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A STUDY OF THE AWARENESS, ATTITUDE AND PRACTICES OF DOCTORS, NURSES AND PHARMACISTS TOWARDS ADVERSE DRUG REACTION REPORTING & MONITORING IN A TERTIARY CARE HOSPITAL

Pharmacology

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ABSTRACT

Introduction- Pharmacovigilance is science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problem. This study focuses upon study of the awareness, attitude and practices of doctors, nurses and pharmacists towards adverse drug reaction reporting & monitoring in a tertiary care hospital. Methods- This is a cross-sectional study involving the use of a structured questionnaire for obtaining information related to knowledge, attitude and practices (KAP) of doctors, nurses and pharmacists towards adverse drug reaction reporting & monitoring. Participants were also asked about some suggestions to improve the adverse drug reaction reporting practice. **Results-** There is a significant lacuna in the existing knowledge, attitude and practice of health care professionals regarding ADR reporting. Majority of the participants felt the need of more help and coordination from institutional ADR monitoring centre for filling ADR forms. **Conclusions-** There is an inadequate knowledge and poor beliefs and practices in medical professionals regarding ADR reporting.

KEYWORDS

adverse drug reaction monitoring centres, adverse drug reaction reporting, KAP study, pharmacovigilance

Introduction

Pharmacovigilance is defined as science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problem. The aims of pharmacovigilance are to enhance patient care and patient safety in relation to the use of medicines and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk benefit profile of medicines [1]. Pharmacovigilance largely focuses on assessment of adverse drug reactions (ADR), which are defined as any response to a drug which is noxious and unintended, including lack of efficacy[2]. It is important to monitor every undesirable effect of medicines in order to determine any new information available in relation to their safety profile. In a vast country like India with a population of over 1.3 billion with vast ethnic variability, different disease prevalence patterns, practice of different systems of medicines, different socio-economic status, it is important to have a standardized and robust pharmacovigilance and drug safety monitoring programme for the nation. Collection of this information and analysis of this data to reach a meaningful conclusion on the continued use of these medicines is the rationale of pharmacovigilance [3].

For an efficient pharmacovigilance system to occur in a hospital, it is important that the doctors, nurses and other paramedical staff should be having an adequate knowledge about the system and go for regular ADR reporting, realizing its importance in the medical field. Hence, this study was designed to assess the knowledge, attitude and practices of doctors, nurses and pharmacists about ADR reporting in a tertiary care hospital along with suggestions for improvement of pharmacovigilance system.

Subjects and Methods:

The study was a cross-sectional study, conducted at BPS Government Medical College for women, Khanpur Kalan, Sonepat which is an approved adverse drug reaction monitoring centre. The junior residents, senior residents, doctor faculty (assistant professors, associate professors and professors), nurses and pharmacists were included in the study after obtaining their written informed consent. The participants were divided in three groups ie senior faculty (assistant professors, associate professors and professors), residents (junior residents and senior residents) and para medical staff (nurses & pharmacists). The participants were given a predesigned and pretested performa [3,4,5] to fill the questionnaire. The questionnaire had 21 questions to assess the knowledge (7), attitude (8) and practices (6) of the participating health care professionals towards pharmacovigilance. The knowledge part of the questionnaire was to assess the knowledge of pharmacovigilance programme and the ADR reporting method. Attitude part of the questionnaire was to evaluate the beliefs of the health care professionals regarding importance of ADR reporting and its potential consequences. The practice part of the questionnaire was to judge how the knowledge and attitudes of the health care professionals were practically put into action. The questions asked from the participants are described in table 1. Each correct response was given a score of 'one' and each wrong answer or unsure response was given a score of 'zero'. The maximum scores for knowledge, attitude and practice part were 7, 8 and 6 respectively. Five possible suggestions were also included in the questionnaire so as to get new ideas for improvement of pharmacovigilance system. The participants were also asked for any suggestion from their side, if it had not been included in the list given in the questionnaire. The mean scores for each parameter were calculated. Anova test was applied for comparing the 3 groups collectively in terms of overall knowledge, attitude and practice scores. Post hoc analysis was later applied to see how these groups differ among themselves. Numbers of participants of each group responding correctly to each individual question were compared by chi square test for any statistically significant difference. The suggestions were compared and analysed by percentages.

Table 1- Questions to assess knowledge, attitude and practice of ADR reporting and monitoring

S no.	Questions
	Knowledge Questions
K1	Are you aware about national pharmacovigilance centre of India?- yes or no
K2	Do you know about elements of Pharmacovigilance (detection, assessment, understanding, prevention)?- yes or no
K3	Are you aware of the fact that BPS GMC for women, Khanpur Kalan is an approved Adverse drug reaction monitoring centre (AMC)? –yes or no
K4	What is ADR reporting to be done for?- Allopathic medicines, Indian system of medicine, Medical devices or All of the above

K5	What to report?- Serious adverse events, All adverse events, Adverse drug reactions (ADRs) or All of the above
K6	Whom to report ADRs?- National Pharmacovigilance center, ADR monitoring center of institution, Treating physician (in case of nurses and pharmacists), Any of above, Kept personally for future reference or Do not know
K7	Do you know how to fill an ADR reporting form? Yes or no
	Attitude questions
A1	Is ADR reporting as necessary as managing a patient? (yes/ no)
A2	Who benefits from ADR reporting?- Health Care Professionals, Patients, Health regulatory authorities or All of above
A3	Does ADR reporting damage professional image? (Yes/No)
A4	Can ADR reporting lead to legal issues on the part of treating doctor?- Yes or No
A5	Can ADR reporting lead to patient confidentiality issues?- Yes or No
A6	Do you think ADR reporting would lead to extra work?- Yes or No
A7	What are the pharmaceutical products to be monitored for ADRs? - New drug, Old drug, Medical devices, Vaccines or All of the above
A8	Do conferences/ workshops on pharmacovigilance improve reporting? (Yes/No)
	Practice questions
P1	How do you find ADRs?- Only ask from patients, Only ask from patient's relatives, Only monitor the patient's reports, Clinical judgment or All of the above
P2	Do you have regular access to ADR reporting form?- Yes or No
P3	What you do with ADRs?- Directly report to national pharmacovigilance centre, Report to institutional adverse drug reaction monitoring centre (AMC) or Do not inform to anybody as it is routine part of the treatment
P4	Which severity of ADRs do you report?- Minor (no therapy required), Moderate (required therapy), Severe (life- threatening) or All of the above
P5	Is there any routine inter and intra departmental discussion on ADRs?- Yes or No
P6	Do you mention the ADRs on the patient's record?- Always, Once in a while, Never or Manage it without mentioning

Results

A total of 140 participants filled the questionnaire. Out of these, 43 participants were from senior faculty (assistant professors, associate professors and professors), 47 participants were residents (junior residents and senior residents), and 50 participants belonged to para medical staff (nurses & pharmacists).

Table 2 summarizes the mean scores of the participants for each parameter like knowledge, attitude and practice. It was found that there was a statistically significant difference ($p<0.05$) in the mean knowledge, attitude and practice scores when the three groups were compared collectively by Anova. The results of post hoc analysis reveal that there was no statistically significant difference in the knowledge and attitude scores of senior faculty and residents but knowledge and attitude scores of paramedical staff was significantly less than the two other groups. In terms of practice, it was found that practice scores of senior faculty was significantly higher than residents and paramedical staff although the practice scores of residents and paramedical staff did not differ significantly among themselves.

Table 2- Mean scores of the participants for each parameter.

	Maximum scores	Senior faculty score (Mean ± SEM)	Residents (Mean ± SEM)	Paramedical staff (Mean ± SEM)	p value
Knowledge	7	4.79 ± 0.21	4.82 ± 0.19	3.72 ± 0.18	<.0001*
Attitude	8	5.97 ± 0.20	6.00 ± 0.16	5.28 ± 0.22	.016*
Practice	6	4.09 ± 0.16	3.8 ± 0.17	3.42 ± 0.17	.022*

The percentage of participants responding correctly to each individual question of each parameter is indicated in Figures 1-3.

Figure 1- Frequency distribution of participants according to their knowledge of adverse drug reaction reporting and monitoring

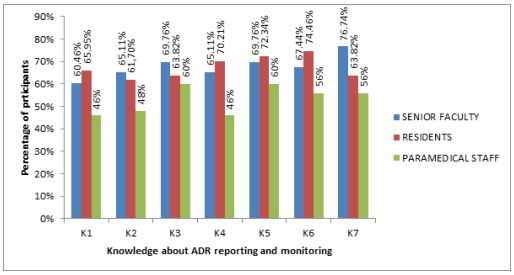


Figure 2- Frequency distribution of participants according to their attitude of adverse drug reaction reporting and monitoring

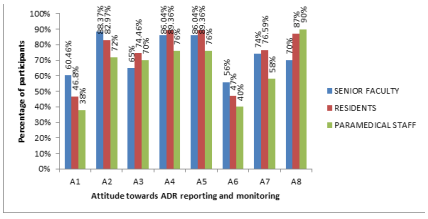
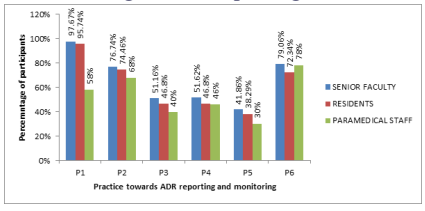


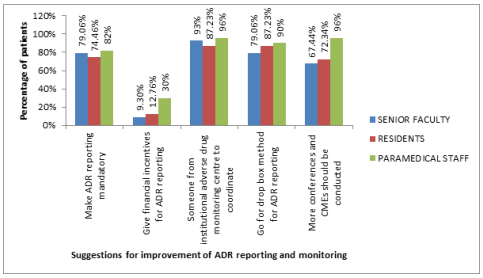
Figure 3- Frequency distribution of participants according to their practice of adverse drug reaction reporting and monitoring



The results of the chi square test reveal that there was a statistical difference in the knowledge of the groups regarding the method of filling ADR form ($p=0.016$) and what ADR reporting to be done for - Allopathic medicines, Indian system of medicine, medical devices or all ($p=0.033$). The attitude of the participants differed significantly only regarding possibility of legal issues for the doctor after ADR reporting ($p=0.039$) and whether conferences/ workshops can improve ADR reporting ($p=0.048$). The practice of correct method for finding ADRs also differed significantly between the groups ($p<0.001$).

Figure 4 describes the suggestions given by the participants for improvement of ADR reporting and monitoring.

Figure 4- Frequency distribution of participants according to their suggestions for improvement of adverse drug reaction reporting and monitoring



Discussion

This study suggests that there is a lacuna in the existing knowledge of

doctors, nurses and paramedical staff towards adverse drug reaction reporting & monitoring in this tertiary care hospital. This lacuna was seen more in paramedical staff as compared to doctors. The least known facts were about the location of national pharmacovigilance centre of India, about the four major elements of pharmacovigilance and what ADR reporting is to be done for. The knowledge of correct method of filling ADR forms was significantly less in paramedics as compared to doctors.

The majority of the participants also realised the benefits of ADR reporting at all levels and that it can't cause patient confidentiality issues and legal issues on the part of treating doctor. But many participants still do not give it same importance as treating the patient and consider it to be an extra work burden. Also many participants hold the opinion that ADR reporting can damage professional image. Still a lot of health care professionals, especially the paramedical staff and residents feel that regular conferences/ workshops on pharmacovigilance can improve ADR reporting.

In terms of practice, it is seen that ADR reporting is still far from satisfactory, especially from paramedical staff. Many health care professionals who had good knowledge and attitude about ADR reporting still did not practically put it into action. Although many health care professionals largely employ correct method of finding ADRs and they have a regular access to ADR reporting form, but adverse drug reactions are not routinely reported in a significant number of cases. Busy schedule of the health care professionals and their opinion that a single report would not make a lot of difference, might be actual reasons for less ADR reporting. Another reason for this under reporting might be the belief that reporting should be done when there is a certainty that the reaction is caused by the use of a particular drug. Also, all ADRs are not reported and the ADR reporting is largely restricted to moderate and severe type of adverse drug reactions. Another lacking area is routine inter and intra departmental discussion of ADRs.

When asked about suggestions on how to improve ADR reporting and monitoring from the institute, majority of the participants wanted someone from the institutional ADR monitoring centre to coordinate with them for filling the ADR form. The busy schedule of the doctors and paramedical staff was the prime reason for this. Another major suggestion was to start a drop box method for ADR reporting which would make this process even easier. Realising their existing lacuna in the knowledge about filling the ADR form and to keep them regularly motivated, a lot of health care professionals, especially paramedical staff suggested that more conferences and CMEs should be conducted so as to give them good training for ADR reporting. They should be motivated to give ADR reporting same importance as treating the patients and not consider ADR reporting as an extra work burden. They should also be asked to report all cases of ADRs, irrespective of their severity, even if their causality is not certain. Another major belief of health care professionals is that the only way of improving pharmacovigilance is to make ADR reporting mandatory. A small set of participants also held the opinion that giving financial benefits for ADR reporting would also improve pharmacovigilance.

This study clearly points towards inadequate knowledge and poor beliefs and practices in medical professionals regarding pharmacovigilance. There is a belief in the minds of health care professionals that ADR reporting is not only an extra work but also can damage their professional image. Busy schedule of the health care professionals and their opinion that a single report would not make a lot of difference even further decreases the practice of regular ADR reporting. These findings necessitate the need for spreading large scale awareness of pharmacovigilance among health care professionals, especially para medical staff, for better understanding of importance of ADR reporting, changing their false beliefs about pharmacovigilance and motivating them for the same. More coordination and help to the health care professionals by the ADR monitoring centre of the institute can further go a long way in improving practice of pharmacovigilance.

References

1. Pharmacovigilance [online]. [cited 2018 Feb 5]. Available from:http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/
2. Adverse drug reactions. [online]. [cited 2015 Jan 27]. Available from:http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/Informationforhealthcareprofessionals/Adversedrugreactions/
3. Mishra H, Kumar V. Pharmacovigilance: Current scenario in a Tertiary Care Teaching Medical College in North India. J pharmacovigilance 2013;1(2):1-4.
4. Datta S, Sengupta S. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim. Perspect Clin Res 2015;6:200-6.
5. Dhananjay K, Esanakula H. A study of assessing knowledge, attitude and practice of pharmacovigilance among medical students of a South Indian teaching hospital. Int J Basic Clin Pharmacol 2017;6:43-7.