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Commentary

Behavioral Aspects of Pharmacovigilance in both Developed and Developing Countries

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DESCRIPTION

The role of pharmacovigilance is to assess whether the benefits of a drug outweigh its risks and do not stop after the drug is approved. PV involves continuous monitoring of the drug for safe use, especially as previously undetected adverse events can occur at any time.

In fact, there are several reasons why clinical trials may not reveal all possible side effects. The number of people taking medicines in the study is relatively small compared to the general distribution, so additional reactions may occur.

In addition, certain groups, such as the elderly, may not participate in the trial because clinical trials are actively managed to protect high-risk patients, but prescribe medications for general use may be done. Once certified, drug monitoring can also be rigorous, inevitably introducing more variables.

This is the science needed to detect, assess, understand, and prevent adverse events, suspicious side effects, side effects, events attributed to vaccination or immunization, or other safety issues associated with the use of medicines. It is internationally defined and the vaccine is responsible.

Its implementation is very important as it is one of the public health activities and an important tool for ensuring the quality, safety and efficacy of medicines. Therefore, it is an activity that shares the responsibilities and obligations of the national healthcare system, healthcare professionals, institutions, pharmaceutical industry, distributors, marketers, and patients to participate.

Medical devices need to heal people and make them feel better. But sometimes they can do harm. Side effects of medicines, especially those unexpected by healthcare providers and patients, are of concern as they can adversely affect patients and undermine confidence in the healthcare system. As new drugs and vaccines hit the market, concerns about harm are exacerbated based on limited data from clinical trials conducted in a small selected population.

Establishing Pharmacovigilance (PV)-both passive (ie voluntary) and active (eg cohort event monitoring) – once a product is on the market, a true safety and efficacy profile of the product in a particular population. It's important to make a decision, effects that are not always observed in clinical trials. This role lies with national drug regulators and involves a wide range of stakeholders in doctors, nurses, pharmacists and other healthcare providers, consumers, industry and public health programs (national TB, HIV, malaria programs, etc.).

However, most Low- and Middle-Income Countries (LMICs) are less regulated and functional systems to effectively monitor, mitigate, and prevent side effects from medical devices that threaten patients, quality of care, and the achievement of desirable health is missing. This poses a particularly great risk in recent years, as many new drugs have been introduced into LMIC at the same time as or in place of high-income countries.

USAID MTaPS helps LMIC build or extend PV systems to build the ability to generate, analyze and leverage safety data to improve health and quality of care. The program implements the WHO Global Benchmark Tool (GBT) as a guide framework to help countries strengthen their regulatory systems, including establishing practical PV systems. This approach includes:

1. Supporting countries to establish the legal and regulatory framework for PV.
2. Improving the demand for and supply and use of country-level safety data for clinical decision making.
3. Risk identification and characterization, risk assessment/assessment, risk minimization, and enhanced safety communication processes.
4. Supporting the establishment of active safety monitoring systems for new and other high-risk medicines.

The aims of pharmacovigilance are:

1. To improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions.

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2. To improve public health and safety in relation to the use of medicines by the provision of reliable, balanced information resulting in more rational use of drugs.
3. To promote rational, safe and more effective (including cost-effective) use of medicines.
4. To contribute to the assessment of benefit, harm, effectiveness and risk of medicines.
5. To promote understanding, education and clinical training and
6. To establish mechanisms to detect and combat counterfeit medicines entering the local market.