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Opinion Article

Therapeutic Management in Pharmacovigilance and Drug Safety Surveillance

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DESCRIPTION

Pharmacovigilance is concerned with the identification, evaluation, comprehension, and prevention of any drug-related issue or bad consequences for patient safety. The core of pharmacovigilance is post-marketing drug surveillance, or monitoring adverse effects after a medicine is introduced to the market. It allows for efficient long-term drug safety monitoring. Following the three stages of clinical trials that are intended to evaluate a medicine's safety and effectiveness, post marketing drug surveillance refers to the observation of medications once they are sold on the market.

The goal of post marketing drug surveillance utilizing interventional or non-interventional clinical trials is to assess the efficacy of medications used by people in a variety of situations over an extended length of time. Such monitoring has a far higher likelihood of spotting any previously unknown drug-related benefits or drawbacks. Sildenafil clinical trials have not revealed elevated risks of myocardial infarction or stroke. However, strokes linked to sildenafil have been mentioned in post marketing drug surveillance programmes, and case reports have been released.

For pharmacokinetic reasons, children are not only more susceptible to medication-related injuries than adults some estimates put the inpatient risk up to three times higher for children but they are also more vulnerable to additional risk factors.

Many drugs are used off label, with dosing based on experience and subject to error, as a result of the aforementioned legal limits on paediatric drug research. Even when paediatric information is provided with a medication, it is frequently not presented clearly and may not be very helpful to the doctor. For instance, the indications part of the labeling frequently omits the age range for which a medication is officially approved. When available, approved paediatric-specific dose information is given in a different part of the label. The findings of studies focusing on children are frequently located in a different section, under specific populations. The initial pharmacogenetic research on asthma centre on SNPs in candidate genes with biological justification. As a result, gene pathways were examined (see "Pharmacogenomics of Leukotriene Modifiers"). Both strategies came from methods that purportedly understood the mechanisms driving the action of a certain pharmacologic intervention and additional systems that might have been involved in drug delivery, metabolism, and degradation.

The use of spontaneous adverse event reports voluntarily reported to the holder of the marketing authorization or the regulatory body is one of the passive surveillance techniques. Here, statistics pertaining to the negative reactions are gathered and stored in a national or local database.

This approach strives to count the number of adverse drug reactions totally through a pre-planned methodology, and it monitors some specific medication-related adverse events. It is sometimes referred to as toxicity or safety monitoring.

In this approach, the monitoring study is prepared before the drug therapy even starts. A group of individuals is exposed to a drug for a predetermined amount of time and is closely monitored throughout treatment.

CONCLUSION

The public's health and the manufacturer's financial health benefit from careful drug safety monitoring. As shown, paying attention to fundamental concepts is crucial and could be enough to address some issues. More awareness among health experts and creative approaches are required to strengthen spontaneous reporting programmes as an efficient post marketing surveillance strategy. Future pharmacovigilance may include integrating pharmacogenetic data. These developments aim to shorten the time it takes to uncover drug-related dangers and confirm their absence. New operational ideas for safety, surveillance, and PV will therefore be required both at the strategic and tactical levels. This comprises updated business operations, support for new IT and analytical technologies, integrated data-driven decision making skills, and new governance standards.

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