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QUESTIONNAIRE STUDY REGARDING KNOWLEDGE, ATTITUDE AND PRACTICE (KAP) OF PHARMACOVIGILANCE AMONG THE HEALTHCARE PROFESSIONALS IN A SUBURBAN TERTIARY CARE TEACHING HOSPITAL.

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ABSTRACT

Aim: Evaluation of the knowledge, attitude, and practices of the healthcare professionals about pharmacovigilance and assess the cause of adverse drug reaction (ADR) underreporting in a suburban tertiary care teaching hospital.

Methodology: After taking the consent to participate, healthcare professionals and students were given questionnaires to assess the KAP of pharmacovigilance. The data from questionnaires was analyzed by SPSS.

Results: 61% gave correct response regarding the definition of pharmacovigilance. 78% participants agreed that ADR reporting is a professional obligation. 91% agreed that pharmacovigilance should be taught in detail. 84% have experienced ADRs in patients, but only 5% were ever reported. The most common reason for underreporting was belief that only serious ADRs should be reported.

Conclusion: The knowledge and attitude towards pharmacovigilance is improving among healthcare professionals, but actual practice of ADR reporting is substantially low due to lack of pharmacovigilance training.

KEYWORDS : Pharmacovigilance, knowledge, attitude, practice.

Introduction:

India has one of the largest drug consuming population with availability of many brands of drugs, which are irrationally prescribed. The faulty prescribing practices and misuse has led to development of adverse drug reactions (ADRs) that are one of the major causes of mortality and morbidity, social and economic burden. Therefore, early identification of ADRs is necessary for both government and non-government health care organizations.[1]

As per World Health Organization (WHO) ADR is defined as "any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or treatment of the disease".[2] Pharmacovigilance (PV) is defined as "The science and the activities related to the detection, assessment, understanding and the prevention of adverse effects or any drug-related problems".[3]

Central Drugs Standard Control Organization (CDSCO) in 2004 established National Pharmacovigilance Programme of India (PvPI) to monitor ADRs and to provide drug safety reports to the Uppsala Monitoring Centre (UMC, WHO), Sweden.[1] Contribution of India in the UMC database although increasing was only 2% in 2013.[4]

Spontaneous reporting of suspected ADRs to PV centers is very important to generate the safety data of marketed drugs.[1] In India, under-reporting of suspected ADRs by health professionals is a widespread problem.[5] Hence to increase awareness of the PV programme among health professionals and to improve ADR reporting by developing various strategies, a questionnaire study was performed to know the existing knowledge, attitude and practice (KAP) of ADR reporting and PV in the health professionals at our tertiary care teaching hospital.

Methods:

This study was conducted at a tertiary care teaching Hospital in suburban Maharashtra, India, after the approval from the institutional ethics committee. Study was a cross-sectional questionnaire-based study. The participants were the working healthcare professionals and students (doctors, residents and Interns) who gave their informed consent.

A 20 question questionnaire was designed to know and assess the knowledge, attitude and practice (KAP) of PV and ADR reporting of the participants. Of the 20 questions 7 were knowledge related, 4 for attitude and 8 related to practice. One question was designed to know the reason for underreporting.

250 questionnaires were distributed to the healthcare professionals and students. time of 2 days was given to fill and collect the forms. Information from the collected forms was entered and analyzed by SPSS software v16.[6]

Results:

The demographic details of the respondents/participants are summarized in Table 1.

Table 1: Demographic details of the respondents (n=200)

	Frequency
Gender	
Male	128
Female	72
Professional status	
Doctors	47
Residents	59
Interns	94

Response rate

250 questionnaires were distributed to the healthcare professionals and students. Out of which 220 responded, 15 of which were incompletely filled and 5 had picked multiple options. Hence the remaining 200 questionnaires were selected for analysis.

Knowledge

61 % participants gave correct response regarding the definition of pharmacovigilance. 65% participants opted for "To identify safety of the drug" as the most important purpose of pharmacovigilance. 78% agreed that ADR reporting is their professional obligation. 51% participants were aware about the existing Pharmacovigilance Programme of India. 25% knew regulatory body for ADR monitoring in India is Central Drugs Standard Control Organization (CDSCO) and 21% were aware that International Center for ADR monitoring is located in Sweden.

Attitude

90 % of participants accepted that reporting ADR is necessary. 44 % participants had previously read about prevention of ADRs. 94% participants agreed that ADR monitoring center should be established at our hospital. 91% participants had a view that there should be thorough teaching of pharmacovigilance to the healthcare professionals and students.

Practice

84% participants have experienced ADRs in patients but only 5% have ever reported ADR to pharmacovigilance center. Only 10% participants were aware that a serious adverse event should be reported to the regulatory authority within 14 calendar days.

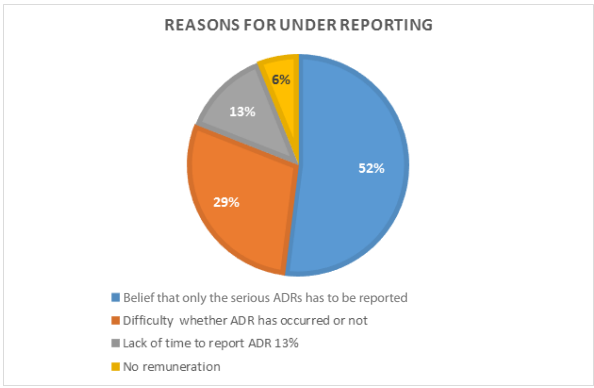
Merely 15% knew that rare ADRs can be identified during phase 4 studies i.e. the post marketing studies.

Reasons for under-reporting

The reason for under-reporting opted by the participants were:

Belief that only the serious ADRs has to be reported 52%
Difficulty to decide whether ADR has occurred or not 29%
Lack of time to report ADR 13%
No remuneration 6%

Fig 1: Reasons for under-reporting of ADRs (n=200)



Discussion:

Our study showed that majority of participants who responded agreed that it is necessary to report ADRs and there should be thorough teaching of pharmacovigilance.

There was huge gap between the ADR experienced (84%) and ADR reported (5%). These results are comparable to the previous studies from Ahmedabad [7] and from Trivandrum. [8] Causes of underreporting, Belief that only the serious ADRs has to be reported 52%, Difficulty to decide whether ADR has occurred or not 29%, Lack of time to report ADR 13%, No remuneration 6%.

The knowledge of pharmacovigilance of healthcare professionals and students about definition and existence of PvPI of our study was comparable to the findings in study done by Pimpalkhute S. A. et al at Nagpur [9] and Gupta, et al at Tamil Nadu.[6]

The adverse event reporting rate from our study is very low in comparison to previously reported different Indian studies from Nagpur [9] and Jalandhar [10]. Reason for this is that there was no formal training of the doctors, residents and interns in pharmacovigilance and ADR reporting.

91% participants had a view that there should be thorough teaching of pharmacovigilance at our institute which is similar to results from Tamil Nadu [6] and Manipal.[11] This shows a positive attitude of the healthcare professionals and students towards the learning of pharmacovigilance and ADR reporting.

Conclusion:

Pharmacovigilance has an important place for knowledge and prevention of the ADRs. However even though the knowledge of pharmacovigilance and attitude of healthcare personnel is good, the actual practice of ADR reporting is very low. There is a need to impact on the minds of the healthcare professionals that reporting ADR is as important as treating them. Various factors which are responsible for this underreporting were found to be, lack of time to report ADR, belief that only the serious ADRs has to be reported, and difficulty to decide whether ADR has occurred or not. So to nullify these factors suggestions to improve the ADR reporting rate are:

1. Inclusion of pharmacovigilance in the undergraduate (UG) healthcare curriculum
2. Regular training on basic principles of pharmacovigilance including adverse drug reaction (ADR) reporting
3. Easy accessibility to ADR reporting forms
4. Regular updates on the safety of drugs
5. Spontaneous reporting of adverse drug reactions through electronic submission
6. Establishing a network of doctors for ADR reporting

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