IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Review on Concept of Pharmacovigilance

Praveen V. Patil, Sanjay K. Bais, Swapnil B. Chandanshive
Fabtech College of Pharmacy, Sangola, Solapur, Maharashtra, India
swapnilchandanshive11@gmail.com

Abstract: *In order for clinical practise, public health efforts, and effective drug regulatory systems to function effectively, pharmacovigilance—the term used to describe the processes for recording and analysing adverse drug reactions—must be implemented. A high level of skill is required to grasp pharmacovigilance in order to swiftly identify pharmacological dangers and to defend the product against an unjustified withdrawal. The volume of data handled has increased as a result of the reporting of number of the adverse drug reactions (ADRs). The present global network of pharmacovigilance centres, which is supervised by the Uppsala Monitoring Center, would be strengthened by an independent review procedure. This would consider disputed and important pharmaceutical safety problems that might have a detrimental effect on public health across international borders. Recently, the main goal of pharmacovigilance has been to identify previously unrecognised or poorly understood adverse drug reactions. Clinical research must include pharmacovigilance, which is becoming more and more popular in many countries. To improve drug safety and monitoring, pharmacovigilance faces significant obstacles at the turn of the millennium. Currently, a number of pharmacovigilance centres are engaged in this global effort to monitor the safety of pharmaceuticals. We'll discuss medication safety, the role of worldwide pharmacovigilance centres, the benefits and downsides of pharmacovigilance, and how the healthcare sector can employ it in the future in this review. (4) Pharmacovigilance encourages the correct and safe use of drugs. Adverse drug responses (ADRs) must be reported spontaneously, and this is a crucial part of pharmacovigilance. ADRs are, nonetheless, considerably underreported. In developing nations, adverse medication responses are now a significant issue. Understanding pharmacovigilance could serve as the foundation for actions meant to increase reporting rates and lower ADRs. (1).*

Keywords: Drug safety, erice declaration, pharmacovigilance, Adverse reaction, drug, pharmacovigilance, reporting

I. INTRODUCTION

The medications have altered how diseases are managed. The known risk of medication therapy is unpleasant reactions, despite all the benefits of pharmacotherapy. A prevalent and frequently avoidable cause of disease, disability, and death is an adverse drug response (ADR). According to one definition, an ADR is "An appreciably harmful or unpleasant reaction, that is resulting from a the intervention related to the use of a medicinal product, that is predicts risk from the future administration and the warrants prevention or a specific treatment, or an alteration of the dosage regimen, or the withdrawal of the product." (1)

Pharmacovigilance is described as "the science and practises connected to the detection, evaluation, comprehension and prevention of adverse effects of a drug or any other probable drug-related issues" in one definition.

Effective drug regulating systems, public health initiatives, and clinical practise all depend on it.

The committee formed by the Lancet to report on anesthesia-related deaths in Britain and its colonies is one of the earliest pieces of evidence of the formation of a system to monitor medication safety.

In response to the 1848 death of a 15-year-old girl who had received a chloroform anaesthetic for the removal of an ingrown toenail, the committee was established. (1)

Thalidomide was originally produced in 1954, made public in 1956, and was extensively recommended as a non-toxic therapy for nausea and morning sickness. Thalidomide was taken off the market by its manufacturer on November 25, 1961. Between 6000 and 12000 infants are thought to have been born with major congenital defects as a result of maternal thalidomide use.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Eleven nations joined the World Health Organization (WHO) in 1968 to establish a Pilot Research Project for the International Drug Monitoring. These nations were Australia, Canada, Czechoslovakia, Germany, Netherlands, Ireland, New Zealand, Sweden, the United Kingdom, and the USA.

A report that served as the foundation for the current global network of national centres working together on the WHO programme was issued in 1972(1).

II. OBJECTIVES

It is still essential to enhance patient care and safety when using medications in conjunction with medical and paramedical measures.

The goals of pharmacovigilance include demonstrating the efficacy of drugs by tracking their adverse effects over time from the lab to the clinic; improving the public health and safety in relation to drug use; encouraging the safe, prudent, and economical use of drugs; promoting knowledge,a education, and a clinical training in pharmacovigilance; and effectively communicating to the general public. (14)

Along with creating strategies and procedures for gathering and analysing data from patients and doctors, it also provides information to consumers, practitioners, and regulators on how to utilise medications effectively. This information leads to the goals of pharmacovigilance studies. (10,14)

2.1 Types / Methods

1. Passive surveillance
2. Active surveillance
3. Comparative observational studies
4. Clinical studies

A. Passive Surveillance

a. Spontaneous reporting
b. Stimulated reporting
c. Intensified reporting
d. Targeted spontaneous reporting

a. Spontaneous Reporting

- A working ADR system that tracks the safety of all drugs.
- A Health care professionals, pharmaceutical corporations, or patients voluntarily submit reports to the pharmacovigilance centre.
- Systems for reporting are based on suspected ADRs.
- A Data are gathered and stored in a central or local database.
- The reporting form includes information about the reporter, the patient, and the suspicious product.
- the specifics and explanation of an alleged reaction.
- This information is based on the possible medication side effects.
- Cases are not systematically gathered.(2)

b. Intensified ADR Reporting

- This is an expansion of a software for unprompted reporting.
- It attempts to improve early post-marketing ADR reporting of the particular drugs.
- The process is typically followed for novel medications, biological medications, and medications that need extra research.
- Example: Antiretroviral drugs administered through a different programme (2)

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

c. Targeted Spontaneous Reporting

- This approach is used to discover more about a medicine's population-based ADR profile.
- To calculate the prevalence of a known adverse drug reaction (ADR) in a population.
- Monitoring renal toxicities associated with antiretroviral therapy regimens based on tenofovir, for instance.(2)

B. Active Surveillance

- Active surveillance employs a continuous, pre-planned approach as opposed to passive observation in an effort to determine the precise number of undesired events. In general, compared to a passive reporting system, an active monitoring system is more likely to be able to gather significant data on individual adverse event reports. (3)

a. Sentinel Sites

A By checking medical records or speaking with patients and physicians in portion of sentinel sites, active monitoring may be accomplished to guarantee that comprehensive and accurate data on the reported adverse events are acquired from these locations.

The selected locations can offer data from certain patient subgroups that aren't available in the passive spontaneous reporting method.(3)

b. Active pharmacological vigilance monitoring of medical events. This approach is used in cohort-based, prospective, and observational studies. Patients may be identified using computerised or automated health insurance claims for the purpose of tracking drug occurrences.

With proper monitoring, a single prescription or series of prescriptions might be created. To collect outcome data, a follow-up questionnaire may be issued to each prescribing doctor or patient at predetermined intervals. (3)

c. Registries

The registry is a list of patients with the same representation who have presented (s). This picture could show a situation or a particular exposure (medicine registry). Data may be gathered prospectively for both types of registrations—which only differ in the patient data of interest—by utilising standard questionnaires.

Information on pharmacological exposure as well as other features of clinical conditions can be gathered from the registries for the blood dyscrasias,a severe cutaneous reactions, or congenital malformations. In a case-control research, cases found through a disease registry might be compared to controls chosen from patients in the register with associated disorders or from patients outside the registry to determine how much drug exposure each group of patients experienced.

d. Cross-sectional study

A cross-sectional study is one that gathers information about patients' residents throughout a specific period of time, regardless of exposure or disease status.

Disadvantage:

the time link between exposure and result cannot be directly addressed in cross-sectional studies.

In ecological analysis, it is used to track the basic link between exposure and result. Studies that are cross-sectional are most useful when exposures do not alter over time. (3)

e. Case-control study

A case-control study locates cases of disease (or events). Then, carefully chosen individuals from the population that served as the case's source are utilised as controls, persons with the condition, or people in whom the relevant event has not occurred.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

The controls should be the selected such that the exposure prevalence of the source population may be compared to that of the controls. The exposure status of two groups is then compared using the odds ratio, which is an estimation of relative risk of illness in the two groups. (3)

f. Cohort Study

To track the occurrence of the disease, the population that is at risk for it is watched throughout time. Each patient's follow-up period includes access to information on exposure status. A patient may be exposed to the medication during follow-up at one point but not at another.

Cohorts of interest are chosen based on their history of medication use and are tracked throughout time in the numerous cohort studies on medicine exposure. Cohort studies can be useful when it's important to comprehend adverse event incidence rates in addition to relative risks.

Due to the fact that they are created for the administrative or billing purposes, they could not contain all the relevant information necessary for a certain research project, such as verified diagnostic data or laboratory results. Since patient medical data can be used to generate and confirm test findings and diagnoses, one should be aware of the privacy and privacy requirements that apply to this information. (3)

g. Specific clinical research

It may occasionally be necessary to undertake pharmacodynamic and pharmacokinetic studies to determine if a certain dose recommendation would increase the likelihood of unfavourable patient outcomes. Additionally, depending on the pharmacological properties and predicted usage of the medication in general practise, it may be useful to conduct specific studies to assess possible drug-drug and food-drug interactions.

This approach has the potential downside of having an outcome measure that is too brief, which may affect the trial's overall quality and relevance of its findings. Similar amounts of resources are required for large, simplified experiments. (3)

C. Comparative Observational Studies

A cross-sectional study: Regardless of exposure or disease condition, the information gathered from the patient population may be traced to a specific point in time.

A case control study: Cases/patients with adverse events are found utilising an existing data base or by using information gathered especially for the study.

Cohort research (2)

D. Cohort Event Monitoring

A cohort is a collection of individuals who have a similar trait, such as having used drugs within a specific time frame.

It is an observational prospective cohort study of adverse outcomes linked to one or more medications.

Prior to the start of the medication's treatment, the study was organised.

Every patient has had their adverse events monitored ever since they began receiving therapy, and all of them have been documented.

Anti-retroviral drug ADR monitoring, as an example.(2)

Pharmacovigilance Programme of India (PvPI)

Before a medication is approved for use and sold in a country, its safety and efficacy are evaluated during clinical trials. Trials aim for persistently unfavourable responses.

Clinical trials might miss some significant reactions, like those that take a while to manifest or those that happen seldom.

Clinical trials are conducted under carefully monitored conditions, which may not always be representative of real-world usage. In order for a medication to be deemed safe, its expected benefits must outweigh any possible risks of adverse reactions. For example, pharmacovigilance is crucial.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Pharmacovigilance uses data from a variety of sources to screen the safety of medications. It includes a method for reporting accidental drug reactions (ADRs); medical literature that has been published internationally; and regulatory bodies' actions in other nations.

Adverse medication reactions can have significant societal and economic repercussions, and using adequate risk management can have a favourable return on investment.

The PvPI's goal is to gather data, process it, and analyse it in order to draw conclusions that can be used to suggest regulatory responses in addition to informing healthcare professionals and the public about dangers.(3,13)

Implementation of PvPI

In order to improve patient safety, the IPC presumptively saw a need for the local hospital-based centres to be established across the country.

In order to ascertain any new information regarding the safety profile of the medications, it was important to monitor both previously known and unrecognised side effects.

It was essential to have a standardised and effective pharmacovigilance and drug safety monitoring programme for the country in a huge country like India with a population of over 1.2 billion and it is vast ethnic variability, different disease prevalence patterns, practise of different systems of medicines, and different socioeconomic status.(3)

Short-term objectives

- To initially enrol all MCI-approved medical institutions in the programme servicing India's north, south, east, and west.
- To develop and implement an Indian pharmacovigilance system.
- To compel health professionals to record any unfavourable effects of drugs, vaccines, devices for treating patients, and biological products.
- To compile statistics and case studies (3)

Long-term objectives

- To expand the pharmacovigilance programme to all public health programme centres, private hospitals, and government hospitals across India.
- To create and implement a system for electronic reporting (e-reporting)
- To make ADR reporting required of healthcare practitioners;
- To foster a culture of reporting among healthcare professionals (3)

Causes of the failure of implementation of pharmacovigilance in India

A As a result of the enormous number of new medications that will be introduced to the market, the pharmacovigilance system has to be enhanced in order to protect the Indian people from any potential harm that any of the new pharmaceuticals may cause. The following are some of the various obstacles and difficulties that have made it difficult to develop a reliable pharmacovigilance system:

1. The pharmacovigilance systems are not adequately financed or organised to assist patients and the general public in a huge country like India.
2. The data collected up to this point at zonal centres from a number of peripheral centres is typically mediocre and improperly handled. The precise incidence of particular ADRs is unknown because there hasn't been enough research done on them in India.
3. Healthcare professionals' involvement, expertise, and enthusiasm for pharmacovigilance (in rural areas, urban areas, and hospitals) are minimal. The department of health doesn't do anything to encourage greater training or to raise people's awareness of the need for better reporting.
4. A lot of consumer organisations in India encourage patients to report any bad responses they have, despite the fact that there is no information allowing consumers to file ADRs to the regulatory authorities directly.(3)

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Update on the Pharmacovigilance Programme of India

Pharmacovigilance, a branch of pharmaceutical research, is concerned with the identification, assessment, comprehension, and prevention of negative consequences, particularly the long-term and short-term side effects of drugs (WHO-Essential Medicines and Health Products, 2002).

It has been noted that medications that have worked well for a vast patient group frequently don't function for some patients of diverse ancestries.

Eg When initiating treatment with carbamazepine, those with Asian heritage are at higher risk for significant cutaneous responses.

Therefore, a clinical trial with rigorous pharmacovigilance monitoring is required in the population of different races and ethnicities, even though the drug had already received approval in another nation.(6,17)

In 1986, 12 regional offices in India launched a formal ADR monitoring system. And in 1997, India joined the WHO Program for International Drug Monitoring, which is run by the Swedish Uppsala Monitoring Center (UMC).

At the time of their establishment, the six regional centres for ADR monitoring in the nation were located in Mumbai, New Delhi, Kolkata, Lucknow, Pondicherry, and Chandigarh. Of these six centres, only Mumbai and New Delhi were operational, which had a negative impact on the amount of ADRs that were reported on their own.

As a result, the National Pharmacovigilance Programme (NPvP) was created by the Indian government in November 2004 with a five-year World Bank grant of US$0.1 million (Gupta, 2010). Midway through 2009, the World Bank's funding for the programme came to an end, and it was briefly put on hold.

A Recognizing the need for improved ADR monitoring throughout the nation, the Health Ministry's agencies developed the Pharmacovigilance Programme of India in July 2010 as a nationwide revision of the ADR monitoring programme (PvPI).

The All India Institute of Medical Sciences in New Delhi served as the National Coordination Centre (NCC) for this national initiative until it was relocated to the Indian Pharmacopoeia Commission (IPC), Ghaziabad, in April 2011.

Dr. G. N. Singh, a Scientific Director of IPC, was nominated by a National Coordinator of PvPI to direct ADR monitoring across the country. Healthcare personnel from the Adverse Drug Reaction Monitoring Centers are detecting and disclosing ADRs in accordance with the PvPI on their own initiative (AMC). (6)

III. CONCLUSION

The only way to guarantee the safety of a medicine during its entire life cycle is through pharmacovigilance.

It is extremely important because clinical trials often struggle to find rare and extremely rare ADRs.

It is crucial for drug regulators to have knowledge and information about a medicine's safety before making a decision that will protect the public's health.

The majority of ADRs are reported by health care providers. Globally, there are significant percentages of underreporting.

It is today's biggest challenge.

Although attention to the dangerous unlabelled types of ADRs is more crucial, every report made by healthcare providers is still vital.

After the notion evolved, there were considerable effects on the pharmacovigilance to make it more functional, and day by day we are approaching the goal.

It is our duty to make sure the pharmacovigilance system is operating properly. Health care practitioners should view ADR reporting as a very essential responsibility rather than an additional clinical burden in order to promote safer drug usage globally.

Pharmacovigilance is essential in order to address the issues brought on by the expanding diversity and strength of medications. To ensure that the general public has the knowledge required to comprehend the information, it is imperative that side effects and medication toxicities be documented, investigated, and conveyed.

Despite the fact that a large quantity of data on their beneficial usage and adverse effects has already been acquired, the effective use of medications in certain populations, such as children, pregnant women, and the elderly, requires additional research.

IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Furthermore, it is presently important to enhance communication between health experts and the general public and provide regulators with the information they need to update recommendations for the use of pharmaceuticals., and educate health professionals on the benefits and dangers of the medications they recommend. (1)

Systems for pharmacovigilance are required to protect the public's health. A little amount of emphasis has been placed on developing data that can help a patient or healthcare provider make medication-related decisions. Pharmacovigilance's main objective is to gather and disseminate this information.

REFERENCES

[1]. Ankur Rohilla, Nishant Singh, Vipin Kumar, Amarjeet Dahiya, Review article of the Pharmacovigilance.
[2]. Dr. Satish Sharma. Method of Pharmacovigilance.
[3]. Pharmacovigilance Programme of India Duvvuru Ashok Kumar*, Languluri Reddenna, Shaik Ayub Basha.
[4]. Pharmacovigilance: A Worldwide Master Key for Drug Safety Monitoring. G.Jeetu and G.Anusha.
[5]. Olsson S. Pharmacovigilance training with focus on India. Ind J Pharmacol 2008:40:S28-S30.
[6]. An Update on the Pharmacovigilance Programme in India. Ratan J Lihite and Mangala Lakhar.
[7]. WHO Policy Perspectives on Medicines. Geneva: WHO; 2004. Geneva: World Health Organization.
[8]. Klepper MJ. The periodic safety updates report as a Pharmacovigilance tool. Drug Saf 2004; 27:569- 78.
[9]. Livio F, Renard D, Buclin T. Pharmacovigilance. Rev Med Suisse 2012; 8:116-9
[10]. WHO, Safety of medicines in public health programmes: Pharmacovigilance an essential tool,WHO,2006.
[11]. Skalli S, Soulaymani Bencheikh R. Safety monitoring of herb-drug interactions: acomponent of pharmacovigilance. Drug Saf 2012;35:785-91.
[12]. WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO 2004.
[13]. The importance of pharmacovigilance; safety monitoring of medical products, Geneva, WHO, 2002.
[14]. Policy Perspectives on Medicines. Geneva: WHO; 2004. Geneva: World Health Organization.
[15]. Livio F, Renard D, Buclin T. Pharmacovigilance. Rev Med Suisse 2012;8:116-9
[16]. Harmark L, van Grootheest AC. Pharmacovigilance: Methods, recent developments and future perspectives. Eur J Clin Pharmacol 2008;64:743-52.