

## Spontaneous reporting of Adverse Drug Reactions

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### ABSTRACT

Drugs are used for the benefit of the patient however drugs also produce adverse drug reactions. Adverse drug reaction is an adverse drug event that results in undesirable or unexpected event that requires some changes in the clinician's care of the patient, modifying a dosage, prolonging hospitalization or administering supportive treatment. Monitoring and Reporting of adverse drug reaction should be a part of comprehensive health care provided to the patients. This letter stresses on the need for the health care professional to report and monitor the adverse drug reactions.

**Key words:** Adverse drug reaction, monitoring, drug

Almost every person has taken one or other drug in his life. Drugs are well known to cause adverse effects as a collateral or side effect. Talking more than one drugs for single disease or coexistent diseases, taking a drug for a long time for chronic diseases, presence of co-morbidities (malnutrition, anaemia, worm infestation etc) and use of alternative systems of medicine (homeopathy, ayurveda, yoga, sidha etc) further increases the risk of developing unforeseeable adverse events and adverse drug reactions (ADR).<sup>[1]</sup>

An 'adverse event' is defined as any untoward medical occurrences that may present during treatment with a drug, but which does not necessarily have a causal relationship with its use.<sup>[2]</sup> An 'adverse drug reaction' is a noxious, unintended and undesirable effect of a drug, occurring at a

does recommended in acceptable medical practice for prophylaxis, diagnosis, therapy or modification of physiological functions<sup>[3]</sup> and results in:

- A change in drug therapy including change in dosage or discontinuation of therapy.
- Initial or prolonged hospitalization
- Intervention supportive treatment to prevent permanent impairment or damage
- A life threatening event
- Permanent disability
- Death
- Congenital anomaly

ADR also includes all reactions to new drugs i.e. drugs in the market for 3 years or less. There are many types of adverse drug reactions:

- Type A- Augmented & pharmacologically predictable adverse effects
- Type B- Bizarre and unpredictable
- Type C- arising from Chronic use
- Type D- Delayed reactions to drugs
- Type E- End of dose reactions
- Type F- Failure of therapy

Adverse effects may cause medical complications of a disease or procedure and negatively affect its prognosis. They may also lead to non compliance with a treatment regimen. But, fortunately many 'adverse events' and 'adverse drug reactions' are predictable, preventable and many drugs have safer alternatives available. But, this requires 'suspicion' as well as intelligent observation of adverse drug effects on the part of practicing doctor and timely reporting to the authorities so that necessary regulatory actions can be taken.

### **Need for Pharmacovigilance**

In a vast country like India, with more than 1 billion population, the health needs are vast. Pharmaceutical industry has grown and flourished over time and at present India is the fourth largest producer of pharmaceuticals in world. Although a new drug is marketed only after undergoing a variety of preclinical and clinical tests in experimental animals and human beings during various phases of development. But, this is not enough, as premarketing frequencies of ADRs are based on clinical trials carried out on a 'select study population' for a limited period of time. Therefore Safety data generated from these trials fails to identify infrequent and late onset adverse drug reactions. Moreover when a new drug is marketed minimal or no information is

available regarding its safety in special groups like children, elderly patients, pregnant and lactating females. Several new drugs are being launched in Indian market almost simultaneously as in worlds market. Hence post marketing safety data (which is a better overall reflection of adverse effects in general population) is not at all available at the time of introduction of a new drug in market.<sup>[4]</sup> If the postmarketing monitoring and reviewing process is absent, the pharmacological effects of drugs, their adverse effects, interaction and misuse threaten to play havoc with the health system of the country. Hence identifying 'signals' of drug safety problems as early as possible is of utmost importance. A 'signal' is the 'reported information' on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Detection of ADRs requires the vigilance of all health care professionals. In other words a vibrant Pharmacovigilance system is needed to protect the population from potential harm that may be caused by these new drugs.

According to WHO 'Pharmacovigilance' refers to the science and activity relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems. It includes identification of side effects of drugs, their treatment, documentation, reporting and regulatory decisions based on them.

### **National Pharmacovigilance program**

The Central drug standard control organization (CDSCO) launched a highly participative 'National Pharmacovigilance programme' in November 2004, with the aim of collecting, analyzing and archiving ADR data for making

regulatory decisions regarding drugs marketed in India. It promises to maintain a close watch over the use of drugs and their effects on people. The immediate objective is to foster a culture of notification of ADRs among doctors as well as other health care providers viz pharmacists and nurses and the long term objective is to generate ADR data.<sup>[5]</sup> In order to have a viable ADR data capturing system, the National Pharmacovigilance program is structured and 2 zonal Pharmacovigilance program is structured as a three tier system. It consists of 24 peripheral, 5 regional and 2 zonal pharmacological centers. At the apex is National Pharmacovigilance advisory committee and National Pharmacovigilance center based at CDSCO, New Delhi. Spontaneous reporting of adverse events and drug reactions by health care seems to be the most suitable method for generating safety data.<sup>[6]</sup> Practicing physicians should report (on suspected adverse drug reaction reporting from published by CDSCO) observed adverse events and ADRs to peripheral centers (established in teaching and non teaching hospitals, clinics and pharmacies) which forward the received information to its respective regional center on weekly basis. It maintains patients confidentially.

Reporting of all suspected adverse reactions to drugs and other medicinal substances including herbal, traditional or alternative remedies must be encouraged. The reporting of seemingly insignificant or common adverse reactions would be important since it may highlight a wide spread prescribing problem. The 5 regional centers covering north, east, central, west and south record ADR data locally, scrutinize the data received from peripheral centers, subject its data to

causality assessment and report to its zonal center. The 2 zonal centers also generate their own ADR data, Pharmacovigilance center. All centers can report for National Pharmacovigilance center directly so that regulatory decisions can be taken promptly. The National Pharmacovigilance center then recommends the CDSCO for regulatory actions, including amendments to label and suspension or withdrawal of product. In last 2 decades many drugs have been withdrawn from market because of detection of serious adverse reactions during postmarketing surveillance. A very recent example is of rofecoxib, a selective COX2 inhibitor which has been banned due to severe cardiovascular side effects. The relevant information is then disseminated through ADR news bulletins, drug alerts and seminars.

But the success of the program rest on the shoulders of health professionals. To derive maximum benefit from the program it is important that all clinicians assume responsibility in reporting adverse drug reactions. ADR reporting form published by CDSCO and list of all peripheral, regional and zonal centers can be downloaded from website of CDSCO. ([www.cdsco.nic.in](http://www.cdsco.nic.in)) It maintains patient confidentiality. However identification of notifier is obligatory to allow for verification of information and to avoid submission of spurious data.

#### **Benefit of ADR monitoring and reporting**

1. It assesses the safety of drug therapies especially important for new drugs. Reporting of ADRs for new drugs has led to withdrawal of many drugs from the market and modification of the package insert information.

2. It allows important modifications in use of drug involved e.g. Change in dose administration recommendations.
3. Provides a method for indentifying preventable ADRs
4. Education health professionals regarding adverse drug effects.
5. Provides quality assurance screening findings for use in drug use evaluation programs.
6. Provides a measurement of ADR rates over time.

#### Limitation

1. Although in principle, medical professionals are encouraged to report all adverse effects related to a specific from of therapy, but in practice it is at the discretion of the attending physician to determine whether a medical event is related or not to the therapy. So routine adverse effects reporting may often not include long term and subtle effects that may ultimately be attributed to therapy.
2. Sometimes putative medical adverse effects, which are not yet conclusively proven, generate controversies and heated discussions in society and unnecessary lawsuits against drug manufactures.
3. In case of widely used medications such as hormonal contraception or HRT, even marginal probabilities of adverse effects of a serve nature like therapy, although its benefits largely surpassed the statistical risks.

To conclude spontaneous reporting of all suspected adverse drug events and ADRs by health professionals is the backbone. The practicing physicians should assume responsibility in reporting the observed ADRs to authorities, so that necessary preventive steps can be taken to protect our fellow beings from these avoidable risks associated with drug use.

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