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ARTIFICIAL INTELLIGENCE IN DRUG SAFETY AND PHARMACOVIGILANCE

Mrs. Deepa Chaudhary[1], Pankaj Kumar Prajapati[2]*, Sagar Shukla[3], Tarun Namdev[4]

[1]Pharmacovigilance Associate, RTC, AMC, AIIMS Bhopal.

[2,3]Department of Pharmacy, Barkatullah University Bhopal.

[4]Truba Institute of Pharmacy, Bhopal.

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***Corresponding Author**
Pankaj Kumar Prajapati
Department of Pharmacy,
Barkatullah University Bhopal.

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ABSTRACT

Pharmacovigilance focuses on monitoring the safety of medicines by identifying, evaluating, and preventing adverse drug reactions after a drug is introduced into clinical use. Adverse drug reactions are unintended and harmful effects that may occur following the use of medicines and can significantly affect patient safety and treatment outcomes. The conventional pharmacovigilance process includes several stages such as the collection of safety data, medical review of case reports, coding of clinical information, causality assessment, and submission of reports to regulatory authorities. While these activities are essential for drug safety, they often require substantial time, skilled manpower, and technical resources, which can limit efficiency in large-scale safety monitoring. Recent developments in artificial intelligence have provided innovative tools to address these limitations in pharmacovigilance. Machine learning and natural language processing techniques enable automated analysis of large and complex safety datasets obtained from sources such as electronic health records, spontaneous reporting systems, and patient-reported data. These technologies support faster identification of adverse drug reactions, early detection of safety signals, and improved prediction of drug-drug interactions. By reducing manual workload, Al allows pharmacovigilance professionals to focus more on clinical evaluation and decision-making, thereby enhancing the overall quality of safety assessments. 0In addition to improving operational efficiency, artificial intelligence supports a shift towards more proactive and real-time drug safety surveillance. However, the

integration of Al into pharmacovigilance also presents challenges, including concerns related to data privacy, algorithm bias, transparency, and regulatory acceptance. Addressing these issues through proper validation, ethical use, and regulatory alignment is crucial for the successful implementation of Al-based systems. This article discusses the role of artificial intelligence in strengthening pharmacovigilance practices and highlights its potential to improve accuracy, responsiveness, and public health protection.

KEYWORD: Artificial Intelligence, Pharmacovigilance, Adverse Drug Reactions, Causality Assessment, Status of PvPI, Trends of Al.

INTRODUCTION

Pharmacovigilance is a vital component of healthcare systems, aimed at ensuring the safety of medicines throughout their lifecycle. The formal development of pharmacovigilance began in the early 1960s following a major drug safety crisis. In December 1961, an Australian physician, W. McBride, published a case report in The Lancet describing a possible association between thalidomide use during pregnancy and severe congenital abnormalities, particularly phocomelia. Thalidomide had been widely prescribed as a sedative and antiemetic for pregnant women, and the discovery of its harmful effects highlighted serious gaps in drug safety monitoring after marketing. This incident marked a turning point in the global approach to medicine safety and emphasized the need for systematic monitoring of adverse drug reactions.

In response to growing concerns about drug-related harm, the World Health Organization initiated the Programme for International Drug Monitoring in 1968. This program aimed to collect and analyse adverse drug reaction data from different countries in a centralized manner, allowing early identification of safety signals that might not be evident at the national level. The primary goal was to support timely detection of risks associated with medicines and to promote safer use of drugs worldwide. During the mid-1970s, the term "pharmacovigilance" was formally introduced by a group of French pharmacologists and toxicologists to describe activities related to the assessment and prevention of adverse effects linked to drug therapy.

The international framework for pharmacovigilance was further strengthened through regulatory and policy initiatives. In 1967, the World Health Organization adopted Resolution 20.51, which laid the foundation for a global system of adverse drug reaction monitoring.

Later, the Council for International Organizations of Medical Sciences (CIOMS) played a significant role in harmonizing international reporting standards for adverse drug reactions. These efforts contributed to the development of consistent methods for safety reporting and data exchange across countries. Additionally, Good Pharmacovigilance Practices (GVPs) were introduced to provide clear guidance on the roles and responsibilities of marketing authorization holders, with an emphasis on continuous risk assessment and patient safety. Regulatory bodies such as the European Medicines Agency also contributed to strengthening pharmacovigilance systems by establishing structured regulatory oversight and standardized practices.

In India, the evolution of pharmacovigilance began in 1986 with the establishment of a formal adverse drug reaction monitoring system consisting of multiple regional centres. These centres were designed to collect safety data from large populations and contribute to international monitoring efforts, India later became a participant in the global adverse drug reaction monitoring programme coordinated from Uppsala, Sweden. A major milestone was achieved in 2005 with the launch of the National Pharmacovigilance Programme under the supervision of the Central Drugs Standard Control Organization. This programme was further strengthened through collaboration with the Indian Pharmacopoeia Commission, which functions as the National Coordinating Centre. The nationwide pharmacovigilance framework aims to protect patient health by systematically monitoring adverse drug reactions, improving reporting practices, and supporting regulatory decision-making. Over time, pharmacovigilance has evolved into an essential public health activity, forming the foundation for safer and more effective use of medicines.

Objectives of Pharmacovigilance

1. To maintain patient safety by keeping an eye out for adverse drug responses and reducing medication - related damage.

2. To assess how well drugs balance their advantages and disadvantages in order to maximise their use and encourage wise decision-making.

3. To optimise treatment results while lowering hazards, encourage the sensible and economical use of medications.

4. To improve knowledge and proficiency in medication safety monitoring and reporting, healthcare professionals and the public should be given more opportunities to comprehend, learn about, and receive training in pharmacovigilance techniques.

5. To assist patients, healthcare professionals, and the general public in making informed decisions and managing risks by ensuring that medication safety information is promptly and accurately delivered to them.
6. To acknowledge and resolve how free trade and globalisation affect the availability and distribution of medications by coordinating pharmacovigilance initiatives across borders.

Artificial Intelligence

Artificial Intelligence (AI) refers to the ability of computer-based systems to perform tasks that usually require human intelligence, such as learning from experience, identifying patterns, understanding language, and supporting decision-making. In recent years, Al has gained increasing importance in healthcare, particularly in areas where large volumes of data need to be processed efficiently and accurately. Pharmacovigilance is one such field where Al is emerging as a valuable supporting tool.

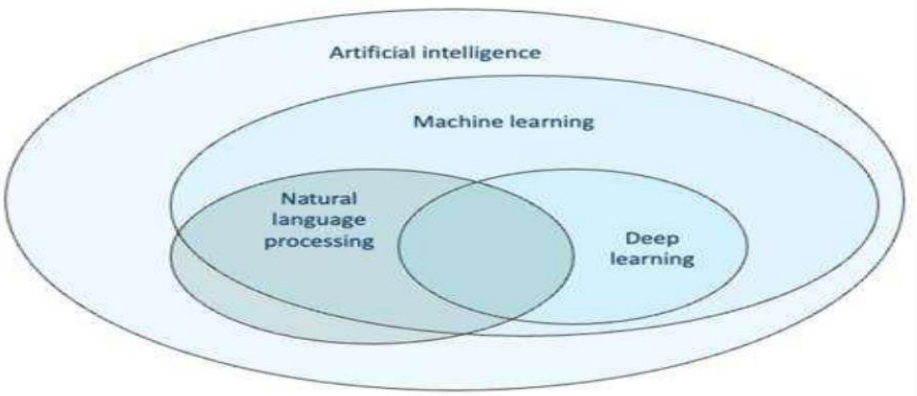
In pharmacovigilance, Al is mainly applied to the management of Individual Case Safety Reports (ICSRs).

An ICSR is a standardized document used to record information related to adverse events, product-related problems, and consumer safety reports in line with regulatory requirements. Traditionally, ICSR processing involves manual steps such as data entry, medical review, coding, and causality assessment, which are time-consuming and may lead to inconsistencies. Machine learning techniques help automate these activities, enabling faster processing and improved consistency while reducing the overall workload on pharmacovigilance professionals.

Al also supports the identification and analysis of adverse drug reactions by examining data from various sources, including spontaneous reporting systems, electronic health records, and patient-reported information. Natural language processing allows Al systems to understand and extract relevant details from unstructured text, such as clinical narratives and free-text safety reports. Through advanced pattern recognition, Al can assist in signal detection, prediction of potential drug side effects, identification of drug-drug interactions, and recognition of patient populations at higher risk of experiencing drug-related toxicity.

Despite its advantages, the use of Al in pharmacovigilance presents certain challenges. Data privacy and security are major concerns, as Al systems rely on access to sensitive health information. In addition, the reliability of Al tools depends heavily on the quality of the data

used for training. Regulatory acceptance, transparency of algorithms, and accountability for errors also require careful consideration. Therefore, while Al holds strong potential to enhance pharmacovigilance activities, its responsible and well-regulated implementation is essential for ensuring patient safety.



Importance of Pharmacovigilance

Pharmacovigilance refers to the scientific study related to the identification, evaluation, understanding, and prevention of adverse effects caused by medicines, including both short-term and long-term effects.

In India, approximately 0.7% of all adverse drug reactions (ADRs) lead to hospital admissions, while 3.7% of hospitalized patients experience ADRs.

Additionally, 1.8% of all ADRs are linked to fetal harm. Research indicates that adverse drug reactions are among the top causes of human mobility, ranking between fourth and sixth. Globally, ADRs contribute to about 5-15% of all hospital admissions, with an average mortality rate of 2.7% due to ADRs. Furthermore, around 10-20% of hospitalized patients experience ADRs worldwide.

Pharmacovigilance is essential for ensuring the safety of medicines by detecting, assessing, and understanding the harmful effects of pharmaceutical products.

One of the most crucial activities in pharmacovigilance is the spontaneous reporting of suspected adverse drug reactions by healthcare professionals, such as doctors, pharmacists, and nurses, especially when these reactions were not identified during pre-market clinical trials.

Using Al to detect Adverse Drug Reactions (ADRs)

Adverse Drug Reactions (ADRs) are harmful responses to medications that can range from mild to life-threatening. These reactions can be further divided into two main types: Type A and Type B. Type A reactions are related to the known effects of a drug, while Type B reactions occur unexpectedly, even when the drug's known effects do not suggest such a response. The use of artificial intelligence (AI) in detecting ADRs has evolved significantly since the late 1990s, transforming pharmacovigilance (PV) practices.

This development can be divided into three distinct phases, each marked by advancements in statistical methods, natural language processing (NLP), and machine learning techniques.

Al systems analyze historical patient data, including genetic profiles, existing health conditions, and demographic information, to identify individuals who may be at a higher risk of experiencing ADRs.

By examining patterns across various populations, Al can predict potential drug reactions before they occur, allowing for more proactive monitoring and improved patient safety.

DATA BASE USE IN PHARMACOVIGILANCE

VigiFlow

VigiFlow is a web-based system specifically developed to manage Individual Case Safety Reports (ICSRs) for national centres involved in the WHO Programme for International Drug.

Monitoring.

It is built according to the ICH E2B standard and is a trademark of the UMC. The UMC, based in Uppsala, Sweden, maintains this system. VigiFlow offers a straightforward, efficient, and secure web-based solution that improves all aspects of adverse drug reaction (ADR) reporting.

VigiBase

VigiBase is the global database of ICSRs maintained by the WHO.

It contains reports of adverse reactions submitted by member countries since 1968. VigiBase is the largest and most extensive database of its kind worldwide. It is developed and managed by the UMC on behalf of the WHO.

VigiMine

VigiMine was introduced in 2008 as part of the VigiSearch project.

It offers access to statistical information on all drug-ADR combinations reported to VigiBase.

VigiMed

VigiMed is a web-based platform used by professionals working at national centres in the WHO Programme. It allows users to easily access safety concerns raised by other countries, check regulatory status, and quickly share drug-related information.

VigiSearch

VigiSearch is a strong search tool that provides access to all case reports in VigiBase.

It enables searching across multiple drugs and ADRs simultaneously, and includes various filters to help users obtain more accurate results.

VigiLyze

VigiLyze is a robust search and analysis tool that gives access to more than 8 million ICSRs in VigiBase, submitted from over 100 countries.

VigiAccess

VigiAccess is a publicly available web application that allows users to easily explore and access data on adverse drug effects from VigiBase.

VigiMatch

VigiMatch is an algorithm designed to identify similar individual case reports using probabilistic pattern matching.

NEED OF ARTIFICIAL INTELLIGENCE IN PV

The need for Al in pharmacovigilance arises from the significant challenges faced by traditional methods in handling large volumes of data. The rapid increase in health-related information from electronic health records, social media platforms, and patient reports has exceeded the capabilities of manual processes. Al in. pharmacovigilance serves as a transformative solution, allowing teams to manage and analyze this data effectively and efficiently.

Pharmacovigilance refers to the science and practices involved in identifying, evaluating, understanding, and preventing adverse effects of medications or any drug-related problems.

It encompasses various activities such as processing reports, detecting safety signals, and managing risks.

Al is revolutionizing drug safety by automating the processing of data, enhancing the ability to detect signals, and supporting real-time analysis of adverse events across different healthcare data sources.

It enables the examination of electronic health records and social media to gain timely and valuable insights.

AI TOOLS USE IN PHARMACOVIGILANCE

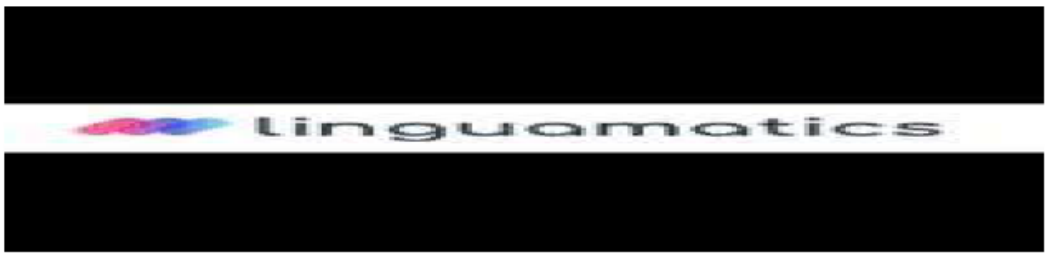
1. VigiLanz

VigiLanz®
An Inovalon solution

The Care Management Software by Inovalon, previously known as Vigilanz, is a cloud-based clinical monitoring and patient safety tool that turns complex patient data into meaningful and actionable real-time alerts.

It uses natural language processing and machine learning to detect possible adverse drug reactions and safety concerns from electronic health records.

2. Linguamatics' I2E



Linguamatics' 12E has been used effectively to monitor the safety of the COVID-19 vaccine, mainly for pharmaceutical and healthcare applications.

This combination of natural language processing and machine translation technologies has deep understanding of language, culture, and regulatory standards, allowing for the efficient scaling of adverse event reporting.

3. FDA's Sentinel Initiative

The Sentinel System is used to analyse large healthcare databases to identify potential safety signals linked to drugs and other medical products.

In addition to the FDA, this system is available to collaborators from the healthcare system, academic institutions, and private sector organisations.

4. Oracle's Life Sciences Products

Oracle's Life Sciences Solutions provide full audit trails to track changes and ensure accountability.

These solutions include Clinical Research, Safety and Pharmacovigilance, and Real-World Evidence, helping organisations with pharmacovigilance activities.

5. TCS ADD

Natural Language Processing (NLP) improves pharmacovigilance by automating data extraction and analysis from various sources.

This guide outlines key steps such as defining objectives, data collection, annotation, model building, adverse event detection, signal analysis, system integration, validation, continuous improvement, regulatory compliance, collaboration, and ethical considerations.

6. ArisGlobal's LifeSphere MultiVigilance

LifeSphere's MultiVigilance tool uses machine learning models to analyse large sets of adverse event data, identify patterns, and provide insights to support professionals in making informed decisions. LifeSphere offers solutions in Safety, Regulatory, Quality, Medical Affairs, and Data and Analytics to speed up the R&D lifecycle.

7. Natural Language Processing (NLP)

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BENEFITS OF ARTIFIAL INTELLIGENCE

1. Benefits of Artificial Intelligence in Pharmacovigilance.
2. The most important benefits of Al are reduced cycle times. Due to this method, the processing is spontaneous.
3. Improve the quality and accuracy of the information.
4. Al can handle or manage diverse types of incoming data formats.
5. It can be used for the identification of ADRs.
6. Al is useful to reduce the burden and time of case processing.
7. Al tools extract the information from the adverse drug event form and evaluate the case validity without the workforce.

APPLICATION OF AI IN PHARMACOVIGILANCE

Regulatory

Although Al has been developed and applied in various areas of pharmacovigilance, the following outlines the relevant regulatory approaches:

Food And Drug Administration (FDA): The FDA released a five-year plan to integrate Al into the existing pharmacovigilance framework even before the outbreak of the epidemic.

European Medicines Agency (EMA): The EMA exchanges information and opinions on policies, guidance, and regulations related to the use and regulation of Al in pharmacovigilance.

The EMA explores ways to align each agency's vision and approach regarding the use and regulation of Al in pharmacovigilance.

The EMA fosters leadership and collaboration on international regulatory initiatives.
Central Drugs Standard Control Organisation (CDSCO): Clinical studies are approved with just a simple notification, reducing the challenges associated with obtaining licenses.

By incorporating Artificial Intelligence (Al) into regulatory processes, CDSCO is enhancing efficiency while maintaining accountability, ensuring less supervision without affecting patient safety.

These changes are expected to help strengthen India's position as a global pharmaceutical center, especially in the rapidly growing US generics export market.

Therapeutic Goods Administration (TGA): The TGA mainly focuses on regulating and inspecting how sponsors use Al to ensure that drug monitoring is compliant and safe.

Al technologies are also transforming how safety data is managed to meet TGA requirements.
Pharmacovigilance Program of India (PvPI): The Pharmacovigilance Program of India (PvPI), under the Indian Pharmacopoeia Commission, has also incorporated Al into its Adverse Drug Reaction (ADR) monitoring system.

Clinical: it typically takes about 10 to 12 years, including 5 to 6 years of clinical trials, for a medicine to be approved and made available on the market.

Predictive safety: Chemical, target, and real-world data are used to predict potential adverse reactions or drug interactions using similarity-based machine learning and deep learning algorithms.

Causality assessment: According to the WHO-UMC categories.

Causality term	Assessment criteria*
Certain	Event or laboratory test abnormality, with plausible time relationship to drug intake
	Cannot be explained by disease or other drugs
	Response to withdrawal plausible (pharmacologically, pathologically;
	Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon)
	Rechallenge satisfactory, if necessary
Probable / Likely	Event or laboratory test abnormality, with reasonable time relationship to drug intake
	Unlikely to be attributed to disease or other drugs
	Response to withdrawal clinically reasonable
	Rechallenge not required
Possible	Event or laboratory test abnormality, with reasonable time relationship to drug intake
	Could also be explained by disease or other drugs
	Information on drug withdrawal may be lacking or unclear
Unlikely	Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible)
	Disease or other drugs provide plausible explanations
Conditional / Unclassified	Event or laboratory test abnormality
	More data for proper assessment needed, or
	Additional data under examination
Unassessable / Unclassifiable	Report suggesting an adverse reaction
	Cannot be judged because information is insufficient or contradictory
	Data cannot be supplemented or verified

*All points should be reasonable complied with.

CURRENT STATUS

Pharmacovigilance in India (PvPI): India first joined the WHO International Drug Monitoring Programme in 1997 through the Adverse Drug Reaction Monitoring Scheme introduced by the Central Drugs Standard Control Organization (CDSCO).

However, it was not until 2010 that a centralized and well-organized program-the Pharmacovigilance Programme of India (PvPI) - was formally established by the Ministry of Health and Family Welfare (MoHFW), Government of India.

Data Submission to WHO-Uppsala

India is a member of the WHO Global ICSR Database (VigiBase), which is managed by the UMC in Sweden.

The Individual Case Safety Reports (ICSRs) collected under PvPI are regularly sent to VigiBase, contributing to the worldwide collection of drug safety information. This ensures

that India is actively involved in international pharmacovigilance activities and helps in identifying global safety signals and assessing risks.

NEW TRENDS

Al is now being used to improve automated case processing, signal detection, risk prediction, adverse event classification, and real-time safety monitoring through natural language processing.

By 2026, Al-powered pharmacovigilance is expected to be a key part of regulatory submissions, safety updates, and post-marketing surveillance. This change will help drug safety teams spot risks faster, increase accuracy, and offer more timely actions.

The FDA's first draft guidance on the use of artificial intelligence in drug and biologic development, published in January 2025, was a major development for pharmacovigilance professionals.

Mobile Health (mHealth) Technologies

Mobile health technologies, such as wearable devices and health apps, are becoming more common among patients.

These tools can collect real-time health information, including vital signs, medication use, and reports of adverse events. By incorporating mHealth data into pharmacovigilance systems, drug safety monitoring can be improved, leading to better patient outcomes. Al can be used to analyze this data, identify possible safety concerns, and provide tailored advice to patients and healthcare providers.

CHALLENGE

Scientific Challenge

The process of handling adverse event (AE) cases in pharmacovigilance (PV) is a complex task that involves multiple decision points and adjudication within a regulated and audited system.

There has been a clear role of clinical evaluation and the clinician's perspective in assessing causality and detecting signals.

Technological Challenges

The dataset must be extensive and diverse, sourced from various origins, encompassing all types of reports, and representative of the global population to ensure the algorithm is valid and robust in real-world scenarios.

This necessitates integration, linkage, annotation, labeling, and ongoing maintenance of datasets to effectively train and implement the technology from concept to execution..

High Implementation Costs

Introducing Al into pharmacovigilance activities requires substantial initial investment in software, IT infrastructure, and system integration.

For smaller biopharma companies with constrained budgets and competing business priorities, these costs are difficult to justify without a clear return on investment.

Validation and Documentation

Regulatory authorities demand rigorous validation of Al systems.
Preparing documentation that meets compliance standards is both time-consuming and often underestimated in terms of resources required.

CONCLUSION

Artificial intelligence makes it easier to process and analyze large volumes of data and can be used to address various health issues.

In conclusion, using Al to improve pharmacovigilance offers great opportunities to enhance the monitoring of drug safety.

Al-based systems can effectively analyze large datasets, detect adverse drug reactions more quickly, and decrease errors made by humans. However, successfully implementing Al involves overcoming challenges such as ensuring data quality, making algorithms transparent, and following regulations.

Although Al has great potential in improving processes like detecting adverse drug reactions and assessing their causes, much of this potential is still limited to academic models and theoretical discussions, with limited real-world use in standard pharmacovigilance activities. More work is needed to close this gap and fully incorporate Al into everyday

pharmacovigilance tasks. There are now IT tools that automatically handle the processing of ADR reports.

With the use of Al, the entire process from receiving a case to reporting it can also be automated. These methods will help reduce costs while improving accuracy and the overall quality of the work.

Future initiatives should focus on realizing the full potential of Al in pharmacovigilance by

1. Enhancing the availability and quality of pharmacovigilance data.
2. Encouraging the ethical, transparent, and responsible use of Al.
3. Investing infrastructure and training to strengthen the capacity of low-and middle-income countries.
4. Creating regulatory standards that are recognized globally.

Al has a bright future for making drug development and medication monitoring more intelligent. However, its use must be guided by moral principles and fairness and should align with international public health goals. Overall, Al has the potential to transform pharmacovigilance into a more proactive and accurate process.

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