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Study of Adverse drug reactions & its Mechanisms- Dr Sheela Ankolekar- Norgine UK

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An adverse drug reaction (ADR) is an injury caused by taking medication. ADRs may occur following a single dose or prolonged administration of a drug or result from the combination of two or more drugs. The meaning of this term differs from the term "side effect" because side effects can be beneficial as well as detrimental. The study of ADRs is the concern of the field known as pharmacovigilance. An adverse drug event (ADE) refers to any injury occurring at the time a drug is used, whether or not it is identified as a cause of the injury. An ADR is a special type of ADE in which a causative relationship can be shown. ADRs are only one type of medication-related harm, as harm can also be caused by omitting to take indicated medications.

Adverse drug reactions can be considered a form of toxicity; however, toxicity is most commonly applied to effects of overingestion (accidental or intentional) or to elevated blood levels or enhanced drug effects that occur during appropriate use (eg, when drug metabolism is temporarily inhibited by a disorder or another drug). For information on toxicity of specific drugs see the table Symptoms and Treatment of Specific Poisons. Side effect is an imprecise term often used to refer to a drug's unintended effects that occur within the therapeutic range.

In the US, 3 to 7% of all hospitalizations are due to adverse drug reactions. ADRs occur during 10 to 20% of hospitalizations; about 10 to 20% of these ADRs are severe. These statistics do not include the number of ADRs that occur in ambulatory and nursing home patients. Although the exact number of ADRs is not certain, ADRs represent a significant public health problem that is, for the most part, preventable.
Incidence and severity of adverse drug reactions vary by patient characteristics (eg, age, sex, ethnicity, coexisting disorders, genetic or geographic factors) and by drug factors (eg, type of drug, administration route, treatment duration, dosage, bioavailability). Incidence is higher with advanced age and polypharmacy. ADRs are more severe among the elderly (see Drug-Related Problems in Older Adults), although age per se may not be the primary cause. The contribution of prescribing and adherence errors to the incidence of ADRs is unclear.

Classification:

Adverse drug reactions are usually classified as mild, moderate, severe, or lethal. Severe or lethal ADRs may be specifically mentioned in black box warnings in the physician prescribing information provided by the manufacturer.

Symptoms and signs may manifest soon after the first dose or only after chronic use. They may obviously result from drug use or be too subtle to identify as drug-related. In the elderly, subtle ADRs can cause functional deterioration, changes in mental status, failure to thrive, loss of appetite, confusion, and depression.

Mechanism:

The most common mechanism for an ADR is the augmented pharmacological action, which is the known, inherent pharmacologic effect of the drug and is dose related; example insulin given for diabetes may cause hypoglycemia. A different mechanism of ADR is drug interaction which is a reaction between two or more drugs or between a drug and a food, beverage, or supplement. When two drugs are used together, their effects can be additive, synergistic or antagonistic. Photosensitivity is another mechanism of ADR which could be either phototoxic or photoallergic. Additionally, selected drugs cause drug dependence which could be psychological or physical. Some drugs cause intolerance which is a characteristic pharmacologic effect produced by an unusually small dose, so that the usual dose tends to induce a massive overaction. Another mechanism is teratogenicity. A teratogen acts by different mechanisms like folate antagonism, neural crest cell disruption, endocrine disruption, oxidative stress, vascular disruption, specific receptor or enzyme mediated teratogenesis. Example: Thalidomide has antiangiogenic actions which has been proposed to play a role in thalidomide teratogenesis. Mutagenicity and carcinogenicity are other mechanisms of ADRs. Deoxyribonucleic acid (DNA) is the most common primary target for chemical carcinogen and for a single DNA polymerase, DNA damage can affect replication in different ways. Finally, idiosyncratic reaction and drug hypersensitivity are largely unpredictable ADRs. Affected people may have genetic differences in the way their body metabolizes or responds to drugs and this can occur even with smaller doses. Knowledge of the mechanism of ADRs can help to prevent or reduce these reactions.

Conclusion:

The FDA Adverse Event Reporting System In the United States, the primary adverse event reporting system is MedWatch, the FDA Safety Information and Adverse Event Reporting Program. Health care professionals and consumers voluntarily report ADRs, ADEs, and medication errors for entry into the FDA Adverse Event Reporting System (FAERS)

This work is partly presented at Joint Event on 20th International Conference and Exhibition on Pharmaceutics & Novel Drug Delivery Systems March 18-20, 2019 at Edinburgh, Scotland

database. The events are evaluated by clinical reviewers in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This evaluation may lead to regulatory action by the FDA, including labeling changes, communicating new safety information to the public, restricting use of the drug, or removing the drug from the market. The FDA may also require Risk Evaluation and Mitigation Strategies (REMS), which are plans that use risk minimization strategies beyond professional labelling to ensure that the benefits of the drug outweigh the risks.

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