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GLOBAL PERSPECTIVES ON ADR MONITORING: A COMPARATIVE REVIEW OF PHARMACOVIGILANCE SYSTEM

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ABSTRACT

Pharmacovigilance (PV) is necessary to implement drug safety measures and reduce adverse drug reactions all over the world. This review compares pharmacovigilance practices in various countries, including India, the United States, Malaysia, Singapore, Thailand, China, Nepal, Australia and European countries, highlighting the global nature of ADR surveillance systems. This study highlights the development of PV systems, their current status and the challenges they face, such as low reporting, lack of national recognition, varying regulatory frameworks and regulatory shortcomings. While developed countries generally have more mature systems, many developing countries are still building capacity. The part of the World Health Organization (WHO) in social development safety efforts is highlighted. A comparative analysis effectively reveals common barriers to ADR, including a lack of proper training, public reporting processes and low participation. Future directions Take advantage of emerging technologies such as AI, increase global assistance rates and reporting, and suggest disease-focused approaches to improve data quality. Improving drug safety surveillance systems is crucial to ensuring the safety of safe forms and enhancing clinical outcomes globally.

KEYWORDS: Pharmacovigilance, Adverse drug reaction, Global comparison, Public awareness, Patient care, Drug safety.

INTRODUCTION

Pharmacovigilance (PV) is the exploration and scientific inquiry related to the search, perception and obviation of any other problem related to drugs. In 1961, after the Thalidomide disaster, the World Health Organization established the International Drug Monitoring Program (PIDM) in 1968. The World Health Organization is also known as the Service Center for International Drug Supervision.[1]

The primary goal of pharmacovigilance is to improve patient safety and ensure that the benefits of any medicine are achieved. It involves monitoring the safety of medicines after they are approved for use, taking necessary actions to reduce any adverse reactions and harms. Pharmacovigilance involves the collection, monitoring and analysis of data from various sources, such as clinical trials, post-marketing surveillance, health care providers and patients themselves. The information provided by the regulatory authorities helps to make informed decisions about the continued use of medicines, improvements to labels, and even withdrawal from the market, when the risks outweigh the benefits. Role of the World Health Organization (WHO) in Pharmacovigilance - World Health Organization (WHO) plays a key role in the global development of pharmacovigilance. It supports Member States in securing the welfare of the people and improving public health outcome.[2]

The role of world health organization includes

1. Providing specialized support, advice, training and expertise to the organization for safety signals
2. Position international standards.
3. Assisting national pharmacovigilance systems.
4. Coordinating global level drug monitoring schedule.[2]

Any drug has the potential to cause unwanted effects.

According to the Institute for Health Care Policy Research, in 1998, more than 50% of drugs approved in the United States were associated with some type of side effect that was not detected prior to approval. Several studies in the United States have identified adverse drug reactions (ADRs) as the quarter and sixth primary causes of death (beyond motor vehicle accidents, breast cancer, or AIDS), with an estimated mortality rate of 0.32% among hospitalized patients. Hospitals in the America pay an estimated $4 billion annually for drug-related injuries.

Another American study found that for each dollar paid out on drugs in nursing homes, $1.33 was spent on treating drug-related problems.

In England and Wales, ADR-related deaths have increased over the past decade. It was also speculated In 2000, ADRs were responsible for up to 7% of all deaths. The number of beds in hospitals in the UK is very high. About 2% of general practitioner (GP) consultations are due to ADRs and many medicines are returned to pharmacies by patients because of ADRs. In another UK study, 37% of pharmacists had identified an ADR in the previous year. More recently, a study found that 33% of hospital accident and emergency visits were due to side effects of ADRs in 2,636 patients over a two-year period. In 1999–2000, 2–3% (about 140,000 admissions) of all hospital admissions (5.9 million) in Australia per year.[3]

The Pharmacovigilance system in India was initiated in 1986 with formal ADR surveillance System. India joined the World Health Organization's International Drug Monitoring Programme in 1998. Malaysia established its drug monitoring system in 1987 and became a member of the World Health Organization's International Drug Monitoring Programme in 1990.

The Malaysian Adverse Drug Reaction Committee (MADRAC) has monitored the drug monitoring programme since its inception.

The Adverse Drug Reaction Monitoring Unit (ADRMU) in Singapore was established in 1993. This unit joined the World Health Organization in 1994. The Thai National ADR Monitoring Centre was established in 1983 as part of the Thai Food and Drug Administration, Ministry of Public Health. PV initiatives in Indonesia first started as a pilot project involving six public hospitals between 1975 and 1978. Subsequently, in 1980, a national adverse drug reaction surveillance program was initiated through individuals choosing to report on their own health care providers.

In 1990, the NADFC joined the WHO's Worldwide Drug Monitoring Program. The ADR reporting system in the Philippines was organized in August 1994 and was accredited as a member of the WHO National Worldwide Drug Monitoring Agency, Uppsala, in February 1995.[4,17-22]

METHODS

This methodology included reviewing research articles, review articles, and other literature from internet sources.

A thorough search was conducted to analyze the insufficient reporting of ADR in various journals, articles, and reports in different countries. The information obtained helped understand the status and history of pharmacovigilance in India, as well as in different countries. In this process, various factors contributing to the insufficient reporting of adverse drug reactions were also identified.[1]

ADR monitoring in different countries

INDIA

Drug safety Surveillance is an fundamental part of standard healthcare processes, but it is not yet widely accepted in India. ADRs (pharmaceutical exposure control) significantly increase morbidity and mortality. The entire number of ADRs reported in India is very low. This is because the country is yet in its development phase. Like any other developed country in the world, India realized the need for drug safety monitoring.

Pharmacovigilance in India began in 1986, when an ADR monitoring system consisting of 12 regional institutions, each covering 50 million people, was officially proposed. However, no progress was made until 1997, when India allied the World Health Organization ADR monitoring.[1]

Challenges, including:

1. Under reporting: health professionals and Many adverse drug reactions due to lack of awareness about the importance of reporting in patients Adverse reactions are not reported.
2. Quality of Data: Variation in the quality of aggregated data can affect the reliability of pharmacovigilance results. Inconsistent Reporting format and incomplete information We have problems
3. Training and awareness: There is a need for better training for health professionals regarding the PV process, including ADR reporting and data Management is also involved
4. Infrastructure and Resources: Limited resources and infrastructure for monitoring and analyzing ADRs can hamper effective pharmacovigilance.
5. Regulatory Challenges: The regulatory framework for pharmacovigilance is evolving, But enforcement and There are still gaps in compliance.
6. Public awareness: About role of pharmacovigilance and importance of reporting of ADRs absence of knowledge among the general public may limit the effectiveness of this system. [1],[2],[4],[5]

USA

The primary adverse drug reaction (ADR) reporting system in the US is the FDA Adverse Event Reporting System (FAERS), a database managed by the US Food and Drug Administration (FDA) that collects reports of adverse events and medication errors related to drugs and biological products. Healthcare professionals, pharmaceutical companies, and the general public can submit reports through Med Watch for drug-related events or through the Vaccine Adverse Event Reporting System (VAERS) for vaccines, which are then incorporated into the FAERS database.

In the United States, the rate of adverse drug reaction (ADR) monitoring is difficult to quantify as a single "rate" due to the diversity of reporting, although the FDA's Drug Adverse Event Reporting System (FAERS) is the primary database, with over 1.25 million serious events reported in 2022. However, a meta-analysis of studies showed that serious ADRs occurred in approximately 6.7% of hospitalized patients and death causing side effects in approximately 0.32% of hospitalized patients. Other estimates indicate 6 ED visits for drug-related injuries per 1,000 patients, resulting in hospitalization in approximately 38% of cases.[1,3]

Malaysia

In 2009, the number of ADR reports from healthcare providers through MADRAC reached 5850. Although, according to the WHO guidelines for the eighth National PV Centre, the number of ICSRs is considered low. Throughout the world, the Malaysia's system for reporting PV cases also suffers from under-reporting of ADRs from healthcare providers. Over a period of 15 years, the Malaysian ADR Monitoring Centre, the National Medicines Regulatory Agency, reviewed and analyzed all relevant ADRs submitted to complementary and alternative medicine products (including health supplements). The data included a total of 74,997 ICSR reports, 930 of which involved CAM products. Malaysia has recently introduced user reporting to improve compliance levels. Various guidelines are being developed for the goal of ensuring patient safety and expediting the availability of bio similar products. Pharmacy students from many Malaysian universities have confirmed that they have been certified by pharmacovigilance as pharmacy students during their current pharmacy course.[4,10]

Singapore

To ensure the proper use of the PV system in Singapore, the Health Sciences Authority (HSA) has established a Pharmacovigilance Advisory Committee (PVAC), take in experts from the fields of medicine, pharmacology, pharmacy, and forensics. Their primary role is to evaluate the impact of major drug safety issues and advise on appropriate regulatory actions to enhance drug safety. Mechanical adverse event (AE) reports submitted by healthcare providers and companies are a vital source of information for the drug monitoring system. In Singapore, the Health Sciences Authority is accountable for managing the Voluntary Reporting System. Key positive features of risk management programs include identifying and assessing risks by evaluating reports of serious and unusual reactions, and regular communication about risks from HSAs to HCPs through bulletins.

The PV Unit of the Institute for Pharmaceutical Management in Singapore is accountable for monitoring ADR reports and has been operational since 1993 Physicians, dentists and pharmacists report all ADRs related to medicines using the ADR report. The PV Unit collects ADR reports from across the country and collaborates with other national centre.[4]

Nepal

Approximately 75% of medicines in Nepal are imported from abroad because Nepal has limited manufacturing capacity. Before a drug is marketed, the regulatory authority, the Department of Drug Administration (DDA), conducts a thorough evaluation of the drug based on data available from other countries. Pharmacovigilance activities in Nepal are in the early stages of development ADR reporting is primarily limited to healthcare professional.[1]

Europe

Adverse drug reaction (ADR) surveillance in Europe is a coordinated system overseen by the European Medicines Agency. The agency uses the EudraVigilance database to collect, analyse, and manage reports of suspected adverse drug reactions from across the European Economic Area (EEA).

In Europe, reforms after 2012 led to significant increases in patient reports and a decline in ratio of HCP-to-patient reporting .According to 2015 reports, 3.6% of patients hospitalized in Europe suffer from ADRs, while 10% of patients in European hospitals have a personal experience with an ADR during their stay. Furthermore, it is approximately of 5% of total hospitalizations in the EU occurs as a consequence of ADRs.[15,8]

China

China has been developing its pharmaceutical system since the 1980s, and in recent years it has undergone significant reforms to bring it closer to international standards. It has a national drug monitoring system operated by the China National Medical Products Administration. It collects reports on adverse reactions from hospitals, physicians, patients and pharmaceutical companies. Hospitals and doctors report ADRs through a centralized online platform. Furthermore a public reporting where patients can report directly. Reports are collected and analyzed to detect safety issues early. Strong focus on monitoring traditional Chinese medicines (TCM) with modern medicines. Increasing the use of major statistics and AI to improve monitoring. China's national unintended drug effect surveillance network received 1.676 million reports in 2020, of which a recent and critical ADR reports accounted for 30.2% and 10.0%, respectively. The comprehensive trend shows a general growth in reporting rate.[16]

Australia

Under the current legislation, the Medicines Regulatory Agency (TGA)[1] has established a system of monitoring pharmaceutical products that aims to balance the advantages and disadvantages of unregistered drug products by managing the consumer's income. The TGA has issued a safety profile for the product in Australia and is taking immediate action to protect it. It is carried out by adverse drug reaction advisory committee (ADRAC). Follow the steps to find the desired topic Reporting reaction to bad income Requirements Reporting of special condition. The Therapeutic Goods Administration monitors the protection of therapeutics in Australia through a pharmacovigilance system, managed by the Adverse Drug Reactions Advisory Committee (ADRAC). Sponsors are required to promptly report serious harmful effects that emerge in Australia. They are not required to immediately report serious adverse reactions that occur outside Australia, but they must notify the Therapeutic goods administration within 3 days if they identify a significant safety concern or if foreign regulators take action regarding the safety of the product. There is no set "ADR surveillance ratio" for Australia, but studies show high underreporting rates, with drug-related harms leading to hospitalizations reaching 3% and hospitalizations reporting rates as high as 82%. In one survey, approximately 36% of consumers who experienced an ADR reported it to authorities, indicating low consumer participation in reporting systems, despite high awareness, according to a 2024 study.[3,5]

Thailand

Adverse drug reaction (ADR) surveillance in Thailand is fundamentally managed by the Thai National ADR Surveillance Center, established under the Thai Food and Drug Administration in 1983. The surveillance system relies on Thai VigiBase, a National database for voluntary incident reporting that collects ADR reports from healthcare professionals and the holders of marketing approval for a product with valid reports requiring identifiable patients, senders, suspect drugs, and adverse events. transitioned from hospital- based to community- based monitoring in 2010, receiving approximately 50,000 reports annually.[4]

Comparative Analysis

Country	Year pharmacovigilance joined WHO program	Main regulatory body
1.India	Pharmacovigilance started in 1986; joined who in 1998	PV program of India (PvPI)
2.Malaysia	Started 1987; joined WHO in 1990	MADRAC (Malaysian Adverse Drug Reaction Committee)
3.Australia	Long-standing PV (formal under TGA)	Therapeutic Goods Administration (TGA); ADRAC
4.Thailand	Pharmacovigilance started 1983 under Thailand FDA	Thailand National ADR Surveillance Center
5.Singapore	Started 1993; joined WHO in 1994	Health Sciences Authority (HSA); PVAC (Advisory Committee)
6.Europe (EU)	Coordinated reforms in 2012	European Medicines Agency
7.Nepal	Early 2000s (developing stage)	Department of Drug Administration (DDA)
8.USA	System evolved since 1960s	FDA
9.China	National system since 1980s	National Medical Products Administration

Common challenges in ADR monitoring

Challenges Related to Awareness and Knowledge

- **Lack of knowledge:** Many healthcare professionals and patients are unaware of what constitutes an ADR or the process for reporting it.[1]
- **Unawareness of reporting centers:** There is a general lack of public awareness about how and where to report ADRs, including national regulatory agencies.[6]
- **Failure to recognize ADRs**

  Healthcare professionals may not recognize ADRs due to insufficient training or knowledge, leading to underreporting.[7]

Challenges Related to Reporting Systems and Processes

- **Inaccessible reporting forms**: Reporting forms may be unavailable, difficult to access, or too complex for physicians and patients to use.[12]
- **Time-consuming procedures:** The reporting process can be seen as too time-consuming and can compete with direct patient care, especially for busy clinicians.[7]
- **Lack of feedback:** A lack of timely and relevant feedback on submitted reports can discourage future reporting.[8]

Challenges Related to Professional and Cultural Factors

- **Fear of legal liability:** Healthcare professionals may fear legal repercussions or professional consequences for reporting ADRs.[8]
- **Lack of motivation and culture:** There is often a lack of motivation, reporting culture, and incentives, which are crucial for fostering a positive reporting environment.[9]
- **Perceived lack of impact:** Many believe that reporting a single case does not make a difference, or that all known ADRs are already identified.[7]

Challenges Related to Identifying and Attributing ADRs

- **Difficulty with causality:** It can be difficult to definitively link an adverse event to a specific drug, especially when multiple factors or medications are involved.[10]
- **Anticipating ADRs to resolve:** Patients sometimes believe that ADRs will resolve after treatment completion and see no benefit in reporting them.[7] Challenges Related to Organizational and System Issues
- **Inadequate infrastructure:** Hospitals and healthcare systems may lack the proper infrastructure and routines to support effective ADR reporting.
- **Resource limitations:** There may be insufficient funding and resources to support robust pharmacovigilance programs.[13]
- **Limitations of Clinical Trials:** Clinical trials are often not designed to detect rare adverse events, making PV systems essential for capturing post market safety data.[14]

Future Directions

Some of the key opportunities in this area include leveraging emerging technologies, aggregating real-world data, enhancing global collaboration, and promoting patient-centered reporting. By addressing challenges and capitalizing on opportunities, pharmacovigilance can address business complexities, ensure regulatory compliance, and contribute to a safer and more effective healthcare system that prioritizes patient well-being.[11]

CONCLUSION

This article provides a comprehensive overview of the medicines management system and the importance of monitoring adverse drug reactions to ensure patient safety. While countries such as the America and Europe have developed robust reporting systems, many developing countries, such as India and Nepal, are still developing the necessary awareness and infrastructure. Common challenges such as underreporting, lack of training, and fear of legal repercussions affect ADR reporting worldwide. The article emphasizes the need for better education, simple reporting tools, and the utilization of technologies such as AI to improve drug safety monitoring. It also highlights the importance of international cooperation and patient engagement. Strengthening medicines management systems is essential to making healthcare safer and more effective for all.[1,2,3,8,13,14]

REFERENCES

1. Dutta A, Banerjee A, Basu S, Chaudhry S. Analysis of under-reporting of Adverse Drug Reaction: Scenario in India and neighbouring countries. IP Int J Comprehensive Adv Pharmacol, 2020; 5(3): 118-124.
2. Swapnil. Shinde*, Vyankatesh Dharanguttikar, Swapnali Dharanguttikar, Parag Shinde, Pratiksha Mahajan, Pratik Shitole, Comparative Review of Pharmacovigilance System in Different Countries, Int. J. of Pharm. Sci., 2025; l3(2): 1628-1636. https://doi.org/10.5281/zenodo.14892698

3. Reza S.M.Rabbur and Lynne Emmerton An introduction to adverse drug reaction reporting systems in different countries March International Journal of Pharmacy Practice, 2005; 13(1). DOI:10.1211/0022357055821
4. Dutta A, Banerjee A, Pramanik P, Pradhan N, Chaudhry S. Pharmacovigilance in India and five ASEAN countries (Malaysia, Singapore, Thailand, Indonesia, Philippines): A comparison study. IP Int J Comprehensive Adv Pharmacol, 2021; 6(1): 1-4.
5. Sachdev Yadav status of adverse drug reaction monitoring and Pharmacovigilance in selected countries- Indian J Pharmacol, 2008 Feb; 40(Suppl1): S4–S9. PMCID: PMC3038524 PMID: 21369413
6. Suyagh, M., Farah, D., & Farha, R. A., Pharmacist's knowledge, practice and attitudes toward pharmacovigilance and adverse drug reactions reporting process. *Saudi Pharmaceutical Journal*, 2015; *23*(2): 147-153.
7. Jyothi DB, Swetha K. Knowledge awareness and practice of pharmacovigilance among health-care providers at a tertiary care hospital – A questionnaire-based study. Natl J Physiol Pharm Pharmacol, 2020; 10(03): 270-275.
8. Patricia García-Abeijon, Catarina Costa, Margarita Taracido, Maria Teresa Herdeiro, Carla Torre, Adolfo Figueiras- Factors Associated with Underreporting of Adverse Drug Reactions by Health Care Professionals: A SysPtematic Review Update PMCID: PMC10279571 PMID: 37Drug Saf., 2023 Jun 6; 46(7): 625–636. doi: 10.1007/s40264-023-01302-7277678
9. Maysa Suyagh, Doaa Farah, Rana Abu Farha - Pharmacist's knowledge, practice and attitudes toward pharmacovigilance and adverse drug reactions reporting processSaudi Pharmaceutical Journal, April 2015; 23(2): 147-153, https://doi.org/10.1016/j.jsps.2014.07.001
10. Tze Seong Chen, Kien Seang Kwong, Sai Hong Lee, Noor Ashikin Nordin, Chiew Ping Tan, Mohd Faiz Mohd Wahiza, Yi Heng Lim, Nurul Syahamah Shakar and Nuraini Arshad, Knowledge, Practices & Attitudes Towards Adverse Drug Reaction Reporting among Public Healthcare Professionals in West Pahang. Malaysian Journal of Pharmacy (MJP), 2023; 2(9): 29-36. https://mjpharm.org/knowledge-practices-attitudes-towards-adverse-drug-reaction-reporting-among-public-healthcare-professionals-in-west-pahang/
11. https://nanoschool.in/nstc-blog/challenges-and-opportunities-in-pharmacovigilance-navigating-complexities-and-ensuring-compliance/#:~:text=Pharmacovigilance%20faces%20several%20challenges%2C%20but,%2C%20electronic%20health%20records%2C%20wearables.
12. ANBEO, Z. G., & ABACIOĞLU, N., A Systematic Review of Healthcare Professionals' Knowledge, Attitudes, and Practices Regarding Adverse Drug Reaction Reporting in Ethiopia. Turkish Journal of Pharmaceutical Sciences, 2023; 20(3): 198-209. https://doi.org/10.4274/tjps.galenos.2022.28034
13. Anant Khot and Ganesh Dakhale-Challenges and Possible Solutions of ADR Monitoring (Pharmacovigilance) in Low- and Middle-Income Countries DOI: 10.5772/intechopen.1006043
14. Zaka Un Nisa, Ayesha Zafar, Farooq Sher -Assessment of knowledge, attitude and practice of adverse drug reaction reporting among healthcare professionals in secondary and tertiary hospitals in the capital of Pakistan - Saudi Pharmaceutical Journal, May 2018; 26(4): 453-461n -https://doi.org/10.1016/j.jsps.2018.02.014
15. https://www.google.com/search?q=adr+monitoring+ratio+in+europe&rlz=1C1CHBF_enIN830IN830&oq=adr+monitoring+ratio+in+eu&aqs=chrome.1.69i57j33i160l2.20472j0j15&sourceid=chrome&ie=UTF-8 https://english.nmpa.gov.cn/2021 https://english.nmpa.gov.cn/2021-03/26/c_654833.htm-03/26/c_654833.htm

16. Haibo Song, Xiaojing Pei, Zuoxiang Liu, Chuanyong Shen, Jun Sun, Yuqin Liu, Lingyun Zhou, Feng Sun, Xiaohe XiaoPharmacovigilance in China: Evolution and future challenges: British journal of clinical pharmacology https://doi.org/10.1111/bcp.15277
17. World Health Organization (WHO). The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products. WHO, 2002.
18. Edwards IR & Aronson JK. Adverse drug reactions: definitions, diagnosis and management. The Lancet, 2000; 356(9237): 1255–1259.
19. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis. JAMA, 1998; 279(15): 1200–1205.
20. Rabbur SMR, Emmerton L. An introduction to ADR reporting systems in different countries. Int J Pharm Pract, 2005; 13(1): 91–100.
21. Waller P. An introduction to pharmacovigilance. Wiley-Blackwell, 2010.
22. Uppsala Monitoring Centre (WHO Program).WHO Programme for International Drug Monitoring. WHO-UMC, 2018. (Use for the 1968 WHO PIDM reference and thalidomide history.)