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A Questionnaire Based Study on the Knowledge, Attitude and Practice of Pharmacovigilance among the Medical Officers Working in Peripheral Areas of Ajmer District, Rajasthan (India)

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ABSTRACT

Introduction: Medical officers are an integral part of the Indian Primary health Care services. . The aim of this study was to investigate the Knowledge, Attitude and Practice of Medical officers working at Remote and Rural area about Pharmacovigilance and to suggest possible ways of improving spontaneous reporting.

Materials and Methods: It was a questionnaire-based cross-sectional study. The study participants consisted of 126 Medical officers working at various Remote and rural government sector hospital in Ajmer district, Rajasthan. One hundred one (101) Medical officers who gave written informed consent were included in the study. The data was analyzed by using the SPSS statistical software, version 16

Results: The response rate was 80.15 %.Medical officers had satisfactory knowledge of purpose of Pharmacovigilance and who can report an ADR. While less known facts about existence of national PvPI programme of India. The participants attitude was positive towards Pharmacovigilance. 87 % of the participants thought that reporting an ADR should be professional obligation and should be taught to all Health care professionals (92.5%).

The major factors found to be responsible for underreporting of ADR include fear factor, insufficient training to identify ADRs, lack of time and lack of awareness about existence of Pharmacovigilance program.

Conclusion: These gaps need to be filled by improved training in Pharmacovigilance Spontaneous ADR reporting can further be improved by carrying out regular workshops, CMEs, training and periodic awareness programme to provide them guidance and encouraged them to report ADRs in the future

Key words: Pharmacovigilance, Medical officers, ADRs, PvPI

INTRODUCTION

Drugs are a boon to the mankind but they are also associated with unavoidable and undesirable adverse drug reactions (ADRs). Adverse drug reactions are considered among leading causes of morbidity and mortality associated with high prevalence rate of 3% to 6% and ranked fifth among all causes of death and an increase in hospital costs[1] heightened interest in ADRs was stimulated by thalidomide tragedy in 1960s[2]

Detection of ADRs is a challenging matter. Animal toxicological studies and pre-clinical trials cannot reflect all the drug related hazards. While previously unidentified ADRs can also occur. Thus Post marketing surveillance of drugs is important for the identification of unseen ADRs and should be an inevitable part of clinical practice.[3] The study of adverse drug reactions (ADRs) is the concern of the field known as Pharmacovigilance (PV)[4]. It is related to detection, assessment monitoring and prevention of adverse effects with pharmaceutical products.[5]

Postmarketing surveillance uses a number of methodologies to monitor drug

and device safety, including spontaneous reporting databases, prescription event monitoring, electronic health records, patient registries, and record linkage between health databases.[1] These data are reviewed to highlight potential safety concerns in a process known as data mining.

In India Central Drugs Standard Control Organisation (CDSCO), New Delhi has initiated a nationwide pharmacovigilance programme under the aegis of Ministry of Health & Family Welfare, Government of India in 2011 and the programme is coordinated by the Indian Pharmacopoeia Commission (IPC), Ghaziabad.[9]

Medical officers are an integral part of the Indian Primary health services; they are captain of health team at PHC working both in morning and evening hours and ensures that the national health programmes are being implemented in their area properly. Currently there are around 126 Medical officers posted at government hospitals of district Ajmer. .

Very few studies are available related to Medical officers Knowledge about Pharmacovigilance. The aim of this study was to investigate the Knowledge, Attitude and Practice of Medical officers working in Remote and Rural Government Hospitals about Pharmacovigilance and to suggest possible ways of improving spontaneous reporting based on our findings.

MATERIAL AND METHODS

This study was a Cross-Sectional Questionnaire-based study. The study participants consisted of 126 Medical officers working at various PHC,CHC and other government sector hospital in Ajmer district ,Rajasthan. One hundred one (101) Medical officers willing to participate and who gave written informed consent were included in the study. A validated structured questionnaire[6,7,8] which consisted of 30 Multiple choice questions was designed to assess knowledge of pharmacovigilance, attitudes towards pharmacovigilance, and their practice on ADR reporting. The data was analyzed by using the Statistical Package for Social Sciences (SPSS) statistical software, version 16

RESULTS

A total of 126 Medical officers working at Remote and Rural Government Hospitals of Ajmer district, Rajasthan at the time of study. Among those, 101 participated with a response rate of 80.15%. A validated structured pretested questionnaire was distributed among the Medical officer for their assessment of-

KNOWLEDGE

While assessing the knowledge of Pharmacovigilance of Medical officer, it was found that majority of the Doctors had knowledge of purpose of Pharmacovigilance (61 %) and who can report an ADR (88 %), While less known facts about existence of national PvPI programme of India(50%) and number of ADR monitoring centres in Rajasthan (18.75 %) and India(25%)

ATTITUDE TOWARDS PHARMACOVIGILANCE

The participants attitude was positive towards Pharmacovigilance. 87 % of the participants thought that reporting an ADR should be professional obligation and should be taught to all Health care professionals (92.5%) while 55 % thought that Pharmacovigilace centre should be established in every hospital.

PRACTICE REGARDING PHARMACOVIGILANCE

Unfortunately only 18.75 % of MO were trained for reporting adverse reactions. Among the participants, 70 % had experienced ADRs in patients, but only two (2) have reported ADR to pharmacovigilance center.

The most important factors that discouraged doctors from reporting an ADR was found to be fear of legal action (28.75%) and difficulty in identify an ADR (27.5%)

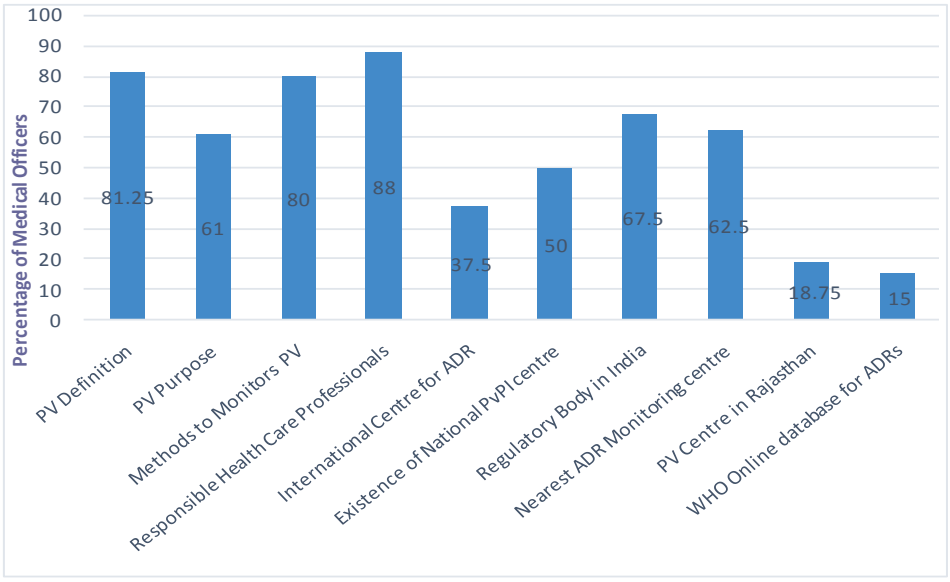

Fig 1: MOs Response to Knowledge related Questions

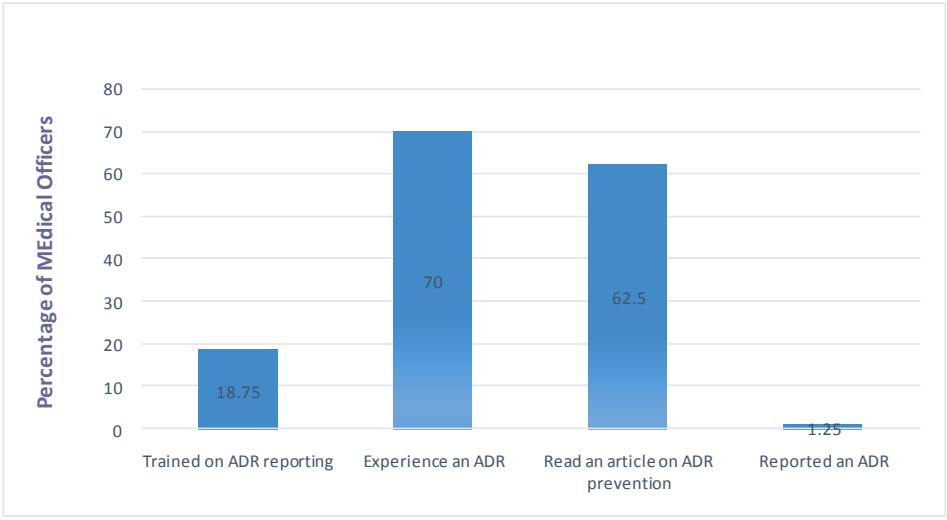

Figure- 2 : MOs response to Practice Related Questions

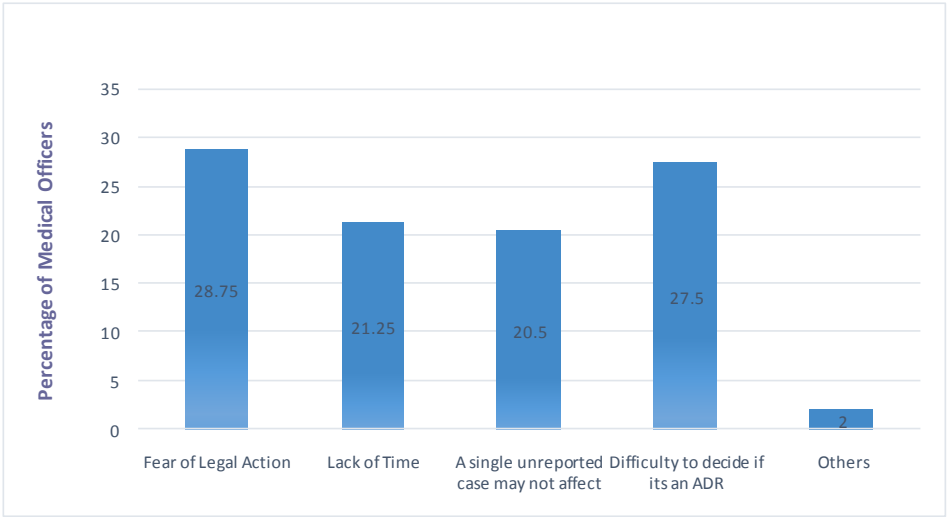

Figure- 3 : Factors causing under-reporting among MOs

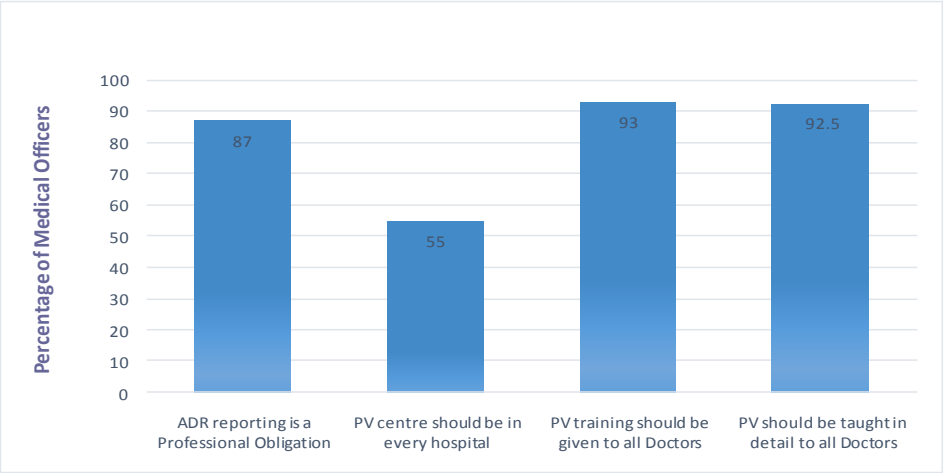

Figure- 4- MOs response towards Practice related Questions

DISCUSSION

Medical officers plays an important role in the rational use and post marketing surveillance of medicines by providing information about adverse drug reactions (ADRs) of general population. Spontaneous reporting is most commonly used system in reporting an ADR and under-reporting is major challenge, so assessing the KAP of Pharmacovigilance among the Medical officers is very important as it will ensure the extent of correct knowledge, right attitude and proper practice in reporting an ADR.

Knowledge regarding ADR is very essential when it comes to reporting ADR. Medical officers working in public sector units must possess knowledge of ADR and know procedure of reporting ADR. This study showed satisfactory knowledge amongst Medical officers about Pharmacovigilance however significant numbers of the respondents were not aware of the existence of a PvPI programme of India (50%).

Findings related to the knowledge in the present study were much better than studies carried out in India earlier [5,6,7,10,11]. As this PvPI started very late in 2010 very few doctors have been taught about it at their undergraguate or post graduate level. Therefore, awareness programs appear necessary to improve ADR reporting among Medical officers. ADR reporting should be made mandatory and each hospital should have a database on ADR which should be assessed by healthcare professionals

The study points out that the awareness about ADR reporting system, amongst doctors is very low. More alarming, however, is the fact that very few MOs have ever reported (1.25%) while most of them have experienced an ADR in their clinical practice. This finding is similar to the result obtained in other studies [5,6,7,10,11].

The attitude of the MOs was quite positive. Large number of respondents believed that ADR reporting is necessary and should be taught in detail to all health care professionals with proper training programs. Since most of MOs consider ADR reporting is necessary and considers ADR reporting as their professional obligation. About 87 % respondents agreed that ADR reporting should be mandatory and it is also similar to previous studies [8, 10, 11]. However, in developed countries ADR reporting rate is higher than India[9]. The main reason behind this is that the ADR monitoring system is well established, as well as ADR reporting is mandatory in those countries.

Another important finding of this study about cause of underreporting of ADR, was fear of legal action, difficulty in identifying an ADR and lack of time, these were discouraging factors for healthcare professionals to report ADR, which is in similar with the other studies [8,10,11]

In India, all healthcare professionals including doctors, nurses, and pharmacists can report an ADR by filling an ADR form . It is important for healthcare professionals to know how to report and where to report an ADR. The active participation of healthcare professionals in the Pharmacovigilance program can improve the ADR reporting.

The positive attitude of respondents towards ADR reporting will help in understanding the attitude of healthcare professionals and proper action can be taken to improve participation of healthcare professionals in ADR reporting. Lot of efforts is required in order to collect ADR data which will generate safety surveillance of billions of therapeutically active substances.

CONCLUSIONS

The Medical officers had satisfactory knowledge and poor practice of ADR reporting. The present study revealed that these gaps need to be filled by improved training in pharmacovigilance However, the attitude towards the PV was good. Spontaneous ADR reporting can further be improved by carrying out regular workshops, CMEs, training and periodic awareness programme to provide them guidance and encouraged them to report ADRs in the future. ADR reporting forms should be freely available in all hospitals as it can improve the reporting rates of ADR. Doctors should also be sensitized at their undergraduate and postgraduate levels.

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