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Review Article

Pharmacovigilance: A Brief Summary of History, Need, Database System in India, USA and Europe

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ABSTRACT

Pharmacovigilance (PV) is the action of gathering, monitoring, investigating, analyzing, and evaluating pertinent data with the goal of lowering the frequency and severity of adverse effects. There is no doubt that pharmaceutical risk and risk-benefit analysis will continue to evolve in the future, but at the price of upheavals, disputes, and challenges to established institutions. It also shows that the patients are involved in the clinical trial for ensuring the safety of medicines. The Centre National de Pharmacovigilance et de Materiovigilance was created and supported by the Algerian Ministry of Health (MOH) in 1998. Due to the absence of long-term safety data as well as unanticipated interactions along with underlying clinical disorders and other medication regimens, rare side effects may not always be detected in clinical studies. In this review, the comparison of the pharmacovigilance between US, India and Europe show that the PV in the India show better activity for measuring the adverse effect due to the large number of populations.

Keywords: Pharmacovigilance; Materiovigilance; Curricula; Pertinent

ABBREVIATIONS

ADRs: Adverse Drug Reactions; AEFIs: Adverse Event Following Immunization; AEs: Adverse Events; AFSSAPS: Agence Française De Sécurité Sanitaire Des Produits De Santé; AIFA: Agenzia Italiana del Farmaco; AMC: Monitoring Centers; CDSCO: Central Drugs Standard Control Organization; CNPM: Centre National de Pharmacovigilance et de Materiovigilance; DGHS: Directorate General of Health Services; EMA: European Medical Agency; FDA: Food and Drug Administration; HCPs: Health Care Professionals; ICSRs: Individual Case Safety Reports; IPC: Indian Pharmacopoeia Commission; LRP: Local PV Representatives; MAHs: Marketing Authorization Holders; ME: Medical Error; MOH: Ministry of Health; MOHFW: Ministry of Health and Family Welfare; NCEs: New Chemical Entities; NMRAs: National Medicine Regulatory Agencies; NRA: National Regulatory Authority; PV: Pharmacovigilance; PVPI: Pharmacovigilance Programmed of India; RPC: Regional PV Centers; UMC: University; Medical Center: WHO World Health Organization

INTRODUCTION

In the pharmaceutical business, Pharmacovigilance (PV) is a relatively recent field. PV has expanded quickly during the past 20 years and currently affects a wide range of research and development fields [1]. Pharmacovigilance (PV) is the process of gathering, monitoring, investigating, analyzing, and evaluating pertinent data with the goal of lowering the frequency and severity of adverse effects [2]. It significantly contributes to the advancement of clinical treatment, public health, drug regulation, as well as the mitigation of future negative effects from licensed pharmaceuticals [3]. The prospective effects of such tendencies on the advancement of research are briefly discussed in pharmacovigilance initiatives over the next ten years. The development of better healthcare systems in this international arena is now fraught with difficulties for pharmacovigilance. Globalization, information and web-based sales, bigger security issues, community healthiness *vs.* economic development of pharmaceutical industry, intensive care of

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current pharmaceuticals, emerging and rising nations, attitudes and views regarding benefit and damage, outcomes as well as effect, and are some of the primary difficulties [4]. A national reporting system serves as the cornerstone of any national PV system. A system like this makes it easier to gather data on Adverse Events (AEs), information about the usage of medical products in unique circumstances from consumers and patients, and to quickly submit suspected Adverse Drug Reactions (ADRs) as Individual Case Safety Reports (ICSRs). A nationwide dataset for pharmaceuticals is built on ICSR data. Based on the data obtained, this dataset is continually changing [5]. PV's objectives are well acknowledged. It can be described as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem" by the World Health Organization (WHO). Primary goal of the pharmacovigilance is to increase patient care with relation to responsible as well as the safe administration of medication [6]. Additionally, healthcare professionals must be proficient in PV techniques [7]. It also focuses on detecting the risk factors and the source of ADRs, as well as the early diagnosis of undiscovered ADRs [8]. Drug regulatory authorities and PV programs must collaborate so that the regulatory agency is kept up to date on any new safety issues. Simultaneously, regulatory bodies must be aware of the crucial importance of the PV idea, which will allow them to focus on the licensing of the new drugs, and also on the safety of the drugs [9]. The WHO-UMC, a WHO collaborating center for the monitoring of the international drug based on the Sweden, Uppsala, is in-charge of the technological and operating integrity of pharmaceuticals as well as operation of ICSRs into the worldwide drug surveillance program. Each nation's national pharmacovigilance center must adhere to specific requirements in order for it to be a member of the WHO-UMC [10].

PV HISTORY

CNPM was created and supported by the Algerian Ministry of Health (MOH) in 1998 [11]. Pharmacovigilance begins to decline in the first decade of the twenty-first century. It should be noted that prior scandals and incidents, such as the coxib dispute for the FDA or the benfluorex crisis for the AFSSAPS in France, have occurred. The pharmaceutical risk and risk-benefit analysis will continue to evolve in the future, but at the price of upheavals, disputes, and challenges to established institutions. But let us not forget that pharmacovigilance is being developed on a daily basis, in collaboration with all parties involved, carried patients along with their associations, with the goal of ensuring patients the highest level of safety they have the right for expect from the therapeutic medicine which have been granted for marketing authorization [12].

NEED FOR PHARMACOVIGILANCE

Information concerning a new drug's side effects becomes accessible when it is put on the market, which might lead to its removal, usage limitations, and labelling adjustments. Healthcare experts and the general public are concerned about several side effects. Thousands of volunteers who took part in carefully controlled clinical studies serve as the basis for the majority of data on medication effectiveness and safety. Due to the absence of long-term safety data as well as unanticipated interactions along with underlying clinical disorders and other medication regimens, rare side effects may not always be detected in clinical studies. Only when a larger population has used a medicine and it has been under observation for a longer length of time can the risks as well as profits that connected with it be better recognized. This technique is aided by observational science. Clinicians must carefully monitor a new drug's effects in 'real world' practice in order to characterize its full safety profile. Pharmacovigilance aids in the identification of pharmaceutical safety problems and assists regulatory bodies or manufacturers in making choices on medication withdrawal, usage limits, or labelling changes [13,14].

PHARMACOVIGILANCE IN PRACTICE

By reducing the frequency of ADRs as well as establishing the warning network for comprising many healthcare practitioners, consumers and manufacturers, we may initiate corrective action in a timely and organized fashion [15], and the health care system which incorporates PV increases the safety of drugs. Patients, healthcare workers, governments, and pharmaceutical corporations are the main parties involved in pharmacovigilance. The most important stakeholder among these is the healthcare industry [14]. Identifying ADRs is the sole responsibility of nurses in pharmacovigilance, which is challenging for other healthcare professionals [16]. By implementing pharmacovigilance procedures and report the ADRs which have the beneficial for dentistry as a whole, dentists may contribute to the development of a better pharmacovigilance system [17]. Important pharmacovigilance components have to be incorporated into current curricula and the courses for medical, dental, pharmacy, as well as nursing education [18].

PV IN EUROPE, USA, INDIA

In USA

In United States, the FDAAE reporting system was designed for promote postmarked surveillance, that allows the manufacture, medical management specialists, and people to contribute adverse event data. The database contains data on patient demographics, adverse events, medication mistakes, complaints regarding product quality, and product recalls. MedWatch is an FDA web-based reporting system that enables users for the voluntarily report which associated with the serious adverse events as well as another negative issues it believes are related for the uses of an FDA-regulated product. The FDA or the manufacturers can be informed in detail of the adverse events. Information on both required and optional reporting is available from Med Watch. The ADR reports filed online using form 3500As or 3500Bs are evaluated by the Center for Biologics Evaluation or Drug Evaluation and Research. The FDA developed the Sentinel Initiative in response to the USFDA Amendments Act of 2007, which obliged manufacturers to report adverse occurrences.

PV in Europe

The Eudra Vigilance framework is used to gather, manage, and

assess suspected Adverse Drug Reactions (ADRs) related with medications that have received European Economic Area approval. For the purpose of evaluating pharmaceuticals, the European Medical Agency (EMA) was founded in 1995. Healthcare providers or Patients report the suspected ADR to MAHs or Eudra Vigilance. The risks associated with medications and their management are assessed by the Pharmacovigilance Risk Assessment Committee. The aforementioned committee considers the therapeutic benefit of the medicine while taking into account the reduction, assessment, findings and announcement the risks of ADRs.

In India

On July 14, 2010, the Ministry of Health, Government of India and also Family Welfare introduce the Pharmacovigilance Programmed in the India. The Indian Pharmacopoeia Commission (IPC) now oversees its operations. There are now 567 ADR Monitoring Centers (AMC) operating under PVPI in India. The CDSCO, which is part of the DGHS and MOHFW, is India's National Regulatory Authority (NRA) [19]. Through its many ADR monitoring centers and the Pharmacovigilance Programme of India (PVPI), India also established reliable PV system. After conducting a thorough quality check on each Individual Case Safety Report (ICSR), India sends this data to the UMC using the online application VigiFlow®. The global ICSR repository, VigiBase®, receives this information and stores it. Based on the information gathered on drug safety, PVPI generates alerts, suggests label changes (if necessary), and locates signals in order to assist the National Regulatory Authority. PVPI has created a number of mechanisms for stakeholders to report ADRs at the national level [20]. According to estimations, the pharmaceutical business of India is approximately 3.5% of the worldwide pharmaceutical business. It is anticipated to reach US $100 billion before 2025, becoming the sixth-largest market in the world in pharmaceuticals [21]. About 80% of the market is made up of branded generics, and as New Chemical Entities (NCEs) become more acquainted in the country, they start for plying the bigger role in the sector of clinical research and different outsourcing initiatives [22,23].

CONTRASTS BETWEEN UNITED STATES, EUROPE AND INDIAN PV

When the comparison is conducted to the PV systems of USA and EU, PV is in its infancy in India. Both nations mandate the mandatory reporting of all significant adverse events, however before to the implementation of PVPI, India had no specific reporting requirements for ADRs other than Schedule Y.33 MAHs were just recently obliged to report ADRs under PVPI in 2018. The web-based Adverse Drug Reaction reporting systems for the European Union and the United States are MedWatch and Eudra Vigilance, respectively, but India used the Vigiflow system of the WHO-based. Unlike the systems in the United States and the European Union, the ADR forms in India are not separated into two categories [24].

PHARMACOVIGILANCE DATABASE AND SYSTEM IN ITALIAN

Italian PV System which depends upon the network that have the capacity to connects the Italian Medicines Agency to 21 regional authorities, including Regional PV Centers (RPC), Local PV Representatives (LRP), local health hospitals/ authorities/research institutes, and pharmaceutical firms. The AIFA oversees post-marketing surveillance for medications and vaccines. RCPs and the AIFA work together to track negative medication responses and identify warning signs. They support the preventative strategies used in vaccine surveillance programs. The National PV Database that was established in 2001, was used to compile and examine reports of adverse reactions. The majority of the RNF data come from patients, active monitoring initiatives, and Health Care Professionals (HCPs) who voluntarily report potential adverse events. Spontaneous reports are sent to LRPs via a web-based system (Vigifarmaco) or in paper copy form. The Medical Dictionary for Regulatory Activities is utilized for code AEFIs, lab tests, and treatment indications [25].

SYSTEM FOR REPORTING MES

The majority of the ME reporting systems in African nations exhibited the traits of efficient ME reporting systems, including independence from healthcare professional regulatory or accreditation processes, the opportunity to assess error causes, non-punitive reporting methods, and providing the feedback on the examination of erroneous data to individuals which is included in the ME report. The existence of rules, secrecy, as well as voluntary reporting are a few more [26,27].

National Medicine Regulatory Agencies (NMRAs) generally hosted Medical Error (ME) reporting in African nations and were in charge of data collection, feedback, regulatory action, analysis, which is except into two countries that is Democratic Republic and Morocco of the Congo where the organization of these procedures in the NMRA that was not directly responsible. All nations having reporting mechanisms portrayed their systems as voluntary, with the exception of one where healthcare practitioners were required to report MEs. To lessen the dread of reporting that the majority of participants felt, national centres should emphasize the non-punitive character and voluntary for reporting systems. Third characteristic of the ME report systems in the Africa that was the lack of instructions on MEs in the pharmacovigilance guidelines that are currently in existence in the majority of the countries assessed. Without rules, a ME reporting system cannot adhere to accepted global norms. These nations must take action to modernize their current rules and regulations to incorporate ME reporting. These recommendations will assist in providing information on reportable MEs and other reporting-related topics. The volunteers and the expert committee can assist the national center for exam the reports of the ME that the collection was seen on the fourth occasion. Before providing comments to reporters, these committees or volunteers provide nations the chance to analyze news and determine causation.

The provision of feedback was the last trait to be recognized, and all 16 nations having ME reporting systems highlighted it. Appropriate feedback mechanisms enhance reporting, according to various research [28-31]. The majority of countries were found to lack access to resources such as technological, electronic reporting tools, financial, human, and database. According to several writers, African nations are still building their pharmacovigilance systems and have few personnel and financial resources [32-35]. Given the amount of nation delegates who identified issues with the sufficiency of human resources and financial, our findings therefore support the literature already in existence.

FACILITATORS AND BARRIERS IN MEs REPORTING

Barrier which are mentioned from the participants for low reporting rates of MEs that extensively researched. People worry about repercussions of the reporting [36-40], lack of understand the system of reporting as well as processes, lack of the feedback, time, incapacity for identify the MEs. Additionally, we discovered that impediments to patient reporting of MEs included sociocultural as well as religious views, political persecution, illiteracy, anxiety of being victimized by the professionals, and language hurdles. ME reporting is affected by elements that either directly or indirectly affect patient safety, like illiteracy, sociocultural, health care delivery system, religious view, and also language barrier [41]. The patients who are participants in the ME reporting is projected to increase the reporting rate and also cause root inquiry, hence by decreasing the number of the errors. Patients are engaging in the reporting drug error is critical since they are typically the first to identify any complications caused by MEs [42]. As a result, patient engagement in the ME reporting can shows the early discovery of the new safety signals along with the drugs, healthcare products, as well as to decrease the needless in the adverse events [43]. MEs are underreported because people are afraid of legal repercussions, blame individuals rather than the system, lack adequate reporting procedures, don't get feedback, and assist the person who committed the error [44-47]. Soydemir, et al. highlighted a number of obstacles to the use of drug error reporting systems, including the absence of such systems and a lack of awareness of such systems [48].

CONCLUSION

In this review article, we discussed about the focus of PV on gathering, monitoring, investigating, analyzing, and evaluating the data, for lowering the adverse effects. It also shows that the patients are involved in the clinical trials for ensuring the safety of medicines. In this article it describe about a study of pharmacovigilance in the United States, India, and Europe reveals that the PV in India is more active in measuring adverse effects because to the vast number of populations. Thousands of volunteers who took part in carefully controlled clinical studies serve as the basis for the majority of data on medication effectiveness and safety.

REFERENCES

1. Beninger P. Pharmacovigilance: An overview. Clin Ther. 2018;40(12):1991-2004.
2. Luo Y, Thompson WK, Herr TM, Zeng Z, Berendsen MA, Jonnalagadda SR, et al. Natural language processing for EHR-based pharmacovigilance: A structured review. Drug Saf. 2017;40:1075-1089.
3. Jeetu G, Anusha G. Pharmacovigilance: A worldwide master key for drug safety monitoring. J Young Pharm. 2010;2(3):315-320.
4. Biswas P, Biswas AK. Setting standards for proactive pharmacovigilance in India: The way forward. Indian J Pharmacol. 2007;39(3):124.
5. Peters T, Soanes N, Abbas M, Ahmad J, Delumeau JC, Herrero-Martinez E, et al. Effective Pharmacovigilance system development: efpia-ipvg consensus recommendations. Drug Saf. 2021 Jan;44:17-28.
6. Pharmacovigilance. World Health Organization.2023.
7. Reumerman M, Tichelaar J, Piersma B, Richir MC, Van Agtmael MA. Urgent need to modernize pharmacovigilance education in healthcare curricula: Review of the literature. Eur J Clin Pharmacol. 2018;74:1235-1248.
8. Pappa D, Stergioulas LK. Harnessing social media data for pharmacovigilance: A review of current state of the art, challenges and future directions. Int J Data Sci Anal. 2019;8(2):113-135.
9. Alomar M, Palaian S, Al-Tabakha MM. Pharmacovigilance in perspective: Drug withdrawals, data mining and policy implications. F1000Res. 2019;8.
10. Being a member of the WHO Programme for International Drug Monitoring. World Health Organization. 2018.
11. Alshammari TM, Mendi N, Alenzi KA, Alsowaida Y. Pharmacovigilance systems in Arab countries: Overview of 22 Arab countries. Drug Saf. 2019;42(7):849-868.
12. Caron J, Rochoy M, Gaboriau L, Gautier S. Histoire de la pharmacovigilance. Therapie. 2016;71(2):123-128.
13. Pillans PI. Clinical perspectives in drug safety and adverse drug reactions. Expert Rev Clin Pharmacol. 2008;1(5):695-705.
14. Jose J, Al Rubaie MH, Al Ramimmy H, Varughese SS. Pharmacovigilance: Basic concepts and an overview of the system in Oman. Sultan Qaboos Univ Med J. 2021;21(2):e161.
15. FIP statement of policy the role of the pharmacist in pharmacovigilance. International Pharmaceutical Federation (FIP). 2023.
16. Mendes Marques JI, Polónia JM, Figueiras AG, Costa Santos CM, Herdeiro MT. Nurses' attitudes and spontaneous adverse drug reaction reporting: a case–control study in Portugal. J Nurs Manag. 2016;24(3):409-416.
17. Carnelio S, Khan SA, Rodrigues G. Pharmacovigilance in clinical dentistry: Overlooked or axiomatic. Gen Dent. 2011;59(1):24-8.
18. van Eekeren R, Rolfes L, Koster AS, Magro L, Parthasarathi G, Al Ramimmy H, et al. What future healthcare professionals need to know about pharmacovigilance: Introduction of the WHO PV core curriculum for university teaching with focus on clinical aspects. Drug Saf. 2018;41:1003-1011.
19. Singh P, Vaishnav Y, Verma S. Development of pharmacovigilance system in India and paradigm of pharmacovigilance research: An overview. Curr Drug Saf. 2023;18(4):448-464.
20. Prakash J, Sachdeva R, Shrivastava TP, Jayachandran CV, Sahu A. Adverse event reporting tools and regulatory measures in India through outcome of pharmacovigilance programme of India. Indian J Pharmacol. 2021 Mar;53(2):143.
21. Zaki SA. Adverse drug reaction and causality assessment scales. Lung India. 2011;28(2):152-153.

22. Brahmachari B, Fernandes M, Bhatt A. Pharmacovigilance for clinical trials in India: Current practice and areas for reform. Perspect Clin Res. 2011;2(2):49.
23. Gupta YK. Ensuring patient safety-launching the new pharmacovigilance programme of India. Pharma Times. 2010;42(8):21-26.
24. Jose J, Rafeek NR. Pharmacovigilance in India in comparison with the USA and European Union: Challenges and perspectives. Ther Innov Regul Sci. 2019;53(6):781-6.
25. Moretti F, Gonella L, Gironi S, Marra AR, Santuccio C, Felicetti P, et al. Ten years of vaccinovigilance in Italy: An overview of the pharmacovigilance data from 2008 to 2017. Sci Rep. 2020;10(1): 14122.
26. Medication Without Harm WHO Global Patient Safety Challenge. World Health Organization. 2023.
27. Mekonnen AB, Alhawassi TM, McLachlan AJ, Brien JA. Adverse drug events and medication errors in African hospitals: A systematic review. Drugs Real World Outcomes. 2018;5:1-24.
28. Sabblah GT, Darko D, Härmark L, van Puijenbroek E. Patient preferences and expectation for feedback on adverse drug reaction reports submitted in Ghana. Ghana Med J. 2019;53(2):150-155.
29. Hartnell N, MacKinnon N, Sketris I, Fleming M. Identifying, understanding and overcoming barriers to medication error reporting in hospitals: A focus group study. BMJ Qual Saf. 2012;21(5): 361-368.
30. Evans SM, Berry JG, Smith BJ, Esterman A, Selim P, O'Shaughnessy J, et al. Attitudes and barriers to incident reporting: A collaborative hospital study. BMJ Qual Saf. 2006;15(1):39-43.
31. Benn J, Koutantji M, Wallace L, Spurgeon P, Rejman M, Healey A, et al. Feedback from incident reporting: information and action to improve patient safety. Qual Saf Health Care. 2009;18(1):11-21.
32. Barry A, Olsson S, Minzi O, Bienvenu E, Makonnen E, Kamuhabwa A, et al. Comparative assessment of the national pharmacovigilance systems in East Africa: Ethiopia, Kenya, Rwanda and Tanzania. Drug Saf. 2020;43:339-350.
33. Olsson S, Pal SN, Stergachis A, Couper M. Pharmacovigilance activities in 55 low-and middle-income countries: A questionnaire-based analysis. Drug Saf. 2010;33:689-703.
34. Isah AO, Pal SN, Olsson S, Dodoo A, Bencheikh RS. Specific features of medicines safety and pharmacovigilance in Africa. Ther Adv Drug Saf. 2012;3(1):25-34.
35. Ampadu HH, Hoekman J, Arhinful D, Amoama-Dapaah M, Leufkens HG, Dodoo AN. Organizational capacities of national pharmacovigilance centres in Africa: Assessment of resource elements associated with successful and unsuccessful pharmacovigilance experiences. Global Health. 2018;14:1-7.
36. Stratton KM, Blegen MA, Pepper G, Vaughn T. Reporting of medication errors by pediatric nurses. J Pediatr Nurs. 2004;19(6): 385-92.
37. Chiang HY, Lin SY, Hsu SC, Ma SC. Factors determining hospital nurses' failures in reporting medication errors in Taiwan. Nurs Outlook. 2010;58(1):17-25.
38. Patrician PA, Brosch LR. Medication error reporting and the work environment in a military setting. J Nurs Care Qual. 2009;24(4): 277-286.
39. Aseeri M, Banasser G, Baduhduh O, Baksh S, Ghalibi N. Evaluation of medication error incident reports at a tertiary care hospital. Pharmacy (Basel). 2020;8(2):69.
40. Bahadori M, Ravangard R, Aghili A, Sadeghifar J, Gharsi Manshadi M, Smaeilnejad J. The factors affecting the refusal of reporting on medication errors from the nurses' viewpoints: A case study in a hospital in Iran. ISRN Nurs. 2013.
41. Sabblah GT, Seaneke SK, Kushitor M, van Hunsel F, Taxis K, Duwiejua M, et al. Evaluation of pharmacovigilance systems for reporting medication errors in Africa and the role of patients using a mixed-methods approach. PLoS One. 2022;17(3):e0264699.
42. Brabcová I, Bártlová S, Tóthová V, Prokešová R. The possibility of patient involvement in prevention of medication error. Kontakt. 2014;16(2):e65-70.
43. Hazell L, Cornelius V, Hannaford P, Shakir S, Avery AJ, Yellow Card Study Collaboration. How do patients contribute to signal detection? A retrospective analysis of spontaneous reporting of adverse drug reactions in the UK's Yellow Card Scheme. Drug Saf. 2013;36:199-206.
44. Poorolajal J, Rezaie S, Aghighi N. Barriers to medical error reporting. Int J Prev Med. 2015;6.
45. Bahadori M, Ravangard R, Aghili A, Sadeghifar J, Gharsi Manshadi M, Smaeilnejad J. The factors affecting the refusal of reporting on medication errors from the nurses' viewpoints: A case study in a hospital in Iran. ISRN Nurs. 2013;2013.
46. Lee E. Reporting of medication administration errors by nurses in South Korean hospitals. Int J Qual Health Care. 2017;29(5):728-34.
47. Stewart D, Thomas B, MacLure K, Wilbur K, Wilby K, Pallivalapila A, et al. Exploring facilitators and barriers to medication error reporting among healthcare professionals in Qatar using the theoretical domains framework: A mixed-methods approach. PLoS One. 2018;13(10):e0204987.
48. Soydemir D, Seren Intepeler S, Mert H. Barriers to medical error reporting for physicians and nurses. West J Nurs Res. 2017;39(10): 1348-1363.