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Correspondence

Adverse drug reactions reporting culture in Pharmacovigilance Programme of India

Sir,

Adverse drug reactions (ADRs) have been reported to be among leading causes of morbidity and mortality[1-4]. The spontaneous reporting of ADRs is considered as the foundation of post marketing surveillance of drug safety[5-7]. The main function of spontaneous reporting is the early detection of signals of new, rare and serious ADRs[8]. It is also one of the cheapest methods of monitoring the safety of medicines as utilized by many drug regulatory agencies worldwide[9,10]. Therefore, pharmacovigilance programme plays a vital role in ensuring the drugs' safety. In many countries (including India) a pharmacovigilance system is operational; however, under-reporting is a major problem[11-14]. An increase has been observed 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) reports 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)[15]. The objective of this study was to ascertain the contribution of different stakeholders in reporting of ADRs, reporting status of government medical institutions (GMI), non government medical institutions (NGMI) and corporate hospitals (CH) under the fold of PvPI.

All Individual Case Safety Reports (ICSRs) received by the NCC between July 1, 2011 and December 31, 2012, were taken into account for analysis. The data were entered manually into VigiFlow along with the mandatory field of 'Information on Primary Source' where a reporter has to specify his/her name, contact details and qualification.

Analysis of a total number of 23,975 ICSRs revealed that the majority of ADRs were reported by physicians (n=15440, 64.4%). Relatively lower reporting was done by the pharmacists (n=3620, 15.1%). Other HCPs (nurses, physiotherapists *etc.*) contributed to (n=4891, 20.4%) reports; while reporting by non HCPs was found to be (n=24, 0.016%) only. The highest reporting rate was observed in GMI (74.4%) as compared to NGMI (24.5%) and CHs (1.0%). This study also revealed the rate of reporting of ADRs month-wise and it was found that the reporting rates were consistently increased after disseminating the information through PvPI Newsletter, awareness programme, sending circulars to the ADRs monitoring centre, *etc*.

The ADRs reporting percentage of physicians in the Programme (n=15440, 64.4%) was higher as compared to pharmacists (n=3620, 15.1%) and other HCPs (n=4891, 20.4%). The reporting rate of pharmacists was low as compared to physicians because in India, the system of distribution does not leave much scope for the pharmacists to be a significant source of ADRs reporting. Similarly, even though nurses are in closer contact with the patients for a longer duration, in the event of ADRs observed by the nursing staff, it would be reported to the treating physician, who in turn if deemed appropriate, communicates the information to the relevant higher authorities. In some of the European countries only those authorized to prescribe medication are allowed to report ADRs[16]. Therefore, co-ordination among clinician, pharmacist and nurse appears to be of vital importance to contribute each of their respective expertise and experience to promote the rational and safe use of medicines.

Lack of knowledge of where, what and how ADRs should be reported also affects reporting. The reason for poor reporting may also include financial incentives, legal aspects, apprehension that the serious ADRs are already documented when a drug is introduced in the market, and that a single report

would make no difference, ignorance (that only serious ADRs are to be reported) and lack of time or over load[17]. NCC has taken steps to tackle this by addressing this issue in various forum and conferences, circulating questionnaire form, writing to professional bodies, scientific journals, *etc*. In the next step, NCC may recommend Medical, Pharmacy and Nursing Councils of India to include pharmacovigilance in their respective education curriculum. These measures could improve the quantity and quality of the reports. Pharmacovigilance Programme of India can only be vibrant if utilized effectively with active participation of HCPs.

This preliminary study may be useful in devising strategies to create awareness in ADRs reporting among health care professionals under PvPI. Further, awareness programmes to sensitize healthcare professionals are necessary to improve pharmacovigilance.

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