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Assessment of knowledge, awareness and reporting of pharmacovigilance among the healthcare providers in a tertiary care center

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ABSTRACT

There is a considerable increase in awareness about the issues related to drug safety among health care providers, healthcare institutions and the public. Our aim of this present study was to assess the knowledge; awareness and reporting of adverse drug reactions among health care professionals. Methodology: A questionnaire model was prepared, focusing on the awareness, knowledge of various adverse drugs reactions and the algorithm of reporting systems of pharmacovigilance programme of India. A total of 76 healthcare professionals were included in this study. The questionnaire was distributed among the Doctors working in various specialties. Completed questionnaire were collected and analysed statistically. Data collected was analysed and was reported as percentage of responders and non-responders. Total responders were 55 and non-responders were 21. The awareness of Pharmacovigilance programme of India in this study was 74% where as 26% were non-responders. This indicates that the knowledge of ADR reporting was not up to the mark which emphasizes urgent need to implement, appropriate strategies to strengthen the awareness of pharmacovigilance practices and the importance of ADR reporting in this hospital.

Key words: Pharmacovigilance Programme of India, Awareness, Knowledge, Reporting Healthcare professionals

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INTRODUCTION

World Health Organization defines pharmacovigilance as "the science and activities relating to the detection, evaluation, understanding, reporting and prevention of adverse drug effects or any other drug related problems. The term pharmacovigilance has evolved to recognize the importance for monitoring and improving the safe use of medicines. The burden of adverse drug reactions (ADRs) in the global scenario is highly accountable for considerable morbidity, mortality, and financial commitment to the patients [1,2]. In England, 0.9% of the total hospital admissions were due to ADRs during the year 1999–2008. ADRs are common in Australian healthcare system also and they contribute to 1% of hospital admissions. In the United States of America, ADRs contribute 3.4%–7% of hospital admissions. The percentage of hospital admissions due to ADRs in certain countries is 10% or more [3]. India, with a current population of 1.27 billion, is the fourth largest producers of pharmaceuticals in the world with more than 6000 licensed manufacturers and over 60,000 branded formulations in the market. Studies revealed that ADRs are leading to hospitalization and constitute a significant economic burden on patients in India. A study showed that hospital admissions due to ADRs accounted for 0.7% of total admissions and deaths due to ADRs accounted for 1.8% of total admissions in a territory referral center in South India [4,5].

Promoting safe use of medicines is a priority of Indian Pharmacopoeia Commission that functions as the National Coordination Center (NCC) for Pharmacovigilance Programme of India (PvPI). One hundred and seventy-nine adverse drug reactions (ADRs) monitoring centers currently report ADRs to NCC. Current India contribution to global safety database reaches 3% and the completeness score is 0.93 out of 1. NCC is taking several measures to enhance patient safety including capacity building for monitoring, surveillance, collaboration with national health programs and other organizations to increase ADR reporting and to ensure that PvPI is a vital knowledge database for Indian regulators. The Central Drugs Standard Control Organization has notified important safety label changes on drugs such as carbamazepine and piperacillin + tazobactam in the year 2015, other drugs are under monitoring for regulatory interventions [6].

In developing countries such as India, under – reporting of ADR remains a serious concern. In India the Information and Technology (IT) is becoming a great facilitator for promoting public health. India is cementing its place at IT sector through mobile connections to reach every individual in a population of 1.27 billion, where approximately 77.58% population is already using mobile phones. Hence, it is more rationale to introduce the concept of PvPI to stakeholders through mobile phones. NCC- PvPI in technical collaboration with NSCB Medical College, Jabalpur, developed a mobile application for the healthcare professionals to promote easy and instant reporting of ADR. This facility was launched by Secretary Health, MoHFW, Government of India, on May 22, 2015 [7,8].To improve the active participation of patients, healthcare professionals, and the pharmaceutical industrial reporting of suspected ADRs to the PvPI, NCC recently launched a helpline number (toll free), i.e., 1800 180 3024 facility for reporting adverse events. This facility was dedicated to the nation on October 11, 2013. This may be one of the innovative methods to create awareness in each and every corner of the country for the pharmacovigilance activity. This facility will be useful for the healthcare professionals who are working in tertiary healthcare system and also who are working in other health care functionary for easy reporting of ADRs. Adverse events-related information received at NCC and the same will be communicated to the nearest AMCs for analysis and validation of the reports. Since sending timely feedback or acknowledgement will build up public confidence and this facility has been upgraded by sending short massage service feedback/ acknowledgment to the ADRs reporters [9].

METHODOLOGY

About 76 health care professionals were included in the study. Questionnarire developed by PvPI to assess the knowledge, awareness and reporting of pharmacovigilance awareness of Pharmacovigilance programme of India. The Questionnarire of PvPI were distributed to all the participants. The questionnaire model was clearly explained to each and every participant. Sufficient time was given to fill up the feedback forms. Completed feedback forms were collected from the participants. The feedback forms were divided into responders and non-responders. The results were analyzed on the basis of number who has responded correctly by marking yes / no and the same was reported as percentage for statistical significance.

RESULTS

Statistical analysis of the study is shown in table 1. Which showed the responses to the Question number 1 and 2 was 100%. The response to

question number 3, 4, 5,7 and 10 were around 60% to 95% which was satisfactory. Whereas the response to questions 6,8,9,11 and 12 were below 50%, and the same is shown clearly in fig:1, which was not up to the mark.

DISCUSSION

The positive response to question number one and two regarding adverse drug reactions and their personal experience at any time following any medicinal use was satisfactory whereas the response for knowledge, relating to existence of pharmacovigilance programme of India (PvPI), for safe use of medicines and if at all any adverse drug reactions occurs, when, to whom, where to report and what are the step wise procedures involved in reporting were only below 40% as shown is in table 2. This study is not in accordance with one previous study, where only 2.7% were aware, and ignorance about ADRs reporting were 71.4%, address to report 68% unaware to report 52.2% and needless to report were 44.4%%[10]. The awareness and knowledge of various pharmacovigilance programme of India monitoring centers in their region, the specifically designed formats for reporting ADRs and the availability of toll free helpline number (**1800-180-3024**) to report any suspected ADRs after the use of medicines and medicine safety promotional materials, were below 20% only. All participants were very eager to participate PvPI [11].

The burden of adverse drug reactions in medicine safety initiatives of (ADRs) in the global scenario is high and accounts for considerable morbidity, mortality, and extra – cost to the patients [12, 13]. In England, 0.9% for the total hospital admissions was due to ADRs during the year 1999 – 2008. ADRs are common in Australian healthcare system also and they contribute to 1% of hospital admissions. In the Untied States of America, ADRs in contribute 3.4% - 7% of hospital admissions. The percentage of hospital admissions due to ADRs in certain countries is 10 % or more. India, with a current population of 1.27 billion, is the fourth largest producers of pharmaceuticals in the world with more than 6000 licensed manufactures and over 60,000 branded formulations in the market. Studies revealed that ADRs are leading to hospitalization and constitute a significant economic burden on patients in India. Various studies have showed that hospital admissions due to ADRs accounted for 0.7% of total admissions and deaths due to ADRs accounted for accounted for 1.8% of total admissions in a territory referral center in South India [14].

Therefore, medicines safety monitoring is an essential element of healthcare and for high quality medical care. Since safety monitoring of medicines as an integral part of clinical practice, the Ministry of Health of Health and Family Welfare (MoHFW), Government of India launched the nationwide Pharmacovigilance Programme of India (PvPI) in the year 2010 to inspire confidence and trust among patients and healthcare professionals with respect to medicines safety. Indian Pharmacopoeia Commission (IPC) under the MoHFW has been functioning as the National Coordination centre (NCC) for PvPI since April 2011. There has been rapid progress in reporting of ADRs by the healthcare professionals in the past 5 years [15].

Periodic safety update reports (PSURs) are a tool to monitor the safety of ongoing medicines in the market. In India, marketing authorization holders (MAHs) are required to prepare PSURs and to submit them to CDSCO twice in a year for 2 years and annually for another 2 years [16]. Since PSURs are not directly linked with PvPI, NCC has taken the initiatives in collaboration with CDSCO to utilize the data for PvPI. The first interactive session of "Review of Periodic Safety Update Report/Post Marketing Surveillance Date and Pharmacovigilance planning of Marketed Produced" was held on December 18 and 19, 2013 at New Delhi. Representatives from MAHs, CDSCO, and NCC-PvPI had participated and discussed the issues and roadmap for better coordination and participation of MAHs in PvPI [17].

CONCLUSION

The present study shows the lack of awareness and knowledge among healthcare professionals. Our findings provide information to healthcare policy makers and health authorities that can be implemented in the future evaluation and reinforcement plans to improve the pharmacovigilance awareness.

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TABLE: 1 SHOWING POSITIVE AND NEGATIVE RESPONDERS

Questions	Number of participants	Positive response	Negative response
1	54	54	0
2	54	54	0
3	54	50	4
4	54	49	5
5	54	47	7
6	54	19	35
7	54	34	20
8	54	24	30
9	54	23	31
10	54	38	16
11	54	12	42
12	54	9	45

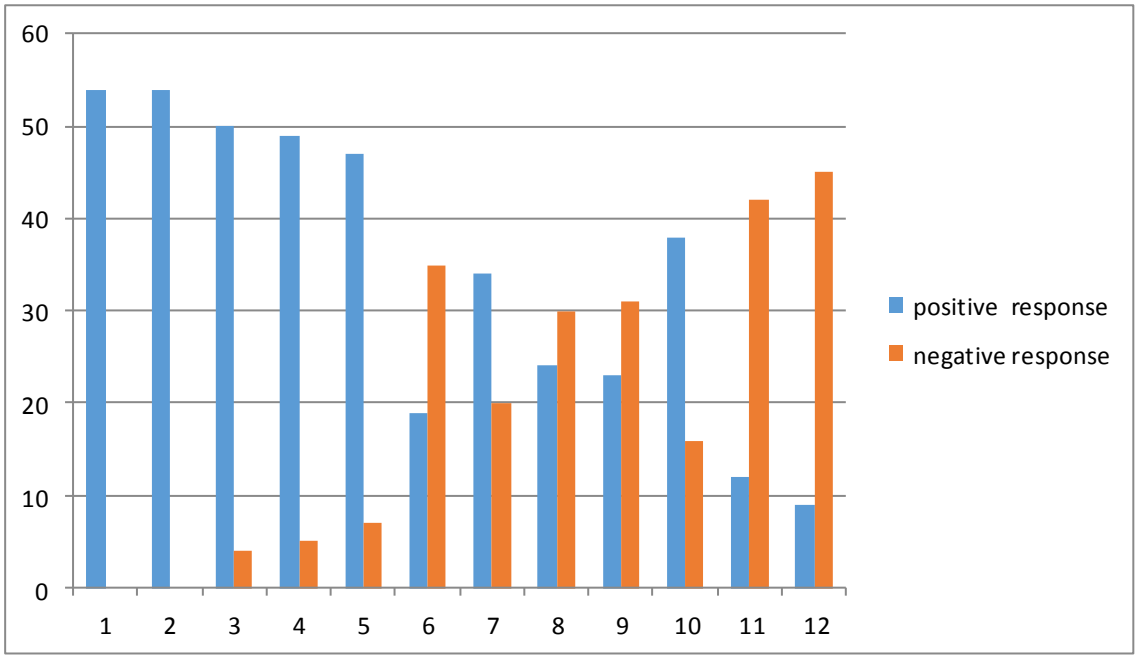
Table: 1 shows Qn:1,2 positive response 54 and no negative response, Qn:3,4,5 shows Positive response 50,49,47 and negative response 4,5,7. Qn: 6,7,8 shows positive response 19,34,24 and negative response 35,20,30.Qn:9,10,11,12 shows positive response 23,38,12,9 and negative response 31,16,42,45.

Table - 2: SHOWING THE PERCENTAGE OF POSITVE&NEGATIVE RESPONSE

Questions No	Positive response	Percentage (%)	Negative response	Percentage (%)
1	54	100	0	0
2	54	100	0	0
3	50	93	4	7
4	49	90	5	10
5	47	87	7	13
6	19	35	35	65
7	34	62	20	38
8	24	44	30	56
9	23	42	31	58
10	38	70	16	30
11	12	22	42	78
12	9	16	45	84

Table: 2 shows Qn:1,2,3 shows percentage of positive response 100,100,93 Negative response 0,0,7. Qn:4,5,6 shows percentage of positive response 90,87,35 Negative response 10,13,65. Qn:7,8,9 shows percentage of positive response 62,44,42 Negative response 38,56,58. Qn:10,11,12 shows percentage of positive response 70,22,16 Negative response 30,78,84.

Fig-1: HIGH LIGHTING THE NEGATIVE RESPONSES



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