Editorial

Pharmacovigilance: Drug Safety Monitoring

*Hilmi SR

According to WHO definition 2002, Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.1

Medicines are supposed to save lives but no medicine is risk free. Vigilant assessment of the risks and benefits of medicine promote safety. Dying from a disease is sometimes unavoidable; dying from a medicine is unacceptable. Pharmacovigilance promotes rational use of medicines, adherence and promotes public health by ensuring the safety, efficacy and quality of medicines and other health products.

Before a medicine is authorized for use, evidence of its safety and efficacy is limited to the results from clinical trials. These studies have limited duration and are conducted on limited numbers of patients that are selected by strict eligibility criteria. Sometimes rare and long-term adverse reactions remain unrevealed during this period. But after authorization large number of populations get access to that medicine. Certain side effects may disclose this time. Therefore, post-marketing surveillance of medicines play a key role for better understanding of drugs safety profile and filling the gap of pre-marketing assessment. It is therefore essential that the safety of all medicines is monitored throughout their use in healthcare practice.2

All pharmaceutical products have potential adverse effects; however, the consequences vary in severity and frequency which imposes health risk. Adverse events may occur due to known or unknown pharmacological properties, poor quality of pharmaceutical products, errors in prescribing or administering the medicine. A serious adverse reaction that occurs at any dose may require inpatient hospitalization or prolongation of hospital staying, may also cause persistent or significant disability or may be life threatening. Adverse drugs reactions (ADRs) not only add the sufferings of patients by increasing morbidity and mortality but also add a financial burden to the society. Cost of drug related morbidity and mortality in the US exceeded $177.4 billion in 2000. ADR related cost to the country exceeds the cost of the medications themselves. Therefore, all suspected adverse events and related information should be reported through the appropriate channels. 3,4

Pharmacovigilance was introduced in Bangladesh in 1996. However, due to a shortage of manpower and a lack of financial support, the program became dormant. It was revived in 2013 when the DGDA (Directorate General of Drug Administration) established the ADRM (adverse drug reaction monitoring) Cell with technical assistance from SIAPS (Systems for Improved Access to Pharmaceuticals and Services).5

All health care professionals including doctors, nurses and pharmacists; Community health workers; Patients, consumers and even the general public can report for the ADR. Patients should report any unexpected deterioration in physical, chemical or neurological status following the use of a medicine or other health product and any quality concerns about a product to an HCP (health care provider). If a patient does not have immediate access to an HCP or facility, he or she can report to a community health worker or directly to the ADRM Cell. HCPs should fill out the adverse event notification form and submit it to the pharmacovigilance focal point at their facility.[5]

If a facility does not have a designated pharmacovigilance focal point or other appointee to receive ADR forms, the HCPs can report directly to the ADRM Cell. Pharmacovigilance focal points should collect all notification forms and submit the forms to the ADRM Cell. Adverse drug event reports can be submitted to the ADRM cell by email, mail or fax.[6]

Pharmacovigilance helps in early detection of ADRs and identification of risk factors which contributes to the protection of patients and helps in maintaining public health. physicians are an integral part pharmacovigilance plan. Therefore, reporting to any adverse drug event is a crucial responsibility of a physician, that can save millions of valuable lives globally.

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Syeda Rubayat Hilmi
Assistant Professor
Department of Pharmacology
ZH Sikder Women's Medical College, Dhaka