

# An Evaluation of Knowledge and Perception of Pharmacy Students toward Pharmacovigilance and Adverse Drug Event Reporting

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## Abstract

To evaluate the knowledge and perception about pharmacovigilance (PV) and adverse drug event (ADE) reporting among undergraduate pharmacy students. A cross-sectional study was conducted in the month of August 2013 using a questionnaire form given to B. Pharmacy students of V<sup>th</sup> semester onwards including five different pharmacy colleges of Anand district in Gujarat. Before starting the study, approval from Institutional Ethics Committee was taken. Participants were explained properly about the study and confidentiality was maintained at all levels. A total of 300 filled forms were collected from the participants. Of these 142 (47%) were from V<sup>th</sup> semester, remaining were from VII<sup>th</sup> semester. One hundred and thirty-six students (45%) were aware of PV. One hundred and twenty-four students (41%) replied that pharmacist is qualified to report ADEs. One hundred seventy-six students (59%) replied that all types of ADEs should be reported. Two hundred and four students (68%) advocated compulsory ADE reporting. Two hundred and eighty-six students (95%) said that ADE reporting is either very important or important. Only 58 students (19%) knew about PV program of India. Pharmacists can play a crucial role in both ADE reporting and PV activities. The knowledge about PV and ADE reporting is found quite low among pharmacy students in our study. Hence, they need to be well trained on how to recognize, prevent, and report ADE as they are future pharmacy practitioners.

**Key words:** Pharmacovigilance, pharmacy students, adverse drug event

## INTRODUCTION

There are no really safe biologically active drugs. There are only safe physicians - Harold A. Kaminetzky (1963).<sup>[1]</sup>

Complete drug safety remains elusive with no consensus in the terms of safety and method of assessment. Following-up the safety of marketed medicines for clinical use in large populations becomes essential, and the science pertaining to this is known as pharmacovigilance (PV). Cost of drug-related morbidity and mortality exceeded \$177.4 billion in 2000.<sup>[2]</sup>

Adverse drug events (ADEs) are associated with significant morbidity and mortality, and are an important cause of hospitalization.<sup>[3]</sup>

In India, a huge populous country, people have easy access to drugs. They approach local community pharmacists for

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medicines without consulting a physician for many illnesses as it is convenient, less time-consuming and economical for them. Survey by market research firm IMS health 29% of medicine sales in India performed without prescription.<sup>[4]</sup>

There are thousands of community pharmacies which operate as a retailer or as a part of corporate chains. Pharmacists provide management of medication therapy through the use of pharmaceutical care. The early detection of ADE as well as monitoring the effectiveness of medicines is also an important responsibility of the pharmacist. The pharmacist is a source of both information and critical evaluation of drug information. The pharmacist's expertise is crucial to the application of the safety profile of a medicine to the needs of a particular patient.

Pharmacists can play a pivotal role in both ADE reporting and PV activities.<sup>[5]</sup> Pharmacists are more likely to detect ADEs than are other healthcare professionals, either in the hospital or community setting.<sup>[6]</sup> In the hospital setting, pharmacists can play an important role in ADE reporting because they have access to the information necessary to report ADEs.<sup>[7,8]</sup> Because they may be the first to be contacted by patients for information about ADEs, community pharmacists are an important source of ADE reports.

Although previous studies indicated that pharmacists are pivotal players in ADE monitoring and reporting, most pharmacists are unaware or not knowledgeable about the guidelines used by their respective countries' drug regulatory bodies responsible for assessing ADEs.<sup>[9,10]</sup>

It is the need of the hour to train pharmacy students on how to recognize, prevent, and report ADE as they will turn into pharmacy practitioners in the future. Few studies have been conducted to evaluate pharmacy students' knowledge and attitudes about ADE reporting.<sup>[11-13]</sup>

The present study was conducted to evaluate the knowledge and perception of undergraduate pharmacy students of Anand district in Gujarat about PV and ADEs reporting.

## MATERIALS AND METHODS

This was a cross-sectional, questionnaire-based study, conducted during the month of August 2013. The initial draft of the survey questionnaire was developed using information from the literature about ADE reporting among healthcare professionals.<sup>[14-16]</sup> It was pretested on 25 pharmacy students and based upon their responses it was modified accordingly. Final version of the questionnaire form consisted of 12 questions-both open and close-ended questions with 2-6 options in each.

B. Pharmacy students of V<sup>th</sup> semester onwards from five different pharmacy colleges of Anand district were selected.

These colleges had 480 students at that time, but not all of them were present at the time when the study was carried out. Thus, in our study, questionnaires were distributed randomly among 382 pharmacy students. Eighty-two students were excluded from the study analysis as these students either failed to return the questionnaire or did not complete it. Therefore, in total, 300 questionnaires were analyzed (response rate = 78.5%). Before starting the study, approval from Institutional Ethics Committee was taken. Permission to approach the students and to conduct the study had been obtained from the respective head of institutions of the pharmacy college. Pharmacy colleges selected for this study were AR College of Pharmacy, Ipcowala College of Pharmacy, Shivam Pharmacy College, Anand Pharmacy College and Sardar Patel College of Pharmacy. Participants were explained properly about the research study. They were encouraged to attempt questions only what is known to them and avoid cross-consultations among themselves and other references. They were asked to mark the option/s which they felt was/were the best. They were kept free to refuse to complete the questionnaire or any particular question(s). Anonymity and confidentiality were ensured. Consent for participation was implied by the completion. Data entry was done in Microsoft Office Excel 98, and appropriate descriptive analysis was done.

## RESULTS

A total of 300 filled forms were collected from the participants. All of the students completed and returned the questionnaire. Of these 142 (47%) were from V<sup>th</sup> semester, remaining were from VII<sup>th</sup> semester. One hundred and thirty-six students (45%) were aware of PV. They defined PV correctly. One hundred and twenty-four students (41%) replied that only pharmacist is qualified to report ADEs. More than 20% replied that both doctors and pharmacist are qualified to report ADEs. Less than ten percent (9% and 5% respectively) responded that only doctors and nursing staff are eligible to report ADEs. One percent student said that self-reporting of ADEs by patients is allowable. One hundred seventy-six students (59%) said that all types of ADEs should be reported while 12% students said that ADE only to new drugs should be reported. Eleven percent students were in favor of reporting of only serious ADEs. Three percent and 6% students said that ADEs of herbal drugs and unknown ADEs of old drugs should be reported. Two hundred and four students (68%) believed ADE reporting is compulsory while 25% said it was voluntary. Two percent students replied that reporters are remunerated on ADE reporting. Two hundred and eighty-six students (95%) said that ADE reporting is either very important or important. In the study, it was found that only 13% students had been trained on how to report ADE. Only 58 students (19%) knew about PV program of India (PvPI) run by Government of India. One hundred and twenty-nine students (43%) were aware at least one drug that has been banned in India due to ADRs. One hundred

**Table 1: Statements about PV**

Statement	Yes (%)	No (%)
Defined PV correctly	45.33	54.67
Pharmacists can report ADE	61.63	38.37
All types of ADEs should be reported	58.80	41.20
ADE reporting is compulsory	68.0	32.00
Explore new indication of established drug is also an objective of PV	56.30	43.70
Do you know PvPI run by Government of India	19.33	80.67
Have you been trained on how to report ADE	13.3	86.70

ADE: Adverse drug event, PV: Pharmacovigilance, PvPI: Pharmacovigilance Program of India

and seventy students (56%) students knew that explore new indication of established drug is also an objective of PV [Table 1].

## DISCUSSION

B. Pharmacy students of V<sup>th</sup> semester onwards only were included for the study as PV is a part of IV<sup>th</sup> semester syllabus of B. Pharmacy students. Even then, level of knowledge about PV of study participants was not meeting the expectation.

In our study, 45% students were able to define PV correctly. This finding was in consonance to study done by Sharma *et al.*<sup>[17]</sup> in Punjab in which 44% responded correctly. PV is a part of IV<sup>th</sup> semester syllabus of B. pharmacy students, even though such a low proportion of students knowing the definition of PV is surprising. In our study, it was found that 50% pharmacy students were aware of PvPI, which is the Government of India initiative to report ADE. Knowledge about this parameter in the study done by Sharma *et al.*<sup>[17]</sup> found slightly higher (56%). In our study, 13% replied that they have been trained on how to report ADEs. This may be the reason only 12% of pharmacist ever reported an ADE in a study conducted in south India<sup>[18]</sup> while study done by Elkalmi *et al.* in Malaysia<sup>[19]</sup> 87% said they have been trained about ADE reporting. Thus, it is necessary for the adverse drug reaction reporting committee to increase the knowledge and create awareness regarding adverse drug reaction reporting among other health care professionals along with physicians.<sup>[17]</sup> In our study, 62% replied that pharmacist are qualified to report ADE while this figure was found 90% in the study done in Malaysia.<sup>[19]</sup>

The findings of this study should be interpreted in the light of its limitations. Because this study was conducted in only five pharmacy colleges in Gujarat that were accessible to the researcher, the findings may not be confidently extrapolated to the pharmacy students in other colleges. There are issues that need further investigation. More empirical research

should be conducted to confirm the study findings using a different population studying in other states.

## CONCLUSION

Our study strongly suggests that there is a great need of increasing knowledge and creating awareness among pharmacy students so that they can be able to identify the type of ADE to be reported. Considering pharmacists as an important member of health care team and imparting proper education will help the community to overcome the incidences of ADE.

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