IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.301
Volume 3, Issue 12, May 2023

Pharmacovigilance: Essential Branch of Pharmacology

Ms. Manisha A. Lavate*, Prof. Sujit T. Karpe[1], Mr. Madanna R. Bhandare[2], Mr. Sidaray N. Biradar[3], Ms.Tejaswini B. Gote[4]
Sojar College of Pharmacy, Khandvi, Barshi, Solapur
Corresponding author: Ms.Manisha A. Lavate
Gmail : madannabhandare@gmail.com

Abstract: *The national pharmacovigilance centers have become a significant influence on the drug regulatory authorities, at a time when drug safety concerns have become increasingly important in public health and clinical practice. Pharmacovigilance is a crucial component of patient safety and helps to guarantee their safety during the entire pharmacokinetic and pharmacodynamic process of drug. The ICH guidelines for human use are included in this report, together with PV planning, Pharmacovigilance history, and PV methods. These days, PV in India raises awareness of ADR, and this evaluation provides details on PVPI. The purposemethods and overview of PV's presence in India. Through the observation of drug interactions and the consequences of those interactions on the human body, pharmacovigilance plays a significant role in the healthcare system. In the following article, good clinical practices and the International Conference on Harmonization recommendations for pharmaceuticals intended for human use are addressed as crucial elements in the transformation of clinical trials to the goal of pharmacovigilance. India overtakes other nations to claim third place in the world for pharmaceutical output. Pharmacovigilance now raises awareness of adverse drug reactions in India, and this review provides details on how pharmacovigilance connected with pharmacology. The goal and methodology of pharmacovigilance were summarised in this article along with an overview of how it is currently practised in India, its difficulties, and its prospects for the future.*

Keywords: ICH Guidelines, PV Planning, PvPi and PV methods, ADR.

I. INTRODUCTION

Clinical research includes pharmacovigilance as a crucial and vital component [1]. Throughout the lifecycle of a product, post-marketing pharmacovigilance and clinical trial safety are both essential. "Defined as the pharmacological science relating to the detection, assessment, understanding, and prevention of adverse effects, particularly long-term and short-term adverse effects of medicines," is how pharmacovigilance isdescribed [2]. "An adverse event is defined as any untoward medical occurrence that may present during treatment with a drug but which does not necessarily have a relationshipwith its use".The biggest problem in the world is the under-reporting of adverse drug reactions (ADRs), which can be linked to a lack of time and report forms.It is well known that the World Health Organization (WHO) has started a programme to record any negative drug responses [3]. The main aim of pharmaceutical company is to innovate new drugs in the market; the company has to conduct clinical trials as per ICH GCP guidelines.Pharmacovigilance is an integral and important part of clinical trials.[4]. The Lancet published a case report in December 1961 by W. McBride, an Australian physician who was the first to assert a causal relationship between thalidomide, a medication used during pregnancy as an antiemetic and sedative, and serious fetal deformities (Phocomelia).[5]

The "Programmed for International Drug Monitoring" was promoted by the World Health Organisation (WHO) in 1968. . Additionally, PV plays a variety of responsibilities, including identifying, quantifying, and documenting drug-related issues that lead to drug-related injuries [6].

AIMS of PV:

1. To better safeguard the public from new medications [19]

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.301
Volume 3, Issue 12, May 2023

2. To aid in the evaluation of the effectiveness, safety, and risk of medical treatments.[19]
3. Support constructive community dialogue.[19]
4. To encourage the safe and responsible use of medications.[19]
5. The effectiveness of medications and their monitoring of side effects.[19]
6. Enhance public health and safety in connection to the application of pharmacovigilance through promoting awareness, instruction, and clinical training [19]
7. Improve patient care and safety in relation to the use of medicines and all medical and paramedical intervention.[18,19]
8. Improve public health and safety in relation to the use of medicines

.

History of pharmacovigilance :

Year	Incident
1848	Hannah's death caused by chloroform
1937	USA with solvent diethyl glycol
1938	Federal Food, Drug, and Cosmetic Act was established and the public health system renovated
1955	GIT toxicity of ASA was proved
1961	McBride's letter about the tragedy of Thalidomide
1964	The Yellow card was structured in the UK
1965	European legislation was developed
1968	WHO Program for International drug monitoring was instituted
1995	EMA was set up
2001	Eudravigilance was funded
2012	New European PV legislation
2017	New Eudravigilance format[7]

About 170 years ago, pharmacovigilance began, though it was not yet recognised by that name. It is a planned activity in the professional healthcare field that has major social and commercial implications that aims to monitor the risk/benefit ratio of medications while enhancing patient safety and quality of life. In this commentary, we outline the key turning points in pharmacovigilance up to the present, in order to understand all the steps that have shaped the historical development. [20] A significant development in European Pharmacovigilance occurred in 1961 as a result of the tragedy of thalidomide. Australian physician Dr. McBride made a relationship between thalidomide and congenital malformations in infants in a letter to the editor of the Lancet Journal. In fact, he discovered that thalidomide use during pregnancy raised the risk of congenital abnormalities in newborns (1.5%) by up to 20%.[21] The first recorded instance of pharmacovigilance occurred 169 years ago, on January 29, 1848, when Hannah Greener, a little child from the north of England, passed away following the administration of a chloroform anesthetic prior to the excision of an infected toenail. Chloroform was a potent and safe anesthetic that Sir James Simpson had discovered and introduced into therapeutic use. To comprehend what happened to Hannah, the causes of her death were looked into, but it was hard to pinpoint the exact cause of her death. She most likely succumbed to pulmonary aspiration or a fatal arrhythmia. [22]

II. NEED OF PHARMACOVIGILANCE

It is commonly acknowledged that the clinical development of medications is a difficult process that takes a long time to complete. When a medicine is marketed, it exits the safe and secure scientific setting of clinical trials and becomes available for use by the general public. Currently, only a small number of carefully chosen individuals have been used to test the short-term safety and effectiveness of the majority of medications.

Pharmacovigilance is therefore required, which entails assuring the early detection of novel adverse responses or patient subgroups of extraordinary sensitivity; establishing specified methods to mitigate such risks. Consequently, the necessity for pharmacovigilance develops, which involves ensuring the early detection of novel adverse reactions or patient subgroups of extraordinary sensitivity; and establishing specified strategies to mitigate such risks.[23]

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.301
Volume 3, Issue 12, May 2023

ICH Guidelines:

Principle of ICH:

Around the world, numerous nations have created their own pharmacovigilance regulations in an effort to have a structured method for safety reporting. Six ICH recommendations cover different facets of medication safety:[8]

PV Methods:

Numerous researchers created various techniques for determining the causality of ADRs by using various criteria, such as the timing between the administration of the drug and the occurrence of the ADR, checking for non-drug related causes, validating the reaction in vivo or in vitro, and antecedent data on homogeneous events linked to the suspect drug or its therapeutic class, among other things [9-10]. There is currently no mechanism for determining the cause of ADRs that is universally acknowledged [11]. There are numerous computational techniques for determining causality at the moment, but none of them are regarded as the gold standard due to their flaws and differences.[12] We would briefly explain each of them as given below.

III. METHODS

Hypothesis Generating Methods

1. Spontaneous ADR reporting
2. Prescription event monitoring

Hypothesis testing Methods:-

1. Case control study
2. Cohort studies
3. Randomized controlled trials

PV Programme In India:

A national database or management system for adverse drug reaction reports; the WHO programme for international drug monitoring; a national spontaneous reporting system with a national individual case safety report (ICSR) form; a national pharmacovigilance advisory committee capable of providing technical assistance on causality assessment, risk assessment, risk management, and case investigation; and a clear communication strategy for routine clinical trials.[26,27]

1. Steering committee, technical support committee, and strategic advisory committee are the first administrative bodies. [13]
2. Zonal, regional, and periphery PV centers make up the national PV center [13].
3. ADRs monitoring center: MCI-approved medical college, independent institution, and private hospital/health center. [13]

PVPI's objectives are as follows:

1. To create and execute an Indian pharmacovigilance system [24, 25]
2. To urge medical personnel to disclose any negative effects from medications, vaccinations, medical equipment, or biological products[24,25]
3. Gathering data and case reports.[24,25]
4. All medical colleges that received approval from MCI ran the programmes.[24,25]

Long-term targets:

1. To extend the pharmacovigilance initiative to all Indian hospitals and public health centers
2. To require healthcare practitioners to disclose ADRs.
3. To create a mechanism for electronic reporting.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.301
Volume 3, Issue 12, May 2023

Involvement of PV in Clinical Pharmacology

For a variety of reasons, academic departments and university hospitals have proven to be successful locations for national and regional pharmacovigilance centers. They consist of the following:

1.In that setting, epidemiology and experimental and clinical pharmacology can be easily linked.[17]

2. In addition, the location facilitates peer review of adverse reaction data and gives university departments' quick access to hospital specialists. A National Centre advisory panel with scientific and medical experts can be established from such a base.[17]

3. Information gleaned from impromptu reports can be incorporated into undergraduate and graduate health sciences instruction [17]

4. Health professionals are likely to feel comfortable reporting issues and therapeutic quandaries to an academic unit with which they are familiar.[17]

5. Strategies for medical education that work well include academic detailing[15] and feedback.Reminders and asking recognised professionals for assistance with specific problems are most easily attainable in these situations.[17,16]

Major challenges in Pharmacovigilance

Due to lack of priority, pharmacovigilance faces difficulties in the delivery of healthcare. Another major problem is the bias of the medical delivery system's drug.[29]The implementation of the pharmacovigilance project is being hampered by inadequate staffing, inadequate budget, and mostly political constraints. Health experts are few in number but many prescriber, which presents additional difficulties. Another significant problem is the lack of continuous medical education and the challenges in finding pharmacological information. Numerous drug varieties being available in households and untrained individuals dispensing medications are two issues with drug use that contribute to hurdles in India's pharmacovigilance programme [30] Injection usage is prevalent, antibiotic use is high, treatment guidelines are inadequate, and prescribing practices are poor, among other issues with drug use. Diseases such as TB, HIV/AIDS,

IV. CONCLUSION

India is the world's fourth-largest pharmaceutical producer, and it is increasingly becoming a significant center for clinical trials. ADRs and can produce signals for rare and extremely rare types of ADRs. We can make our world safer than it is currently if all medical practitioners view ADR reporting as an ethical need and a substantial responsibility. However increased awareness and training of public and medical professions, framing of strong regulations for reporting of ADRs, effective implementation and collaborative efforts between government, regulatory officials, pharmaceutical companies, health care professionals and patient may lead to an effective pharmacovigilance system in India to insure the availability of safe medicines to public.

REFERENCES

[1] Pipasha, B. , Arun , K.B.,„Setting standards for proactive pharmacovigilance in India : The way forward", Indian J pharmacol , 2007; 39(3): 124-128.

[2]Kumanan, R., Sudha, S., Vijayashre, P., Charumath, S., Gowridevi, K.C., Mahesh, M. „Imperative Approach on pharmacovigilance in Indian systems of medicines", International journal of pharma sciences and Research (ijpsr), 2010; 1(9): 378-390.

[3]WHO. Policy Perspectives on Medicines. Geneva: WHO; 2004.

[4] http://dx.doi.org/10.21474/1JARO1/10289

[5] Skalli S, SoulaymaniBencheikh R. Safety monitoring of herb-drug interactions: A component of pharmacovigilance. Drug Saf 2012;35(10):785-91.

[6] Arnott J, Hesselgreaves H, Nunn AJ, Peak M, Pirmohamed M, Smyth RL, et al. What can we learn from parents about enhancing participation in pharmacovigilance? Br J Clin Pharmacol 2013;75(4):1109-17.

[7] Kumar, S.; Baldi, A. Pharmacovigilance in India: Perspectives and Prospects. Journal of Drug Delivery and Therapeutics2013, 3 (4), 237–246.

[8] Tyagi, P. Pharmacovigilance - A Review. 2017, 5 (1), 12–17.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.301
Volume 3, Issue 12, May 2023

[9] Patel, A.; Giles, D.; Thomas, V.; Pm, G.; Patel, R. Pharmacovigilance: A Review. International Journal of Pharmaceutical & Biological Archives 2011, 2 (6), 1569–1574.
[10] Danan G, Benichou C. Causality assessment of adverse reactions to drugs--I. A novel method based on the conclusions of international consensus meetings: Application to drug-induced liver injuries. J ClinEpidemiol 1993;46(11):1323-30.
[11] Agbabiaka TB, Savovic J, Ernst E. Methods for causality assessment of adverse drug reactions: A systematic review. Drug Saf 2008;31(1):21-37.
[12] Macedo AF, Marques FB, Ribeiro CF, Teixeira F. Causality assessment of adverse drug reactions: Comparison of the results obtained from published decisional algorithms and from the evaluations of an expert panel. Pharmacoepidemiol Drug Saf 2005;14(12):885-90.
[13]. Wanmali, V. V; Brahmane, R. I.; Gupta, R. Review Article PHARMACOVIGILANCE.
[14] Liu, X. Identifying Adverse Drug Events from Patient Social Media: A Case Study for Diabetes. 1–12.
[15] Soumerai SB and Avorn J. Principles of educational outreach ("academic detailing") to improve clinical decision taking. Journal of the American Medical Association 1990; 263: 549-556.
[16] Davis DA, Thomson MA, Oxman AD and Haynes RB. Changing physician performance: A systematic review of the effect of continuing medical education strategies. Journal of the American Medical Association 1995; 274: 700-705
[17] The Importance of Pharmacovigilance (Report). World Health Organization. 2002. ISBN 9241590157. Retrieved December 31, 2020.
[18].https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3221205/#:~:text=The%20Purpose%20of%20Pharmacovigilance&text=The%20specific%20aims%20of%20pharmacovigilance,to%20the%20use%20of%20medicines
[19]. [**SangitaFulchandPawar and VikramLimbajiMusale (2020);** PHARMACOVIGILANCE: A REVIEW *Int. J. of Adv. Res.* **8** (Jan). 235-243] (ISSN 2320-5407). www.journalijar.com http://dx.doi.org/10.21474/IJAR01/10289.
[20] Fornasier G, Francescon S, Leone R, Baldo P. An historical overview over Pharmacovigilance. Int J Clin Pharm. 2018 Aug;40(4):744-747. doi: 10.1007/s11096-018-0657-1. Epub 2018 Jun 15. PMID: 29948743; PMCID: PMC6132952.
[21] McBride WG. Thalidomide and congenital abnormalities. Lancet. 1961; ii:1358.
[22]Routledge P. 150 years of pharmacovigilance. Lancet. 1998;351:1200–1201. doi: 10.1016/S0140-6736(98)03148-1.
[23]The importance of pharmacovigilance. Geneva: World Health Organization; 2002.
[24]Livio F, Renard D, Buclin T. Pharmacovigilance. Rev Med Suisse 2012;8:116-9
[25] WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO 2004.
[26]WHO. Safety monitoring of medicines. Guidelinesfor setting up and running a pharmacovigilance centre. Geneva, World Health Organization, 2000.
[27]Department of CDSCO, Ministry of health &family welfare, Government of India: Protocol fornational pharmacovigilance programme,November 2004.
[28]Ghewari, P. S. Salunkhe, S. S.; Bhatia, N. M.. Killedar, S. G. Strategies and Current Scenario of Pharamcovigilance in India. 2014, 1 (3).
[29]Wal, P.: Mehra, R.: Rizvi, S.; Vajpayee, R. Review Article PHARMACOVIGILANCE: NEED FOR INDIAN PHARMA INDUSTRY. 2015, 6(11), 740-743. 14. Singh, S.: Prakash, J. Goyal, N., Tomar, R.: Chaudhary, A. Review on Pharmacovigilance. 2015, 4 (06), 266- 275.
[30]Liu, X. Identifying Adverse Drug Events from Patient Social Media: A Case Study for Diabetes. 1-12.