Knowledge, attitude and practice of adverse drug reaction reporting among doctors in a tertiary health care centre in South India

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ABSTRACT

Background: A fundamental determinant to medical drug safety surveillance is voluntary adverse drug reaction (ADR) reporting; but there exists substantial under-reporting which is the main drawback of the system. The objective of the study was to evaluate the knowledge, attitude and practice of ADR reporting among doctors in a tertiary health care center.

Materials and Methods: A cross sectional questionnaire based study was conducted on doctors in a tertiary health care center. Participants were selected randomly and those not willing to participate were excluded from the study. Collected data was assessed by frequency, percentage, mean and standard deviation. Statistical analysis was performed by using SPSS version 13.0.

Results: 75% (45) of respondents were aware of the existence of ADR reporting system in India; on the contrary only (11.7%) of respondents were aware of regional center for ADR reporting. All respondents (100%) felt that seriousness of the ADR event, unusual reaction (95%), reaction to new drug (98.33%), and the certainty of ADR reaction (91.66%) would encourage them to report an ADR event. However, only 15 out of 60 respondents (25%) have reported ADRs.

Conclusion: Though the level of knowledge about ADR reporting and the attitude towards ADR reporting were adequate, our study has shown that the actual practice of ADR reporting is unsatisfactory. This indicates that there is a need to create an awareness of the importance of ADR reporting through continuous medical education and training of ADR reporting among doctors.

Key words: Adverse drug reaction, ADR reporting.

INTRODUCTION

World Health Organization defines Adverse Drug Reaction (ADR) as “any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy.”[1] A study in South India showed that ADRs came up to 0.7% of total admissions and 1.8% of total ADRs lead to death.[2] A fundamental determinant to medical drug safety surveillance is Voluntary ADR reporting; but there exists substantial under-reporting which is the main drawback of the system.[3] A study conducted by Okezie EO et al observed that the lack of knowledge about the availability of reporting forms (70.9%) and ignorance of reporting procedure (69%) were the commonest factors that discouraged ADR reporting.[4]

Based on the systematic review conducted by Lopez-Gonzalez E et al, it was observed that the other factors related with under-reporting among doctors included ‘ignorance (95%)’ that there is only a need to report severe ADRs, ‘diffidence (72%)’ that is the fear of appearing ridiculous for reporting merely suspected ADRs; ‘lethargy’ in 77% of cases; ‘indifference’ that the one case which an individual doctor might see could not contribute to medical knowledge; ‘insecurity’ where it is nearly impossible to determine whether or not a drug is responsible for a particular adverse reaction in 67%; and ‘complacency’ that only safe drugs are allowed on the market in 47% of studies. Unlike personal and professional factors which show a weak influence, it was observed that the knowledge and attitudes of health professionals emerge to be strongly linked with reporting of ADRs in large number of studies.[5]

Due to its simplicity, the main method for detecting rare or unexpected adverse drug events is voluntary reporting by clinical physicians but low reporting rate will compromise the usefulness of this method.[6] Therefore this study was taken up to assess the knowledge, attitude, and practice of ADR reporting among doctors in a tertiary health care center. By conducting a knowledge, attitude and practice study, we would be able to identify reasons for under-reporting of ADRs.

MATERIALS AND METHODS

Study design

This was a cross sectional questionnaire based study conducted on doctors in a tertiary care health center in South India. They were surveyed with a questionnaire which was designed to know the demographic details and the participant’s knowledge, attitude and practice of ADR reporting. The study was conducted after receiving the approval from the Institutional Ethics Committee of Father Muller Medical College, Mangalore, India.

Study questionnaire

A questionnaire comprising of 40 questions was used in this study (appendix 1). The questionnaire was a newly designed one, based on similar studies conducted previously and inputs from faculty. The questionnaire was tested for its validity and reliability by conducting a pilot study. The correct responses were scored 1 point and wrong responses were given zero point for knowledge related questions and practice related questions. The attitude related questions were scored based upon the participant’s degree of agreement using Likert scale. The score was as following; ‘0’ – strongly disagree, ‘1’ – disagree, ‘2’- uncertain, ‘3’- agree and ‘4’-strongly agree.

Study participants

The study included doctors from Father Muller Medical College, Mangalore, Karnataka, India. 60 doctors (PG residents & junior doctors) participated in the study. Doctors were randomly selected and informed consent was taken from them. Those who were not willing to participate were excluded from the study. The questionnaire was handed over to interested participants and the time allotted to fill the questionnaire was 1 hour.

Statistical analysis

Collected data was analyzed by frequency, percentage, mean and standard deviation. Statistical software used was SPSS version13.0.

RESULTS

Assessment of Knowledge

In our study, 75% (45) of respondents were aware of the existence of suspected ADR reporting system in India; however, only 7 out of 60 respondents (11.7%) were aware of regional center of ADR reporting. 59 out of 60 (98.3%) respondents were of the opinion that polypharmacy is commonly associated with ADR.
All respondents agreed that suspected medication should be included as a part of essential information while reporting an ADR. 50% of respondents were of the opinion that there is no need of disclosing the name of the reporter while reporting ADR. 95% of the respondents were aware of drugs that had been withdrawn from the market due to safety reasons. 48.3% of respondents were of the opinion that it is not their duty to report ADRs caused by herbal medicine. 26 out of 60 (43.3%) respondents feel that there is no need to report ADR if there is no certainty whether the product itself has caused the reaction. 98.3% of respondents agreed that reporting is required when ADRs are caused by over the counter [OTC] drugs and topical agents. Therefore, the overall level of knowledge of ADR reporting among doctors was found to be adequate according to statistical analysis [Table 1]. The score of 0-5 (0-29%) was considered as inadequate.

### Table 1: Overall level of knowledge and attitude among the participants. (n=60)

<table>
<thead>
<tr>
<th></th>
<th>Minimum</th>
<th>Maximum</th>
<th>Maximum possible score</th>
<th>Mean ± SD</th>
<th>Mean (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall knowledge (/17)</td>
<td>7</td>
<td>17</td>
<td>17</td>
<td>12.93 ± 2.29</td>
<td>76.08</td>
</tr>
<tr>
<td>Overall attitude (/84)</td>
<td>37</td>
<td>76</td>
<td>84</td>
<td>59.88 ± 9.81</td>
<td>71.29</td>
</tr>
</tbody>
</table>

### Assessment of attitude

All respondents were of the opinion that ADR reporting system would benefit patient care and 98.3% felt that reporting of ADR is a duty of health care professional.

### Factors that encouraged ADR reporting

All respondents (100%) feel that seriousness of the ADR event would encourage them to report. Other factors that would encourage them to report ADR includes unusual reaction (95%), reaction to new drug (98.33%), and the certainty that the reaction is an ADR (91.66%).

### Reasons for not reporting ADRs

69.99% of respondents were of the opinion that non-availability of reporting forms discouraged them from ADR reporting. Other factors that discouraged them from ADR reporting included busy schedule (41.6%), apprehension (38.33%), previously known ADRs (38.32%), inability to diagnose ADR (34.99%), concern of extra work (31.6%), busy practice (29.99%), non-remuneration (23.3%) and feeling that not sending one report may not contribute a lot to patient care (13.32%).

The overall level of attitude towards ADR reporting among doctors was found to be adequate (71.29%) according to statistical analysis [table 1]. The score of 0-28 (0-33%) was considered as inadequate.

### Assessment of practice

96.7% of respondents (58 out of 60) have never even attended any Continuing Medical Education (CME) program ME on ADRs, which shows that there is lack of awareness creating programs stressing on the importance of ADR reporting. Despite having heard of ADRs reporting system, only 15 out of 60 respondents (25%) have ever reported ADRs, indicating that there exists a poor practice of ADR reporting among doctors. This poor practice would inversely affect the system of Medical Safety Surveillance.

### DISCUSSION

Under-reporting of ADRs is an universal phenomenon, that exists as an inherent weakness of current voluntary reporting schemes.[7] This study was therefore taken up to evaluate the knowledge, attitude and practice of ADR reporting among doctors in a tertiary health care center.
Our study observed that despite the adequate level of knowledge and attitude among doctors, only 25% of them have ever reported any ADRs indicating the existence of poor practice of ADR reporting in our hospital. A similar study conducted by Kharkar M et al[7] observed that even though the medical practitioners were aware of ADR reporting and had the right perception towards it, their practice of ADR reporting was very poor. Their results were comparable to our study. A survey conducted by Chatterjee S et al[8] which included 138 clinicians observed good knowledge but poor attitude and practice with regard to ADR reporting. Their study also concluded that there is a need to spread awareness of pharmacovigilance by including it in medical teaching and training curriculum.[8]

Since adverse drug reactions (ADRs) escalate health care costs by increasing patient morbidity and mortality, there is a need to create awareness among physicians towards ADR monitoring.[9] 75% of respondents in our study were aware of suspected ADR reporting system in India, on the contrary almost half of respondents (40.4%) were not aware of the existence of NPC (National Pharmacovigilance Centre) in a study conducted in Nigeria.[10]

Our study observed that all respondents were of the opinion that seriousness of the ADR event would encourage them to report. Other factors that would encourage them to report ADR includes unusual reaction (95%), reaction to new drug (98.33%), and the certainty that the reaction is an ADR (91.66%). This was similar to the responses obtained in the study conducted by Oshikoya KA et al, where respondents were encouraged to report ADRs if the reaction was serious (77.8%) and unusual (70.7%) in nature, if the reaction was to a new product (58.6%), certainty that the reaction was truly an ADR (45.5%), and if the reaction was well recognized for a particular drug (46.5%).[10]

All respondents in our study were of the opinion that ADR reporting would benefit patient care. In a survey conducted by Belton KJ et al[11], it was observed that factors that discourage ADR reporting included unavailability of report forms, contact number or address of the reporting agency; lack of knowledge on how to report; and lack of enough time to report ADRs. Uncertainty that ADR was definitely caused by the drug, reaction being too trivial to report or too well known to report are other common reasons for not reporting.[12]

Only 15 out of 60 respondents have ever reported any suspected ADR, indicating that there is under-reporting in our tertiary care health centre. Since spontaneous reporting is an important determinant in pharmacovigilance and one of the best methods to detect new or rare adverse drug reactions (ADRs), existence of under-reporting would adversely affect this system.[13] In our study, 96.7% of respondents have never attended any CME on ADR reporting. However, it has been demonstrated that an educational intervention can improve physician’s awareness of ADRs, and enable them to incorporate the knowledge into their daily clinical practice.[14] Apart from educational interventions, professional support, acknowledgements and feedback to reporter about ADRs reported by them, would further help in strengthening ADR reporting.[15]

The Drug Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) have put a lot of effort in setting up many ADR monitoring centers in various parts of India; despite their efforts pharmacovigilance is still in its infant stage in India.[7]

The main limitation of our study was the small sample size. We could have also included nurses and pharmacists, as they also play an important role in pharmacovigilance. By conducting this knowledge, attitude and practice [KAP] study, we were able to identify various factors associated with under-reporting of ADR in our hospital. This study has given us an insight on how to plan ahead in future to improve our pharmacovigilance.
In conclusion, the present study has shown that though the level of knowledge about ADR reporting and attitude towards it was adequate, yet doctors showed poor practice of ADR reporting. Therefore, there is a need to increase the awareness regarding the importance of ADR reporting through Continuous Medical Education at regular intervals, training the doctors on how to report an ADR and also including pharmacovigilance awareness programmes for undergraduates. All these steps would further help the doctors to contribute to pharmacovigilance efficiently.

**ACKNOWLEDGEMENT**

Not reported.

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**Appendix 1:**

Questionnaire used in this survey to assess knowledge, attitude and practice of adverse drug reaction reporting among doctors in a tertiary health care centre in South India

**Demographic details:**
Name: __________  Age: __________  Qualification: __________

**Knowledge of ADR reporting:**
1. Are you aware of suspected adverse reaction reporting system in India? Yes/No
2. Are you aware of regional center of ADR reporting? Yes/No
3. Following are commonly associated with ADRs
   a. Old age Yes/No
   b. Multiple co-morbidities Yes/No
   c. Poly-pharmacy Yes/No
   d. Patients in ICU Yes/No
   e. Children aged 1-4yrs Yes/No
4. Following are essential information while reporting an ADR
   a. Patients initials Yes/No
   b. Date of start of reaction Yes/No
   c. Suspected medication Yes/No
   d. Outcome of the event Yes/No
   e. Name of reporter Yes/No
5. Are you aware of any drug withdrawn from market due to safety reason? Yes/No
6. ADR reporting is required in following circumstances
   a. When it is caused by herbal medicine Yes/No
   b. When it is not certain that drug has caused the reaction Yes/No
   c. When it is caused by OTC drugs Yes/No
   d. When it is caused by topical agents Yes/No

**Attitude of ADR reporting**
1. Do you agree that ADR reporting system would benefit patient care? Strongly agree/ Agree/ Neutral/ Disagree/ Strongly disagree
2. Would you suspect ADRs when drug is administered in normal dose? Strongly agree/ Agree/ Neutral/ Disagree/ Strongly disagree
3. Do you think reporting of seemingly insignificant ADRs is required? Strongly agree/ Agree/ Neutral/ Disagree/ Strongly disagree
4. Reporting of all ADRs for a new drug is essential? Strongly agree/ Agree/ Neutral/ Disagree/ Strongly disagree
5. Reporting of ADR is duty of health care professional? Strongly agree/ Agree/ Neutral/ Disagree/ Strongly disagree
6. Factors that encourage you to report ADRs?

<table>
<thead>
<tr>
<th>Factors</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
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<tbody>
<tr>
<td>a. Seriousness of event</td>
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<td>b. Unusual reaction</td>
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<td>c. Reaction to new drug</td>
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<td>d. Certainty that the reaction is an ADR</td>
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<tr>
<td>e. Well recognized event that are known to occur with the drug</td>
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</table>
Practice of ADR reporting among doctors

7. Reasons for not reporting ADRs

<table>
<thead>
<tr>
<th>Reasons</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neutral</th>
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<th>Strongly disagree</th>
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<tbody>
<tr>
<td>a. Apprehension about sending inappropriate forms</td>
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<td>b. Busy Schedule to fill the form</td>
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<td>c. Non-remuneration for reporting</td>
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<td>d. Concern that extra work is required to fill &amp; send the report</td>
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<td>e. Not sending one report may not contribute a lot to patient care</td>
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<td>f. Busy practice to look actively for ADR</td>
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<td>g. Difficult to diagnose ADR in clinical practice</td>
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<td>h. Non-availability of reporting form at work place</td>
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<tr>
<td>i. Feeling that reporting of previously known ADR is not required.</td>
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</table>

8. The CDSCO suspected adverse drug reaction reporting form is complex to use

   Strongly agree/Agree/Neutral/Disagree/Strongly disagree

9. Do you agree that reporting of ADRs be made compulsory?

   Strongly agree/Agree/Neutral/Disagree/Strongly disagree

Practice of ADR reporting

1. Have you reported any suspected adverse drug reaction?  Yes/No
2. Have you attended any CME on ADR reporting?         Yes/No

REFERENCES


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