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AWARENESS OF PHARMACOVIGILANCE AND ADVERSE DRUG REACTIONS AMONG HEALTH CARE PROFESSIONALS OF A MEDICAL COLLEGE IN KERALA

Pharmacology

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ABSTRACT

This study aims at assessment of knowledge, attitude and practice of health care professionals regarding pharmacovigilance in a tertiary care hospital. Study was conducted among 133 health care professionals of a tertiary care hospital in Kerala. Data was gathered using questionnaire containing 20 questions. Based on score of knowledge 25(18.8%), 71(53.4%), 37(27.8%) were in excellent, good and poor categories respectively. 98(73.7%) participants agreed that ADR monitoring will benefit the patients and 93(69.9%) considered it as a professional obligation. 86(64.7%) knew to fill ADR form and 80(60.2%) had reported ADR before. 119(89.5%) participants agreed to report ADR hereafter and most important discouraging factors for reporting ADRs were lack of time and fear of legal issues. Awareness of health care professionals regarding pharmacovigilance has improved over past 3-4 years. Pharmacists are the major group of health care professionals properly sensitized.

KEYWORDS

Awareness, Adverse Drug Reaction, Pharmacovigilance, Health Care Professionals

INTRODUCTION

Pharmacovigilance is the branch of pharmacology which deals with adverse drug reactions (ADR). WHO has defined pharmacovigilance as the science and activities relating to detection, assessment, understanding and prevention of the adverse drug reactions.[1] Adverse drug reactions are the leading cause of mortality and morbidity in all health care systems. ADRs are assumed to be the cause for 2.9–5.6% of all hospital admissions.[2] Around 35% of all hospitalized patients experience an ADR during the stay in hospital.[3]

Thus prevention, identification of predisposed individuals, early detection and treatment of ADRs has become very important in modern health care facilities. Animal toxicity studies and clinical trials are done to collect drug safety data before marketing, but still those studies are done among a limited number of trial subjects and has certainly a lot of limitations in exploring the whole safety profile of drugs. It is the post marketing studies and spontaneous reporting which can gather near complete information, especially with respect to the long term effects and the use in the patient population with comorbidities and on multidrug therapy. For this, health care professionals need to identify, report and analyze ADRs. Detection and reporting of ADRs is carried out by various methods of which voluntary or spontaneous reporting is commonly practiced which offers many advantages such as being inexpensive and easy to operate. Hospital based ADR monitoring and reporting programs can throw some light upon the profile of ADRs and ways to prevent them, facilitating rational drug use. Because of variation in drug response, individual prescribing habits, drug regulatory systems, and availability of drugs, it has been recommended by WHO for every country to set up their own Pharmacovigilance Program.[4]

The history of pharmacovigilance dates back to the thalidomide tragedy which happened in 1960's. It was introduced as a hypnotic but was extensively used as an effective remedy for pregnancy induced morning sickness. But its use was without adequate safety data in pregnancy which resulted in birth of thousands of congenitally malformed babies. Both WHO and FDA were very much alert regarding drug safety data from all concerned groups of individuals after this tragic episode in the history of modern medicine and it opened up eyes of drug regulatory bodies of all major countries towards ADRs and drug safety. WHO took up initiative to set up a world wide programme for ADR reporting and analysis in 1968.

The Uppsala Monitoring Centre (UMC), Sweden is the WHO collaborating centre internationally for ADR monitoring and is maintaining the international database of ADR reports from several national centres of different countries. It works by collecting, assessing and communicating information to the National pharmacovigilance centers of the member countries in regards to the benefits, harm, effectiveness and risks of the drugs. UMC developed and maintains a global individual case s afety report database known as Vigibase on behalf of WHO.[5]

In India, the Pharmacovigilance programme (PvPI) was initiated in 2010 with the mission to ensure that the benefits outweigh the risks associated with the use of medications and to safeguard the health of the Indian population.[5] ADR monitoring centres (AMC) have been set in various parts of the India under the PvPI to ensure the safety of patients receiving medications.[6] Training programs and workshops are also organized by PvPI to improve the awareness, knowledge, attitude and practice of health care professionals. Even after putting best efforts by PvPI and the Ministry of health and family welfare, still the participation of health care professional in this programme and reporting of ADRs are less.[7] The program lacks continuity and suffers from underreporting of ADRs by the health care professionals, the reason for which may be lack of awareness regarding the necessity of ADR reporting, lack of knowledge, heavy patient loads, meagre funds, lack of trained staff and disregard attitude and practice.[8] Underreporting still remains as one of the major obstacles for the success of PvPI.

So the challenge comes in detecting and reporting ADRs in timely manner through all groups of health care professionals. To make this happen, it is important to improve the knowledge, attitude, and practice of the healthcare professionals regarding ADR and Pharmacovigilance. Therefore, this study was planned to evaluate KAP of healthcare professionals in a tertiary care hospital and to provide a training session to improve their skills, so as to make reporting of ADRs more vibrant by inculcating culture of reporting and strengthening the Pharmacovigilance.

METHODS

This questionnaire based study was conducted among 133 health care professionals, including doctors, nurses and pharmacists of a tertiary care hospital in Kerala. A Questionnaire containing 20 questions was given to the participants and were asked to answer it within 20 minutes. The questionnaire was developed by modifying the questionnaires obtained from previous studies. Questions 1-14 were multiple choice questions with 4 options and were to assess the knowledge. Each correct answer was given 1 mark and wrong answer was given zero mark. There was no negative marking. The questions from 15 -19 were for replying yes or no which was used to assess the attitude and practice. Question 20 had four options to gather data on discouraging factors in reporting ADR. Following data collection, 2 hour session on pharmacovigilance and ADR reporting was taken for the participants. Participants were provided hands on training on ADR reporting using pre-structured clinical scenarios. Doubts regarding ADR reporting and pharmacovigilance were cleared and the necessity of ADR reporting was conveyed during the session. The data entry was done on excel sheet. The score of each health care professional was calculated for

initial 14 questions to assess knowledge. Participants were categorized to excellent, good or poor based on score. Those who scored between 0-5 were considered as poor, between 6-10 as good and above 11 as excellent. Participants who score to get included in excellent and good categories will be considered as aware regarding the pharmacovigilance and ADR reporting and the rest will be considered as unaware. Attitude and practice were assessed on the basis of questions 15 to 20. Response to KAP questionnaire was analyzed with Chi-square test for assessment and comparison of knowledge, attitude and practice.

RESULTS

Among 133 health care professionals took part in the study, there were 48 doctors, 53 nurses and 32 pharmacists. All the participants successfully completed the questions within stipulated time frame. Based on score of knowledge domain 25(18.8%), 71(53.4%), 37(27.8%) were in excellent, good and poor categories respectively. Those included in excellent and good categories 96(72.2%) can be considered as aware regarding the pharmacovigilance and ADR reporting .The results of knowledge based on multiple choice questions is given in table 1 and the categorization to excellent, good and poor is given in table 2.

Table 1: Results of knowledge based on multiple choice questions

Questions	Correct Answer	Wrong Answer
Pharmacovigilance is the study that relates to	84(63.2%)	49(36.8%)
Pharmacovigilance includes	71(53.4%)	62(46.6%)
National Pharmacovigilance Programme in India is governed by	70(52.6%)	63(47.4%)
The national coordinating centre for Pharmacovigilance in India is at	69(51.95)	64(48.1%)
The international centre for ADR monitoring is located in	63(47.4%)	70(52.6%)
Which one of the following is the “WHO online database” for reporting ADRs	61(45.9%)	72(54.1%)
The healthcare professionals responsible for reporting ADR in a hospital is/are	87(65.4%)	46(34.6%)
Rare ADRs can be identified in the following phase of a clinical trial	77(57.9%)	56(42.1%)
Activities involved in pharmacovigilance include	94(70.7%)	39(29.3%)
Which of the following scales is commonly used to assess the causality of an ADR's	77(57.9%)	56(42.1%)
What type of ADRs to be reported	90(67.7%)	43(32.3%)
Life-threatening ADR are those which result in	68(51.1%)	65(48.9%)
Measures to be taken when ADR is suspected	94(70.7%)	39(29.3%)
Regarding classification of ADR, correct option is	80(60.2%)	53(39.8%)

Table 2: Categorization based on multiple choice questions

Categories	Frequency	Percentage
Poor	37	27.8
Good	71	53.4
Excellent	25	18.8
Total	133	100.0

Among the 25 participants in excellent category 21 were pharmacists (84%). Doctors (2) and nurses (2) contributed 8% each. Among participants in good category there were 32(45.1%) nurses, 28(39.4%) doctors and 11(15.5%) pharmacists. Poor category contained 18(48.6%) doctors and 19(51.4%) nurses.

Out of 48 doctors took part in the study 2, 28, 18 were in excellent, good and poor categories respectively. We can consider 30(62.5%) were aware regarding ADR reporting and Pharmacovigilance. Among the 53 participants from nurses 2, 32, 19 were in excellent, good and poor categories respectively. 34(64.1%) got considered as aware. The current study had 32 pharmacist participants. Among them 21(65.6%) were in excellent category and 11(34.4%) were in good category. None among the pharmacists got included in poor category and thus all pharmacist participants need to be considered as aware. There was a statistically significant difference in knowledge regarding ADR and pharmacovigilance, between major groups of health care professionals. Pharmacists have better sensitization in ADR reporting as per this study. Comparison of knowledge of different groups of health care professionals based on scoring depicted in Table 3.

Table 3:Comparison of knowledge of different health care professionals

Designation	Knowledge about Pharma covigilance			Total	Chi-square test	p value
	Poor	Good	Excellent			
Doctor	18 (48.6%)	28 (39.4%)	2 (8.0%)	48 (36.1%)	63.780	0.001*
Nurse	19 (51.4%)	32 (45.1%)	2 (8.0%)	53 (39.8%)		
Pharmacist	0 (0.0%)	11 (15.5%)	21 (84.0%)	32 (24.1%)		
Total	37 (100%)	71 (100%)	25 (100%)	133 (100%)		

When it comes to the assessment of attitude, 98(73.7%) participants agreed that ADR monitoring and reporting will benefit the patients and 93(69.9%) considered it as a professional obligation. Among the 133participants 119(89.5%) agreed to report ADR hereafter. Results are detailed in table 4

Table 4: Assessment attitude of different health care pro-fessionals

Attitude - Questions	Yes	No
Do you think ADR monitoring and reporting will benefit patients	98(73.7%)	35(26.3%)
Is ADR monitoring a professional obligation	93(69.9%)	40(30.1%)
Will you report ADR here after	119(89.5%)	14(10.5%)

We had two questions for the evaluation of practice regarding ADR reporting. Among 133 health care professionals, 86(64.7%) knew how to fill an ADR form and 80(60.2%) had reported ADR before.

Table 5: Assessment practice of different health care professionals

Practice	Yes	No
Do you know how to fill an ADR form	86(64.7%)	47(35.3%)
Have you ever reported an ADR form	80(60.2%)	53(39.8%)

The last question was regarding discouraging factors for ADR reporting. The most important discouraging factors for reporting ADRs were lack of time (40.6%) and fear of legal issues (27.1%). Frequency and percentage of all discouraging factors studied are detailed in table 6.

Table 6: Discouraging factors in ADR reporting

Discouraging factors in reporting an ADR	Frequency	Percentage
Lack of time	54	40.6
Fear of legal issues	36	27.1
No remuneration	29	21.8
No significance	14	10.5
Total	133	100.0

DISCUSSION:

This study was conducted using a KAP questionnaire developed by modifying the questionnaires obtained from previous studies. We had 14 questions on knowledge, 3 questions on attitude and 2 questions on practice. The last question was for analysis of discouraging factors for ADR reporting.

Based on score of knowledge domain 25(18.8%), 71(53.4%), 37(27.8%) were in excellent, good and poor categories respectively. Those included in excellent and good categories 96(72.2%) were considered as aware regarding the pharmacovigilance and ADR reporting. Similar results could be seen in previous studies done by Meena Kumari et al and Sandeep Kumar Guptha et al with 75 and 75.2 percentage awareness respectively.[9,10]

Out of 48 doctors took part in the study 2, 28 were in excellent and good categories respectively. So we can consider 30(62.5%) were aware regarding ADR reporting and Pharmacovigilance. In the previous study conducted by Noor B Almandil among doctors, pharmacists pharmacist technicians and nurses, only 12.5% doctors were aware regarding pharmacovigilance and ADR reporting.[11] In another study done by Mohammed M.M et al 39.2% doctor were aware.[12] Among the

53 participants from nurses 2, 32 were in excellent and good respectively. 34(64.1%) got considered as aware. Results from the previous studies done by Noor B Almandil and Mohammed M.M et al show 18% and 27.2% awareness respectively among nurses.

The current study had 32 pharmacist participants. Among them 21(65.6%) were in excellent category and 11(34.4%) were in good category. None among the pharmacists got included in poor category and thus all pharmacist participants (100%) need to be considered as aware. Study by Noor B Almandil gives 60.5% and work by Mohammed M.M et al shows 70.27% awareness among pharmacists.[11,12]

The above mentioned reference studies were published between 2014 and 2016. The comparatively higher rate of awareness among different group of health care professionals in the current study may be an indicator of the slowly spreading awareness on pharmacovigilance and ADR monitoring over past 3-5 years. In the current study, there was a statistically significant difference in knowledge regarding ADR and pharmacovigilance, between major groups of health care professionals. Pharmacists were found to be better sensitized in ADR reporting as per this study. We have similar results from previous studies done by Noor B Almandil and Mohammed M.M et al.[11,12] This could be due to better involvement of pharmacists in pharmacovigilance wing of drug manufacturers and drug regulatory authorities. Pharmacovigilance is better covered in pharmacist curriculum compared to others. The institution where this study was done had a good quantity of Clinical pharmacist who are well trained in pharmacovigilance during their study course and internship and are capable of educating other health care professionals regarding ADR reporting. This might be an important factor for overall better awareness among all the health care professionals and especially good awareness among pharmacists in the current study.

When it comes to the assessment of attitude, 98 (73.7%) participants agreed that ADR monitoring and reporting will benefit the patients and 93(69.9%) considered it as a professional obligation. In the current study 119(89.5%) participants agreed to report ADR hereafter. Almost similar results could be seen in the previous study done by Sandeep Kumar Guptha et al, in which 97% of heath care professionals agreed that ADR reporting is necessary for patient safety and 69.3% considered it as a professional obligation. In another study by Noor B Almandil 87.1% participants believed that ADR reporting system will benefit the patients and 75.9% agreed it as a professional obligation. In the study by Anjan Adhikari et al 92% believed that, it is necessary and would be beneficial for the patient to report ADRs and 74% also believed that ADR reporting is a professional obligation. [13]

We had two questions for the evaluation of practice regarding ADR reporting. Among 133 health care professionals, 86(64.7%) knew how to fill an ADR form and 80(60.2%) had reported ADR before. In the study done by Sandeep Kumar Guptha et al in 2017, 53.5% participants were trained on filling ADR form but 22.8% had reported ADR.[10] This shows that more number of professionals have started to get trained in pharmacovigilance and reporting ADR and we need to reinforce the habit through periodical workshops.

In the study done by Kiran Prabhakar Vakade et al among intern doctors in a teaching hospital 88.63% interns thought that ADR reporting is necessary but only 38.64% considered ADR reporting as a professional obligation. Only 17.4% were trained on ADR reporting and 2.27% had actually reported an ADR.[14] Thus percentage values of interns are low compared to health care professionals and it clearly demonstrates the need of early sensitization of budding doctors through inclusion of training on pharmacovigilance in UG curriculum.

The most important discouraging factors for reporting ADRs were lack of time (40.6%) and fear of legal issues (27.1%) and no remuneration (21.8 %) and no significance (10.5%). In the study done by Sandeep Kumar Guptha et al no remuneration (31.7%), lack of time(23.8%), no significance(21.8%) and difficulty to identify ADR(22.8%) were reported as major discouraging factors.[10] In the study done by Meenakumari et al 42.5% suggested difficulty in identifying ADR, 30% participants suggested lack of time and 12% suggested no remuneration as the cause for not reporting.[9]

CONCLUSION

This study threw light upon the knowledge, attitude and practice of health care professionals regarding ADR reporting and Pharmacovigilance in a tertiary care hospital. Compared to similar studies done in past, awareness of health care professionals has improved over past 3-4 years. Pharmacists are the major group of health care professionals properly sensitized and trained in reporting ADRs. Doctors and nurses need to be sensitized more to challenge the underreporting of ADRs and to increase the numbers of ADRs reported in our country.

The ultimate aim of pharmacovigilance is to ensure drug safety and rational therapy and to minimize adverse drug reactions. Sensitization of major health care professionals (Doctors, nurses and pharmacists) regarding the necessity of ADR reporting and pharmacovigilance is the rate limiting factor in obtaining a good quantity of reports from peripheral ADR monitoring centers. This questionnaire based study done among 133 health care professionals was not only done to assess the KAP towards ADR reporting and pharmacovigilance but also to find out discouraging factors in ADR reporting and address the same by providing an awareness session on ADR reporting and pharmacovigilance so that they will be practicing the same in future.

Strength of This Study

The strength of our study was that we have conducted an evaluation of all major health care professionals and could do an intervention session on ADR reporting and pharmacovigilance to make them more aware about the necessity of ADR reporting. The session covered most of the aspects of ADR reporting and pharmacovigilance including how to fill and ADR form and how to report it to the AMC. We could identify major discouraging factors which may be addressed in future to increase the quantity of ADR reports.

Limitations

This is a study was conducted with a limited sample among 133 health care professionals who agreed to participate. We couldn't gather data after the training session provided to assess the effectiveness of the session.

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Conflict of interest

None declared

Ethical approval

The study was approved by the institutional ethics committee

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