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Pharmacovigilance: A Comprehensive Review

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ABSTRACT:

Pharmacovigilance, which includes identifying, assessing, comprehending, and preventing pharmacological side effects, is essential for patient safety. This review addresses its relevance, necessity, operation, purpose, and significance. It also increases awareness of adverse drug reactions (ADR) in India.

KEYWORDS: Pharmacovigilance, Adverse drug reaction, Clinical trial, Drug safety

INTRODUCTION:

First launched in the late 1960s, pharmacovigilance is a dynamic clinical and scientific field that is heavily regulated worldwide and focuses on monitoring, detecting, evaluating, comprehending, and preventing adverse drug responses or related issues.

With 1.27 billion people, India is the world's fourth-largest producer of prescription medications, accounting for 3-7% of hospital admissions in the US and 1% in England.

Pharmacovigilance, according to the World Health Organization (WHO), is the science and practice of identifying, evaluating, comprehending, and averting side effects or other issues associated to medications.

A formal adverse drug reaction (ADR) monitoring system was proposed in 1986, marking the beginning of pharmacovigilance in India. Nonetheless, in 1997, India became a member of the Adverse Drug Reaction Monitoring Program of the World Health Organization (WHO), which established three ADR monitoring centers. These centers, which reported ADRs to the drug regulatory body, were mostly located at teaching hospitals. Under the direction of the National Pharmacovigilance Advisory Committee, the WHO-sponsored and World Bank-funded National Pharmacovigilance Program for India was founded in 2005. To gather data from the nation, two zonal centers were set up.

One important facet of India's pharmaceutical sector is the history of pharmacopoeia:

A botched ADR scrutiny program in 1997 hampered the World Health Organization's (WHO) 1986 implementation of a formal Adverse Drug Reactions (ADR) monitoring system in India.

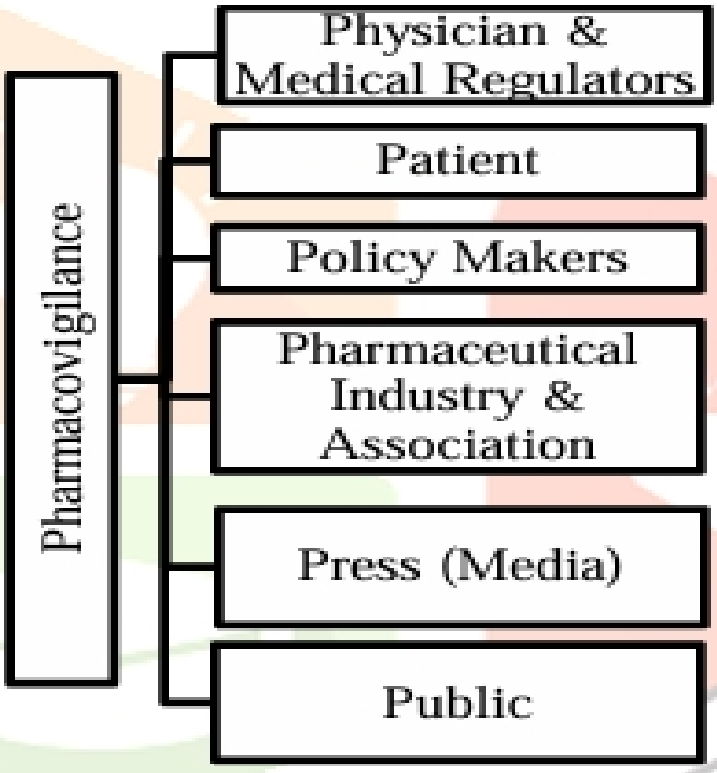
GOAL:

In order to evaluate the adverse effects of medications, including oral, parenteral, and intravenous medications, and to avoid needless side effects, pharmacovigilance is essential. Involving physicians, nurses, other healthcare professionals, residents, and patients, it entails determining and evaluating the source of the injury. It encourages comprehension, instruction, and clear communication in order to avoid needless negative impacts and injury.

This text's goal is to present a thorough summary of the subject:

By tracking side effects, enhancing public health and safety, and promoting the safe, sensible use of medications, pharmacovigilance seeks to prove the effectiveness of drugs.
Promoting economical drug usage, improving knowledge, instruction, and clinical training in pharmacovigilance, and improving efficient public relations are the main goals.

- Establishing a thorough method for reporting patient safety across the country is the aim.
- Finding and analyzing the new signal (ADR) from the reported cases is the goal.
- Providing evidence-based information about the safety of medications is the goal.
- The purpose of the study is to assess the marketed drugs' benefit-risk ratio.
- The goal is to support regulatory bodies in making decisions on the use of pharmaceuticals.
- In order to reduce potential dangers, the goal is to provide all stakeholders with safety information on the use of medications.
- The objective is to become a preeminent national hub for pharmacovigilance initiatives.
- The objective is to provide other national pharmacovigilance organizations with training and consulting assistance.
- Working together with other national centers is intended to facilitate information sharing and efficient data management.



SIGNIFICANCE :

In order to save patients needless suffering, pharmacovigilance—which is backed by physicians, pharmacists, and other health professionals—is an essential monitoring mechanism for the safety of new pharmaceutical medications.

The following succinctly describes the importance of pharmacovigilance:

- One of the most important components of pharmaceutical safety is the safety monitoring of pharmaceuticals.
- Studies that assess the efficacy of different therapies or interventions are known as clinical trials.
- Pharmacoepidemiological research is essential for comprehending how different chemicals affect different body processes.
- The assignment is to create a series of cases.
- Case reports are an essential resource for comprehending and resolving a wide range of problems and circumstances.
- An essential component of comprehending and evaluating different kinds of instances is the examination of case series.
- Product-event combinations are found through the application of data mining.

The reporting and functioning process is the main topic of the text:

In India, pharmacists are required to carry out pharmacovigilance duties, which include gathering, reporting severe adverse reactions, and preparing, with different organizational levels and units participating in the process.

"Need" is an essential component of any business:

Drug development is a complicated process that takes time and pharmacovigilance. It entails implementing suitable risk controls and promptly monitoring new adverse drug reactions (ADRs). With detailed information on usage in particular populations and drug interactions, new medicines are assessed for efficacy and protection in real-world settings.

In the medical field, a pharmacist's function in medicines is vital:

- ADR announcements shouldn't be the only way a pharmacist demonstrates their dedication to pharmacovigilance.
- Helping patients with their current medication regimen, past allergic status, and any drug interactions is the main goal.
- Distributing social insurance offices and counseling medical professionals on appropriate medication collection are the responsibilities of pharmacists.
- The importance of pharmacists in fostering wellbeing is becoming more widely acknowledged in the executive framework.
- recording every suspected reaction that is reported.
- recording every suspected reaction that is reported.
- Participation in the pharmacovigilance system is essential because 73% of pharmacists operate in hospital or pharmacy settings, where they encounter incidents involving ADRs or drug-related issues.

The Indian Pharmaceutical Program has a wide range of applications:

- According to the main notification, ADR, clinical trials are the primary method used to determine drug safety and efficacy expertise before to drug registration and sale within the nation.
- Vital reactions that are slow to develop or infrequent may be undetected in clinical trials.
- Contributing causes include the emergence of spontaneous ADR coverage mechanisms, global medical literature, and regulatory agencies' activities in other nations.
- The goal of India's pharmacovigilance program is to assess and utilize data to support regulatory actions that address hazards to the public and medical professionals.
- Contributing causes include the emergence of spontaneous ADR coverage mechanisms, global medical literature, and regulatory agencies' activities in other nations.

Pharmaceuticals employ a methodical approach to treating a variety of illnesses:

Researchers have created a number of techniques to determine causality in adverse drug reactions (ADRs) based on criteria such prior homogenous events, non-drug related causes, in-vitro and in-vivo testing, and chronological linkage.

1. Dangaumou’s French method
2. Kramer et al. method
3. Balanced assessment method.
4. Naranjo et al. method (naranjo scale).

One essential idea is the basic language employed in the pharmaceutical industry:

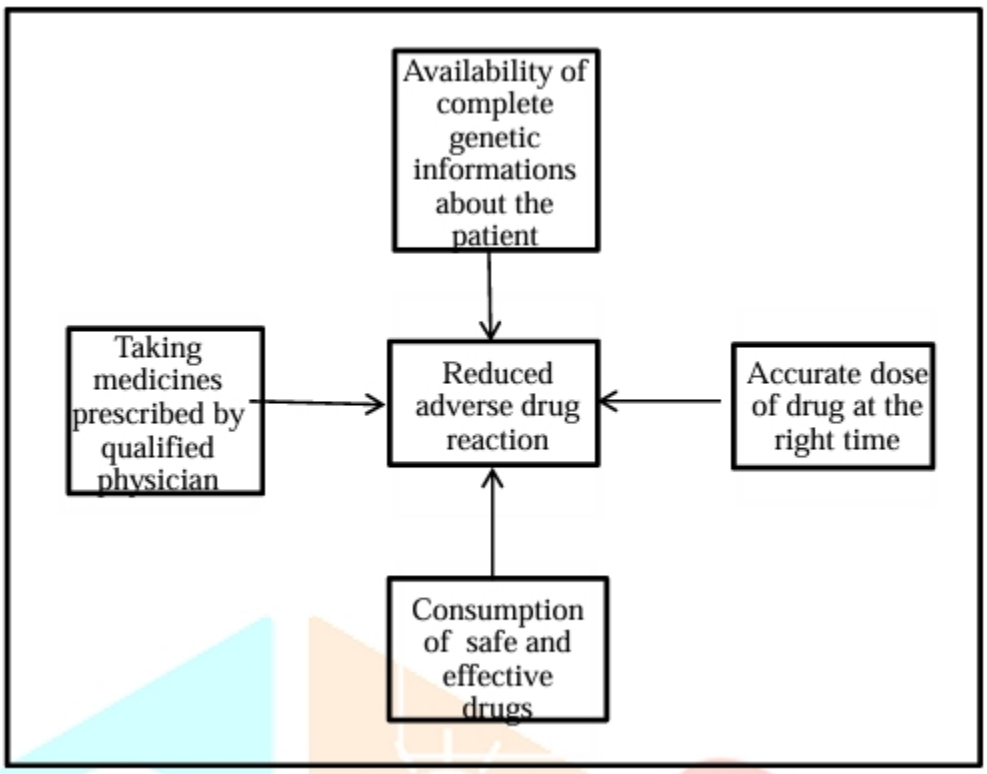
- **The term "adverse drug reaction" (ADR) describes a drug or substance's negative effects on another individual:**
  Unintentional, unpleasant reactions to medications used for diagnosis, treatment, disease prevention, or altering physiological function are known as adverse drug reactions, and they can result in both short-term and long-term hospitalization as well as death.

- **An adverse drug event (ADE) is when a substance enters the body and causes negative side effects:**
  Unwanted medical events that occur during the use of pharmaceutical products could not always be related to the medication.

❖ **ADR Influencing Factors:**

Patient related factor

- Age
- sex
- Total number of medications
- The person has had negative drug reactions in the past.
- concomitant conditions that affect the liver, heart, and kidneys.
- The phrase "genetic influence" describes the hereditary components that affect a person's behavior and growth.



The benefits of ADR monitoring are covered in the article:

Patients suffer, morbidity and mortality rise, and society bears the costly burden of adverse drug reactions (ADRs), which frequently go unreported.
Numerous advantages can be obtained from an ADR monitoring and reporting program.

1. Information about the safety and quality of pharmaceutical products is provided by the organization.
2. Plans for risk management are started by the procedure.
3. The tool helps evaluate compliance with Alternative Dispute Resolution (ADR) and avoids expected negative effects.

CONCLUSION:

By detecting, assessing, and reducing safety concerns, pharmacovigilance plays a critical role in drug regulation to safeguard the public's health. In order to minimize adverse medication responses, it keeps an eye on post-marketing surveillance, drug safety, efficacy, quality, and accuracy of drug information. Nonetheless, the limits of pre-marketing safety data are acknowledged. Rapid marketing and publicity increase pressure on the pharmaceutical sector to expedite approval times for new drugs. Underreporting of adverse medication responses is still a significant problem, despite the fact that pharmacovigilance is crucial in underdeveloped nations.

❖ **REFERANCES:**

1) Gawai PP," Introduction and Evaluation of Pharmacovigilance for beginners", International Journal of Scientific Reports, September 2020, 6 (10), 425-432.

2) Jeetu G.,Anush G., " Pharmacovigilance: worldwide Master key for drug safety monitoring",General pharmacy, J. Younge pharm ,Vol 21,3.

3) Gupta N, Behmani K and Jangra A." Pharmacovigilance, International Classification of Disease and Adverse Reaction Reporting Tools used in the United States of America and Europe", Clinical practice, 2020, Vol-17(2), 1466-1477.

4)) Nimesh S, Chaudhary A, Sharma A and Negi KD," Pharmacovigilance program of India: A review," ACTA Scientific Pharmaceutical Sciences, Vol- 3, issue 9, September 2019.

5) Muhammad Akhtar Abbas Khan, Saima Hamid, and Zaheer-Ud-Din Baber," PV in High- income countries: Current Developments and a Review of Literature, Pharmacy" 2023, 10-11.

6) Soni R, Kesari B ," A Review on Pharmacovigilance" , International Journal of Pharm Science Review and Research, 26 (2), May- June 2014, 237-241.

7)) Rajgopal J, Shilpi K, Srivastav AK," Pharmacovigilance: A review Article", Innovare Journal of medical Science, 4 (4), July 2016, 6-7.

8) Thobari J, D Pharm, PhD," Importance of Pharmacovigilance for Medicine" Gadjah MADA, University Yogyakarta, Indonesia , Adams CP, Brantner VV,(2010), Spending new drug development, Health Econ, 19:130-141 (2010).Clinical practice (2020), 17(2).1466-1477.

9)) Rohilla A, Singh N, Kumar V, Sharma M , Dahiya A, Ashok Kushnoor, " Pharmacovigilance : Needs and objectives," Journal of Advanced Pharmacy Education and Research Oct- Dec 2012, 2 (4), 201-205.

10) Kumar S., Baldi A ," Pharmacovigilance in India: Perspective and Prospects", Journal of Drug Delivery and Therapeutics, 2013, 3(4), 237-246.

11)) I. Lakshmi Anusha*, M.Aashritha, K.Teja and R.Sridhar, "A Review of Pharmacovigilance and its important",World Journal of Pharmaceutical Sciences, 6 (1), 300-310.

12) Mohiuddin AK ," Pharmacovigilance: Present scenario and future goal,"Indian journal of Pharmacy practice, Vol- 12, Issue 1, Jan- Mar 2019.

13) Beninger P, M D, MBA , "Pharmacovigilace: A overview," Clinical Therapeutics ,Vol- 40, Nov.2018,12.

14) Ahmed A M, Izham IM, Subish P," The Importance of the Consumer Pharmacovigilance System in Developing Countries: A case of Malaysia," Journal of Clinical and Diagnostic Research 2010, August,(4), 2929-2935.

15) Jorl Fossouo Tagne, B. Biomed, Reginal Amin Tokon, B Biomed , AACPA; Thu Ja Dang, Rachael Medonaid, Nilmini Wickramasinghe, Grad Dipmgtst, " Reporting , Monitoring and handling of adverse drug reactions in Australia: Scoping Review", JMIR public health surveill 2023, Vol 9, 40080 .

16) Thobari J," Importance of Pharmacovigilance for Medicine" Gadjah MADA, University Yogyakarta, Indonesia , Adams CP, Brantner VV,(2010), Spending new drug development, Health Econ, 19:130-141 (2010).Clinical practice (2020), 17(2),1466-1477.

17) Pawar S and Musal V," Pharmacovigilance: A Review," International Journal of Advanced Research, 8(01), 235-243.

18) Campbell JE, Williams MG, M. G.Lec, "A Review of Pharmacovigilace", West Indian Med J. 2014; 63(7):771.

19)) Patil L, Patil S, Hubale S, Mane R, "Pharmacovigilance - A Review", International Journal of Scientific Research in Science and Technology, 1(3), 21.

20) https://www.semanticscholar.org/paper/Pharmacovigilance-Programme-of-India%3A-Recent-and-Kalaiselvan-Thota/5018295364c26498240e0bbb9466ff38ebe7bb84.

21) https://www.slideshare.net/ramesh_2417/pharmacovigilance-and-role-of-pharmacist.

22) R.D. Kulkarni; Med Toxicol., 1986, 1, 110-3.

23) Protocol for National Pharmacovigilance Program, CDSCO, Ministry of Health and Family Welfare, Government of India, November 2004.

24) Bovine Spongiform Encephalopathy (BSE) http://www.fda.gov/cber/BSE/BSE.htm, Variant Creutzfeldt-Jakob disease, http://www.who.int/inf-fs/en/fact180.htm.

25)] Surveillance of adverse events following immunization, Field guide for managers of immunization programmes, Geneva, WHO, 1997.

26) Immunization Focus, WHO Regional Office for the Western Pacific, Manila, WHO 1999.

27)] M.K. Ang-Lee, J. Moss, C. Yuan, J. the American Medical Association, 2001, 286,208-216.

28) J. Barnes, S.Y. Mills, N.C. Abbot, M. Willoughby, E. Ernst, British J. Clinical Pharmacology, 1998, 45(5), 496-500.

29) J.P. Collet, N. MacDonald, N. Cashman, R. Pless, Bulletin of the World Health Organization, 2000, 78(2), 178-85.

30) Managing the Risks from Medical Product Use: Creating a Risk Management Framework. http://www.fda.gov/oc/tfrm/1999report.html.

31) D.A. Davis, M.A. Thomson, A.D. Oxman, R.B. Haynes, J. the American Medical Association, 1995, 274, 700-705.

32) The Erice Report. International Conference on Developing Effective Communications in Pharmacovigilance, Erice, Sicily, Sep. 1997, 24-27.

33)] F. Davidoff, C. DeAngelis, J.M. Drazen, et al., J. the American Medical Association, 2001, 28(10), 1232-4.

34) R.H.B. Meyboom, A.C.G. Egberts, F.W.J. Gribnau, Y.A. Hekster, Drug Safety, 1999, 21(6), 429-447.

35) http://www.citizen.org/hrg/Publications/1520.htm

36) N.J. White, Proceedings of the XXVIIth CIOMS Conference, Geneva, Switzerland 14-15 Sep. 1993, Z. Bankowski, J.F. Dunne (eds) CIOMS, Geneva 1994, 126 –135.

37) J.P.A. Ioannidis, J.Lau, J. the American Medical Association, 2001, 285 (4), 437-443

38)] Editorial, Safeguarding participants in clinical trials, Lancet, 2000, 355 (9222), 2177.

39)] M. Angell, New England J. Med., 2000, 342 (13), 967-969.

40) Editorial, Safeguarding participants in clinical trials, Lancet, 2000, 355 (9222), 2177.