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Research Article

Assessment of Knowledge and Attitude about Adverse Drug Reaction Reporting Among Interns at a Tertiary Care Hospital: A Questionnaire Based Study

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Abstract: A questionnaire based cross sectional study wherein 110 interns were enrolled to assess their knowledge and attitude regarding suspected adverse drug reaction reporting. Among 110 interns, only 22 % participants were aware of suspected ADR monitoring centre in their hospital. Approximately 36 % were aware of essential factors required for reporting of an ADR. The most common factors encouraging and discouraging reporting of an adverse drug reaction include seriousness of the event (93 %) and fear of reporting (55 %) respectively. The average scores of all participants for attitude related questions were approximately 80 (maximum score 115). The results of the present study indicate there is a need to create awareness about adverse rug reaction reporting. Majority of participants expressed their interest to participate in training programme related ADR reporting.
Keywords: Adverse drug reaction; Questionnaire; Attitude; Knowledge

INTRODUCTION

Adverse drug reaction(ADR) is defined as a 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[1].Reporting of suspected ADR from doctors is the cornerstone for the success of pharmacovigilance Program. Despite the reporting of suspected ADR is an important tool for collecting safety information of marketed drugs, very few cases of ADR were reported [2]. The reporting of suspected adverse drug reactions from doctors in India is low and so Indian contribution to the World Health Organization (WHO) Uppsala Monitoring Centre database is meagre [3].

Spontaneous reporting of suspected ADRs from doctors is an important source for national pharmacovigilance committee. Compared to other methods of drug safety monitoring, it provides highest number of information at low maintenance cost [4]. Under reporting of spontaneous ADR is common and major barrier for the successful implementation of pharmacovigilance programme. As the reporting is voluntary, it depends upon the initiation and motivation of health care professionals [5]. Therefore the present study was undertaken to study the knowledge and attitude of interns about ADR reporting.

MATERIALS AND METHODS

Interns working at a tertiary care hospital were surveyed using validated questionnaire. The questionnaire was used to collect knowledge and attitude domains related to ADR reporting besides demographic details of the participants. The participants were involved in the study after taking informed consent.

RESULTS

Demographic details of participants

The 110 interns working at a tertiary care hospital were participated in the study. The eight percentages of participants were completed six months of internship programme.

Knowledge domain

The majority of participants (80%) had knowledge that doctors, nurses and pharmacists were eligible to report suspected ADR. But 50 % and 23 % of interns were aware of national pharmacovigilance programme

and ADR monitoring centre in the hospital respectively. Approximately 37 % participants were aware of all essential factors required for reporting. The number of participants given correct answer for knowledge question according duration of completed internship schedule is given in Table No 1.

Table 1: Knowledge domain according to gender and completed internship schedule

Sl. No	Knowledge questions	Completed less than six months n=88	Completed more than six months n=22
1	Professionals eligible to report	70(63)	18(16)
2	Awareness about ADR reporting system in India	47(42)	8(7)
3	Awareness about regional centre for reporting	40(36)	8(7)
4	Awareness about ADR reporting at their institution	20(18)	5(4)
5	Essential information for reporting ADR	35(32)	6(5)

Figures in the brackets corresponds to percentage of responders

Attitude Domain

The average scores of all participants for attitude related questions were approximately 80 (maximum score 115). Majority of participants (95%) expressed their interest to attend continuous medical education programmes on ADR reporting.

Table 2: Factors encouraging reporting ADR

Factors	Percentages of responders
Seriousness of event	93
Unusual reaction	87
Confidence that event is an ADR	82
Established events known to be associated with drug	77

Table 3: Factors responsible for low reporting for ADR

Factors	Percentages of responders
Fear of reporting	55
Difficult to diagnose ADR in clinical practice	50
Non- availability of reporting form	48
Lack of encouragement from seniors	44
Poor feedback from regulatory agency	40
Lack of time for reporting	40
Disclosure of identity	40
Concern that extra work is required	32
Not sending one report may not contribute to lot to patient care	20
Busy working pattern to look actively for ADR	18
Feeling that reporting of previously known ADR is not required	15
No financial benefit for reporting	3

DISCUSSION

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems [6]. Adverse drug reactions are causing morbidity and mortality of varying intensity in all age groups. Moreover, it also greatly increases economic burden on the society [7-9]. Sometimes the cost needed to treat morbidity and mortality due to an ADR exceeds the cost needed to treat the actual condition of interest [10]. Approximately fifty percentages of adverse drug reaction can be prevented by adopting appropriate strategies [11].

The spontaneous reporting systems, cornerstone of pharmacovigilance activity helps in the early identification of signals and formulation of hypothesis, leading to further confirmatory investigations which may results sometimes in regulatory warnings, changes of product information leaflets or withdrawal of marketing authorization [12,13]. The best spontaneous reporting rate as per

WHO is over 200 reports per 1000000 populations per year [14]. Consequently, India with population of around 655 millions, it expected at least 131000 reports per year.

Imman summarized knowledge and attitude factors influencing reporting and described it as "seven deadly sins"[15]. But Lopez- Gonzalez et al found three factors described by Inman (lack of financial benefit, fear of enquiry were contributing less to under reporting [16]. Therefore there is no uniformity among factors associated with underreporting worldwide.

Interns working under the supervision of the senior doctors are also responsible for significant number of prescription error [17-19]. According to study conducted by Kazeem A Oshikoya, 66.6% internees had witnessed an ADR. But only 10 % of them reported it to appropriate authority in the hospital [20]. The interns participated in a previous study expressed the need to sensitize about adverse drug reaction reporting [21]. The incidence of serious ADR among hospitalized patients is 6.7 %, making these reactions between fourth and sixth leading cause of death [22].

Our study found that 50 % and 23 % of responders were aware of national pharmacovigilance programme and ADR monitoring centre in their hospital respectively. Similarly in a previous study 59 % of participants was aware organization responsible for collecting and reporting ADR. In contrast, 89 percentages of participants were aware of ADR monitoring system at their hospital according to a study conducted by Madhan ramesh and Gurumurthy parthasarathi [23]. In our survey 37 % of responders were aware of essential factors required for reporting ADR. They were aware that causality assessment is not essential for reporting.

The most common factors for discouraging reporting of ADR was fear of reporting (55 %), followed by difficult to diagnose ADR in clinical practice (50%). Another study conducted at same hospital found that most common factors for discouraging reporting of ADR was non-availability of reporting forms [24]. There is difficult in the detection of ADR in clinical practice. This could be because that ADR are not always obvious, immediate and visible. Sometimes symptoms of ADR are similar to those caused by common diseases [25]. Therefore interns should be trained to include ADR as a part of differential diagnosis in clinical practice. Greater emphasis should be given to ADR reporting at undergraduate curriculum. Regulatory authorities at US have developed online training programme on ADR reporting. Such programmes may enhance the familiarity with reporting forms [26]. Previous study show that continuous medical education (CME), training on ADR reporting would like to improve ADR reporting [14].Therefore there is a necessity of undertaking educational programme in our hospital to improve the attitude and knowledge towards ADR reporting.

CONCLUSION

The study results found that there is need to create awareness programme on suspected ADR reporting. Factors discouraging reporting of suspected ADR can be overcome by appropriate educational intervention. Participants expressed favourable attitude towards attending training programmes on ADR reporting

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