

RESEARCH ARTICLE

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Knowledge and Awareness of Pharmacovigilance among Various Medical Fraternities

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ABSTRACT

The primary objective of this study was to evaluate the knowledge and awareness of various medical fraternities about pharmacovigilance in Government Kilpauk Medical College and Hospital (Tamil Nadu), a tertiary care teaching hospital. A cross-sectional study was carried out using a pretested questionnaire. The questionnaire was designed to assess the KAP regarding pharmacovigilance. The healthcare professionals (final MBBS students, resident doctors and nurses working in the KMC (Tamil Nadu) were included. Only those who gave their consent to participate were included in the study. The data was analyzed by using the Statistical Package for Social Sciences (SPSS) statistical software, version 16. One hundred and fifty pretested questionnaires were distributed among the healthcare professionals and 116 responded. This study demonstrated that knowledge and attitude towards pharmacovigilance is adequate among healthcare professionals and practice of ADR reporting is catching up.

Introduction:

The safe use of medicine is an important aspect that affects each and every member of society. Reducing the incidence and consequences associated with adverse drug reactions is a crucial challenge in drug use. Despite the importance of medicine in the prevention and curing of diseases, its usage is sometimes associated with undesirable adverse reactions and even fatal reactions¹.

Adverse Drug Reactions (ADRs) are associated with a significant morbidity and mortality. In order to identify the culprit drugs causing ADRs, several countries have initiated pharmacovigilance programs in the recent past. Because of the variation in drug response among individuals, prescribing habits, drug regulatory system, availability of drugs etc, it has been recommended for every country to set up their own pharmacovigilance programs.

The ultimate aim of pharmacovigilance is to ensure safe and rational use of medicines, once they are released for general use in the society. The most important outcome of pharmacovigilance is the prevention of negative consequences of pharmacotherapy.

Pharmacovigilance programs have played a major role in detection of ADRs and banning of several drugs from the market. However, under reporting of ADRs is one of the major problems associated with pharmacovigilance programs.

Although pharmacovigilance programs are successful in improving drug use patterns, under reporting of ADRs is felt as a major problem. In order to improve the reporting rate, it is important to improve the Knowledge, Attitude and Practices (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance. Prior to carry out any intervention, it is necessary to evaluate the baseline KAP of the healthcare professionals regarding ADR monitoring and Pharmacovigilance².

Pharmacovigilance plays an important role in the rational use of medicines by providing information about ADRs in the general population.

Communicating the potential harm of drug-use to patients is a matter of high priority and should be carried out by every prescriber³.

Good pharmacovigilance programs will identify the risks and the risk factors in the shortest possible time so that harm can be avoided or minimized. Physicians, pharmacist and nurses are in a position to play a major key role in pharmacovigilance programme. Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as attitudes that are associated with a high degree of underreporting⁴.

Effect and adverse effect are two sides of the medicines, so not only to prescribe the right medicine for the right disease, but also not to produce extra harm

to the patient is legal responsibility of every physician. One of the important long term goal of this programme is to develop reporting culture among healthcare professionals and make ADR reporting mandatory for health care professionals⁵.

ADR leads to number of medical and economic consequences like prolonged hospital stay, increase in the cost of treatment and risk of death. Hence, early detection and prevention of ADR is necessary. Because of variation in drug response, individual prescribing habits, drug regulatory systems, and availability of drugs etc., it has been recommended for every country to set up their own Pharmacovigilance programme.

Need for the present study Pharmacovigilance is a shared responsibility of all the stake holders. Under-reporting of ADRs is a serious issue. The lack of awareness and knowledge on how to report ADRs have led to poor reporting in the past. Proper surveillance system in place will help improve ADR reporting. The participation of health care professionals is the vital force of dynamics of this programme⁶.

Safety and efficacy are the two major concerns about a drug. While efficacy of a drug can be quantified with relative ease, the same cannot be said about safety. This is because, the adverse effect of a drug may be uncommon (but very serious) and many patients may be affected or subjected to a potential risk before the relationship with the drug is established. The contribution of health professionals, in this regard, to ADRs databases is enormously significant and has encouraged ongoing ascertainment of the benefit-risk ratio of some drugs^{4,5},

In order to improve the reporting rate, it is important to improve the knowledge, attitude and practices (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance. The best time to do it is probably during the undergraduate and post graduate education of the doctors⁷.

Hence the present study is undertaken to assess the knowledge and attitude about pharmacovigilance among various medical fraternities

MATERIALS AND METHODS

Study population:

The study included 50 final year MBBS students, 50 resident doctors and 50 staff nurses of our institution; the study was conducted from March 2015 to April 2015.

Instruments used:

Structured pretested questionnaire containing 20 items to check knowledge and awareness was used for the study. Participants were explained the purpose of study and were requested to complete and return the questionnaire immediately. Consent was obtained from the participants prior to the study

Questionnaire validation:

Each correct answer and each positive response were given a score of '1' whereas the negative response or wrong answers were given a score of '0'. The maximum possible score was '20'.

Ethics:

Ethics approval for the study was obtained from the institutional ethical committee, Government Kilpauk medical college, Chennai.

DATA ANALYSIS

Data analysis was analyzed using MS Excel spread sheet and percentage of observations was noted.

RESULTS

A total of 116 responses were obtained. **46 responses from second MBBS, 39 from CRR I and 31 from staff nurses were obtained.** Data from the completed questionnaires is charted categorically in MS Excel, analyzed and results are expressed using suitable pictorial representations and percentages.

TABLE 1

II Year MBBS Students			
Mark	No. of responses	% of responses	Remarks
0-4	0	0	Poor
5-8	3	6.5	Bad
9-12	18	39	Ave
13-16	21	42.9	Good
17-20	4	8.7	Excellent

TABLE II

CRR I			
Mark	No. of responses	% of responses	Remarks
0-4	0	0	Poor
5-8	2	5.1	Bad
9-12	17	43.6	Ave
13-16	10	25.6	Good
17-20	10	25.6	Excellent

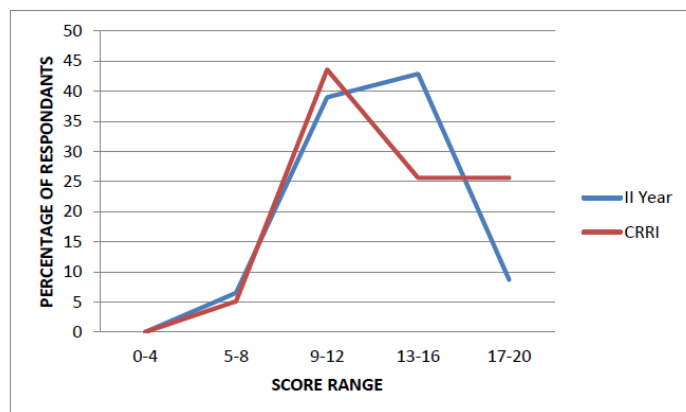
TABLE III

STAFF NURSES			
Mark	No. of responses	% of responses	Remarks
0-4	0	0	Poor
5-8	5	16.1	Bad
9-12	13	41.9	Ave
13-16	12	38.7	Good
17-20	1	3.2	Excellent

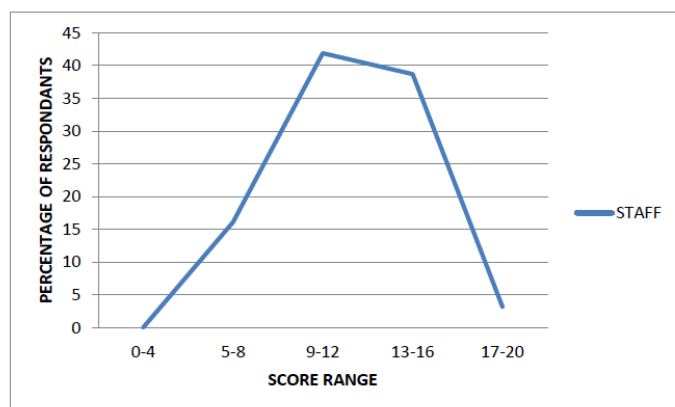
The results were analyzed and tabulated. All the 3 groups were categorized as poor if the score is 0-4, bad if the score is 5-8, average if the score is 9-12, good if the score is 13-16, and excellent if the score is 17-20. The response rate of second MBBS students was better than other two groups. All the three groups have adequate knowledge about pharmacovigilance. The percentage of participants having good knowledge about pharmacovigilance is comparable in all 3 groups. Interestingly participants in all the 3 groups had the scores above average. The participants in the CRR I group obtained the highest score in the excellent

category. Participants in all the 3 groups are aware of the pharmacovigilance programme and have intention to report the adverse drug reaction.

GRAPHICAL REPRESENTATION OF II YEAR AND CRR I SCORE



GRAPHICAL REPRESENTATION OF STAFF NURSES SCORE



DISCUSSION

The World Health Organization (WHO) defines pharmacovigilance as “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems”⁸.

Modern medicines have changed the way in which diseases are managed and controlled. However, despite all their benefits, evidence continues to mount that adverse reactions to medicines are a common, yet often preventable, cause of illness, disability and even death. In some countries,

Adverse drug reactions (ADRs) rank among the top 10 leading causes of mortality. Aside from the intrinsic dangers associated with the products themselves, individual patients may exhibit particular and unpredictable sensitivities to certain medicines. In addition, if more than one medicine is prescribed, there is always a risk of negative interactions. The selection and use of the best and safest medicine(s) for a given individual out of the many choices available thus requires considerable skill on behalf of the prescribing practitioner. In order to prevent or reduce harm to patients and thus improve public health, mechanisms for evaluating and monitoring the safety of medicines in

clinical use are vital. In practice this means having in place a well-organized pharmacovigilance system.

Pharmacovigilance, an umbrella term used to describe the processes for monitoring and evaluating ADRs, is a key component of effective drug regulation systems, clinical practice and public health programmes⁹.

Adverse drug reactions (ADRs) are global problems of major concern and considered as one among the leading causes of morbidity and mortality. The epidemiological importance of ADR is justified by its high prevalence rate- they cause 3% to 6% of hospital admissions at any age, and up to 24% in the elderly population. They rank fifth among all causes of death and represent 5 to 10% of hospital costs and so is a great cause of concern to the medical profession. In order to identify the offending drugs causing ADRs, several countries have initiated pharmacovigilance programs in the recent past¹⁰.

Pharmacovigilance is an integral and essential part of patient care. Healthcare systems rely mainly on the detection and reporting of the suspected ADR, to identify the new reactions, record the frequency with which they are reported, evaluate factors that may increase risk and provide information to prescribers, with a view to prevent future ADRs. With this view National Pharmacovigilance Programme has been launched in India

The most important outcome of the pharmacovigilance is the prevention of patients being affected unnecessarily by negative consequences of pharmacotherapy. Pharmacovigilance programmes have played a major role in detection of ADRs and banning of several drugs from the market.

However underreporting of ADRs is one of the major problems associated with

Pharmacovigilance programmes. Even in countries like UK where Pharmacovigilance programmes are well established, a high level of underreporting is documented¹¹.

Reporting of ADR is an essential component of pharmacovigilance and is crucial to the safety surveillance of marketed medicinal products. Spontaneous ADR reporting is a vital method for detecting new safety issues related to drugs. ADR contribute significantly to morbidity and mortality in clinical practice with its associated economic consequence⁵.

The ultimate aim of pharmacovigilance is to ensure safe and rational use of medicines, once they are released for general use in the society. The most important outcome of pharmacovigilance is the prevention of patients being affected unnecessarily by negative consequences of pharmacotherapy¹².

Pharmacovigilance programs have played a major role in detection of ADRs and banning of several drugs from the market¹³. However, under reporting of ADRs is one of the major problems associated with pharmacovigilance programs¹⁴.

One of the better means of overcoming under reporting is to increase the KAP of the healthcare

professional regarding ADR monitoring and pharmacovigilance programmes. The intervention can be of presentation regarding ADR monitoring and pharmacovigilance in clinical meetings, supply of leaflets to the healthcare professionals regarding drug safety issues etc.

Hence the present study was conducted to assess the knowledge and awareness regarding pharmacovigilance among health care professionals. The results of the present study showed that all the three groups of medical fraternities have good knowledge and awareness. Resident doctors have highest scores in the excellent category, which may be due to the clinical exposure and personnel experience in drug handling and managing adverse drug reactions. The second year MBBS students have adequate knowledge and attitude regarding pharmacovigilance comparable to residents. Nurses have good knowledge about adverse drug reactions but their awareness on pharmacovigilance programme is not adequate.

Despite all the medical fraternities have fairly good knowledge about Pharmacovigilance programme the actual reporting of adverse drug reaction is not adequate, may be because of their work load and not knowing where and whom to report

CONCLUSION

The study identified the Knowledge and awareness of healthcare professionals of Kilpauk Medical College, Tamilnadu. Overall the knowledge and awareness is good among all professionals. The resident doctors had high scores compared to the final year MBBS students, which is due to their clinical exposure, handling drugs and managing adverse drug reactions in the hospital. Nurses also have adequate knowledge about ADR, but awareness about reporting is not adequate. The majority of the healthcare professionals felt ADR reporting and monitoring to be important, but only a few had ever reported an ADR. Our findings suggest the need for educational and managerial interventions to improve the knowledge and awareness of health professionals about pharmacovigilance .Teaching pharmacovigilance to medical students will make them aware of their responsibility to report ADRs. Pharmacologists have the primary responsibility of running a pharmacovigilance programme. Conducting CME programmes for health personnel in teaching hospitals and making all doctors in the peripheral hospitals and private practitioners, nurses and pharmacists to participate will definitely improve the reporting of adverse drug effects by the health personnel.

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