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AWARENESS OF PHARMACOVIGILANCE AMONG THE HEALTH CARE PROFESSIONALS (PHARMACISTS) AT TERTIARY CARE HOSPITAL, SOLAPUR, MAHARASHTRA

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ABSTRACT

Background: Adverse drug reactions (ADR) are negative role played by drugs. ADRs are major cause of patient mortality and morbidity. True essence of pharmacovigilance is spontaneous reporting by all healthcare professionals. Under-reporting is very common problem. **Objectives:** Current study was conducted to investigate role of pharmacists in ADR reporting. **Material and methods:** It was prospective, cross-sectional, observational, questionnaire-based study among the pharmacists of the tertiary care hospital Solapur. A questionnaire evaluating knowledge, attitude and practice was distributed among pharmacists and filled questionnaire were collected back and data analyzed by microsoft excel 2013. **Results:** Response rate of our study was 100%. 6 (50%) pharmacists were knowing meaning of pharmacovigilance while 10 (83.33%) participants knew that all drugs available in market are not safe. Taking proper medication history before prescribing drugs was considered important by 12 (100%) participants. 12 (100%) participants were aware about Pharmacovigilance program of India. All 12 respondents said maintaining records of ADR plays important role in prevention of ADR. **Conclusion:** Pharmacists of tertiary care hospital, Solapur had adequate knowledge and appreciable attitude towards pharmacovigilance but practice needs to be improved.

KEYWORD: Adverse drug reactions (ADR), Pharmacovigilance.

INTRODUCTION

According to World Health Organisation (WHO), pharmacovigilance (PV) can be defined as the science and the activities with respect to the assessment, detection, understanding and the prevention of the harmful results or any adverse drug-related issues. [1] Data available in pharmacovigilance is nothing but the reports of adverse drug reactions (ADR) from various parts of world. The true success of a pharmacovigilance program would be achieved only when healthcare professionals such as doctors, pharmacist, and nurses in cultivate habit of voluntary ADR reporting.[2] Spontaneous reporting is a crucial step in preventing and reducing incidence of ADR.[3]

ADR are negative consequences of drug therapy.[4] The burden of ADRs is expected to be even higher in developing countries due to extensive prevalence of self-medication, fake and adulterated medicine.[5] The World health Organisation (WHO) defines ADR as any type of response caused by a drug that is unintentional, noxious and takes place at the drug doses which are used for diagnosing, prophylaxis, or treatment of a disease or due to the medications for the physiological functions.[6]

Spontaneous reporting by healthcare professionals is a crucial step for preventing or reducing ADRs and cost effective surveillance system and is the cornerstone of safety monitoring of drugs in clinical practice.[3] This type of reporting is completely voluntary in nature and reported by healthcare professionals. The ADR reporting rate in India is below 1% compared to the worldwide rate of 5%.[7] The Uppsala Monitoring Center (UMC) Sweden maintains the global database of ADRs reported from pharmacovigilance programme of various countries. However, it is estimated that only 6-10% of ADRs reported worldwide.[5]

The Pharmacovigilance Programme of India (PvPI) was launched under the Ministry of Health & Family Welfare in July 2010 to safeguard the health of the Indian population by ensuring the safety of marketed drugs.[8]

However, few studies are done to evaluate knowledge, attitude and practice of pharmacists with regard to ADR reporting. Hence, this study was conducted to analyze the knowledge, attitude, and practice (KAP) related to ADR reporting among pharmacists in tertiary care hospital, Solapur.

MATERIAL AND METHODS

This was a prospective, cross-sectional, observational, questionnaire-based study among the pharmacists working at tertiary care teaching hospital, Solapur. Prior approval was taken from the Institutional Ethics Committee to conduct the study.
Pharmacists working in the hospital were enrolled in the study. The completion of the questionnaire by respondents was taken as their consent to participate in the study. Those who were not willing to participate or did not return the questionnaire within the stipulated time were excluded.

Structured pretested questionnaire containing 25 questions, out of which 15 questions to study knowledge regarding the ADR reporting system, 4 for attitude and 6 to study practices of ADR reporting.

Three questions were open ended, while the others were close ended. The participants were personally briefed about the study questionnaire and were requested to complete and return the questionnaire immediately.

The information was recorded and analyzed using the Microsoft Excel worksheet (Microsoft Office 2013)

RESULTS

A total of 12 pharmacists working at tertiary care hospital, Solapur received the questionnaire. All accepted to respond the questionnaire, yielding response rate 100%.

a) Knowledge about pharmacovigilance and ADR reporting (table and graph I)

In the questionnaire 15 items were designed to assess pharmacist's knowledge.

Participants were asked about safety of drugs available in market, 10 participants (83.33%) believed drugs available in market are not safe.

According to eight respondents (66.66%), serious adverse event includes life threatening event, disability, death, hospitalization.

When asked about meaning of Pharmacovigilance, 6 respondents answered adverse drug reaction monitoring. 3 respondents (25%) replied as vigilance over the pharma company for drug production and 3 respondents (25%) said all options were correct.

All 12 respondents (100%) answered all healthcare professionals' doctors, pharmacists and nurses can report ADR.

9 respondents (75%) answered that non-medical persons should report ADR, if they experience any, to nearby medical person as early as possible.

ADR reporting is professional obligation, 1 respondent (8.33%) were agree to this sentence while 7 (58.33%) were not agree and 4 respondents (33.33%) were not knowing.

The information generated in Pharmacovigilance is useful in educating doctors about adverse drug reaction and in the official regulation of drug use, this sentence found true by all 12 respondents (100%).

Main purpose of pharmacovigilance i.e. reducing risk of drug related harm to patient and promoting rational use of drugs were correctly known by all 12 respondents (100%).

According to 1 respondent (8.33%), Pharmacovigilance provides basis for assessing safety of medicine which is correct while remaining 11 respondents (91.66%) said it provides basis for assessing both efficacy of medicine and safety of medicine.

Activities involved in Pharmacovigilance are post marketing surveillance, prescription event monitoring and anecdotal care reports. 7 respondents (58.33%) mentioned that. 4 respondents (33.33%) said only prescription event monitoring is involved and 1 (8.33%) respondent was not knowing.

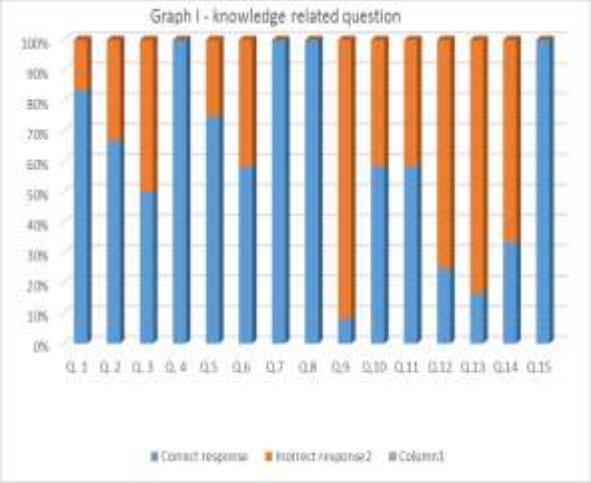
According to 7 respondents (58.33%) voluntary reporting depends on initiative and willingness of health professional while 5 (41.66%) respondents answered only initiative of health professional is sufficient.

Only 3 respondents (25%), 2 respondents (16.66%) and 4 respondents (33.33%) were knowing Pharmacovigilance International Collaborating Centre, Pharmacovigilance National Collaborating Centre and ADR monitoring Centre in Maharashtra respectively.

All 12 respondents (100%) were aware about the Pharmacovigilance Programme of India.

Table I: Questions related to knowledge.

Knowledge related questions	Correct response	Incorrect response
1. safety of available drugs in market	10	2
2. regarding serious adverse event	8	4
3. meaning of Pharmacovigilance	6	6
4. who can report ADR	12	0
5. ADR reporting by non-medical person to medical person	9	3
6. ADR reporting is professional obligation	7	5
7. Pharmacovigilance's usefulness in educating doctors about ADR and in regulation of drug use	12	0
8. main purpose of Pharmacovigilance	12	0
9. Pharmacovigilance provides basis for assessing	1	11
10. activities involved in Pharmacovigilance	7	5
11. regarding voluntary reporting	7	5
12. Pharmacovigilance International Collaborating Centre	3	9
13. Pharmacovigilance National Collaborating Centre	2	10
14. ADR monitoring Centre in Maharashtra	4	8
15. Awareness of Pharmacovigilance Programme of India	12	0



Graph I.

b) Attitude based question (table and graph II)

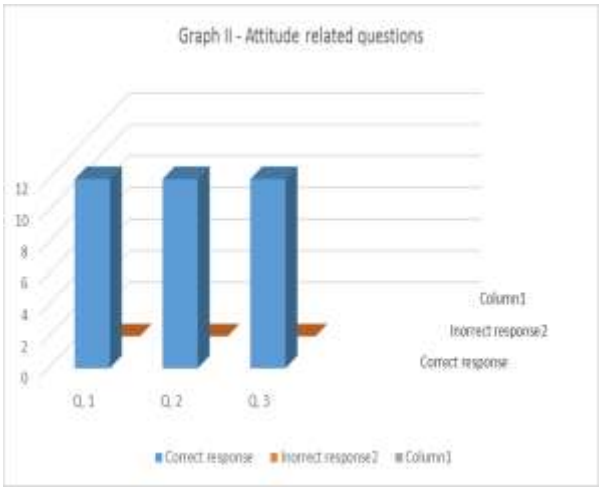
Taking proper medication history before prescribing drugs was considered to be important by all 12 (100%) of the respondents.

12 respondents (100%) said that it is necessary to make ADR reporting.

12 respondents (100%) had strong thinking that ADR reporting and monitoring system would definitely benefit the patients.

Table II – questions related to attitude.

Attitude related Questions	Correct response	Incorrect response
1. Importance of taking medication history	12	0
2. necessity of ADR reporting in today's clinical practice	12	0
3.ADR reporting and monitoring system would benefit the patient	12	0



c) Practice based questions (table and graph III)

All 12 respondents believed that common ADRs (headache, fever, vomiting) should be reported.

According to 6 respondents out of 12 (58.34%), mandatory elements while recording ADR involves identifiable patient's details, identifiable reporter's details and details about suspected medicinal products.

4 respondents (33.33%) said only details about suspected medicinal products were enough and 1 respondent mentioned only patient's details were required.

Keeping records of experienced ADR found to be important for all 12 respondents (100%).

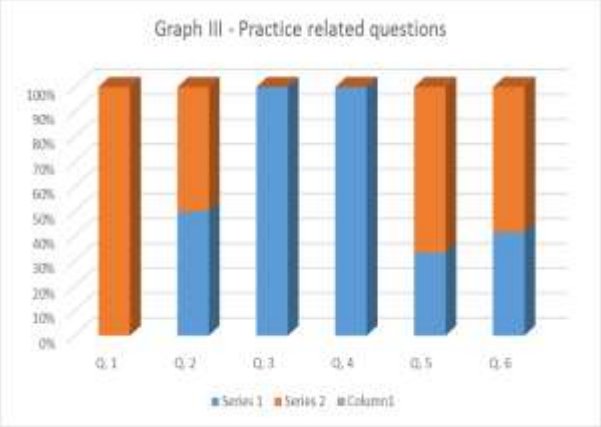
Maintaining confidentiality while reporting ADR, 12 respondents (100%) felt it is necessary.

10 respondents (83.33) said no, they didn't worry about legal problems; 2 respondents (16.66) said yes they worried about legal problems.

6 (50%) and 5 (41.66%) respondents said yes, confidentiality of patient's identity and reporter's identity should be maintained respectively. 6 (50%) and 7 (58.33%) answered no to maintain confidentiality of patient's identity and reporter's identity respectively.

Table III – questions related to practice.

Practice related Questions	Correct response (n=12)	Incorrect response (n=12)
1. regarding reporting of common ADRs (headache, fever, vomiting)	0	12
2. elements mandatory to record	6	6
3. keeping record of ADR	12	0
4. maintaining confidentiality while ADR reporting	12	0
5. Patient's identity kept confidential?	6	12
6. Report's identity kept confidential?	5	7



DISCUSSION

The pharmacovigilance programme has been started in several nations to recognise ADRs. Voluntary reporting ADR is an essential component of Pharmacovigilance which is minimal in India.

The results of our study indicated that the participating pharmacists were quite knowledgeable towards the PV and the ADR reporting.

Studies in Mumbai[9] and Ahmedabad[10] have shown that prescribers have high knowledge and appreciable attitude with regards to ADR reporting but practice it poorly. Our study also found similar results. The response rate (100%) was high compared to other studies carried out in Liverpool[11], Kuwait[12] and Netherlands.[13]

74.8% participants answered correctly purpose of Pharmacovigilance in study by Fatemah Alsaleh at Kuwait.[12] But in present study it was 100%.

In present study 16.66% (2) participants believed drugs available in market are safe. A small number (n = 20; 5%) of responders believed that all drugs available in the market were safe in study by Akram Ahmad at Tamil Nadu.[3]

16.7% (22) participants had an idea about the PV centre and the program in Iraq[14] while in present study only 16.66% (2) participants had idea about it.

65% pharmacists feared facing legal problems due to reporting ADRs in study at Tamil Nadu[3]. In present study we found 83.33% (10) pharmacists didn't fear facing legal problems.

Present study showed 100 % pharmacists believed reporting ADRs will improve patient safety while other similar study at Tamil Nadu 95% pharmacists believed reporting ADRs will improve patient safety.[3]

In study conducted at Iran, around 84.1% (111) participants agreed that "reporting the ADR was a part of the pharmacist's professionalism".[14] In other similar study by Akram Ahmad at Tamil Nadu, nearly all pharmacists (*n* = 325; 81%) felt that ADR reporting was their duty.[3] Significant proportion (85.6%) reported considering ADR reporting as professional obligation in Kuwait study.[12] In present study only 41.66% (5) participants was agree to this sentence.

65% pharmacists were unaware about the existent national ADR reporting system,[3] only 7% were aware of existence of ADR reporting system in Kuwait (pharmacists) but in our study 100% pharmacists were aware about it.

CONCLUSION

The pharmacists working in tertiary care hospital in Solapur have good knowledge and attitude. But they are poor in practice. This calls for the need of interventional educational initiatives, training courses for pharmacists. ADR should also be reported related to the over the counter drugs. It will play essential role in Pharmacovigilance data.

Limitations of the study

The main limitation of our study was the questionnaire was administered to hospital-based pharmacists only, relatively small number of respondents (pharmacists). It remains to be extrapolated to pharmacists working in other setting like community pharmacists.

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