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Research Article

THE ROLE OF SENSITISATION ON CLINICIANS AND NURSING STAFF IN ADVERSE DRUG REACTION REPORTING IN A NEWLY ESTABLISHED MEDICAL COLLEGE

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ABSTRACT

Objective: The PvPI (Pharmacovigilance program of India) expects medical colleges to be part of ADR (Adverse Drug Reaction) reporting. However a newly established medical college with limited infrastructure and human resources faces several challenges. The aim of this study was to look for solutions in such a facility and impact of regular sensitization.
Material and methods: We undertook a study from Dec 2017 to June 2108 on the impact of Group sensitization programme like seminars, one to one sensitization of clinicians and nursing staff by the faculty of Department of Pharmacology against conventional methods like office notification, ADR collection boxes, posters on the ADR reporting. The ADRs were collected using (Indian Pharmacopiea Commission) IPC-PvPI ADR monitoring form, causality was assessed using WHO-UMC criteria and categorized as per type of ADR and reporting department.
Results: The total ADRs reported pre and post sensitization were 36 and 77 respectively for a period of three months each. There was significant improvement in the reporting of ADRs both qualitatively and quantitatively post sensitization.
Conclusion: It was deduced that even a newly established medical college with meagre facilities can show improvement in ADR reporting by implementing a well designed sensitization programme.

INTRODUCTION

As per WHO, an Adverse Drug Reaction (ADR) is "a response to a drug that is noxious and unintended which usually occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function. [1] The pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, that could be long term and short-term adverse effects of medicines is known as Pharmacovigilance. [2]

In India, a formal ADR monitoring system had its advent 1986 with 12 regional centers. In 1997, India became the member of WHO Programme for International Drug Monitoring which was under the management of Uppsala Monitoring Centre (UMC), Sweden. The foundation of this program was started with 6 regional centers that were set up in Mumbai, New Delhi, Kolkata, Lucknow, Pondicherry, and Chandigarh for ADR monitoring in the country. [3]

The Pharmacovigilance Programme of India (PvPI) was formally inaugurated in 2010 to ensure the safety of medicines, and the Indian Pharmacopoeia Commission functions as the National Coordinating Centre (NCC) for the PvPI under the aegis of Ministry of Health and Family Welfare, Government of India. [4] Indian Pharmacopoeia Commission (IPC), Ghaziabad is functioning as a National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) .[5] Over 200 ADR monitoring Centres (AMCs) in the country are now acknowledged to monitor and report ADRs. [6]. All centres upload ADR reports into VigiFlow which is the World Health Organization-Uppsala Monitoring Centre's (WHO-UMC) web-based system to collate ADRs worldwide. [7]

ADR reporting involves voluntary submission of patient-specific information on a suspected ADR, to a drug regulatory agency, following administration of at least one medicinal product. It remains the foundation of pharmacovigilance and patient safety. [8, 9] ADR monitoring includes different studies for the identification of adverse events. These include Case reports, Anecdotal reporting, Impulsive reporting system, Intensive monitoring studies, Contingent studies, Case–control studies (Retrospective Studies), Case cohort studies, Record linkage, Meta analysis and utilitization of resident's statistics.[10]

Inspite of the persistant efforts by the Pharmacovigilance Programme (PvPI)of India towards inculcating a culture of ADR monitoring; underreporting is still very prevalent. It is found that only 6-10% of all ADRs are reported. Such high rate of underreporting is a matter of grave concern which can delay detection of serious ADRs and consequently have a major negative impact on the public health. [11]

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Table 1 December 2017 to February 2018

Deptt.	Dermatitis	Urticaria	Amenorrhea & hyperprolactinemia	Oral Ulceration	Lichenoid Eruptions	Nausea and vomiting	Sexual dysfunction	Facial swelling and edema	Fixed drug eruption	TOTAL ADRS
Psychiatry	01	01	01	----	----	01	01	01	01	07
Medicine	01	02	----	01	----	01	----	----	----	05
Surgery	01	02	----	----	----	01	----	----	----	04
Gynae	01	01	----	----	----	01	----	----	----	03
Dermatology	03	04	----	----	03	----	----	----	02	12
Ortho	02	----	---	----	----	01	----	----	----	03
ENT	----	01	----	----	----	01	----	----	----	02
										36

Table 2 April 2018 to June 2018

Deptt.	Dermatitis	Urticarria	Amenorrhea with hyperprolacticania	Oral Ulceration	Lichenoid eruptions	Nausea vomiting Diarrhea	Sexual dysfunction	Facial swelling and edema	FDE	Dresses syndrome	Restlessness Vertigo	Dyspnea	TOTAL
Psychiatry	----	02		----	----	----	----	01	02	01	02	01	09
Medicine	----	05		----	01	01	----	----	01	----	01	---	09
Surgery	02	05		----	----	02	----	01	----	----	01	----	11
Gynaecology	01	05		----	----	01	-----	----	----	----			07
Dermatology	----	07		01	01	-----		01	04	01			15
Orthopeadics	02	05		02		02	----	----	01	----	01		12
ENT	----	01		----		01	----	----	----	----			02
Dental	02	03		----	01	01	01	02			01		11
													76

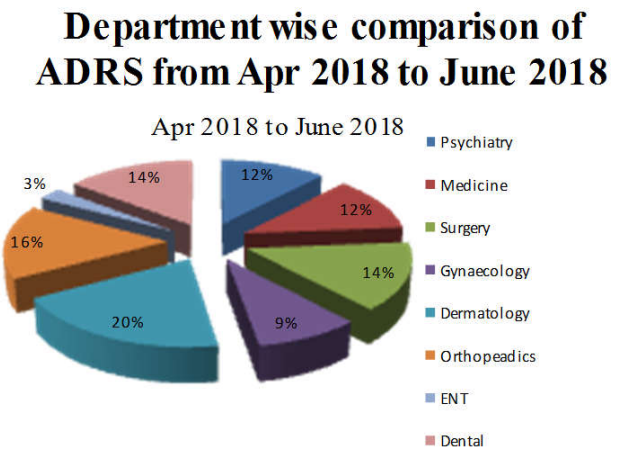

Fig 1

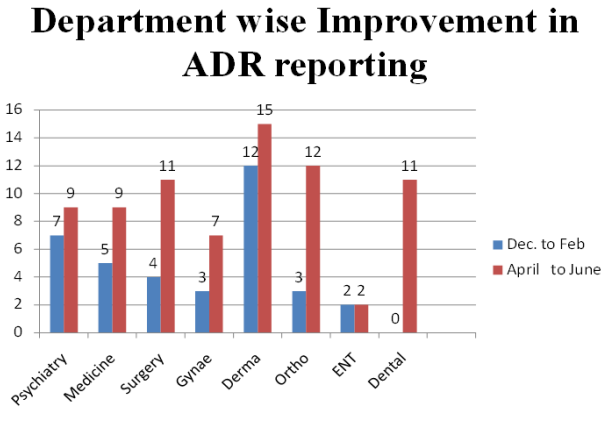

Fig 2

Spontaneous ADR reporting is important to monitor known and unknown adverse effects of medicines. [12] They are currently recognized as the foundation of postmarketing surveillance of drug safety. [13] The main aim of spontaneous reporting is the early detection of signals of new, rare and serious ADRs.[14]It is also one of the cheapest methods of monitoring the safety of medicines as utilized by many drug regulatory agencies worldwide.[15] But the main problem in India is underreporting even under the best methods have been provided.[16]

There has been a drastic improvement in the current reporting culture of ADRs under Pharmacovigilance Programme of India (PvPI) after conducting regular training and awareness programme and circulating the 'PvPI Drug Safety Newsletter'. Healthcare professionals (HCPs) are required to report ADRs to nearest ADR Monitoring Centres (AMCs) under PvPI and the same is collected and collated by the Indian Pharmacopoeia Commission (IPC), National Coordination Centre (NCC).[17] There is a requirement for constant training and enactment of regulations for ADR reporting among healthcare professionals. In the previously conducted studies it was found that underreporting of ADR is related with shortcomings in the knowledge and attitude among healthcare professionals. [12, 18]

Under PvPI, ADR monitoring centres (AMCs) were to be established in Medical Council of India (MCI) approved medical colleges and hospitals, private hospitals, centers running public health programs, and autonomous institutes. Five-year roadmap of PvPI targeted to include 300 medical colleges as AMCs by the year 2014 only in a phase-wise manner of including 40 medical colleges in the year 2010–2011, 60 in the year 2011–2012, and then, an increment of 100

each for year 2012–2013 and 2013–2014. Going by that rate, by now, all the MCI approved medical colleges in India should have been covered under PvPI and included as AMCs. [19]

However, ground situation is different. As of September 2017, as per IPC website information, 250 centers have been marked as AMCs, and that include medical colleges and other hospitals too. [20]

Thus the main objective of the present study was to see that a new developed medical college attempted to increase the incidence of Adverse Drug Reporting by increasing the sensitization among the health care professionals.

MATERIAL AND METHODS

This prospective study was conducted from Dec 2017 to June 2018 on the ADRs collected from all the departments (inpatient as well out patient department) in Kalpana Chawla Government Medical College, Karnal. Reporting of ADRs was done by either telephonic / direct reporting to the Dept. of Pharmacology on "PvPI ADR Reporting form". [21] Causality assessment was done by WHO causality assessment scale [22] categorized as per type of ADR and reporting department. In the initial phase of the study that is from Dec 2017 to Feb 2018 conventional methods like office notification, ADR collection boxes, and posters were used for bringing awareness. The ADRs reported during this time were noted. Then newer methods like group sensitization program which included one to one sensitization of the clinicians and nursing staff and other health care professionals was done by the faculty of department of Pharmacology for the whole month of KCGMC of March 2018. The impact of the on reporting post this sensitization programme on the quality and quantity of ADRs was noted for the subsequent three month that is from April to June. This was seen as increase in the number ADRs reported in each department. Descriptive Analysis was used to interpret the results.

RESULTS

The number of ADRs reported in the month of April to June 2018 gradually doubled as compared to those reported in the month of Dec. 2017 to Feb 2018. Thus the number increased from 36 to 76. The exact number was 77 in the second half of the study was, but that was underreported and could not be assessed. Therefore the number was taken as 77.

The maximum number of ADRs reported in the first half of the study was by the Department of Dermatology (12) followed that of Psychiatry (7). However in the second half of the study the maximum number of ADRs reported was by the Department of Dermatology (15) followed that of Orthopaedics (12). (Table 1 and Table 2). (fig .1 and fig. 2). The Department of Dental Sciences which had no ADR reported was the one showing almost 100% improvement.

DISCUSSION

Kalpana Chawla Government Medical College, Karnal is newly established College which was given the status of Adverse Drug Reaction (ADR) Monitoring Centre in the recent past. Increased efforts were made to make the health care professionals aware of the importance of ADR reporting.
This was done through the sensitization programme held by the Department of Pharmacology, like holding regular seminars and individual visits by the faculty in all the indoor and outdoor departments and making the clinicians about the beneficial effects of ADR reporting and besides that there were also told about the possible ADRs due to all the class of drugs and how could they be avoided if proper reporting was done. This could reduce the morbidity and help in the proper treatment of the patients.

Many studies have found that ADR underreporting is a worldwide problem, even in countries where pharmacovigilance programs are well established.[23] The reason for underreporting has been due to lack of time and knowledge about ADRs is often considered to be a cause of underreporting. [24,25,26] Sometime the healthcare professionals were not provided with appropriate forms and also lacked knowledge about Pharmacovigilance program.[27] However by increasing the awareness the amongst the healthcare professionals by educational intervention programme can have positive effect reporting as supported by the in a similar educational pharmacovigilance study of Li Q, Zhang *et al* on pharmacovigilance.[28] In a study conducted by Tabali *et al* demonstrated that an educational intervention could increase health care professionals awareness of ADRs and that physicians showed improvement in ADR reporting further supporting the results of the present study.[29]

CONCLUSION

Thus we can conclude that the effect of sensitization effects of the educational intervention were constructive and beneficial. These sensitizations programme were temporary Further such intervention programme should be conducted at regular intervals that could lead to more durable improvements in ADR reporting rates in everyday practice.

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