

**"KNOWLEDGE AND ATTITUDE ABOUT ADVERSE DRUG REACTION REPORTING AMONG DOCTORS AT A TERTIARY CARE HOSPITAL"****SATHISHA AITHAL*¹. TANUJA V HOOLI² AND VARUN HV³**¹Associate Professor, Department Of Pharmacology, SSIMS & RC, Davangere,²Associate Professor, Department of Pharmacology, ESIC Medical College, Gulbarga,³Postgraduate, Department of Pharmacology, SSIMS & RC, Davangere**ABSTRACT**

Adverse drug reactions are responsible for mortality and morbidity during medical care. Spontaneous reporting of adverse drug reaction from treating physician plays an important role in assessing the benefit and risk profile of marketed drugs periodically. To assess the knowledge and attitude about adverse drug reaction reporting among the health care professionals working in a tertiary care hospital. This was a cross-sectional study conducted on doctors working at a tertiary care hospital using a standardized questionnaire. The participants were enrolled in the study after obtaining informed consent. Forty two doctors (N=42) agreed to participate in the study. Around 38% of responders were aware of adverse drug reaction reporting centre in their institution. 26% of participants were aware of essential factors required for reporting of an ADR and also knew that causality assessment is not a must for reporting. The most common factors for discouraging reporting of adverse drug reaction was non-availability of reporting forms (47%) followed by lack of time (42%). The most common factors encouraging reporting of an adverse drug reaction included seriousness of the event (95%). The average scores of all participants for attitude related questions were approximately 76 (maximum score 115). There was no significant difference in attitude scores between gender, and between cadre level (P>0.05). The result of the present study indicates that there is a need to create awareness about adverse drug reaction reporting among doctors. The factors discouraging reporting of an adverse drug reaction could be addressed by the local adverse drug reaction reporting centre.

KEY WORDS: Adverse drug reaction; Questionnaire; Attitude; Knowledge**SATHISHA AITHAL**

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INTRODUCTION

Adverse drug reactions (ADRs) are responsible for a significant mortality and morbidity and in most of the cases are preventable.¹ They are considered to be the fourth leading cause of death in US. Incidence of severe ADRs are found to be 6.7% per year in a meta-analysis of 39 studies from US hospitals from 1966 to 1996.² In a study conducted in a hospital at south India, at least one report of ADR was reported from 2.8 % of hospitalized patients.³ A retrospective study of 437 ADRs by McDonnell and MR Jacobs found that 36% adverse drug reaction required hospitalization with an average hospital stay of 6 days.⁴ According to Pirmohamed and colleagues, adverse drug reactions were responsible for 6.5% emergency hospital admissions and at least 5000 deaths per year.⁵ In a study conducted in general practice at Australia, 10 % of patients had experienced an adverse event in the previous 6 months. Incidence of adverse events were found to be more in patients aged above 45 years, children aged 1-4 years and female patients in this study.⁶ Spontaneous reporting from health care professionals play an important role in detecting unique events that are unnoticed in pre-marketing studies. The US FDA received 2.3 million events for around 600 marketed drugs from 1969 to 2002. A number of drugs have been withdrawn from market, besides changes made in prescription information in the form of black box warning, additional contraindication and also distribution restriction.⁷ Therefore, considering the importance of spontaneous reporting of ADR in the health care delivery system, the present study was undertaken to assess the knowledge of attitude of doctors about ADR reporting in a tertiary care hospital.

OBJECTIVES

1. To study the knowledge, attitude of doctors about ADR reporting
2. To compare the knowledge, attitude about ADR among health care professionals.

STUDY DESIGN

A questionnaire based cross sectional study was conducted on doctors working at tertiary care hospital. A pilot study was undertaken on 20 randomly selected health care professionals to validate the questionnaires. The questionnaire was designed to know the demographic details of participants, knowledge and attitude about ADR reporting. The doctors not willing to participate were excluded from the study. The questionnaire was handed over to the interested participants after obtaining informed consent.

RESULTS

Demographic details of participants

The total number of participants who voluntarily participated in the study was forty two. There were thirty male and twelve female participants. The total numbers of doctors with designation of assistant professor and below were twenty four, while those above the cadre of associate professor were eighteen.

Knowledge domain

The seventy three percent of study participants had correct knowledge that doctors, nurses and pharmacists were eligible to report suspected ADR. Approximately six percentage (6%) and four percentage (4%) of doctors were aware of ADR reporting system in India and regional centre of suspected ADR reporting system respectively. Thirty eight percentage (38%) participants were aware of suspected ADR reporting system in the hospital. Regarding essential information required for reporting ADR, only twenty six (26%) of participants correctly identified all factors required. They were aware that causality assessment was not must for reporting suspected ADR. The number of participants given correct answer for knowledge questions according to gender and cadre is given in Table No 1.

Table 1
Knowledge domain according to gender and cadre

| S.No | Knowledge questions | male | Female | Assistant professor and below | Associate Professor and below |
|------|--|------|--------|-------------------------------|-------------------------------|
| 1 | Health care professional eligible to report | 23 | 8 | 18 | 13 |
| 2 | Awareness about ADR reporting system in India | 17 | 5 | 11 | 13 |
| 3 | Awareness about regional centre for reporting | 2 | - | 1 | 1 |
| 4 | Awareness about ADR reporting at their institution | 15 | 1 | 5 | 11 |
| 5 | Essential information for reporting ADR | 10 | 1 | 3 | 8 |

Attitude Domain

The average scores of all participants for attitude related questions were approximately 76(maximum score 115). The average scores of male and female participants were 79 and 73 respectively. The average score of doctors belonging to assistant professor and below was 78, while those participants belonging to associate and above was 76. The attitude of participants according to gender and professional class was given in Table 3. It was found that there was no significance difference in attitude between the gender, and between professional cadre significantly (P >0.05).

Table 2
Attitudes among male and female professionals

| Sex | Number | Mean ± SD | Male Vs Female |
|--------|--------|-----------|----------------|
| Male | 30 | 79.5 ± 17 | P=0.21* |
| Female | 12 | 73 ± 23.8 | |

*Non significant

Table3
Attitudes among different cadres

| Cadre | Number | Mean ± SD | Assistant Vs Associate |
|-----------|--------|-------------|------------------------|
| Assistant | 24 | 78.7±17.1 | P=0.95* |
| Associate | 18 | 76.3 ± 22.1 | |

*Non significant

Table 4
Factors encouraging to report ADR

| Factors | Percentages of responders |
|---|---------------------------|
| Seriousness of event | 95 |
| Unusual reaction | 88 |
| Confidence that event is an ADR | 78 |
| Established events known to be associated with drug | 92 |

Table 5
Factors discouraging to report a suspected ADR

| Factors | Percentages of responders |
|---|----------------------------------|
| Fear of reporting | 30 |
| Lack of time for filling | 42 |
| No financial benefit for reporting | 9 |
| Concern that extra work is required | 38 |
| Not sending one report may not contribute a lot to patient care | 14 |
| Busy working pattern to look actively for ADR | 21 |
| Difficult to diagnose ADR in clinical practice | 26 |
| Non- availability of reporting form | 47 |
| Feeling that reporting of previously known ADR is not required | 17 |
| Poor feedback from regulatory agency | 38 |
| Disclosure of identity | 19 |
| Lack of encouragement from seniors | 21 |

DISCUSSION

Although 60 % of events were reported from health care professionals, it is well known that under-reporting and poor quality of data is a major barrier to the success of pharmacovigilance.^{8,9} It is estimated that only 6-10% of events were recognized and reported^{10,11}. Under-reporting may lead to more exposure of individuals to the harmful effects of drug. Before the withdrawal of fenfluramine from market because of its association with valvular defect, almost 7 million were exposed to it worldwide.¹² A review on reporting pattern in general practice found that there was higher rate of reporting for severe and serious events.^{13,14} Other studies found lower reporting for new drugs and serious reactions which are not life threatening. A study on determinants of under-reporting found that health professionals did not report when the reaction was previously documented or clinically insignificant. It is well known that good knowledge and positive attitude of health professionals could improve ADR reporting patterns.¹⁵ The response rate to the study calculated as the percentage of filled questionnaire returned was 39. The response rate was low when compared to previous studies conducted where it was 85%. Our study revealed that 6 % and 38 % of responders were aware of Pharmacovigilance system in India and ADR reporting centre in the hospital respectively. These percentages show that spontaneous reporting system as recommended by National pharmacovigilance programme of India is not recognized by study

participants. In contrast, 90 and 89 percentages of participants were aware of ADR monitoring system in India and at their hospital in a study conducted by Madhan Ramesh and Gurumurthy Parthasarathi.¹⁶ In our survey 26% of responders were aware of essential factors required for reporting ADR. They had knowledge that patient identification details, drug name, outcome and name of reporter were essential for reporting any suspected ADRs. They were aware that causality assessment is not essential for reporting. The most common factors for discouraging reporting of ADR was nonavailability of reporting forms (47%), followed by lack of time (42%). The coordinated activities between doctors and local ADR reporting system may be useful to overcome the barriers of reporting the ADRs. The ADR are usually unnoticed in routine practice. ADR related deaths were common in patients above 75 years, male gender and patients on anticoagulants, opioids and immunosuppressants.¹⁷ A study of hospital admissions in the UK, found that 6.5 per cent of people admitted to hospital had experienced an ADR and that in 80 per cent of those, the ADR was the direct cause of the admission.⁵ A meta-analysis of ADRs in hospitalised patients in the USA found overall incidence of serious ADRs (on admission and experienced while in hospital) to be 6.7 per cent and of fatal ADRs to be 0.32.¹⁸ Therefore clinicians should be trained to include ADR as a part of differential diagnosis. Appropriate campaigning can overcome the barriers for

reporting ADRs. Previous studies have shown that educational programmes that enhance the knowledge and improve the attitude can improve the number of ADR reports.¹⁹⁻²¹ In a study conducted by Madhan Ramesh and Gurumurthy Parthasarathi, there was a 63% significant increase in ADR reporting after educational intervention.¹⁶ Another study conducted by Tabali M et al revealed that an initial 148% increase in the number of ADR reports was observed immediately after the educational intervention.²² Therefore there is a necessity of undertaking similar programme in our hospital to create awareness about ADR reporting. The major limitation of our study was low response rate to the questionnaire. This also highlights importance of undertaking appropriate campaigning including personal

meeting, provision of newsletter from pharmacovigilance programme of India (PvPI) and "thank you" note for sending the report. The news letter from PvPI highlights the summary of ADR reported from time to time as well as regulatory matters.

CONCLUSION

Majority of study participants were unaware of ADR reporting centre in their institution. The most common factor for encouraging and discouraging reporting of an ADR includes seriousness of an event and non-availability of reporting form respectively. The result of the study indicates the need to create awareness of about ADR reporting among doctors.

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