An adverse drug reaction clinic: Breathing fresh life into the pharmacovigilance programme

Sir,

After the launch of National Pharmacovigilance Programme in 2004[1], the Government of India came out with a revised programme called "Pharmacovigilance Programme of India (PvPI)" in 2010,[2] to streamline the drug safety monitoring in India. PvPI has come out with five phases in the span of 5 years, from the initiation phase in 2010-2011 to the excellence phase in 2014-2015.[2] Irony is that the hospitals and medical colleges are not still aware of this programme. Even in the teaching curriculum for both under graduates and post graduates, pharmacovigilance is a part of their syllabus, but not much attention is paid to teach this subject. This leads to a sense of ignorance among the young budding doctors, as they do not realize the importance of pharmacovigilance.[3] Most of the young doctors and medical students have neither seen the adverse drug reaction (ADR) form issued by the Central Drugs Standard Control Organization(CDSCO) nor they are aware of the procedure to report an ADR.[4] Most of the hospitals are understaffed with an abysmal ratio of doctors to the population in India, and they are striving to clear their out patient departments(OPDs) in time while trying to maintain an utmost clientele satisfaction.[5] There are hardly any hospitals and institutions which have taken this programme seriously, and have made an organised system for data collection, data maintenance, and data reporting. This scenario does not augur well for the country especially when India has become a major centre for clinical trials.[5] A step has been made in this direction with the establishment of a pharmacovigilance cell becoming mandatory for all medical colleges and hospitals in India.[6] However, this may not be adequate and until all health care providing institutes play an active part in the pharmacovigilance, it may not be fully successful.

An approach to address this issue is to assign the job of pharmacovigilance to an independent unit which is full time dedicated to the job of ADR monitoring. This involves setting up of an adverse drug reaction clinic. An ADR clinic should be an independent unit, whose in-charge should preferably be a pharmacologist in a medical college hospital or a faculty from the department of medicine who should have attended a short course or workshop in pharmacovigilance in the case of other hospitals. This ADR clinic will work in close association with the pharmacovigilance committee of the hospital. Adequate permanent staff should be employed for the ADR clinic.[7] Its location should be near the exit of OPD complex preferably next to the pharmacy.

The clinic will perform passive and active surveillance of the patients. Passive surveillance will involve close interaction with the treating clinicians working in the hospital to identify instance of ADRs, following which the clinic will fill out the necessary reporting forms, and take care of any formalities. This will help in taking away the load from the treating physician. Any case of ADR noticed by any other health care worker will also be referred to the ADR clinic for similar action. The ADR clinic will also perform active surveillance of patients for ADRs. This can be done by actively registering a select group of patients who are at higher risk of ADRs. These are patients on multiple drugs, geriatric patients,[8] or patients in whom a new drug (which has come in to the market since last 5 years) is being given, for which such data regarding ADR, are not substantially available. These patients would register with the ADR clinic, and they can be followed up actively by telephonic calls for identification of any ADR. The ADR clinic should also run a 24 h helpline for assisting patients[9] and also act as a counselling centre, which would advise patients how and when to take drugs, how to maintain compliance and its importance,[10] and how to detect ADR and report it to the treating physician or to the ADR clinic directly.

The clinic could also act in a capacity of an advisory role for medical staff. The ADR clinic would also maintain computerised data for statistical analysis, which would help in research work.[11] Taking these data in to consideration a drug bulletin can be published at a periodic interval and circulated to various clinical and para-clinical departments. To encourage regular spontaneous reporting of ADRs,[12] the ADR clinic should regularly conduct lectures and seminars for the health care staff stressing the importance of PvPI. The ADR clinic should also enrol the private practioners working in the vicinity for reporting ADR and should expand its networking slowly, once established.

The concept of an ADR clinic can breathe life in to the pharmacovigilance system and get the PvPI running smoothly on the right track and help to achieve the goals in time, without overloading the clinicians. This will also encourage interdepartmental coordination which will ultimately benefit the patients.

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