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Commentary

Adverse Drug Reaction Prediction: Using Biological and Clinical Information to Improve Medication Safety

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DESCRIPTION

Adverse drug reactions are unwanted and harmful effects that can occur when medicines are used at normal therapeutic doses. They can range from mild nausea, headache, and skin irritation to serious liver injury, cardiac complications, bleeding, or immune-mediated reactions. Predicting the likelihood of an adverse drug reaction before or during treatment can support safer medication decisions. Such prediction can involve genetic information, patient characteristics, drug properties, laboratory measurements, previous medication history, and molecular data. Individual responses to medicines vary considerably. Two patients receiving the same drug at an identical dose may experience different outcomes because of differences in age, body weight, kidney function, liver function, genetics, disease conditions, diet, and concurrent medications. These factors can influence drug concentration, metabolism, transport, target interaction, and immune activity. A prediction framework can bring these variables together to estimate the likelihood of an unwanted response.

Genetic information is particularly useful for selected adverse reactions. Pharmacogenetic variants can alter drug-metabolizing enzymes, transport proteins, receptors, or immune-related molecules. Variants in *Cytochrome P450 2D6*, *CYP2C19*, *CYP2C9*, and other genes can change the way certain medicines are processed. A patient with reduced metabolic activity may have higher exposure to a medicine, while increased activity may produce lower exposure. The clinical effect depends on the specific medicine and genetic variant. Human leukocyte antigen variants provide another example. Certain Human Leukocyte Antigen (HLA) alleles have been associated with severe immune-mediated reactions to particular medicines. Genetic testing before treatment can identify individuals carrying specific variants when validated clinical recommendations are available. In suitable situations, avoiding the associated medicine can substantially reduce the possibility of a serious reaction.

Patient characteristics are also important for adverse reaction prediction. Older adults may have changes in kidney and liver function that affect drug elimination. Children can process medicines differently because metabolic pathways and body composition change during development. Pregnancy can modify drug distribution and elimination as well. These physiological differences should be considered when selecting medicines and doses. Kidney function has a major influence on medicines and metabolites that are eliminated through the kidneys. Reduced renal clearance can cause accumulation of certain compounds and increase exposure. Estimated glomerular filtration rate and other renal measurements can therefore provide useful information when evaluating medication safety. Dose modification may be appropriate for selected medicines when renal function is reduced.

Liver function is equally important for drugs that undergo extensive hepatic metabolism. Liver injury or reduced hepatic capacity can change the concentration of medicines in circulation. Laboratory measurements such as alanine aminotransferase, aspartate aminotransferase, bilirubin, and other indicators can provide information about hepatic status. Repeated measurements during treatment may help identify emerging toxicity. Drug-drug interactions are another major source of adverse reactions. One medicine can inhibit or increase the activity of enzymes responsible for metabolizing another medicine. Some medicines can also affect transport proteins, altering drug absorption or elimination. When several medicines are prescribed simultaneously, their combined effects should be considered rather than evaluating each medicine separately.

Previous medication reactions provide valuable information as well. A patient who has experienced a specific adverse reaction may have an increased likelihood of experiencing the same or a related reaction after re-exposure. Maintaining an accurate medication history allows healthcare professionals to identify previous problems and select safer alternatives when available.

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Laboratory biomarkers can support prediction and early recognition of medication toxicity. Changes in liver enzymes, kidney markers, blood cell counts, cardiac indicators, or other biochemical measurements can indicate possible organ stress. The interpretation of these measurements depends on the medicine, baseline health status, and clinical context. A single abnormal result does not necessarily indicate a drug-related reaction, so trends and other findings should also be considered.

Molecular biomarkers provide another source of predictive information. Changes in Ribonucleic Acid (RNA) expression, proteins, metabolites, or cellular signaling may occur before a noticeable clinical reaction. For selected medicines, these molecular characteristics may help identify patients who are more likely to experience toxicity. Combining molecular markers with clinical information can provide a broader assessment of medication risk. Computational methods can process large collections of patient and medication data. Machine-learning models can identify relationships between drug exposure, patient characteristics, genetic variants, laboratory findings, and adverse outcomes. These models may assist in identifying patients who require additional monitoring. However, computational predictions need appropriate validation before they are used to influence clinical decisions.