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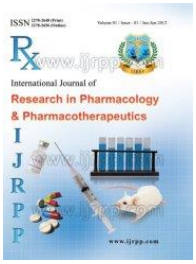

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Knowledge, attitude and practice of adverse drug reaction reporting and pharmacovigilance among healthcare professionals in a tertiary care teaching hospital

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ABSTRACT

Background

India has the largest drug consuming population in the world. Adverse drug reactions (ADR) are commonly encountered in daily practice, many of which are preventable .

Objective

To evaluate the knowledge, attitude and practice of ADR reporting and Pharmacovigilance concept among healthcare professionals.

Materials and Methods

It was a cross-sectional, questionnaire based survey conducted by the staff of the Department of Pharmacology at Dr.B.R.Ambedkar Medical College and Hospital, Bangalore in March 2017. 92 doctors participated in this study.

Statistical analysis

Collected data was analyzed by frequency, percentage and mean using the statistical software SPSS version13.0

Results

98% of respondents were aware of the existence of suspected ADR reporting system in India. 54.6% of respondents were of the opinion that non availability of reporting forms discouraged them from ADR reporting. All respondents were of the opinion that ADR reporting system would benefit patient care. 50(54.3%)of respondents have never even attended any Continuing Medical Education (CME) programme on ADRs, which shows that there is lack of awareness creating programs stressing on the importance of ADR reporting.

Conclusion

This study revealed that though majority of the health-care professionals had good knowledge and positive attitude about Pharmacovigilance, the actual practice of ADR reporting was unsatisfactory.

Keywords: Adverse drug reaction, Knowledge, Pharmacovigilance, Attitude, Spontaneous reporting

INTRODUCTION

India has the largest drug consuming population in the world. Adverse drug reactions (ADR) are commonly encountered in daily practice, many of which are preventable. [1]

WHO defines adverse drug reaction as "response to a drug which is noxious, unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function". [2]

The prevalence of ADR in India is 16.2%. [3] ADRs are also one of the important causes of morbidity and mortality worldwide. [4] A study in South India recorded ADRs as the cause for 0.7% of total admissions and 1.8% ADRs had caused death. [5]

ADRs are associated with prolonged length of hospital stay, increased economic burden and increased mortality. [6] Hence their early detection and prevention is necessary.

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

Spontaneous or voluntary reporting of suspected adverse drug reactions (ADRs) is one of the vital roles of all health care professionals. Even though health care professionals contribute enormously, under reporting remains a major hindrance in the success of pharmacovigilance programmes.

Hence this study was undertaken as it might help us in understanding the reasons for under reporting of ADR's and developing strategies for increasing ADR reporting.

MATERIALS AND METHODS

This was a cross sectional questionnaire based study conducted in Dr.B.R.Ambedkar Medical College & Hospital, Bangalore in March 2017.The study was approved by the Institutional Ethics Committee. The questionnaire was designed based on similar study done previously [8] and minor changes were made after taking valuable inputs from the faculty.

The questionnaire was tested for its validity and reliability by conducting a pilot study. It was used to assess the knowledge, attitude and practice of ADR reporting among 130 healthcare professionals (interns, postgraduates and staff of clinical departments). Those who were not willing to fill up the questionnaire were not forced to take part in the study. 92 doctors took part in this study.

The questionnaire consisted of 18 questions of multiple choice and closed end type. In order to preclude any potential bias the disclosure of name of the responder was made optional.

The questionnaire was handed over to interested participants and the time allotted to fill the questionnaire was 1 hour which was decided based on a pilot study.

The knowledge related questions were scored as 1 if the option yes was chosen and 0 if the option chosen was no. The maximum score which could be obtained is 17 and minimum score possible is 7

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. The maximum score which could be obtained is 84 and minimum score possible is 37. The data was analyzed by frequency, percentage and mean using the statistical software SPSS version13.0.

RESULTS

Assessment of Knowledge

In our study, 98% of respondents were aware of the existence of suspected ADR reporting system in India. However, only 46.7% knew about the regional centre of ADR reporting. 30.4% and 36.9% of respondents were not aware that ICU patients and children aged 1-4years respectively were more prone to develop ADR.

All respondents agreed that suspected medication should be included as a part of essential information while reporting an ADR.49(53.2 %) of respondents were of the opinion that it is not their duty to report ADRs caused by herbal medicine. 28(30.4%) respondents felt that there was no need to report ADR if there is no certainty whether the product itself has caused the reaction. 87(94.5%) and 83(90.2%) of respondents agreed that reporting is required when ADRs are caused by over the counter [OTC] drugs and topical agents respectively. Therefore, the overall level of knowledge of ADR reporting among doctors was found to be adequate according to statistical analysis (Table 1)

Table 1: Scoring Related to Questions on Knowledge and Attitude among the Participants (n=92)

	Minimum	Maximum	Maximum possible score	Mean (%)
Over all knowledge (/17)	7	17	17	87.4%
Over all attitude (/84)	37	76	84	70.1%

Assessment of attitude

All respondents were of the opinion that ADR reporting system would benefit patient care and 92.3%% felt that reporting of ADR is a duty of health care professional.

Factors that encouraged ADR reporting

All respondents (100%) felt that seriousness of the ADR event would encourage them to report. Other factors that would encourage them to report ADR included unusual reaction (96%), reaction to new drug (97.2%) and the certainty that the reaction is an ADR (90.4%). (FIG. 1)

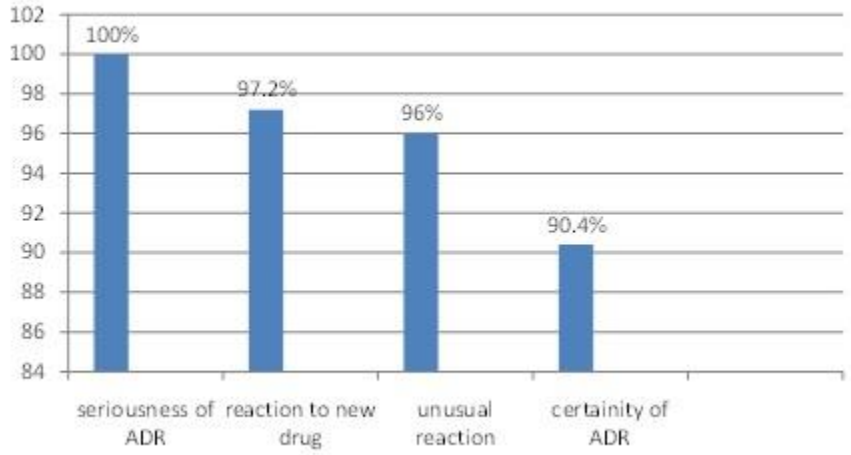

Fig 1: FACTORS THAT ENCOURAGED REPORTING OF ADR

Reasons for not reporting ADRs

54.6% of respondents were of the opinion that non availability of reporting forms discouraged them from ADR reporting. Other reasons included previously known ADRs (46.2%), concern of extra work (41.2%), busy schedule (32.1%), apprehension (28.4%), inability to diagnose ADR (24.3%), non-remuneration (21.3%) and feeling that not sending one report may not contribute a lot to patient care (7.1%).

Assessment of Practice

50(54.3%) of respondents have never attended any Continuing Medical Education (CME) programme on ADR (FIG.2) which shows that there is lack of initiative to attend awareness creating programmes .35 out of 92 respondents (38.04%) have never reported ADRs themselves by filling the ADR reporting form indicating that there exists a poor practice of ADR reporting among doctors. Upon occurrence of serious ADRs, 93.4 % agreed that suspected drug needs to be stopped immediately, 6.5% opined that dose should be tapered and stopped.

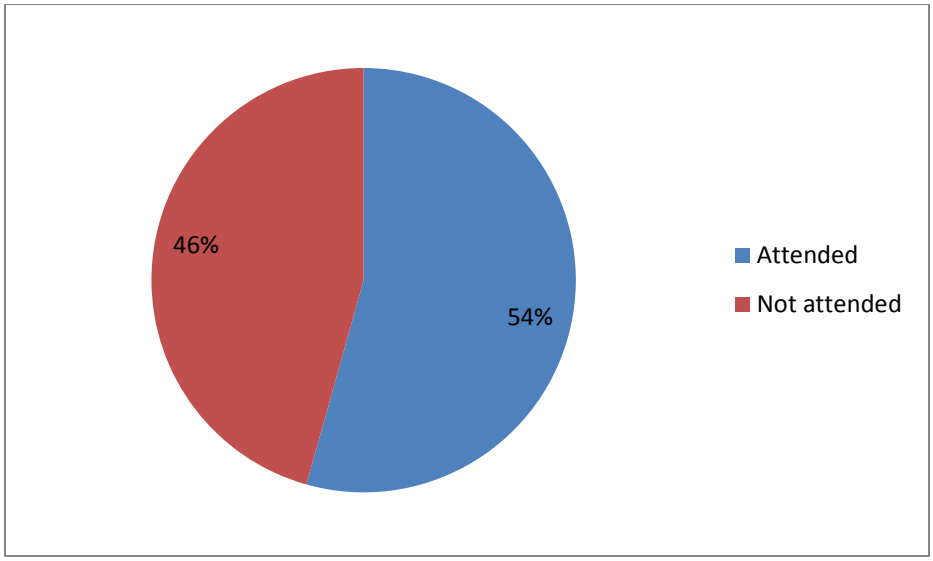

Fig 2: Respondents Attendance in Continuing Medical Education Progamme on ADR

APPENDIX 1

Questionnaire used to assess Knowledge, Attitude and Practice of adverse drug reaction reporting among health care professionals

Knowledge of ADR reporting

1. Are you aware of suspected adverse reaction reporting system in India? Yes/No
2. Are you aware of regional centre 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 the duty of all health care professionals?
Strongly agree/ Agree/ Neutral/ Disagree/Strongly disagree
6. Factors that encourage you to report ADRs?

Factors	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
a. Seriousness of event					
b. Unusual reaction					
c. Reaction to new drug					
d. Certainity that the reaction is an ADR					
e. Well recognized events that are known to occur with the drug					

7. Reasons for not reporting ADRs

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

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 should 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

3. Upon occurrence of serious an adverse drug reaction. What needs to be done with the suspected drug?

a. Stopped immediately
b. Dose tapered and stopped
c. Depends upon the drug & ADR

DISCUSSION

Our study observed that despite the adequate level of knowledge and positive attitude among doctors, only 38% of them have ever reported 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. This is also in concordance with the study conducted by Komaram RB etal [9] which has shown that regarding practice of Pharmacovigilance, less than 30% had experience.

98% of respondents in our study were aware of suspected ADR reporting system in India. 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 included reaction to new drug (97.2%), unusual reaction (96%), and the certainty that the reaction is an ADR (90.4%). This was in concordance with the study conducted by Oshikoya KA et al. [10] A survey conducted by Thomas TM etal [8] also showed similar results.

The factors that discouraged them from ADR reporting included non availability of reporting forms (54.6%), previously known ADRs(46.2%), concern of extra work (41.2%) and busy schedule (32.1%).

A study conducted by Okezie EO etal [11] observed that 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.

Only 35 out of 92 respondents have ever reported any suspected ADR, indicating that there is under reporting in our tertiary care hospital.54.3% of respondents have never attended any CME on ADR reporting.

The limitations of this study were small sample size and non inclusion of nurses and pharmacists.

As evident from this study, though the healthcare professionals had good knowledge and positive attitude about ADR reporting, it was lacking in practice. It emphasizes the need for inclusion of Pharmacovigilance in undergraduate and postgraduate medical curriculum. Regular workshops on Pharmacovigilance should be conducted in all the medical colleges and provision of ADR reporting forms should be made mandatory in all clinical departments.

Sensitization of healthcare professionals about ADR reporting is of utmost importance as willingness to report ADR is the major hindrance in the success of a pharmacovigilance programme.

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