



Adverse Drug Reactions in Modern Pharmacotherapy: From Safety Monitoring to Prevention and Personalized Treatment

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Opinion

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Opinion

Medicines have transformed the treatment of numerous acute and chronic diseases, but no pharmacological therapy is completely free from risk. Adverse drug reactions (ADRs) remain an important challenge in clinical practice and may range from mild and temporary symptoms to severe organ toxicity, hospitalization, or life-threatening events.

Although medicines undergo extensive preclinical and clinical evaluation before approval, it is difficult to identify every possible adverse reaction during development. Rare reactions, delayed toxicities, and events associated with specific patient populations may become apparent only after a medicine is used by a much larger population.

In our opinion, drug safety should therefore be viewed as a continuous process rather than an endpoint of clinical development.

Factors Contributing to Adverse Drug Reactions

The occurrence of an ADR is influenced by both drug-related and patient-related factors. Age, body weight, renal and hepatic function, genetics, underlying diseases, immune status, and concomitant medications can substantially affect individual responses to treatment.

Polypharmacy is particularly important because patients receiving multiple medicines have an increased possibility of drug-drug interactions. Such interactions may alter drug absorption, metabolism, transport, or elimination and consequently increase drug exposure and toxicity.

Genetic differences between individuals can also influence drug metabolism and response. Pharmacogenomics provides an opportunity to identify patients who may be particularly susceptible to certain adverse effects and may support more individualized treatment decisions. A more patient-specific approach to prescribing could therefore become an important component of future pharmacotherapy.

Clinical Trials and Drug Safety

Clinical trials are the foundation of modern drug safety assessment. However, participants in clinical trials are often carefully selected and may not fully represent the diverse population encountered in routine clinical practice.

Patients with multiple comorbidities, advanced age, extensive medication use, or organ dysfunction may be underrepresented. As a result, some safety concerns may only become apparent after a medicine enters widespread clinical use.

Clinical trials should therefore increasingly consider diverse populations and clinically meaningful safety outcomes. Pharmacokinetic and pharmacodynamic analyses, biomarkers, exposure-response relationships, and pharmacogenomic information may further improve the identification of patients who are at greater risk of toxicity. Nevertheless, clinical trials alone cannot identify every ADR. Post-marketing pharmacovigilance remains essential.

Importance of Pharmacovigilance

Pharmacovigilance provides an important connection between clinical development and real-world medicine.

Spontaneous adverse-event reporting, observational studies, patient registries, electronic health records, and active surveillance can identify safety signals that may not have been recognized during clinical trials.

One of the continuing challenges is underreporting. Healthcare professionals may not recognize an adverse reaction, may not consider a medicine responsible, or may lack sufficient time to report the event. Patients may also be unaware that a particular symptom could be associated with their medication.

Digital technologies may help address some of these limitations. Electronic health records and large healthcare databases can be analyzed to identify patterns of medication-related harm. Artificial intelligence and machine-learning methods may further support the identification of potential safety signals.

However, these technologies should complement rather than replace pharmacological and clinical judgment. A detected signal requires careful evaluation before a causal relationship can be established.

Role of Pharmacologists and Clinical Researchers

Pharmacologists and clinical researchers have a central role in improving medication safety. Understanding the mechanisms responsible for drug toxicity can help identify risk factors and guide the development of safer treatment strategies.

Clinical pharmacology contributes to dose optimization, therapeutic drug monitoring, drug-interaction assessment, pharmacokinetic evaluation, and individualized treatment. Clinical researchers can strengthen safety assessment by designing studies that capture clinically relevant adverse outcomes throughout the development process.

Greater collaboration between pharmacologists, clinicians, pharmacists, clinical-trial investigators, epidemiologists, regulatory authorities, and data scientists is needed. ADR prevention should be considered a multidisciplinary responsibility rather than the responsibility of a single healthcare profession.

From Reactive Detection to Prevention

The most effective strategy for managing ADRs is prevention. Before prescribing a medicine, clinicians should consider the patient's age, comorbidities, renal and hepatic function, medication history, potential interactions, and established risk factors.

Therapeutic drug monitoring can be useful for medicines with a narrow therapeutic index, while pharmacogenomic testing may provide valuable information for selected therapies where genetic factors are known to influence safety or effectiveness.

Patient education is equally important. Patients should be informed about how to take their medicines correctly, which symptoms require medical attention, and the importance of informing healthcare professionals about all prescription medicines, over-the-counter products, and supplements they use.

Future Perspective

In our view, future drug-safety research should move increasingly toward early prediction and prevention of adverse drug reactions. Combining pharmacogenomic information, electronic health records, real-world evidence, biomarkers, therapeutic drug monitoring, and artificial intelligence could improve the identification of individuals at increased risk before serious toxicity develops.

At the same time, long-term safety monitoring should remain an essential component of pharmaceutical development. Greater international collaboration and harmonization of pharmacovigilance systems could facilitate earlier recognition of safety signals across different populations.

Drug development should not be judged only by the ability to demonstrate efficacy. A successful pharmacological therapy should also allow clinicians to understand who is most likely to benefit, who may be at risk, and how treatment can be safely individualized.

Conclusion

Adverse drug reactions remain an important challenge despite significant advances in pharmacology and clinical research. Their occurrence is influenced by complex interactions among drugs, patient characteristics, genetics, disease conditions, and concomitant therapies.

Clinical trials provide the foundation for assessing drug safety, but they must be supported by effective pharmacovigilance and real-world evidence. Pharmacogenomics, therapeutic drug monitoring, artificial intelligence, and advanced data-analysis approaches offer promising opportunities to improve the prediction and prevention of ADRs.