Press Release

Importance of pharmacovigilance and reporting of adverse drug events

IMA urges its 2.8-lakh members to report each and every adverse drug reaction to reduce incidence of preventable deaths

New Delhi, January 12 2016: Recently, the pace with which newer drugs are being introduced in India and worldwide has been increasingly steadily. These drugs come from a tightly regulated pipeline of clinical trials and safety evaluations. The drug, once in the market can then be subjected to a final round of scrutiny by monitoring adverse drug reactions (ADR). Reporting of ADR can facilitate early detection of signals of new, rare and serious ADRs. It also can potentially provide information about the safety and efficacy of the drug in the long run and ultimately safeguards the patients.

The specific aims of pharmacovigilance are as follows:

- Improve patient safety and care regarding the use of medicines and medical or paramedical therapeutic interventions.
- Improve public health and safety regarding the use of medicines
- To facilitate the assessment of effectiveness, risks involved and safety of medicines
- Encourage safe, rational, effective and cost effective use of medicines
- Promote an understanding, training and general awareness about pharmacovigilance and its effective communication to the general public

Padma Shri Awardee Dr. K.K Aggarwal - National President, Indian Medical Association (IMA) and President Heart Care Foundation of India (HCFI) and Dr RN Tandon – Honorary Secretary General IMA in a joint statement said, “In India, pharmacovigilance programs to monitor ADR are operational however, the limitation lies in under-reporting. Adverse drug events (ADEs) result in significant injuries and deaths every year. Estimates suggest that over 50% of all adverse drug reactions treated in hospitals and emergency care are preventable.”

Many ADE related injuries, mortalities and incurring hospital costs can be decreased if healthcare institutions strengthen their systems for preventing and detecting ADEs. Research studies have also found that the type and severity of ADE affects length of stay and costs in hospitals. Patients with severe ADEs like arrhythmia, bone-marrow depression, seizures, or bleeding averaged a 20-day
hospital stay while those with less severe cases, for 13 days and those with no ADE, only 5 days. Hospital costs for them were much higher as compared to non-ADE patients.

Many preventable drug reactions like drug overdoses and internal bleeding associated with the improper use of blood thinners and painkillers are life threatening especially in the elderly. There are many reasons for these reactions and may include poor coordination of care, lack of time and knowledge among health professionals, and lack of patient education. Medication errors are a frequent cause of adverse drug events, the factors that may lead to such errors.

**Common medication errors that can precipitate adverse drug events include:**

- Missed dosage
- Illegible prescription
- Wrong technique
- Duplicate therapy
- Drug interactions
- Equipment failure
- Preparation or formulation error
- Improper monitoring

Both in a clinical setting and at the patient community level, adverse drug reactions can be detected and prevented up to a significant extent resulting in significant healthcare cost reductions, decreased hospital stay and patient mortality reduction. Doctors and patients should be more proactive about reporting adverse drug events.

“ADR monitoring and reporting is still inadequate in India; Pharmacovigilance program of India (PvPI) is doing a commendable job. Current adverse drug incident reporting system need to be improved, moreover, strengthening nursing medication and monitoring systems is also required. What is crucial is to create a better environment for healthcare professionals so that they report ADRs without hesitation or fear of punishment or severe repercussions” added Dr KK Aggarwal.

The practice of self-medication also needs to be curbed. Lack of knowledge of where, what and how ADRs should be reported also affects reporting. To strengthen existing ADR monitoring programs, awareness needs to be raised amongst the population about the long-term benefits of reporting the side effects of drugs. Government and local medical organizations can take the initiative in form of mass media distribution through newspapers, radio, television and awareness campaigns.

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**About IMA:** Indian Medical Association is the only representative, national voluntary organization of Doctors of Modern Scientific System of Medicine, which looks after the interest of doctors as well as the well being of the community at large. It has its Headquarter in Delhi and State / Terr. Branches in 29 States and Union Territories. It has over 2, 53,000 doctors as its members through more than 1650 active local branches spread across the country.
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