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Original Research Article

Knowledge, Attitude and Practices of Pharmacovigilance among junior doctors of a tertiary health care institute in North East India

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Abstract: Adverse drug reactions (ADRs) are associated with significant morbidity and mortality. Pharmacovigilance programme is aimed at increasing reporting of ADRs and building a database of ADRs. The contribution of junior doctors to ADR databases by voluntary reporting is enormously significant .The objective of this questionnaire based cross sectional study was to determine the level of awareness among the junior doctors about the necessity of ADR reporting. 167 junior doctors responded in this study. 46.10% of the responders were found to be aware of pharmacovigilance. 65.86% of the responders in this study considered pharmacovigilance to be essential and only 19.16% were in favour of making ADR reporting mandatory. 19.76% of the responders had reported an ADR before. The knowledge, attitude and practices of pharmacovigilance were found to be poor in this study.
Keywords: Adverse drug reactions, KAP, ADR reporting, Adverse effects, Questionnaire

INTRODUCTION

Every single drug in use is associated with some adverse reaction. Adverse drug reactions can be defined as 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]. Medicine and Healthcare products Regulatory agency (MHRA) has classified adverse drug reactions into type A (augmented), B (bizarre), C(chronic), D(delayed) and E(end of use) reactions [2]. The goal of pharmacovigilance is to build a database of these adverse drug reactions. The word pharmacovigilance is derived from pharmakon (greek) meaning drug and vigilare (latin) meaning to keep watch. It is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. WHO (World Health Organization) first established the pharmacovigilance programme for international drug monitoring in response to the thalidomide disaster detected in 1961. Over 134 countries are now a part of the WHO pharmacovigilance programme. It is aimed at enhancing patient care and patient safety in relation to the use of medicines; and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines [3]. In India, a formal ADR (adverse drug reaction) monitoring system consisting of 12 regional centers, each covering a population of 50 million, was first proposed in 1986 [4] . It was however only in 1997 that India joined the WHO ADR Monitoring Programme based in Uppsala, Sweden. From 1 January 2005, the WHO-sponsored and World Bank-funded National Pharmacovigilance Program for India was finally made operational [5]. The Pharmacovigilance Programme of India (PvPI) was initiated by the Government of India in July 2010 with AIIMS (All India Institute of Medical Sciences), New Delhi as NCC (National coordinating centre). The NCC was shifted from AIIMS, New Delhi to IPC (Indian Pharmacopeia Commission), Ghaziabad on 15th April 2011 [6]. AMCs (adverse drug reaction monitoring centers) are the principal data collecting centre in this

programme. These are situated in various medical colleges and hospitals across the country. These centers collect individual case safety reports (ICSRs) and follow up the cases to gather necessary supplementary information and perform scientific evaluation [6]. There are 90 AMCs functioning in India under PvPI [7].

The mission of PvPI is to safeguard the health of the Indian population by ensuring that the benefits of the drugs outweigh the risks. It aims at building a database of adverse drug reactions. These reactions need to be reported to the proper authority in proper manner. Spontaneous reporting is the backbone of pharmacovigilance and the health care professionals need to understand the importance of this programme. Several studies have been conducted to gauge the level of awareness among the heath care professionals about Pharmacovigilance [8-11]. According to the Uppsala Monitoring Centre only 6-10% of all the ADRs are reported [12]. ADRs can be reported by all healthcare professionals including doctors, nurses, and pharmacists filling a spontaneous ADR reporting form of the Central Drugs Standard Control Organization [13]. There is a general lack in the basic knowledge of pharmacovigilance among health care professionals [14]. The healthcare professionals must be aware of what to, how to and whom to report ADRs for the greater benefit of the patient.

Gauhati Medical College & Hospital is a premier healthcare institute in North East India. It has its AMC in the department of Pharmacology, aimed at increasing the rate of ADR reporting from this institute. This study was conducted among the junior doctors of Gauhati Medical College and Hospital to evaluate their knowledge, attitude and practices of pharmacovigilance.

MATERIALS AND METHODS

Study Setting

This study was conducted at Gauhati Medical and Hospital, a tertiary care Hospital in Guwahati, Assam, India.

Ethical Approval

The study was conducted only after receiving due approval from the Institutional Ethics Committee, Gauhati Medical College.

Study Design

The study was a cross-sectional questionnaire-based study.

Study Population

The study participants consisted of post graduate students of all departments and interns of Gauhati Medical College and Hospital.

Questionnaire

KAP (knowledge, attitudes and practices) questionnaire was designed to assess the knowledge of pharmacovigilance, attitudes towards pharmacovigilance, and their practice on ADR reporting. These questions were designed based on earlier studies for assessing KAP of ADR reporting [8-11]. The questionnaire was pre tested by 5 randomly selected health professionals of the institute. The questionnaire had 16 questions in all (eight related to knowledge, four related to attitude, and four related to practice). The respondents were not required to mention their identity on the questionnaires.

Data collection

A total of two hundred questionnaires (200) were distributed among the junior doctors in the morning. The doctors were given one day to respond. Questionnaires were collected by the evening of the same day.

Statistical Analysis

The KAP questionnaire was analyzed and question-wise percentage values were calculated with the help of Microsoft excel spread sheet in MS Office 2007.

RESULTS

A total of 200 questionnaires were distributed, 167 of them were returned back and were analyzed. Percentage of responders: (167/200) X 100 = 83.5%

The percentage based calculation of all the responses were made by taking 167 (the total no. of responders) as the denominator.

Responses to knowledge based questions (Table 1)

77 out of 167 responders had heard about Pharmacovigilance (46.10%).

68 out of 167 responders knew about the existence of a Pharmacovigilance center or AMC in their college. (40.71%)

Only 22.15%, 45.50% and 19.16% of the responders were aware that ADRs can also be reported by nurses, dentists and pharmacists respectively.

26.94% (45 out of 167) considered congenital anomaly as a suspected ADR.

23.35% (39 out of 167) knew the difference between an adverse drug reaction and a adverse event.

Responses to attitude based questions (Table 2)

A healthy 65.86% (110 out of 167) responders considered Pharmacovigilance to be essential and 107

(64.07%) of them expressed their desire to report ADRs in future.

However, only 32 responders (19.16%) were in favour of making ADR reporting mandatory.

78.44% (131 out of 167), 76.64% (128 out of 167), 67.66% (113 out of 167) , and 12.57% (21 out of 167) of responders respectively cited difficulty in follow up, ignorance of the process of ADR reporting, busy work schedule and fear among doctors of consequences due to reporting to be the possible causes of under reporting of ADRs.

22.75% (38 out of 167) felt that there was no real need of spontaneous ADR reporting, as the ADRs of various drugs are documented in text books, prescribing information etc.

Responses to practice based questions (Table 1)

Only 33 out of 167 responders had reported an ADR before (19.76%).

132 out of 167 responders had faced various difficulties in reporting of ADRs (79.04%). Most of them (43.11%) were unhappy about the poor communication from the pharmacovigilance center. Some of them also pointed out that reporting form were not available all the time.

78 out of 167 (46.70%) believed that a suspected drug causing ADR should be immediately stopped. However, the rest felt the drug should be stopped after tapering down the doses or can be continued in reduced doses.

Table-1: KAP Questionnaire with responses (Knowledge related questions)

	Yes	No	Can't say
1. Have you ever heard about Pharmacovigilance?	77	90	00
2. Do we need a Pharmacovigilance center in Gauhati Medical College?	110	33	24
3. Is there a Pharmacovigilance center in Gauhati Medical College?	68	39	60
4. Can nurses report ADRs?	37	87	43
5. Can dentists report ADRs?	76	63	28
6. Can pharmacists report ADRs?	32	93	42
7. Can congenital anomaly be considered to be an ADR?	45	41	81
8. Is an adverse event the same as adverse drug reaction?	39	103	25

Table-2: KAP Questionnaire with responses (Attitude related questions)

	Yes	No	Can't say
1. Will you report a suspected ADR?	107	27	33
2. Is reporting ADR essential?	110	47	10
3. Should ADR reporting be made mandatory?	32	121	14
4. What do you think are the reasons for under reporting of ADRs?			
i. Lack of time due to hectic duty hours.	113		
ii. Unaware of the process of reporting	128		
iii. No time to follow up	131		
iv. ADRs are already documented in literature	38		
v. Fear of consequences.	21		
vi. There is no reward for reporting.	32		

Table-3: KAP Questionnaire with responses (Practice related questions)

	Yes	No	Can't say
1. Have you ever reported an ADR?	33	134	00
2. Did you encounter any difficulty in reporting?	132	22	13
3. What was the difficulty you encountered?			
i. Non availability of reporting forms.	72		
ii. Reporting form too lengthy.	47		
iii. Poor communication from Pharmacovigilance center	112		
iv. Non cooperation by patient.	58		
4. What should be done immediately when an ADR is suspected?			
i. Stop the drug.	78		
ii. Reduce the dose	32		
iii. Slowly taper down the dose.	45		
iv. Depends on the severity	12		

DISCUSSIONS

The foremost thing to be noted in these types of studies is the response of the participants. Karelia *et al* 2014, in is his study on the knowledge, attitude and practices of pharmacovigilance had reported a response rate of 55.33% among private health care professionals [15]. Hardeep *et al*. 2013 found a response rate of 61% [10]. In this study, the response rate was found to be much higher (83.5%). This is a good sign and reflects the inquisitiveness amongst the junior doctors towards a fairly new concept.

The knowledge level about pharmacovigilance was found to be poor in this study. Only 46.10% of the responders were found to be aware of pharmacovigilance. This is much lower in comparison to some other studies conducted in India. 86.14% and 77% of the physicians knew about pharmacovigilance in the study conducted by Karelia *et al*. [15] and Hardeep *et al*. [10] respectively. Ganesan *et al*. found that more than 80% of participants were aware that doctors, nurses, dentists & pharmacists can report ADRs [16]. However, only 22.15%, 45.50% and 19.16% of the responders in this study were aware that ADRs can also be reported by nurses, dentists and pharmacists respectively.

Attitude of the participants towards pharmacovigilance in this study was also poor. 65.86% of the responders in this study considered pharmacovigilance to be essential and only 19.16% were in favour of making ADR reporting mandatory. This is also much lower in comparison to other studies conducted in India. The Ganesan *et al.* 2016 study, reported that 89% of doctors that felt reporting of ADR to be necessary and 70% of them considered it to be a professional obligation [16]. In the Karelia *et al*. 2014 study, 78.30% of doctors were in favour of making ADR reporting a mandatory process [15]. Vora *et al.* 2014 study reported that 91.77% of students and 91.53%of faculties considered reporting ADRs to be essential and wanted ADR reporting to be made mandatory in the interest of patient safety [17]. 74.07% of students and 71.43% of faculties in the Vora *et al.* 2014 study cited non-availability of ADR form to be the reason for under reporting [17]. In this study, 43.11% of the participants have pointed out the same hurdle in ADR reporting.

The pharmacovigilance practice level was also found to be poor in this study. Only 19.76% of the responders had reported an ADR. Karelia *et al.* 2014 had also reported very low figures of ADR reporting in the past [15]. In the Ganesan *et al.* 2016 study, 52% of physicians and 25% of nurses had reported ADRs to their AMC [16].

The knowledge, attitude and practices of pharmacovigilance were found to be very poor in this study. Many studies have shown similar kind of results. Khan *et al.* 2013 in their observational study found that the knowledge, attitude and practice of doctors in a teaching hospital regarding ADR reporting were poor [18]. In spite of poor knowledge and practice, good attitude towards pharmacovigilance among doctors was reported by Sanghavi *et al.* 2013 [19]. Kiran *et al.* 2014 also found good attitude, but poor knowledge and practice amongst clinicians towards pharmacovigilance [20]. In the Thomas *et al.* 2013 study, the knowledge and attitude of doctors were found to be good but the practice level was poor [21]. Aithal *et al* 2014 found that the doctors had poor knowledge but good attitude and practice [22]. Many of these studies have also highlighted the importance of training and education in increasing the awareness about pharmacovigilance. Sanghavi *et al.* 2013 [19], Kamtane *et al.* 2012 [23] and Awodele *et al.* 2011 [24] had cited that knowledge on ADR reporting was not given much consideration during doctors training and the doctors had advocated for the need of training to improve their knowledge of pharmacovigilance. Bisht *et al.* 2014 [25], Khan *et al.* 2013 [18], Shailesh *et al.* 2013 [26] and Thomas *et al.* 2013 [21] in their studies have also pointed out the significance of training of medical students (undergraduates and postgraduates) about pharmacovigilance, which will help in increasing ADR reporting and patient safety.

It must also be mentioned that, not all studies have shown negative results. In some studies, the health care professionals were found to be highly aware of ADR reporting and were reporting ADRs. Muraraiah S *et al.* found that majority of the health care professionals had good knowledge about pharmacovigilance and considered it essential [27]. Thakuria *et al.* 2016 [28], Manjunath *et al.* 2015 [29] and Deepak *et al.* 2014 [30] are some of the other studies which have shown encouraging results.

CONCLUSION

The knowledge, attitude and practices of pharmacovigilance were found to be poor in this study. Spontaneous reporting of ADRs is the main contributor to the international ADR database maintained by UMC. Health care professionals must understand that collation of ADRs, one by one will help in forming the sea of ADR database. This will eventually benefit the patient and also the physician in selection of the safest drug in particular clinical scenario. Regular training of healthcare professionals and students should be employed to increase awareness and improve the reporting culture.

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