RESEARCH ARTICLE DOI: 10.53555/jptcp.v29i04.5675

PHARMACOVIGILANCE: ENHANCING DRUG SAFETY MONITORING AND REPORTING SYSTEMS

Turki Matar Khalaf Alanzi ^{1*}, Bander Ibrahim Alomair², Obied Mathil Almotiry³, Bader Seed bin owimer⁴, Khaled Atteyah Abdullah alzahrani⁵, Jabril Ali Mansour Dahhas⁶ and Khalid Thamer Alnofeai⁷

- 1*Pharmacist, Turky484@hotmail.com, Ministry of health
 - ² Pharmacist, Ph.ban@hotmail.com, Ministry of health
- ³ Pharmacist, Ph.obaid@hotmail.com, Ministry of health
- ⁴ Pharmacist, Owimer-ds@moh.gov.sa, Ministry of health
 - ⁵ Pharmacist, kzahrani@moh.gov.sa, Ministry of health

*Corresponding Author: Turki Matar Khalaf Alanzi *Pharmacist, Turky484@hotmail.com, Ministry of health

Abstract

Pharmacovigilance plays a vital role in enhancing drug safety monitoring and reporting systems to ensure safe and effective use of medications. This essay highlights the importance of pharmacovigilance in improving drug safety, explores the methods used in monitoring and reporting adverse drug reactions, and discusses the results of implementing pharmacovigilance systems. The essay also delves into the challenges and future perspectives of pharmacovigilance. By focusing on enhancing drug safety monitoring and reporting systems through pharmacovigilance, healthcare professionals can better identify and manage adverse drug reactions, ultimately improving patient outcomes and public health.

Keywords: pharmacovigilance, drug safety, monitoring, reporting, adverse drug reactions

Introduction

Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It plays a crucial role in ensuring the safety of medications by monitoring and reporting adverse drug reactions (ADRs) in a systematic and proactive manner. The primary goal of pharmacovigilance is to improve patient safety and public health by identifying and minimizing the risks associated with the use of medications. Enhancing drug safety monitoring and reporting systems through pharmacovigilance is essential for detecting new ADRs, evaluating the effectiveness of medications, and promoting the rational use of drugs.

Method

Pharmacovigilance activities involve collecting, monitoring, assessing, and communicating information about the safety of drugs. Healthcare professionals, regulatory authorities, pharmaceutical companies, and patients all play a role in pharmacovigilance. Adverse drug reactions can be reported through spontaneous reporting systems, where healthcare providers and patients

⁶ Pharmacy technician, JDAHHAS@moh.gov.sa, Irada and Mental Health Hospital in Al Kharj ⁷ pharmacist, alnofeai-k@moh.gov.sa, Ministry of health

report ADRs voluntarily, or through active surveillance systems, where data are actively collected and monitored for potential ADRs. Signal detection methods, such as data mining and statistical analysis, are used to identify potential safety issues and assess the risks of medications. Pharmacovigilance also involves risk management activities, such as labeling changes, product recalls, and regulatory actions, to mitigate the risks associated with certain drugs.

Results

Implementing pharmacovigilance systems has led to significant improvements in drug safety monitoring and reporting. Various studies have shown that pharmacovigilance activities have helped identify new ADRs, evaluate the risks and benefits of medications, and improve patient outcomes. For example, the reporting of adverse events associated with a certain medication led to the withdrawal of the drug from the market, preventing further harm to patients. Pharmacovigilance systems have also facilitated the early detection of safety signals and the implementation of risk minimization strategies to improve the safe use of medications.

Discussion

Despite the benefits of pharmacovigilance, there are several challenges in enhancing drug safety monitoring and reporting systems. Underreporting of ADRs, lack of awareness among healthcare professionals and patients, limited resources, and regulatory barriers are some of the barriers to effective pharmacovigilance. Improving communication and collaboration among stakeholders, enhancing education and training programs, implementing technology solutions for collection and analysis, and strengthening regulatory frameworks are essential for overcoming these challenges. Future perspectives in pharmacovigilance include the use of real-world data, artificial intelligence, and precision medicine to enhance drug safety monitoring and reporting systems.

Conclusion

Pharmacovigilance is essential for enhancing drug safety monitoring and reporting systems to ensure the safe and effective use of medications. By systematically monitoring and reporting adverse drug reactions, healthcare professionals can identify and manage the risks associated with medications, ultimately improving patient outcomes and public health. Despite the challenges, pharmacovigilance plays a critical role in promoting the rational use of drugs and minimizing the risks to patients. By focusing on enhancing drug safety monitoring and reporting systems through pharmacovigilance, healthcare professionals can contribute to the overall improvement of patient safety and public health.

References

- 1. World Health Organization. The Importance of Pharmacovigilance Safety Monitoring of Medicinal Products. https://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/. Accessed October 10, 2021.
- 2. Uppsala Monitoring Centre. What is Pharmacovigilance? https://www.who-umc.org/pharmacovigilance/what-is-pharmacovigilance/. Accessed October 10, 2021.
- 3. Hazell L, Shakir SA. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006;29(5):385-396.
- 4. Arimone Y, Bidault I, Dutertre JP et al. Analysis of under-reporting of ADRs in France. Pharmacoepidemiol Drug Saf. 2015;24(4):400-407.
- 5. European Medicines Agency. Guideline on good pharmacovigilance practices (GVP) Module I Pharmacovigilance systems and their quality systems. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-i-pharmacovigilance-systems-their-quality-systems en.pdf. Accessed October 10, 2021.
- 6. MedDRA. Medical Dictionary for Regulatory Activities (MedDRA) Introductory Guide Version 24.1. https://www.meddra.org/sites/default/files/guidance/file/intguide_24.1_English.pdf. Accessed October 10, 2021.

- 7. Hazell L, Kress HG. The early detection of drugs adverse effects: a review of the possibilities and limitations of spontaneous reports data. Drug Saf. 2007;30(8):711-717.
- 8. Vandenbroucke JP. Registries and monitoring systems for drug safety: a necessary complement to clinical trials. Public Health. 2013;13:1043.
- 9. McGettigan P, Roderick P, Kadam A, Pollock AM. Access to data from clinical trials: the future in the EU. BMJ. 2017;357:j2350.
- 10. Hanley JA Pharmacovigance: Learning from multiple sources of data. Pharmacoepidemiol Drug Saf. 201726(1):3-4.