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Commentary

Pharmacovigilance, Reporting and Management of Adverse Drug Reactions (ADRs)

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DESCRIPTION

Pharmacovigilance is defined as science and activity related to the detection, assessment, understanding, and prevention of adverse events or other drug-related problems.

In 2012, a new law was introduced in the European Union to ensure proper vigilance practices for pharmaceutical companies and drug regulators. This new guidance clearly defines the roles and responsibilities of relevant stakeholders related to drug safety. In particular, the guidelines have introduced programs to enhance monitoring of new pharmacologically active substances and biologically active substances in the black triangular state (i.e., those that require additional monitoring). One of the guiding principles is that the proactive strategy of the risk management policy replaces the previous reactive strategy.

A mainstay of detecting of potential Adverse Drug Reactions (ADRs) over the last half century has been voluntary reporting systems such as the UK's Yellow Card Scheme, run by the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Human Medicine Commission (CHM). This system was established in 1964 after the thalidomide disaster in the late 1950s. Through ad hoc reports, the system collects data on suspicious ADRs associated with all licensed and unlicensed medicines and vaccines, including prescription and over-the-counter medicines. Only four pieces of information are needed for the report to be valid: identifiable patient, reaction, suspicious drug, and identifiable reporter. However, reporters are encouraged to provide as much information as possible, that is, to provide the evaluator with additional data and clinical background. The UK system continues to receive approximately 25,000 reports annually, providing drug regulators with insights into the occurrence of ADR. Unfortunately, underreporting remains an important issue, with an estimated less than 5% of all ADRs reported in the field. This limits the system's ability to provide accurate incidence data. In 2014, NHS England and MHRA issued a joint alert. As part of this, it is automatically reported to the ADR Yellow Card as a result of medication errors submitted to the National Reporting and Learning System.

Patients are becoming more and more involved in their own treatment management, and since early evaluation of patients' yellow card reports proved the value of this approach, all patients are now encouraged to actively report ADRs. Paper reports (of the original yellow card) have been largely replaced by the use of online reporting systems or yellow card apps. Electronic medical records used in general internal medicine and some hospitals may also include integrated reports that send data about ADRs directly to a central authority for processing before being entered into national and international databases. Spontaneous reporting systems are widely used in pharmacovigilance, but when adverse events are rare (less than 1% of treated patients), and the events are drug-induced conditions (erythema multiforme). It is most effective in typical cases. Their use is fairly limited in identifying a slight increase in the frequency of common events such as myocardial infarction and stroke. This is why recent drug safety scandals, such as thiazolidinedione and rofecoxib-induced cardiovascular events, have disappeared despite widespread use of these drugs. Modern signal generation can detect potential damage signals early and alert clinicians to potential new therapeutic risks. Complex statistical data mining algorithms are run on a regular basis to detect such signals, but usually need further evaluation before taking any action. The ability to look for drug exposures and potential adverse events in databases such as the Clinical Practice Research Datalink (CPRD), a database of anonymized long-term primary care records in the United Kingdom, can support or refute the existence of potential signals.

There are many other methods and data streams used in pharmacovigilance. This includes formal pharmacovigilance research, public data, pharmaceutical company data from the Periodic Safety Update Report (PSUR), and shared international data. However, regulators and scholars are also considering the capabilities of other "big data" sources, such as: B. Social media that recognizes early signals. This is an exciting and almost unexplored field of study.

Management of adverse drug reactions

Changing the dosing regimen or withdrawing a medicine that are suspected of causing ADR is common way to manage ADR in the real world. However, ADR treatment strategies may vary from clinician to clinician. Under EU law, approval of new drugs on the market involves a strong MAH risk management program that includes the development of specific therapies to treat specific ADRs and ongoing safety studies. This was the case with anticoagulants for bleeding directly induced by oral anticoagulants.

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