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REVIEW

Drug safety: The concept, inception and its importance in patients' health

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Abstract *Background:* Drug safety is one of the hottest topics in daily medical practice, particularly with regard to approving new medication or questioning the possibility of withdrawing a drug from the market.

Aim: The aim of this review is to highlight the importance of the drug safety concept and its impact on patients' health.

Methods: A literature search was conducted using Pubmed®, EMBASE®, EBSCO and Medline in the period between 1980 and 2013. The terms used in the search included "Drug Safety", "Medication Safety", "Patient Safety", "Drug Interaction", "Drug Pharmacokinetic", and "Adverse Drug Reaction". All retrieved abstracts were evaluated within the context of the review objectives. The full texts of the selected articles were included in this review. Studies in non-English language were excluded in this review.

Results: Since the early days of the past century, many acts, laws, or amendments have been created to make sure that approved drugs are first safe and then effective. Furthermore, these regulations are continuing to change to make sure that these drugs have a positive benefit–risk balance. Personalized medicine should be considered when medications are given to patients because the pharmacokinetic process inside the body varies from patient to patient and from one specific disease state to another. However, adverse drug reactions can be minimized if more precautions are taken by healthcare professionals, especially including the patient as one pillar of the therapeutic plan and providing more patient counseling, which will improve drug safety.

Conclusion: The drug safety concept has earned a lot of attention during the past decade due to the fact it plays a major role in patients' health. Recent laws stress this concept should be included

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in the process of new medications' approval and continued conduct of post-marketing drug evaluations. Benefit–risk assessment should be considered by all health care professionals when they need to give specific drugs to specific groups of patients. Therefore, more care should be given to some patients, such as pregnant women, children and the elderly, since they are considered vulnerable populations.

Contents

1. Background and history

The concept of drug safety, also called "Medication Safety", is not new, especially in the developed countries in the field of health. For instance, we find in the United States of America (USA) an experience for more than a century in the field of the safety of medications, and the use of these drugs led to creation of new acts or changes to the existing ones. For example, in October 1937, the use of the antibiotic sulfanilamide caused the death of more than 100 people in the USA. These deaths were not due to the active ingredient itself; rather, they were caused by the addition of diethylene glycol (DEG), the excipient used as a solvent for the active drug. DEG was supposed to be inert, with no therapeutic benefits; however, it was the toxic substance that led to those fatal side effects. The company claimed they did not foresee these side effects, which was true, as they did not commit animal studies before they marketed the drug. Because of this incident, the U.S. Food and Drug Administration (FDA) approved an act to ensure the safety of any drug by conducting non-clinical and clinical studies before the drugs are marketed for public use (Geiling and Cannon, 1938; Young, 1984; Wax, 1995).

Of course, the problems arising from drugs and their side effects did not stop occurring. A severe worldwide crisis was initiated by the use of the drug thalidomide, which was used as an antiemetic agent for pregnant women in many countries. In the early 1960s, the use of thalidomide during the first trimester of pregnancy led to teratogenic effects manifested by the birth of infants with severe deformities known as "Phocomelia". Babies would be born lacking extremities (hands and legs) or with only very short ones. Many infants died because of this "medication" as well. Overall, more than 10,000 children in 46 countries were victims of thalidomide. It is important to mention that this drug was not authorized or approved for use in the United States because of some concerns that arose during non-clinical studies (animal studies) due to the existence of cases of deformities on animal embryos. Note that those animal studies were conducted according to the act that was initiated following the sulfanilamide incident in the USA; therefore the public was protected and avoided from this crisis (Ito et al., 2011; Kim and Scialli, 2011; Martinez-Frias, 2012).

Up until now, there are drugs that could be taken off the market or withdrawn due to safety issues concerning their relation with the emergence of serious side effects, such as the recent withdrawal of the anti-diabetic agent rosiglitazone (Avandia®) from the global market as a result of its relationship with the incidence of heart attacks. Therefore, we find the concept of drug safety a very important and comprehensive concept that is considered a priority with regard to the use of medications. Actually, this concept can be considered an integrated science in itself that involves many other scientific aspects, such as the side effects of drugs, the quality of medications, medical errors in the use of drugs, lack of efficacy of drugs, and counterfeit drugs (Psaty and Furberg, 2007a,b; Hiatt et al., 2013). In Saudi Arabia, there is a need to educate and enhance the knowledge of healthcare professionals regarding the concept of drug safety since many studies that have been conducted in Saudi Arabia found that there is a lack of culture of drug safety in Saudi Arabia among all levels of healthcare professionals (Aljadhey et al., 2014; Khan, 2013; Mahmoud et al., 2014).

2. Methods

A search of several databases (Pubmed®, EMBASE®, EBSCO and Medline) was carried out in the period between 1980 and 2013. Several terms were used in the search, including