A Survey on Knowledge, Attitude and Practice of Community Pharmacists and Pharmacy Students on Pharmacovigilance

Sunanda Nandikol[*1], Pradeepti K[1], Madura Datar[2]

1. *Assistant Professor, BLDEA's SSM College of Pharmacy & Research Centre, Vijayapura*
2. *M-Pharma Student, BLDEA's SSM College of Pharmacy & Research Centre, Vijayapura*

Corresponding Author: Sunanda Nandikol, Assistant Professor, Department of Pharmacy Practice, BLDEA's SSM College of Pharmacy & Research Centre, Vijayapura
Email.id:sunanda.nandikol@gmail.com

Abstract:

Adverse drug reaction (ADR) reporting is the foundation of any PV system and the timely identification and reporting of ADRs to the regional or national drug-regulating authorities are critical. WHO defines ADRs as 'a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function .The main objective of the study was to assess to evaluate the knowledge, attitudes and practice (KAP) toward adverse drug reactions (ADRs) reporting among community pharmacists (CPs) in Vijayapura & also to assess pharmacy students' Pharm-D Interns. Knowledge and perceptions about pharmacovigilance and reporting of adverse drug reactions (ADRs) at Pharmacy College and pharmacist role in pharmacovigilance and ADR reporting. A total of 162 subjects were enrolled in the study, among them 87 were male subjects and 75 were female subjects, Out of 162 Participants 30 were in the age group of 21-22years, 40 were in the age group of 22-23 years , 39 were in the age group of 23-24 Years and 24 participants were in the age group of 24-25 years followed by 29 members were in the age group of above 25 years, A total of 162 Subjects were participated in the study, among them 66 were B Pharm students, 18 were M.Pharm students, 49 were Pharm-D students and 29 were community pharmacists, A total of 162 participants were enrolled in the study, the standard deviation of B Pharm M.Pharm, Pharm-D, Community Pharmacists on knowledge is 3.75, 2.81, 4.73and 2.18 respectively& the standard deviation of B Pharm M.Pharm, Pharm-D, Community Pharmacists on attitude is 0.84, 1.06, 0.8, and 1.61respectively& the standard deviation of B Pharm M.Pharm, Pharm-D, and Community Pharmacists on practice is0.7, 1.12, 1.23 and 1.18.Our study concluded that Periodic trainings should be conducted by drug safety authorities to update their knowledge on ADR and its reporting. (Pharmacovigilance).

Keywords: *Knowledge, Attitude, Practice, Pharmacovigilance, PharmD*

Introduction

The World Health Organization (WHO) defines pharmacovigilance (PV) as ‘‘the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem”[1]. PV aims at enhancing patient safety by assessing the risk-benefit profile of medicines.Adverse drug reaction (ADR) reporting is the foundation of any PV system and the timely identification and reporting of ADRs to the regional or national drug-regulating authorities are critical. WHO defines ADRs as ‘a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.[1]ADRs have increasingly drawn worldwide attention accounting for significant morbidity and mortality and associated with increased health costs.[2]Medications, regardless of its therapeutic benefits have caused and will continue to cause harm to the life of humans. Adverse Drug Reactions are considered as one the leading causes of mortality and morbidity.[3]In order to minimize or prevent harm to patients arising from their drugs, it is essential to monitor ADRs, to detect ADRs before they are clinically manifested.[4] [4]Adverse drug Reactions ARE Classified in to the following types.

- Augmented**:** Most common and major cause of ADR. It is related to the pharmacological action of drug. It is dose dependent and the level of severity increases with increase in dose. Its occurrence can be limited by slow introduction of low dosages. Predictable by the pharmacological mechanisms.
  E.g.dry mouth with tricyclic antidepressants and respiratory depression with opioids.
  Bizarre: It is rare, not related to pharmacologic action of drug, also unrelated to the dose, unpredictable, mechanisms are unknown. It can be fatal resulting in high mortality.
  E.g. aplastic anemia caused by chloramphenicol, neuroleptic malignant hyperthermia caused by some general anesthetics and antipsychotics. Management includes withholding the drug avoidance in future.
- Dose and Time Related**:** Occurs as a result of continuous drug use i.e. cumulative dose. It is uncommon, unexpected & unpredictable,
  E.g. tardive dyskinesia by antipsychotics, dementia by anticholinergic medications, osteonecrosis of the jaw with bisphosphonates
- Time Related**:** Delayed occurrence of ADRs, Occurs or becomes apparent sometime after use of the drug even after the cessation of treatment
  E.g., corneal opacities after thioridazine, ophthalmopathy after chloroquine, leucopenia with lomustine.
- Withdrawal: Withdrawal reactions which are uncommon and occur soon after the withdrawal. Management includes reintroducing the drug and withdrawing it slowly. Occurs typically with the depressant drugs
  E.g., hypertension and restlessness in opiate abstainer; insomnia and anxiety with benzodiazapenes.
- Failure of Therapy**:** It is common in occurrence, related to dose of drug and interactions between the drugs are the major reason of this type of ADR. Management includes consideration of simultaneous drug therapy [5]

Role of Pharmacist in Detecting, Assessing and Reporting ADR's:

Pharmacist plays an important role in field of medicinal drugs including safety of drugs, i.e., Pharmacovigilance. The occurrence of Adverse Drug Reactions (ADRs) through any drug is very frequent now days. In such situation pharmacist seems to act as back bone who educate patients regarding benefit risk ratio of prescribed medicines, make people more aware towards various ADRs associated with drugs and reporting of that ADRs to competent authority.

Pharmacist ensure an accurate supply of appropriate products, their professional activities also cover counseling of patients at the time of dispensing of prescription and non-prescription drugs, to patients and the general public, and participate in health-promotion programme. They maintain links with other health professionals in primary health care.

The role of pharmacist in the reporting ADRs is not appreciated globally on contrary India is among those countries that widely accepts and promotes ADRs reporting through pharmacist. As stated in literature many countries are accepting ADR reporting from pharmacist yet very few offend the same. Contribution is bit high in countries like Canada, USA, Australia, Netherland, Spain and Japan. After looking into this pharmacist in the country will gain more encouragement to report ADRs and can lead to better patient care.

In today's era, the pattern has changed even different categories of health professional are working out on ADR reporting. Similarly the role of pharmacist has also changed from merely the dispensing of drugs to health care and patient safety, looking into Indian Scenario, reports from pharmacist are acceptable. Individual Case Safety Reports (ICSRs) are entered manually by TAs placed at AMCs into VigiFlow TM along with mandatory field.

1. Pharmacist as a reporter of ADR: The foremost step in detection of ADR is collection of data. Pharmacists can provide early detection of ADRs and other drug related problems by ward visits and interacting with patients. Pharmacist is responsible to report any suspicion of drug unexpectedly causing a risk situation for a patient. TAs as pharmacist with HCPs plays an important role to ensure safety of drugs by identifying and investigating certain patient subgroups with exceptional sensitivities and monitoring the patients prescribed with drugs highly susceptible to cause ADRs. The collected ADRs report with all relevant data are entered into VigiFlow TM for completeness and sent to NCC for further quality review.

2. Pharmacist in ADR assessment: Pharmacist's investigate every suspected ADRs for its nature, probability, severity, identification of the co-morbidities, past and present illness. Also review the reported ADRs to differentiate between suspected ADRs and medication error, alongside develop risk reduction strategies and helps to reduce the risk of ADRs through detecting, reporting and assessing suspected ADRs. They play key role in determining the probability that the event is drug related, categorize severity, track ADRs and incidence. They monitor and document the suspected ADRs and does critical evaluation of drug information for further reporting of the suspected ADRs to the NCC-PvPI.

3. Pharmacist in ADR prevention: Pharmacist keeps the track record and monitors the patients who are at greater risk of developing ADRs. They keep the Follow up of patients to assess the outcome of the reaction, its management and counsel patients while they are discharged. Pharmacists play an integral role in educating patients on various aspects of medication use, including safety as many patients are not aware of risk benefit information

about their medications. Timely conferences and training sessions are organized for the awareness and betterment of public health.[14]

Pharmacists should exert leadership in the development, maintenance, and ongoing evaluation of ADR programs. They should obtain formal endorsement or approval of such programs through appropriate committees (e.g., a pharmacy and therapeutics committee and the executive committee of the medical staff) and the organization's administration. The pharmacist should facilitate:

1. Analysis of each reported ADR,
2. Identification of drugs and patients at high risk for being involved in ADRs,
3. The development of policies and procedures for the ADR-monitoring and reporting program,
4. A description of the responsibilities and interactions of pharmacists, physicians, nurses, risk managers, and other health professionals in the ADR program,
5. Use of the ADR program for educational purposes,
6. Development, maintenance, and evaluation of ADR records within the organization,
7. The organizational dissemination and use of information obtained through the ADR program,
8. Reporting of serious ADRs to the FDA or the manufacturer (or both), and
9. Publication and presentation of important ADRs to the medical community.

Direct patient care roles for pharmacists should include patient counselling on ADRs, identification and documentation in the patient's medical record of high-risk patients, monitoring to ensure that serum drug concentrations remain within acceptable therapeutic ranges, and adjusting doses in appropriate patients (e.g., patients with impaired renal or hepatic function).

Thus, pharmacists are considered as backbone of healthcare system and have an important responsibility in monitoring, detecting and preventing ADRs.

Benefits of ADR Reporting

An ongoing ADR-monitoring and reporting program can provide benefits to the organization, pharmacists, other health care professionals, and patients. These benefits include (but are not limited to) the following:

1. Providing an indirect measure of the quality of pharmaceutical care through identification of preventable ADRs and anticipatory surveillance for high-risk drugs or patients.
2. Complementing organizational risk-management activities and efforts to minimize liability.
3. Assessing the safety of drug therapies, especially recently approved drugs.
4. Measuring ADR incidence.
5. Educating health care professionals and patients about drug effects and increasing their level of awareness regarding ADRs.
6. Providing quality-assurance screening findings for use in drug-use evaluation programs.
7. Measuring the economic impact of ADR prevention as manifested through reduced hospitalization, optimal and economical drug use, and minimized organizational liability.[27]

The importance of reporting ADRs cannot be understated. Studies have shown that optimizing knowledge, attitude and practices (KAP) with regard to PV is important in formulating strategies to encourage ADR reporting. this context, there is an extensive body of literature examining KAP toward ADR reporting among pharmacists working in hospitals or

community, and exploring causes of underreporting, which shows that lack of clinical knowledge and unfamiliarity of the reporting system were major discouraging factors for reporting ADRs.Therefore this study was to carried out to know the knowledge,attitude,and practice of adverse drug reaction reporting among the pharmacy students and the community pharmacists in the Vijayapura city.

Methodology:

Pharmacy Students

The Three months prospective Knowledge Attitude Practice (KAP) Questionnaire based study was carried out in the pharmacy college and community pharmacists of Vijayapura. A total of 162 Subjects were participated in the study, among them out of which 66 were b pharm students and 18 were M.Pharm students and 49 were Pharm-D students and 29 were community pharmacists.

The study criteria included students of M.Pharmacy (Pharmaceutics, Pharmacology & Analysis Departments), Pharm.D (Doctor of Pharmacy) both regular (IV, V, and VI) and post baccalaureate (PB), and final year students of B.Pharmacy. Total of 20 survey items, classified into four groups, were developed. The first part consisted of two demographic questions related to age and gender. In the second part, items were pooled under the heading of 'knowledge of participants regarding ADR and pharmacovigilance. This section contains 12 questions which needs to be answered by students. The third part includes four items each designed to evaluate the pharmacy students' attitude. The forth part of questionnaire consist of four items to assess the participants' practice (practice related questions designed to be fit for students).The questionnaire was validated by three professors of clinical pharmacy practice department from BLDE Pharmacy college.

Community Pharmacists:

The study was a self-administered, cross-sectional, questionnaire-based survey conducted on a random sample of registered pharmacists around Vijayapura city. We created the Questionnaires consist of 15 survey items, classified in to four groups, the first part consisted of demographic questions: age and gender, Education, Profession and Professional Experience. The second part items were pooled under the heading of 'knowledge of participants regarding ADR and pharmacovigilance. The third part includes five items each designed to evaluate the community pharmacist attitude. The forth part of questionnaire consist of 5 questions to assess the pharmacists' practice towards the ADR Reporting

Inclusion Criteria:

The study criteria included students of M.Pharmacy (Pharmaceutics, Pharmacology & Analysis Departments), Pharm.D (Doctor of Pharmacy) both regular (IV, V, and VI) and post baccalaureate (PB), and final year students of B.Pharmacy and community pharmacists and The registered licensed Cps working in vijayapura city 2019 males and females who were willing to participate were included in the study.

Exclusion Criteria:

Any study participants who voluntarily refuse to participate in the study were excluded. First and second and third year pharmacy students were excluded from the study as they have no exposure to pharmacovigilance and adverse drug reaction and Community pharmacists who

were not willing to participate, on leave during the study and unlicensed or unregistered were excluded from the study.

Study design: This was a prospective and questionnaire based survey method.

Source of data collection: Consulting the community pharmacists, informed consent form (ICF), KAP questionnaire on ADR.

Data Collection

Students were included in the study based on their consent, an anonymous survey delivered by hand to each student by the investigator.. No additional assistance or explanation was provided by the team on answering the questions. The survey included consent to participate in the study on a separate front sheet. Time to complete the survey was determined by the respondents, the interviewing team was instructed to ensure the completeness of all survey questions by the participating pharmacists.

Each pharmacist was selected from every pharmacy and the selection was done at the same time of the visit by inviting the available licensed community pharmacist. Pharmacists who were willing to be enrolled in this study were asked to sign informed consent forms. No attempt was made to prompt the respondents by suggesting answers directly.

Results

1. Gender wise distribution

A total of 162 subjects were enrolled in the study, among them 87 were male subjects and 75 were female subjects.

Table No: 1 Gender wise distribution of Participants

Gender	No. of Participants
Male	87
Female	75

2. Age wise distribution

Out of 162 Participants 30 were in the age group of 21-22years, 40 were in the age group of 22-23 years , 39 were in the age group of 23-24 Years and 24 participants were in the age group of 24-25 years followed by 29 members were in the age group of above 25 years.

Table No: 2 Age wise distribution of Participants

Age (Years)	Number of Participants
21-22	30
22-23	40
23-24	39
24-25	24
Above 25	29

3. Education Details

A total of 162 Subjects were participated in the study, among them 66 were B Pharm students, 18 were M.Pharm students, 49 were Pharm-D students and 29 were community pharmacists.

Table No: 3 Education Details of the Participants

Education Details	Number of Participants
B Pharm	66
M.Pharm	18
Pharm-D	49
community pharmacists	29

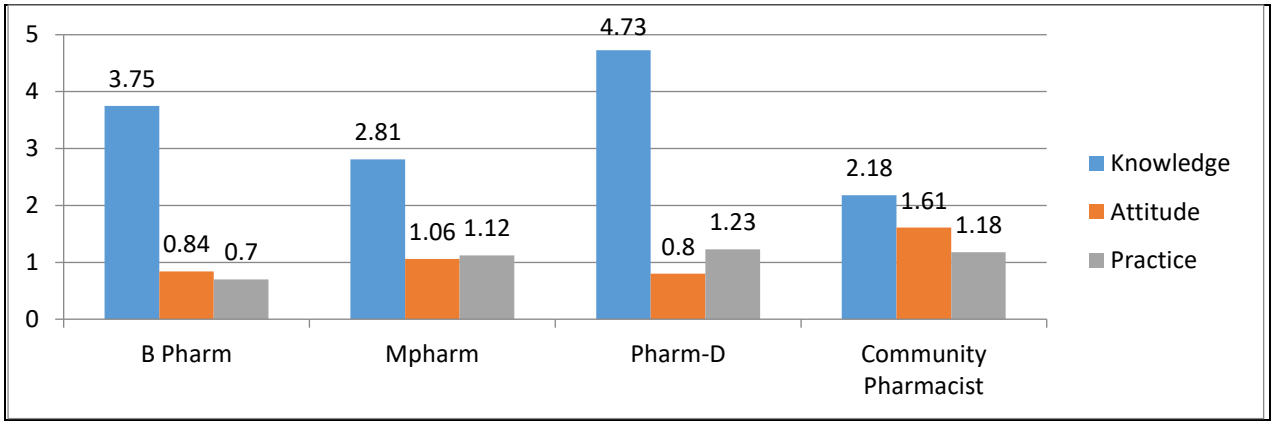
4. Comparison of KAP among Participants

A total of 162 participants were enrolled in the study, the standard deviation of B Pharm M.Pharm, Pharm-D, Community Pharmacists on knowledge is 3.75, 2.81, 4.73and 2.18 respectively& the standard deviation of B Pharm M.Pharm, Pharm-D, Community Pharmacists on attitude is 0.84, 1.06, 0.8, and 1.61respectively& the standard deviation of B Pharm M.Pharm, Pharm-D, and Community Pharmacists on practice is0.7, 1.12, 1.23 and 1.18.

Table No: 4 Standard deviation Comparison of KAP on Participants

Participants	Knowledge	Attitude	Practice
B Pharm	3.75	0.84	0.70
M.Pharm	2.81	1.06	1.12
Pharm-D	4.73	0.8	1.23
Community Pharmacists	2.18	1.61	1.18

Graph: 4 Standard deviation Comparison of KAP on Participants



Discussion

This is the primary study which evaluates the knowledge and perception of students and community pharmacists on pharmacovigilance and ADR reporting. In the present study, an overall response rate of 79.9% was recorded. The number of students who participated in this study was relatively small considering the number of students currently enrolled in college.

Therefore, these results may not necessarily be extrapolated to all students. This figure can be regarded as extremely high, especially when compared with those of other studies on the same topic carried out among pharmacy Students as well as community pharmacist's.[29] A total of 162 participants were enrolled in the study among them 87 were male subjects and 75 were female subjects as shown in (Table No:1) and 66 participants were B Pharm students, 18 were M.Pharm students , 49 were Pharm-D students and 29 were community Pharmacists.[30] as shown in (Table:2) 30 were in the age group of 21-22years, 40 were in the age group of 22-23 years , 39 were in the age group of 23-24 Years and 24 participants were in the age group of 24-25 years followed by 29 members were in the age group of above 25 years as shown in (Table;2)[30]

Based on educational details 66 were B Pharm students, 18 were M.Pharm students, 49 were Pharm-D students and 29 were community pharmacists as shown in (Table No:3)

Based on the survey it was observed that the participants in the study were evaluated for their knowledge, attitude and practice on Pharmacovigilance. When we evaluated their questionnaires we have observed that the standard deviation of B Pharm M.Pharm, Pharm-D, Community Pharmacists on Knowledge is 3.75, 2.81, 4.73and 2.18 respectively& the standard deviation of B Pharm M.Pharm, Pharm-D, Community Pharmacists on attitude is 0.84, 1.06, 0.8, and 1.61respectively& the standard deviation of B Pharm M.Pharm, Pharm-D, and Community Pharmacists on practice is0.7, 1.12, 1.23 and 1.18. According to this, there was a lack of awareness among Indian CPs on ADRs. They should be educated and trained on what to report, how to report, and where to report ADRs. CPs plays a major role in communicating, educating to the patients about the medication while selling or refilling. They have an important role in monitoring, detecting, and thereby preventing ADRs. It is appreciated if they contribute reporting to PvPI programme considering a huge number of pharmacists in India. In India, more studies are to be conducted to understand Indian CPs knowledge, attitude, practice, behavior, and barrier of pre- and post-education and awareness program. The same will be helpful to understand CPs nature of habit toward ADR reporting and to improve the educational tools.

The majority of students (67%) agreed that there is a need to teach and provide pharmacy students with information on pharmacovigilance and how to report ADRs. Meeting this need will require colleges to provide education and training programs on ADR reporting to prepare students for performing their responsibilities as healthcare providers.

Health care provider who receives more education and training on ADR reporting are more likely to report ADRs. The majority of students (80%) believed that serious and unexpected ADRs, including those that are neither fatal nor life threatening, must be reported. The responses to this statement were significantly associated with colleges ($P < 0.001$) and are consistent with the results of previous studies involving pharmacists and other healthcare professionals.[28]

Conclusion:

Our study shows that, commonly lack of knowledge towards pharmacovigilance aspects among pharmacists from Vijayapura city Karnataka. Overall the attitude and practice scores were low.

Our findings suggested the need for evidence based educational and managerial interventions regularly. The basic things like not knowing the location of the nearest ADR reporting centre and unawareness about National Pharmacovigilance Program of India, creates great space for drug safety authorities and regulatory agencies to step forward in direction to pharmacists as well as pharmacy students. It is necessary for pharmacy students to include adverse drug reaction reporting in their academic section to create awareness about pharmacovigilance programme. Attitude has been reported good compared to knowledge and practice, and importantly it should not be washed-off due to barriers while reporting ADRs. Implementing the pharmacovigilance education and training, effectively, into the pharmacy courses can provide boost to them, since majority of community pharmacy practice is running by pharmacy holders. Periodic trainings should be conducted by drug safety authorities to update their knowledge on ADR and its reporting. (Pharmacovigilance).

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