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Identifying the Reasons For Under Reporting Of ADR: A Cross Sectional Survey

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ABSTRACT

Pharmacovigilance mainly involve monitoring and reporting of Adverse Drug Reactions associated with the use of medicinal products. Under-reporting of Adverse Drug Reactions is a serious issue hampering the dynamics of Pharmacovigilance programme. Pharmacovigilance is a shared responsibility of all the stake holders. This study was mainly aimed to assess the Knowledge, Attitude and Perceptions of Health care Professionals towards Pharmacovigilance and estimate factors contributing to under reporting of Adverse Drug Reactions. This was a cross sectional observational questionnaire based study done in a tertiary care hospital in South India. Healthcare professionals who responded (71.4%) includes prescribers, nurses and pharmacists. There was an increase in the awareness and attitude of Health care professionals towards Pharmacovigilance. But inadequate training in methodology of reporting ADR was the main problem. There is a need to provide adequate basic training to all health care professionals by educational interventions through nearest Pharmacovigilance units. It should be of good quality as well as cost affordable.

Keywords: ADR, Adverse drug reaction, Pharmacovigilance, Under-reporting, Healthcare professionals

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INTRODUCTION

An Adverse Drug Reaction is *"an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product."* [1].Adverse Drug Reaction (ADR) can also a common cause of hospitalization and is a serious safety issue. It adds huge costs to the society [2-4]. Surprisingly, the ADRs account for about 5% of the hospital admissions [5]. About 106,000 hospitalized patients died in the US, due to ADRs in 1994 alone. Fatal ADRs are the 4th and 6th leading cause of death in patients [6]. ADRs are one of the primary reasons for discontinuation of medication therapies [7].

A Serious Adverse Event is any untoward medical occurrence that at any dose: Results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect and is a medically important event or reaction. [8]

According to World Health Organization, Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem" [9].ADR monitoring and reporting systems started evolving in various countries, mainly in the wake of the Thalidomide tragedy, during the 1960s [10]. WHO has started its International Drug Monitoring Programme, in response to this disaster. Since 1978, it has been operating from the Uppsala Monitoring Centre (UMC) in Sweden.

WHO- Uppsala Monitoring Centre (UMC) is a forum for WHO member states which includes India to collaborate in the monitoring of drug safety. The individual case reports of suspected ADRs are collected and stored in a common database. The current count of individual ADR cases reporting to Uppsala Monitoring Centre through the National Pharmacovigilance Programme (NPP) of individual countries has increased to about four millions [11].The National Pharmacovigilance Advisory Committee (NPAC) was created under the chairmanship of the Drug Control General of India (DCGI) and Director General of Health Sciences (DGHS). Based at the CDSCO office at New Delhi, NPAC was assigned the primary responsibility of setting up the system to monitor the NPP throughout the country.

New National Pharmacovigilance program of India:

Pharmacovigilance Program (NPP) is revived by the Ministry of Health and Family Welfare in July 2010 and it is overseen by CDSCO, New Delhi. [11,12] Aimed at improving care and safety of the patients by providing reliable and balanced information for the effective assessment of the risk-benefit profile of medicines, the programme now has 134 participating countries [12].The National Pharmacovigilance Programme (NPP) for India is sponsored by the WHO and is funded by the World Bank. The program has three phases. In Phase I the plan is to

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include 40 ADR monitoring centers. In Phase II to include 140 MCI recognized medical colleges by end of 2011and in Phase III ultimately cover the total healthcare system by 2013. The NPP is based on the recommendations made in the WHO document titled *"Safety Monitoring of Medicinal Products - Guidelines for Setting Up and Running a Pharmacovigilance Centre"* [13]. The CDSCO, through its 'Vision 2020', aimed to establish a PV centre in every medical college in the country [12, 13].

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 [14]. A proper surveillance system in place will help improve ADR reporting. The participation of health care professionals is the vital force of dynamics of this programme. Through educational interventions awareness about the importance of monitoring and reporting can be increased and a culture of proper reporting can be fostered. [15]

MATERIALS AND METHODS

Study setting and Study design

This cross sectional observational questionnaire based study was carried out at a tertiary care Hospital in Kerala South India. It was done after approval from Institutional Ethics Committee. Permission from medical superintendent was also obtained prior to the study.

Study population

The study participants include all the health care professionals working at the hospital during the study period. Clinical doctors, postgraduates, nurses and pharmacists who were willing to give informed consent were included in the study. Those who were not willing to give informed consent or fill up the questionnaire were excluded from the study.

Research tool

A KAP questionnaire after preparation was reviewed by subject experts and further validated by a pilot study of Ten randomly selected participants. The questionnaire was designed to be simple and easy to fill up and spread over two pages.[Table1-5]

The questions was structured to obtain the demographic details of the health care professionals, their knowledge of Pharmacovigilance, their attitudes toward it and their training on ADR reporting. These questions were designed based on previous studies for assessing knowledge, attitude and practice of ADR reporting. [16-18] .The last two questions were multiple answering questions regarding factors that encourage or discourage them to report an

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ADR. These were mainly derived from seven sins about underreporting described by Inman.[19] There were provisions to provide suggestions regarding ADR reporting in the hospital All the participants were assured confidentiality about their details and answers of the questionnaire. All information's were entered in M.S. excel data sheet and analyzed.

RESULTS AND DISCUSSION

In spite of the continuous effort by the Government of India in fostering a culture of ADR monitoring; under reporting the worldwide problem is still casting its shadow. In the present scenario of broadening the scope of Pharmacovigilance by including the activities related to the use of biological and medical devices, vaccines, ethno pharmacological and complimentary blood products [20] the active participation of all health care professionals is essential in successful implementation of the programme in any institute. Actually in this venture of ADR Monitoring clinical practioners including surgeons and other health care workers should join hand in hand with trained pharmacologists. Hence proper evaluation and feed back of the knowledge, attitude and perception of the performers will help to rectify the defects and strengthen the programme. Such Pharmacovigilance activities will improve drug safety and patient care. [21]

The questionnaire was administered to 130 nurses, 14 pharmacists and 80 prescribers. A total of questionnaire were returned giving a response rate of 71.4 % [fig 1].Of the total respondents of one hundred and seventy four, 110 were nurses,14 pharmacists, 50 prescribers. Of the 50 prescribers 36 were faculty and 14 were postgraduates. The response rate of pharmacists and nurses were higher over prescribers. Of the total respondents 80.46% were females'. But among the prescribers who had responded 60% were males.

The study results showed that there is an increase in knowledge of health care workers about National Pharmacovigilance Programme in India (67.2 %) and 98.5% are aware that reporting of even one ADR contribute significantly to the programme. This is in contrast to the previous studies done before 2010. [21, 22] Perhaps recent campaigns by Government of India and M.C.I should have contributed to this. Among the participants 82% have experienced Adverse Drug Reactions in patients. Interestingly 60% have not seen the suspected ADR reporting form of CDSCO and only 28.7% know how to report ADR to the Pharmacovigilance centre. This point out the need to accelerate the Pharmacovigilance activities in the institute. Although 17.2% have reported an ADR before, and 27% opined that suspected ADR reporting have to be made more simple and clear. Similar need for better designing of ADR reports was shown in some studies (23, 24). [Figure 2]

The attitude of the Health care workers is reflected in their need for all ADRs should be reported for all drugs (89%), for more than 80% of health care professional ADR reporting is a professional obligation and should be made mandatory to their profession. [Figure 3].This proportion is very low when compared with similar studies [25, 26].

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There is a lack of training of healthcare professionals of the Institute; only 21.8% are trained and 76% of the under trained showed an urge to have a training. All the prescribers who are not trained are willing to undergo training showing their obligation for ADR reporting. Almost 90% of them think feedback of reported ADR is beneficial. [figure4] This is similar to previous studies [27] and it indicates the need to start training centre associated with each Pharmacovigilance unit. Basic training of reporting needs to be given in these units through lectures, demonstrations or CME's. Further they can undergo advanced training in Pharmacovigilance centers. Educational interventions have been shown to improve detecting, reporting and managing ADR in many studies [28, 29].The important factors that encouraging and discouraging them to report an ADR is shown. [Table 4,5] The most common factor that encourage them to report an ADR is the seriousness of reaction or patient safety and the discouraging factors are lack of time to actively look for ADR and fill the report while at work. These findings are in line with similar studies elsewhere [30]. Some of the valuable suggestions by participants include request for training sessions or CMEs on ADR, incorporate ADR reporting in patients case sheet, easy availability of simple reporting forms in the ward and provisions to collect ADR on a regular basis.

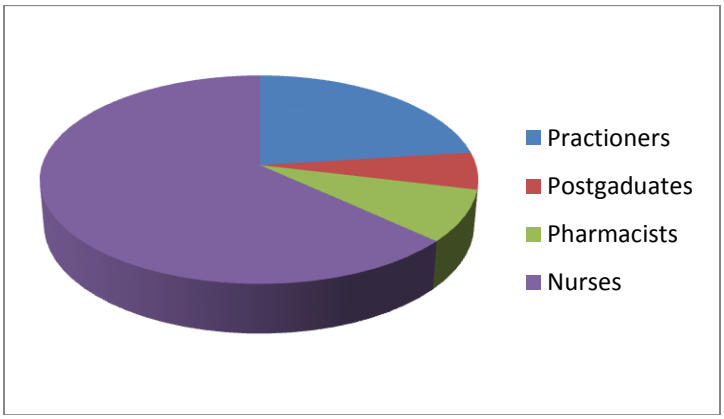

Fig 1 **Participants in the study**

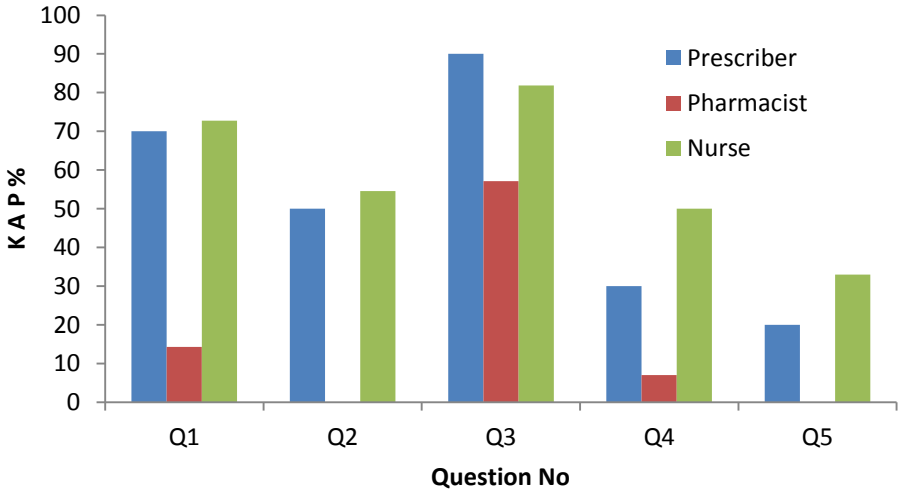

Fig 2.KAP questionnaire assessment for questions1-5

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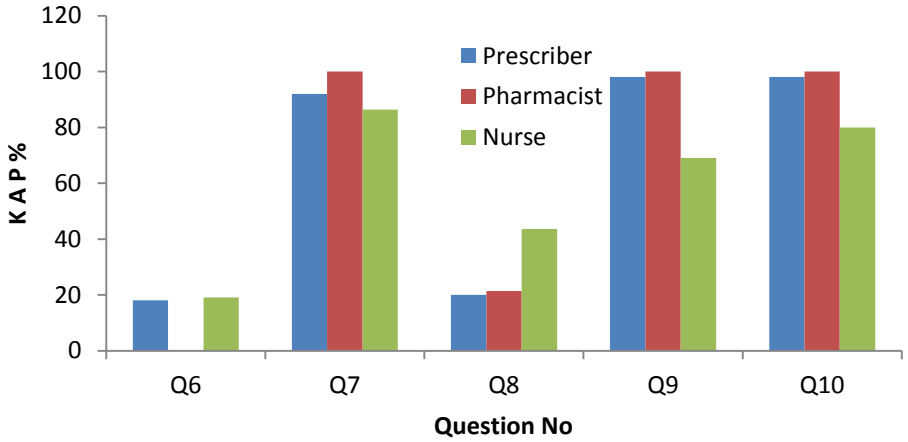

Fig 3. KAP questionnaire assessment for questions 6-10

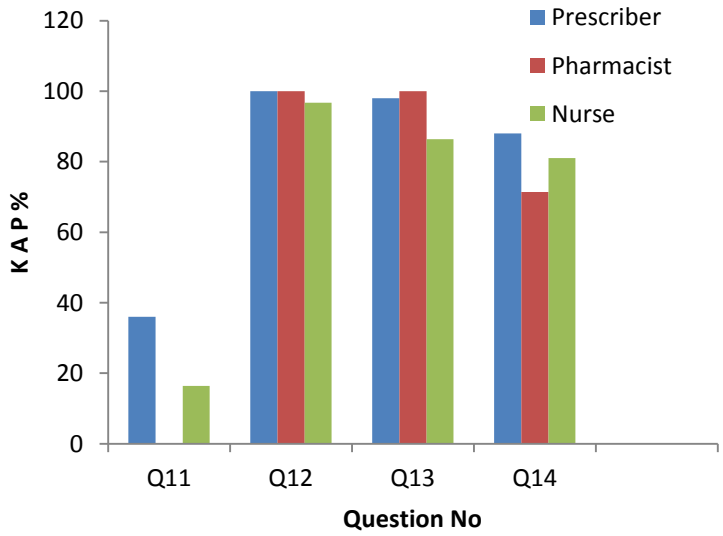

Fig.4 KAP questionnaire assessment for questions 11-14

Q1	I know the existence of a National Pharmacovigilance Programme in India.
Q2	I am aware of the nearest Pharmacovigilance centre in my geographical location
Q3	I have experienced Adverse Drug Reactions in Patients during my Professional practice
Q4	I have seen the suspected ADR reporting form of CDSCO.
Q5	I knew how to report ADR to the Pharmacovigilance centre

Table1: Questionnaire set1

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Q6	Suspected ADR reporting form was found to be simple &clear to me
Q7	All ADRs should be reported for all drugs.
Q8	Only Serious Adverse Event/increased frequency of an ADR of old drugs need to be reported
Q9	Do you think ADR reporting is a professional obligation
Q10	ADR reporting should be made mandatory to my profession

Table2: Questionnaire set2

Q11	I have been trained how to report an ADR/ Do you think training is needed in reporting an ADR?
Q12	I have reported an ADR before.
Q13	Do you think a feedback of reported ADR will be beneficial
Q14	Reporting of only one ADR makes no significant contribution to the National Pharmacovigilance programme /Society

Table3: Questionnaire set3

1. If the reaction was serious
2. If the reaction was unusual
3. If the reaction was to a new product
4. If the reaction was certainly an ADR
5. If the reaction was well recognized for a particular drug

Table 4 Common Factors encouraging to report an ADR

1.Lack of time to fill-in a report
2. Lack of time to actively look for ADRs while at work
3. Concern that the report may be wrong
4.If the reaction was well recognized for a particular drug
5. Lack of confidence

Table 5 Common Factors discouraging to report an ADR

CONCLUSION

Successful implementation of Pharmacovigilance programme and ADR monitoring is mandatory. There is a need to provide adequate good quality basic training to all health care professionals of the institute by educational interventions at an affordable cost.

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