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Review Article

A REVIEW ARTICLE ON CURRENT TRENDS IN THE FIELD OF PHARMACOVIGILANCE

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ABSTRACT

Pharmacovigilance is a crucial a part of drug safety regulation, clinical practice, and public health Programs. The rise within the number of reported Adverse Drug Reactions (ADR's) has resulted in a rise within the volume of information handled, and to know Pharmacovigilance, a high level of experience is required to detect the various types of Adverse drug reactions. The aim of this review is to seem at the present evolution and Development of pharmacovigilance through a brand-new lens. The large number of Adverse event reports generated by marketed drugs and devices suggests that validated Computerized algorithms should be wont to supplement traditional methods of detecting adverse event signals. Today, many pharmacovigilance centers are working for drug safety monitoring during this global pitch. In terms of improving drug safety and Monitoring, pharmacovigilance faces significant challenges and difficulties. In these review, we are going to discuss about drug safety, current pharmacovigilance trends and their roles.

KEYWORDS- Pharmacovigilance,Drugs,Trends,Adverse Drug Reaction, Safety

INTRODUCTION

The World Health Organization (WHO) defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any drug-related problems[1].

The availability of current drugs that can effectively prevent, control, and/or manage disease states has resulted from the rapid and continual progress of medical and pharmaceutical sciences. Pharmacovigilance is not a new concept, with roots dating back more than 50 years. The thalidomide tragedy in 1961 brought to light the importance of assessing drug side effects. The World Health Assembly established the International Drug Monitoring Program between 1965 and 1970, following several meetings and resolutions[2].

Despite significant room for improvement in their functions and methods, current pharmacovigilance systems have been able to identify a large number of major safety issues. These systems include mechanisms such as spontaneous reporting, among other things (SR) [3]The evolution of pharmacovigilance in recent years is described, as is its growing importance as a science critical to effective clinical practise and public health science. At a time when drug safety concerns are becoming increasingly important in public health and clinical practise, national pharmacovigilance centres have gained significant clout with drug regulatory authorities[1].Biomedical informatics has significantly contributed to the development of pharmacovigilance infrastructure. Rapidly evolving biomedical informatics innovations present a challenge to pharmacovigilance in terms of incorporating new sources of safety information, such as social media, massively linked databases, and mobile and wearable wellness applications and sensors.[4]

OBSERVATION

During Preparation of Review article it was found that In 2002, more than 65 countries had their own pharmacovigilance centres which had increased majorly in 2022. Membership in the WHO Collaborating Centre for International Drug Monitoring, also known as the Uppsala Monitoring Centre(UMC), is coordinated by the WHO Collaborating Centre for International Drug Monitoring. The Sixteenth World Health Assembly adopted a resolution (WHA 16.36) that reaffirmed the need for early action in terms of rapid dissemination of information on adverse drug reactions and resulted in the establishment of the WHO Pilot Research Project for International Drug Monitoring.[5]Because of the high number of adverse event reports generated by marketed medications and devices, approved computational algorithms should be used in addition to traditional techniques of detecting adverse event signals. The US Food and Drug Administration (FDA) is testing Multi-item Gamma Poisson Shrinker (MGPS), a Bayesian data mining system, to improve the FDA's ability to monitor the safety of pharmaceuticals, biologics, and vaccines after they have been licensed for several national and international organizations give information and guidelines for pharmacovigilance program implementation. These organizations are excellent sources of information on how to manage the dangers connected with medication use. The World Health Organization (WHO) maintains a comprehensive collection of data on the proper application of pharmacovigilance as a critical instrument for ensuring the safety of medicines in the public domain health[2].

DISCUSSION

Patient reporting provides unique insights and perspectives on ADRs that would otherwise be unavailable. This may help to improve the decision-making process in regulatory matters. Patient reporting has a favorable

impact on the broader public's understanding of ADRs. The majority of investigations confirmed this, albeit in a broad sense. As a result, there is no evidence to support any of the potential disadvantages of patient reporting. These factors include the recognition and accuracy of reported symptoms, the severity of the reactions, and the system's expenses. The systematic study gathered an up-to-date and comprehensive set of data on ADRs reported directly by patients. The included studies have the strength of presenting the current available information on the contribution of patient reporting from various situations and nations, as well as their opinions and perspectives. The subjective information that patients provide to the system can be used to supplement the current pharmacovigilance system with more evidence about the impact of ADRs on patients' daily lives.[3]

Prescription drug labelling is expected to ensure the safe use of medicines and to effect changes in use if new safety information requires such changes. Labeling will be more useful and used by healthcare professionals and patients as a result of regulatory initiatives in many countries. These initiatives appear to aim for a more relevant and extensive characterization of a product's safety profile earlier in the product's life cycle, and appear to parallel changes in the approach to pre-market risk assessment and pharmacovigilance. The potential switch to lists of adverse reactions to describe clinical study experiences in the United States would aid in improving international labelling consistency. Utilizing these technological advancements could significantly improve the effectiveness of labelling for risk management and medication error reduction[7].

Despite the advancement of several pharmacoepidemiological methods, spontaneous reporting of adverse drug reactions (ADRs) continues to be the cornerstone of pharmacovigilance. Few studies, however, have looked at the chronological trends in spontaneous reporting of ADRs over time. Weber described a higher reporting rate in the early years of a product's life, followed by a decline, and Haramburu et al. discovered that unlabeled ('unexpected') ADRs were primarily reported during the early years of marketing [8].

Patient reporting was defined as reports about adverse drug reactions submitted directly to a pharmacovigilance authority by patients or relatives using passive or active surveillance methods. Exclusions include cases in which patients or the general public reported to pharmaceutical companies, patient organizations, or another authority for reasons unrelated to pharmacovigilance; cases in which patients reported ADRs to a hospital for reasons other than reporting to a pharmacovigilance authority; and general public surveys[9].

Pre-clinical studies and randomized controlled trials during drug development provide the foundation for any medicinal product's safety information. However, due to factors such as controlled clinical trial conditions and small sample sizes, this information may not include all possible adverse drug reactions (ADRs). As a result, post-marketing surveillance (PMS) provides critical, additional safety data from millions of patients.[9]

Antibiotic overuse remains a major public health concern in almost every country. Patients can easily obtain over-the-counter antibiotics in community pharmacies, so the prevalence of community DIA cannot be estimated. Data used for health insurance refunds (in-house data) and the number of marketing authorizations

for imported antibiotics show a significant trend toward high volume antibiotic consumption among the population. Prevention of ADRs appears impossible in the context of widespread use or even overuse in community and hospital settings. There is an unmistakable link between antibiotic use and the high rate of drug-related anaphylaxis. Given the large number of drugs with marketing authorizations and active ingredients, it appears difficult to identify and manage specific antibiotics.[10]

The coronavirus disease 2019 (COVID-19) outbreak is a global emergency situation for which drug and vaccine development has been intensively researched around the world. The US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) approved the use of chloroquine and hydroxychloroquine for the emergency treatment of COVID-19 in late March and early April 2020, based on their potential efficacy in this setting.[11] In terms of suspected ADRs reporting, there is a difference between the elderly and the general population. Because of the numerous factors that increase susceptibility to ADRs, these findings suggest that the clinical management of older patients should be optimized.[12]The FDA Adverse Event Reporting System (FAERS) database was used to investigate the link between the use of chloroquine and the occurrence of neuropsychiatric symptoms. [11]Responsible employees of pharmaceutical companies constantly monitor information about adverse reactions and medical efficacy in order to ensure the safety control of medicine use. Doctors, pharmaceutical workers, and patients provide the information. The specialized medical literature is also monitored on a regular basis. All safety information received is entered into the manufacturer's database and also sent to the Federal Service for Healthcare Supervision (Roszdravnadzor) via an automated system for electronic recording of information about unwanted reactions.[13]When a drug safety issue arises, the first reaction is to look for a reason why this could happen. In the case of rofecoxib, this resulted in a critical examination of the current methods and mechanisms for ensuring the safe use of a drug. Following the withdrawal of rofecoxib, the FDA and the current post-marketing surveillance system were heavily criticized on a number of fronts. To begin, when it comes to assembling information on a drug's safety, the FDA only uses a limited number of data sources (clinical trials, spontaneous reporting). Second, the FDA has no authority over the conduct of post-marketing safety studies. The majority of post-marketing study commitments are never fulfilled, and the proportion of completed post-marketing safety studies (phase 4 studies) is low.[14]

WHO encourages all countries to establish a national pharmacovigilance centre to report drug-related adverse reactions and to identify which drugs are more likely to cause ADRs. As a result, several countries now send reports for such drugs to the Uppsala Monitoring Centre (UMC), which further examines and distributes the necessary information globally.[15]

CONCLUSION

Pharmacovigilance continues to play an important role in addressing the issues raised by the ever-increasing variety and strength of drugs, all of which carry an unavoidable and, in some cases, unanticipated risk of harm. When adverse effects and toxicity occur, especially when previously unknown, it is critical that they are

documented, analyzed, and their significance adequately communicated to the audience with the necessary knowledge to comprehend the data. With all drugs, there is a trade-off between the benefits and the risk of side effects. The risk can be reduced by ensuring that high-quality, safe, and effective drugs are used appropriately, and that the patient's expectations and concerns are taken into account when therapeutic decisions are made.

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