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KAP Towards Detecting, Monitoring, and Reporting ADR Among Pharmacy Students: A Cross-Sectional Study

K. Bharathi Priya[1], Anisha Joy[2], Stelphy Stephen[3], Riya Benny[4], Mobina Firozbakhsh[5]
[1,2,3,4,5]Department of Pharmacy Practice, C.L Baid Metha College of Pharmacy, The Tamil Nadu Dr. MGR Medical University, Chennai, Tamil Nadu, India – 600097
Email address: priyabharathi1409@gmail.com[1], anishajoy187@gmail.com[2], stelphystephen@gmail.com[3], riyabenny999@gmail.com[4], m.firozbakhsh@yahoo.com[5]

Abstract*— *Aim: *To assess the knowledge, attitude and practice towards detecting, monitoring, and reporting ADR among pharmacy students through online survey.* ***Methods:*** *Cross sectional study was carried out in pharmacy colleges through online survey in Kerala and Tamil Nadu for a period of 6 months. The data was collected through google forms. Students details were obtained from a specially designed google form contain name, age, gender, state, college, course of study, year of study and email id. The online survey form contains 21 KAP questions. All the response were documented in the google sheets and the response was analyzed using descriptive statistics.* ***Result:*** *A total of 385 pharmacy students participated in the study in which 60.25% were female and 39.74% were male. Most of the students were in between the age group of 22-33 years. A total of (17.9%) B Pharm, (13.7%) D Pharm, (14.2%) M Pharm, (54%) Pharm D students had participated in the study. The present study showed that pharmacy students had difficulty in reporting ADR, of which most of them had difficulty in deciding whether ADR occurred or not (41.81%).* ***Conclusion:*** *The study conclude that pharmacy students have favorable knowledge, attitude, and practice on ADR. Providing special training and educational programme may increase the KAP of the students towards ADRs.*

Keywords— *Adverse Drug Reaction; KAP; Pharmacy students.*

I. INTRODUCTION

The World health organization defines an adverse drug reaction (ADR) as any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, therapy of disease and for the modification of physiological function.[1] Pharmacovigilance program is mandatory to detect and prevent ADR. It is important for every health-care professional to know the importance of ADR reporting as to how, where, and when to report an ADR.[2]

The first practical international co-operation in drug monitoring was established in 1968. In 1960 it was discovered that ingesting thalidomide in pregnant women caused limb deformities in babies. This incident became the modern starting point of a science focusing on patient problems due to medicinal use.[3]

In a recent analysis of 25 different studies of admissions to internal medicine department, 4.2–6.0% of admissions were due to adverse reactions, with a median of 5.8%. A much-cited study from the USA demonstrated that the incidence of serious adverse drug reactions among hospitalized patients was 6.7%, and in 0.3% the outcome was fatal. This makes ADRs between the 4th and 6th leading causes of death in the USA.

A detailed study from the UK showed that 6.5% of hospital admissions were related to ADRs. These patients accounted for 4% of the hospital bed capacity. Approximately 70% of the reaction were considered avoidable. The most commonly implicated medicines were NSAIDs, diuretics, warfarin and ACE inhibitors.[1]

During the development of new medicines, their safety is tested in animal models. A great deal of risk information is obtained from such tests, such as the level of acute toxicity, which organ will be affected of toxicity and the dose dependency will lead to tissue injuries.

Clinical trial programmes are designed to maximize the chance of demonstrating the therapeutic effect in relation to a control group. Children and the elderly people are normally excluded from the studies. For cost reasons, clinical trials often have a very short duration, which means they cannot generate information on adverse effects on long term or delayed type of ADR.[1]

For a report to be valid, four items of information are required: an identifiable patient, a reaction, a suspected medicinal product and an identifiable reporter. ADRs occurring as a result of medication errors reported to the National Reporting and Learning System (NRLS) will automatically be reported to the Yellow Card Scheme.[4]

One of the major deficiencies of spontaneous reporting programmes is failure of health professionals to identify and report drug – related injuries. It has been estimated that even in countries with a long tradition of adverse reaction reporting, less than 10% of drugs – related unwanted events are notified to pharmacovigilance centres. The under – reporting could be compensated for if it was uniform.[3] Hence, there is a need of constant training on ADR monitoring and reporting to improve the knowledge, attitude and practice of pharmacy students.

Pharmacists have access to the data required to report ADRs in the hospital context, hence they play a significant role in ADR reporting. Because they may be the first to be

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contacted by patients for information about ADRs, community pharmacists are an important source of ADR reports. Involvement of pharmacy students in ADR reporting has led to a significant increase in the number of documented ADRs.[5]

A large proportion of ADRs can be prevented by improved drug prescribing, administration and through consistent and prompt recording and reporting. As future pharmacy practitioners, pharmacy students need to be well educated and trained on how to document, distinguish, and report ADRs.[6]

The incorrect prescribing and misuse account for a substantial increase in adverse drug reactions (ADRs), which are the principal reasons for unplanned hospitalization, morbidity, fatality, and raised health-care expenses worldwide. Therefore, for assuring the patient's well-being, this is a call of the hour to recognize ADRs and if practicable prevent them, at a sensible cost.[7]

An important aspect of clinical practice is maintaining and monitoring pharmacological efficacy and safety. Thus, pharmacovigilance is an essential clinical discipline to ensure the appropriate use of medicines and patient safety, worldwide.[8]

Pharmacists are the healthcare professionals who patients can reach out to the most, so with the help of SR initiatives, patients could further be protected from medication-related harm. Appropriate counseling from pharmacists could also help patients deal with any negative outcomes they may have experienced. [9]

With adequate knowledge and practices of pharmacovigilance and ADR reporting, there will be not only increasing reporting of ADR, but also reducing incidence rate as well as health care cost of patient and also banned harmful drug to the patient in actual clinical practices.[10]

Due to the many study types, populations, frequency measurements, and categorization systems, it is highly challenging to estimate the incidence of ADR caused by DDI. Patients with polypharmacy are particularly at risk of these events.[11]

In order to prevent any unintended ADRs, HCPs can play a variety of roles by thoroughly analyzing the entire patient history, including the history of drug allergies and drug-drug interactions. Additionally, a pharmacovigilance strategy that can be used to minimize ADRs is reporting ADRs to the responsible office at their hospital or the regulatory authority because doing so can raise HCPs' awareness of reactions, which could lead to the avoidance of specific drugs, reducing the harm associated with reactions to those drugs.[12]

When a therapy program is implemented, good management also necessitates being aware of potential negative effects. Utilizing premedication techniques as directed can frequently reduce the severity of an adverse reaction Desensitization is essential for achieving the drugs with graduated dosage schedules and maintained through continued administration of the drug. Hence, this study was conducted with the objective to evaluate the KAP toward ADR among pharmacy students. Identification to avoid inadvertent exposure to agents that have caused immunologic reactions in the past is essential.[13]

II. METHODOLOGY

Study Design

The study was a cross – sectional questionnaire based study which was carried out on pharmacy students from various pharmacy colleges.

Study Type

The study was conducted through online survey.

Study Population

The study was conducted in pharmacy students to assess their knowledge, attitude and practice on adverse drug reaction.

Study Site

The study was conducted in the pharmacy colleges.

Sample Size

An estimated 385 people made up the sample.

Study Period

The study duration was for 6 months.

Inclusion and Exclusion criteria

D. Pharm (2nd year), B. Pharm (3rd year, 4th year), M. Pharm and Pharm. D (2nd year to 6th year) was included in the study. D. Pharm (1st year), B. Pharm (1st year, 2nd year) and Pharm. D (1st year) was excluded from the study.

Development of Questionnaire

The KAP questionnaire towards detecting, monitoring and reporting of ADR was generated from literature and adapted from the previous studies. The online survey form has 5 sections in which the first section contained the consent form, the second section contain the demographic details, third section contain 7 Knowledge-based questions, fourth section contain 5 Attitude- based questions, fifth section contain 8 practice- based questions. The questionnaire consists of 20 close ended questions. The Knowledge based question consists of multiple choice questions, the attitude and practice based question consisted of objective type.

Data Analysis

The KAP questionnaire sent to the participants and response was collected. The response was analyzed using descriptive statistics.

III. RESULTS

A total of 385 pharmacy students participated in the study. The questionnaire was sent to the pharmacy students and was collected. The data was analyzed using descriptive statistics. Among 385 participants, 153 (40%) students were male and 233 (60%) were female [Fig. 1]. Based on age wise distribution, the maximum number of pharmacy students belongs to the age group of 22-23 years that is 151 (39%) pharmacy students, followed by above 24 years 105 (27%), 20-21 years 94 (24%) and 18-19 years 35 (9%) [Fig. 2]. Among the pharmacy students, Pharm. D students 208 (54%) participated more in the study, followed by B. Pharm students

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69 (18%), M. Pharm students 55 (14%) and D. Pharm students 53 (14%) [Fig 3].

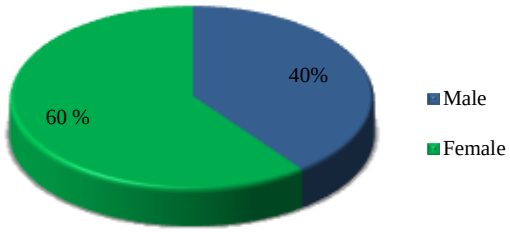

Fig. 1: Gender wise distribution of pharmacy students

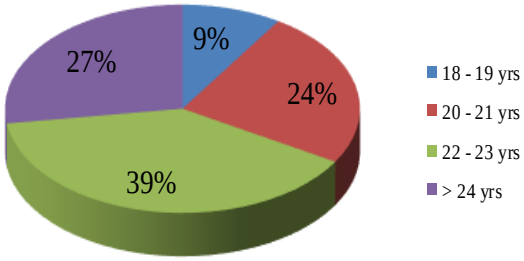

Fig. 2: Age distribution of pharmacy students

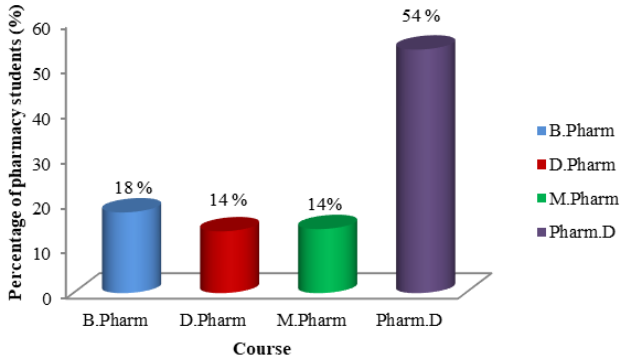

Fig. 3: Course wise distribution of pharmacy students

Table 1 shows the assessment of Knowledge based questions which comprises of 7 questions and out of 385 pharmacy students, a total of 309 (80%) students gave correct response regarding the definition of ADR, 267 (69%) students were aware that in Sweden has the centre for ADR monitoring, 270 (70%) students were aware of who can report ADR, 293 (76%) students were aware that a serious adverse reaction should be reported to the regulatory body within 15 calendar days, 246 (64%) students had a knowledge that vigibase is the WHO online database for reporting ADR, 312 (81%) of students were aware about the treatment of ADR which are independent and 242 (63%) of students gave correct answer on the definition of augmented drug reaction.

Table 1: Assessment of knowledge-based questions

Knowledge- based questions	Correct answer	B. Pharm n=69(%)	D. Pharm n=53(%)	M. Pharm n=55(%)	Pharm. D n=208(%)	Total n=385(%)
An ADR is defined as	Noxious and unintended response to drug	74	55	87	87	80
Location of international ADR monitoring center	Sweden	67	36	75	77	69
Who can report ADR	Doctor, Pharmacist, Nurses All of the above	62	40	53	85	70
A serious adverse reaction should be reported the regulatory body within	15 calendar days	65	51	69	88	76
Which of the following is the WHO online database for reporting ADR	Vigibase	70	43	67	66	64
ADRs which are independent can be treated	By withdrawing the drug, By reducing the dose, Replacing the medications All of the above	74	60	87	87	81
Augmented drug reaction is	Dose dependent, comparatively rare in occurrence, more fatal	64	47	56	69	63

Table 2 shows the assessment of Attitude based questions that comprises of 5 questions and out of 385 pharmacy students, a total of 366 (95%) students agreed that reporting of ADR is necessary, 274 (71%) students agreed that ADR reporting by one person can make a significant difference to the community, 364 (95%) students agreed that reporting ADR will increase patient safety, 310 (81%) students agreed that ADR monitoring center should be there in every hospital and 246 (64%) students disagreed that reporting of ADR is time consuming and cumbersome activity.

Table 3 is the assessment of Practice based questions which comprises of 8 questions and out of 385 pharmacy students, 242 (63%) students have not experienced or encountered an ADR before, 210 (55%) students have seen an ADR reporting form, 198 (51%) students have not been trained on how to report ADR, 215 (56%) students did not find difficulty in reporting ADR, 205 (53%) students answered

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that they have not maintained any records of ADR in their hospital, 246 (64%) students has responded that they have read articles on prevention of ADR, and 271 (70%) students stated that non-medical person can report ADR to a nearby healthcare professional.

Table 2: Assessment of attitude based questions

Attitude - based questions	Answer	B. Pharm n=69 (%)	D. Pharm n=53 (%)	M. Pharm n=55 (%)	Pharm. D n=208 (%)	Total n=385 (%)
Do you think reporting of an ADR is necessary	Yes	90	79	98	100	95
	No	10	21	2	0	5
ADR reporting by one person can make a significant difference to the community	Yes	59	57	86	75	71
	No	41	43	15	25	29
Do you think reporting ADR will increase patient safety	Yes	90	93	96	96	95
	No	10	8	4	4	6
Should there be an ADR monitoring center in every hospital	Yes	65	57	78	92	81
	No	35	43	22	8	20
Do you think reporting of an ADR is time consuming and cumbersome activity	Yes	44	42	56	27	36
	No	57	59	44	73	64

Table 3: Assessment of practice based questions

Practice-based questions	Answer	B. Pharm n=69 (%)	D. Pharm n=53 (%)	M. Pharm n=55 (%)	Pharm. D n=208 (%)	Total n=385 (%)
Have you ever experienced or encountered ADR before	Yes	32	30	47	38	37
	No	68	70	53	62	63
Have you ever seen an ADR reporting form	Yes	30	25	82	63	55
	No	70	76	18	37	46
Have you ever been trained on how to report ADR	Yes	33	26	62	56	49
	No	67	74	38	44	51
Do you find difficulties in reporting ADR	Yes	36	38	46	48	44
	No	64	62	55	52	56
Have you maintained any records of ADR in your hospital	Yes	35	17	53	57	47
	No	65	83	47	43	53
Have you anytime read any article on prevention of ADR	Yes	45	53	78	69	64
	No	55	47	29	31	36
Non-medical person can report ADR to a nearby healthcare professional	Yes	61	49	47	85	70
	No	39	51	53	15	30

Practice –based questions	Answer	B. Pharm n=69(%)	D. Pharm n=53(%)	M. Pharm n=55(%)_	Pharm. D n=208(%)	Total n=385(%)
Factors causing difficulties in reporting ADR	Did not know how to report	28	47	18	27	29
	Not knowing where to report	15	15	6	11	11
	Lack of time	21	13	36	14	18
	Difficult to decide whether ADR occurred or not	38	25	40	48	42

IV. CONCLUSION

Pharmacy students had adequate knowledge, attitude and practice towards detecting, monitoring and reporting ADR. The study also showed that M.Pharm students have a good knowledge on ADR. We conclude that pharmacy students have favorable knowledge, attitude and practice on ADRs. Therefore, providing special training and educational awareness may increase the KAP of the students towards ADRs.

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