asked by the community pharmacy practitioners. Some of the questions asked were "Which gender is more predispose for ADRs?" "Is there any side effect due to Ayurvedic preparations?" "How can one document ADRs?" and "Should one report ADRs to regional center or national center?"
The community pharmacy practitioners were also given the guide "pharmacovigilance in Nepal: A guide for healthcare professionals"[12] as the training materials. The facilitators helped them briefly to understand the contents of the booklet
Session II
The main focus of this session was to collect the feedback from the community pharmacy practitioners on their experiences with ADR reporting after the initial training
During the discussion, several queries/comments were raised by them. Some of them included "simple drug information sources on ADR-related information should be provided by the regional pharmacovigilance center," "training programs can be extended to the healthcare professionals belonging to government sector and also there is a need to extend the training to more community pharmacy practitioners"
During this session, they were also provided with more information on ADRs and predisposing factors for ADRs
Session III
The main aim of this session was to introduce community pharmacy practitioners with the causes of ADRs, their management, and strategies to minimize them in future
Before starting the session, the pharmacists were introduced with the activities of drug information and pharmacovigilance center in MTH
They were also told the proceedings of ADR reports after they report it to pharmacovigilance center. Following this, a presentation was given related to the cause of ADRs, its management and the ways to prevent them which are more important for the community pharmacy practitioners

ADRs=Adverse drug reactions, MTH=Manipal teaching hospital

Data analysis

The filled feedback questionnaires were collected by the researchers, and the data were entered in Microsoft Excel spreadsheet and were analyzed. The SPSS version 12 was used to carry out the descriptive statistics. The feedback scores obtained by the respondents were compared with their demographic profile such as sex, age, and educational qualifications. Normality test was conducted. Mann–Whitney U-test was used for comparing the scores of the subgroups with "two groups" and Kruskal–Wallis test for the subgroups with more than two groups. $P < 0.05$ was considered statistically significant.

RESULTS

Of the total 30 pharmacists, only 25 of them completed the three training sessions. The responses from 25 of them were obtained and analyzed as per the study objectives.

Demography details of the participants and the association with the scores

There was no significant difference between the feedback scores and the various demographic variables. The details are listed in Table 2.

Feedback of the participants

The overall median (Interquartile range) of the responses was 79 (73.5–81.0). The median (interquartile range) of the individual statements is mentioned in Table 3.

DISCUSSION

Our study was successful in evaluating the feedback of the community pharmacists on pharmacovigilance training provided by us. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.[13] Drug retailers in Nepal are often the first and the only source of health care outside the home. The retail pharmacies frequently serve as the public's first point of contact with the health-care system.[11] Due to various reasons, the qualified doctors do not want to set up their practice in rural Nepal. Hence, the role of community pharmacists in the health-care system is, of Nepal, very important.

Authors from many countries have clearly documented the role of community pharmacists in pharmacovigilance programs.[14-17] Although their role is immense, studies from worldwide show a minimum involvement of community pharmacists in pharmacovigilance programs.

In the present study, the participants agreed that the program made them aware of the concept of pharmacovigilance. Studies from Iran[6] and Turkey[7] documented that the community pharmacists have a poor awareness on the existing pharmacovigilance program in their country.

Our training program emphasized the safety profile of over-the-counter (OTC) medications. Many times,

Table 2: Interrelation of the scores with the demographic information (*n*=25)

Demographic parameters	Median score (IQR)	*P*
Sex distribution (*n*)		
Male (18)	79.0 (73.0-84.0)	0.657
Female (7)	78.5 (73.7-81.0)	
Age distribution (*n*)		
Up to 20 (1)	90.0 (90.0-90.0)	0.175
21-30 (8)	80.5 (72.5-83.7)	
31-40 (14)	78.0 (73.7-79.5)	
>40 (2)	75.5 (72.079.0)	
Educational qualifications (*n*)		
Pharmacy (3)	80.0 (70.0-85.0)	0.919
Nursing (2)	79.5 (78.0-81.0)	
CMA (12)	80.5 (73.2-83.0)	
Others (8)	77.5 (73.5-79.0)	
Length of experience in community pharmacy, year (*n*)		
<1 (8)	77.5 (71.0-83.7)	0.929
1-5 (14)	78.5 (76.0-80.2)	
>5 (3)	81.0 (73.0-81.0)	

CMA=Community medical assistant, IQR=Interquartile range

Table 3: Feedback of the participants

Statements on the feedback of respondents	Median (IQR)
The sessions made me aware of the concept of pharmacovigilance	5 (4-5)
Pharmacovigilance is very much essential in developing countries like Nepal	5 (4-5)
ADRs are one of the major causes of death in the world	4 (4-5)
Herbal drugs also carry equal risk of causing ADRs as modern medicines	4 (2-4)
The pharmacovigilance program in Nepal is successful	3 (2-4)
The ADR reporting form should be in a single page	4 (3-5)
ADR reporting will take away my useful time	4 (2-5)
Pharmacovigilance should be made mandatory in Nepal	4 (3-5)
A graduate degree in pharmacy is the minimum qualification required to fill the ADR reporting forms	2 (1-3)
Nepal chemists and druggists association should be involved more on drug safety issues	4 (4-5)
The pharmaceutical industry should report ADRs	4 (3-5)
Pharmacovigilance should be included in the curriculum of pharmacists	4 (4-5)
OTC medications do not cause any ADR	4 (2-5)
Remuneration should be given to the community pharmacists to report ADRs	3 (3-4)
This session may be useful for me in my present job	4 (4-5)
A good number of ADRs can be prevented if appropriate measures are taken	5 (4-5)
ADR reporting will take away my pharmacy sales	4 (2-5)
The sessions were informative and interesting	4 (4-5)
The facilitators performed their roles effectively	4 (4-5)
I would welcome similar sessions in the future	5 (4-5)

The possible maximum and minimum scores for each statement were 5 and 1, respectively. A higher score suggests a positive feedback. In general, participants scored high except for two statements, i.e., numbers 5 and 9 which were neither agree nor disagree, and disagree, respectively.
OTC=Over-the-counter, ADRs=Adverse drug reactions

the community pharmacists believed that OTC medications are not harmful and are relatively safety.

It is well documented that OTC medications can cause severe ADRs.[18-20] A study from Western Nepal reported that self-medication and nondoctor prescribing are common in the Pokhara valley. In addition to allopathic drugs, herbal remedies were also commonly used for self-medication. Drugs, especially antimicrobials, were not taken for the proper duration. Education to help patients decide on the appropriateness of self-medication is required.[21] However, after the training programs, the community pharmacists agreed that OTC medications are also harmful.

The pharmacists wanted the Nepal Chemists and Druggists Association (NCDA) to be involved more on drug safety issues. The NCDA is an association for the community pharmacists in Nepal. It would be a nice approach to involve the association, so as to have a maximum coverage for the training program and to have a better impact.

In contrary to the popular belief that herbal medicines do not possess the risk of ADRs, the community pharmacists agreed that herbal drugs also carry equal risk of causing adverse drug reactions as modern medicines. The topography and climatic zones in Nepal vary from the plain land to the alpine grasslands, and thus offering a variety of herbs and medicinal nature, leading to the culture of self-medication.[22] Various adverse reactions can occur.[23] One publication has suggested that ADRs to herbal remedies are even more underreported than those to conventional OTC medicines.[24]

The community pharmacists agreed that a good number of adverse drug reactions could be prevented if appropriate measures are taken. The ultimate objective of a pharmacovigilance program is to prevent the occurrence of ADRs. Several strategies can be implemented by the community pharmacists to minimize the occurrence of an ADR. Some of them are providing patient counseling to the patients, education to the patients regarding the detection of early symptoms, caution before refilling the prescriptions, etc.

Limitations

Our study had a major limitation. The number of community pharmacists trained was only thirty and hence difficult to generalize the findings to the entire country.

CONCLUSIONS

Overall, the participants liked the sessions and they were interested in participating similar sessions. Training more and more, community pharmacists on pharmacovigilance are very much essential in Nepal, so as to improve medicine safety in the community. The regional pharmacovigilance centers in the country should take the responsibility in training the community pharmacists of the region toward drug safety. Since underreporting is a major limitation with pharmacovigilance programs, involving community pharmacists actively can plan an important role in narrowing the gap associated with underreporting.

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Conflicts of interest

There are no conflicts of interest.

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Appendix

APPENDIX 1

Learning sessions on pharmacovigilance – Community pharmacist feedback

Name:
Age:
Gender: Male/Female
Professional qualification:
Pharmacy Name:
Date:
Length of experience:
Location of the Pharmacy:

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

- The sessions made me aware of the concept of pharmacovigilance
- Pharmacovigilance is very much essential in developing countries like Nepal
- Adverse drug reactions are one of the major causes of death in the world
- Herbal drugs also carry equal risk of causing adverse drug reactions as modern medicines
- The pharmacovigilance program in Nepal is successful
- The ADR reporting form should be in a single page
- Adverse drug reaction (ADR) reporting will take away my useful time
- Pharmacovigilance should be made mandatory in Nepal
- A graduate degree in pharmacy is the minimum qualification required to fill the ADR reporting forms
- Nepal Chemists and Druggists Association should be involved more on drug safety issues
- The pharmaceutical industry should report adverse drug reactions
- Pharmacovigilance should be included in the curriculum of Pharmacists
- Over-the-counter medications do not cause any ADR
- Remuneration should be given to the community pharmacists to report ADRs
- This session may be useful for me in my present job
- A good number of adverse drug reactions can be prevented if appropriate measures are taken
- ADR reporting will take away my pharmacy sales
- The sessions were informative and interesting
- The facilitators performed their roles effectively
- I would welcome similar sessions in the future.

Any other comments (Please use back of the sheet).

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