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EDITORIAL

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Drug safety surveillance /Adverse drug reaction monitoring and establishing Pharmacovigilance Centres in teaching hospitals – A perspective

Shobha V. Huilgol*

Department of Pharmacology, Al-Ameen Medical College, Athani Road, Vijayapur-586108 Karnataka, India

Drug safety monitoring is an essential element for the effective use of medicines and for high quality medical care. It has the potential to inspire confidence and trust among patients and health professionals in use of medicines and contributes to raising standards of medical practice [1].

In view of the national directive to institutionalize a PV centre in every medical college of India, there is an urgent need to inform, educate, and enlighten the readers about the constitution and dynamics of a PV centre. In order to prevent un necessary suffering by patients and decrease the financial loss sustained by patients due to inappropriate or unsafe use of drugs, it is essential that a monitoring system to be established for safe use of medicines.

Present Pharmacology curriculum doesn't give a higher priority to the study of safety of medicines. Ensuring higher priority would lead to enhanced awareness of the balance between the benefits and harms of medicines. An integrated approach to therapeutic decision making to be encouraged. Excessive and irrational drug use, contributes to adverse reactions [2-3]. The misuse of medicines is largely caused by the poor quality and inaccessibility of drug information available to practioners. Pharmacovigilance is a clinical discipline in its own right that contributes to an ethos of safety and serves as an indicator of the standards of clinical care practised within a country.

Pharmacovigilance (PV) is defined as the pharmacological science relating to the detection, assessment, understanding and prevention of adverse, particularly long term and short term side effects of medicines [4].

Planning the basics: A blueprint should be drawn up to establish and get a PV system to work. Care needs to be taken to establish the following

Communication process: Getting in conversation with health authorities and local, regional, national bodies and groups engaged in clinical medicine, pharmacology, toxicology, epidemiology, briefing them about the importance of the project and its applicability in modern therapeutics.

Data acquisition: Designing a template for ADR reporting and making available ADR reporting forms at all times, to hospital departments and general practitioners, on which they can furnish relevant information to the data bank of the center.

Dissemination: Producing printed handouts as well as conducting meetings or workshops in hospitals and academia to acquaint health care professionals about the definitions, goals, scope, and methodology of the PV system to create awareness about its relevance in present times.

Establishment: Hiring the right qualified and interested staff, getting suitable place for accommodating them as well as the center, making arrangements for telephones, computers, printers, word processors, database management, bibliography support services, and internet.

Internal education: Ensuring proper education and frequent updating of the staff belonging to the PV centers by training them in data collection, filtration, mining, verification, interpretation and coding of ADRs, medicines coding, causality assessment, signal detection, risk management, and action in case of serious/fatal adverse drug events (ADE).

Database: Creating a safely stored, classified database which is retrievable and guarded by required degrees of confidentiality.

Promotion: To inculcate and promote the habit of reporting ADRs to the higher center, medical journals, health bulletins and other professional healthcare publications.

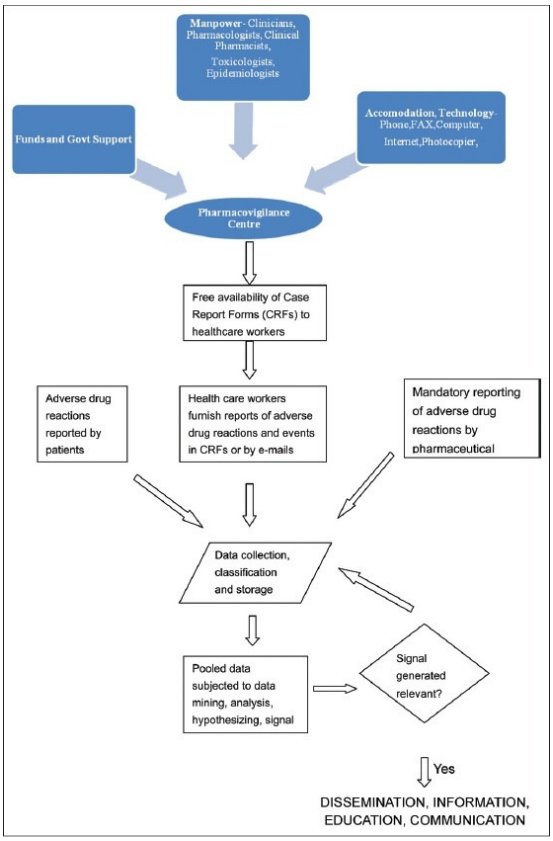
Networking: To encourage healthcare professionals to contact institutions working on a global scale in PV e.g. Uppsala Monitoring Centre (UMC) WHO department of Essential Medicines and Medicines Policy, Geneva, and net groups like International Network for the Rational Use of Drugs (INRUD), E-drug, and Network for Rational Use of Medicines (NetRUM) [1].

National Pharmacovigilance in India: *WHO sponsored* and world bank funded National Pharmacovigilance Program is operational in india from January 2005.This is overseen by Advisory committee , central Drugs Standard Control Organization (CDSCO) ,New Delhi. There are 2 zonal centres (South-West centre,KEM Hospital ,Mumbai and North-east centre ,AIIMS, New Delhi). They collect information from existing 5 regional centres and send it to Uppsala Monitoring Centre at Sweden. Each regional centre in turn has several peripheral centres reporting to it. At present there are 24 peripheral centres [5].

Objectives of NPP:

- To create awareness through nation- wide system for patient safety reporting amongst health care professionals.
- To identify and analyse the new signal (ADR) from the reported cases.
- To generate evidence based information on safety of medicines.
- To Support regulatory agencies in decisiion–making process on use of drugs.

To communicate the safety information on use of medications to stakeholders to minimize the risks.



Pharmacovigilance system – constitution and functioning

Indicators such as the number of serious ADRs prevented, the number of patients counselled, the number of physicians trained and costs due to ADRs saved, need to be developed to evaluate and assess the impact of the pharmacovigilance system and thus justify expenditure on PV in low resource countries as India and other developing countries.

Establishing a robust PV system is an uphill task, but nevertheless, with meticulous planning, proactive approach, continuing zeal and motivation of the concerned staff, if there is will, it can be achieved. PV ensures that future generations will not condemn the present one for its apathy, indifference, and callousness to the gravity of the situation or else modern medicine will be continued to be called as allopathy-the science of other suffering!.

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[*]**About the author:** Author is a member of the Editorial Board of '*Al Ameen Journal of Medical Sciences'*. She can be accessible by huilgol.shobha739@gmail.com