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Perspective

Brief Note on Diagnosis of Adverse Drug Reactions

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DESCRIPTION

Adverse Drug Reactions (ADRs) are "significantly harmful or unpleasant reactions that result from procedures associated with substance use. Normal side effects predict the risk of future dosing and justify prevention or change of specific treatment or dosing regimen or discontinuation of the product."

Since 2012, the definition has included reactions occurring as a result of error, misuse or abuse and to suspect reactions to medicines that are unlicensed or being used off label in addition to the permitted use of the drug at normal doses. This may change the reporting and oversight of manufacturers and drug regulators, but it does not affect the approach to managing ADR in the clinical setting.

Seminal research undertaken in the late 20th and early 21st century in the USA and the UK demonstrated that ADRs are a common manifestation in clinical practice, including as Causes of unplanned hospitalization that occur during hospitalization and appear after discharge. The incidence of ADRs has remained relatively unchanged over time with research suggesting that between 5% and 10% of patients may suffer from an ADR at admission during admission or at discharge, despite various preventative efforts. The frequency of events is necessarily related to the method used to identify such events and the majority of ADRs do not cause serious systemic symptoms. Nevertheless, the incidence of this potential harm is associated with morbidity and mortality, is economically costly and can adversely affect the prescribing patient-prescribing relationship, so be cautious.

Drugs specifically related to ADR-related hospitalization include antiplatelet drugs, anticoagulants, cell growth inhibitors, immunosuppressants, diuretics, anti-diabetic drugs and antibiotics. Bleeding is often the cause of fatal ADRs, most commonly antithrombotic/anticoagulant drugs in combination with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

Causes of adverse drug reaction

- Dose-dependent, predictable, enhanced pharmacological effects. Type (A) reactions, which account for about 80% of side effects are usually the result of the major pharmacological effects of the drug. It is predictable because of bleeding or a low therapeutic index of the drug (eg, nausea due to digoxin). They are dose-dependent and usually mild but can be severe or even fatal (eg, intracranial hemorrhage from warfarin). Such reactions are usually due to improper dosing, especially if drug removal is impaired. The term "side effects" is often used for minor type reaction

Type A and Type B were proposed in the 1970s, and the other types were proposed when the first two proved insufficient to classify ADR.

CONCLUSION

Symptoms that appear immediately after taking a drug are often easily associated with taking the drug. However, diagnosing symptoms from chronic substance use requires considerable suspicion and is often complicated. It may be necessary to discontinue the drug, but it is difficult if the drug is essential and there is no acceptable alternative. If it is important to establish a drug-symptomatic association, re-challenge should be considered, except in the case of severe allergic reactions. Physicians should report the most suspicious side effects to Med Watch, the Food and Drug Administration's (FDA) ADR monitoring program, an early warning system. The FDA's Adverse Event Reporting System (FAERS) is a search tool that improves access to data about adverse drug reactions. The incidence of severe or fatal adverse drug reactions is very low (typically <1 in 1000) and may not be apparent during clinical trials, which are typically not powered to detect low incidence ADRs. Thus, these ADRs may not be detected until after a drug is released to the general public and is in widespread use. Clinicians should not assume that all ADRs are known just

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because the drug is on the market. Post-marketing surveillance is very important for following up on low incidence ADR.