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AI-Driven Pharmacovigilance: Transforming Drug Safety Monitoring

Akash Kishor Rokade[1]*

[1]Faculty of Pharmacy, Universitas Padjadjaran, Indonesia

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ABSTRACT

Pharmacovigilance is important in making a drug safe by detecting, evaluating, and interventional adverse drug reactions (ADRs). The non-modern systems usually have the issues of underreporting, delay of signal detection, data paralysis problems. The review tries to understand the impact of artificial intelligence (AI) on changing the pharmacovigilance practices of analysis, prediction, and decision process. The research has searched in PubMed, Scopus, and Web of Sciences platforms with results restricted to 2010-2024, and the literature review was done using structured literature review. Important insights include the fact that AI can greatly enhance signal detection speeds and accuracy, that it will provide real-time electronic health record and social media monitoring, and can facilitate drug risk prediction modelling. Some rather successful applications like the use of natural language processing of FDA FAERS and WHO VigiBase indicate a better achievement in terms of early detection of signals. This is promising in spite of the fact that there are still impediments regarding transparency, regulatory acceptance and ethical facets. The review outlines that effective validation, ethical governance of AI, and capacity building on low- and middle-income countries are required to facilitate the safe implementation of AI tools. The future research needs should be diverted to standardizing the evaluation frameworks, equal accessibility and increase in AI interpretability to the professionals working in pharmacovigilance. At the end of the review, it is concluded that AI can transform pharmacovigilance all over the world, providing better early warn warning systems, increasing patient protection, and making data-driven regulatory decisions.

Keywords ; Pharmacovigilance, Artificial Intelligence, Drug Safety, Machine Learning

1. INTRODUCTION

Pharmacovigilance is a core component in the verification of medicine safety and effectiveness especially after drugs are available in the market and when they are shared by larger and more diverse groups of people. According to World Health Organization (WHO) pharmacovigilance is the science and practices that focus on the identification, evolution, insight and the heading off of unfortunate effects or any other drug issues. It is not mere identification of the adverse drug reactions (ADRs), the aim being to minimise the damage done, enhance patient safety and regulatory decision making as well. There has been an ever-growing pressure on the pharmacovigilance systems to identify and address ADRs as the global pharmaceutical industry has grown rapidly and approval of new drugs leads to an open cascade. The common forms of pharmacovigilance, which mainly focuses on spontaneous reporting systems have been established as the strength of drug safety monitoring in the past. Nevertheless, their approaches are usually limited by the following disadvantages: underreporting, slow signal recognition, inconsistency of data quality and handling big quantities of unstructured data. Such concerns are of particular concern in low and middle income countries (LMICs) where health care infrastructure, digital systems and regulation are recent developments.

The new developments of Artificial Intelligence (AI) in the past years have offered new opportunities in the improvement of pharmacovigilance. Machine Learning (ML), Natural language processing (NLP) and data mining are AI technologies that have demonstrated strong potential to pharmacovigilance procedures. Such technologies are able to ingest large volumes of data, filter out meaningful patterns in the unstructured data and find out early safety signals which are not easy to spot by traditional methods. Electronic health records (EHRs) social media, spontaneous reporting database and scientific literature are now being used to develop more responsive and smarter drug safety systems.

AI pharmacovigilance has been pioneered by high income countries with well developed health data systems and regulatory capability as well as access to more computational infrastructure. The Sentinel system developed by the FDA, uses advanced analytics and real-world data and has recently begun incorporating AI tools to support safety signal detection. Conversely, LMICs face more restrictions in implementing such technologies, particularly in countries like India and Indonesia.

These are poor digitalization of data, low internet penetration, low levels of pharmacovigilance awareness among healthcare providers and low funding as well as a weak regulatory safeguards by global AI regulations.

However, LMICs do not lack innovation. In India, some pilot projects were under consideration to implement mobile based ADR reporting apps, regional PV centres and collaborations with the academic institutions to conduct AI research in health care. The interest in the digital health has also been growing in Indonesia, with the widespread activates of the Ministry of Health, as well as university partnerships. Such initiatives however are still in small scale and full-scale adoption of AI in pharmacovigilance is still in very initial phase.

In addition to technical and infrastructure issues, ethical and legal aspects should be overcome. Despite the undeniable benefits associated with the use of AI in pharmacovigilance, it is worth wondering how it will affect data security and algorithm/bias issues, as well as the ethics of using information about patients. To establish both institutional and public trust, it is important to make sure that AI has explainable systems and that the regulators, clinicians and patients can trust its decision making.

This review is expected to assess the existing environment of AI in pharmacovigilance and a particular emphasis will be put on the applications in LMICs, it looks at the role of AI technologies in enhancing ADR detection and signal management as well as post marketing surveillance. This review synthesizes evidence from peer-reviewed literature published between 2010-2015, outlines major accomplishments, existing challenges and has policy and practice-based recommendations concerning the future. Through this act, it aims at promoting a better balanced and productive embracing of AI drug monitoring safety in the world.

2. AI vs. Traditional Pharmacovigilance

Underreporting, data silos, and slowing signal identification are restrictions of the traditional pharmacovigilance systems such as spontaneous reporting. Such systems are usually not effective at capturing real-world data, especially in low and middle-income countries (LMICs) where there is little infrastructure and awareness. Artificial intelligence instead is capable of efficiently evaluating large volumes of data, such as electronic health records, clinical notes and records, social media and real time surveillance systems very precisely. Indicatively, a 2021 analysis was able to show that the AI-based natural language processing (NLP) over the FAERS database of the FDA played the role of identifying possible adverse drug reactions four weeks in advance compared to the traditional methods. Likewise, machine learning models developed upon hospital records have attained greater sensitivity and specificity in detecting the rare ADR than manual evaluation. Such benefits do not only help to speed the day of signal recognition but also benefit the improvement of regulatory decisions and resource management within the pharmacovigilance environments.

3. Ethical and Regulatory Considerations of AI in Pharmacovigilance

The use of AI in pharmacovigilance implies a number of regulation and ethical issues that need to be taken into account to make AI use responsible. Privacy and security are also a major concern when using patient data in AI due to the privacy legislation such as the General Data Protection Regulation (GDPR) in Europe or the HIPAA in the United States. Moreover, most AI algorithms work like black boxes, whereby it is hard to understand or interpret the mechanism under which safety related decisions are made. This presents a veil of secrecy that might compromise the relationship between the healthcare providers and the regulators. To overcome such issues, institutions like the U.S. FDA and the European Medicines Agency (EMA) propose regulatory framework and guides on the validation, transparency, and auditability of AI tools in monitoring drug safety. The issues on implementing ethically should also address algorithmic bias, fair access to AI technologies, and human control in decision-making process especially in LMIC context.

4. Materials and Methods

This review is based on a systematic literature search to gather studies on the use of Artificial Intelligence in Pharmacovigilance and medication safety monitoring. A combination of keywords including “Pharmacovigilance”, “Artificial Intelligence”, “Machine Learning”, “Drug Safety”, were used to search database including PubMed, Scopus, Science Direct and Google Scholar.

Inclusion Criteria:

- Article as a Peer-reviewed Publication (The language of the latter is in English)
- Published between 2010 to 2025
- By focusing on using AI/ML applications in pharmacovigilance, ADR detection, regulatory strategies and post marketing surveillance.

- Low and middle income countries (LMICs) Research studies related to high income.

Exclusion Criteria:

- Non peer reviewed publications, Conference abstracts and opinion articles not supported by scientific evidence.
- Articles unrelated to AI integration

The relevance of each article to the review's objectives was carefully evaluated. A total of 30 peer reviewed publications were selected for synthesis and narrative analysis.

5. Result

There has been significant advancement in the application of Artificial Intelligence (AI) to pharmacovigilance systems. The literature reviewed from 2010 to 2025 indicates significant advancements in the application of artificial intelligence. Below is a summary of the main conclusion drawn from the selected studies:

5.1 Traditional Pharmacovigilance systems drawbacks multiple studies identified major limitation in traditional pharmacovigilance methods, including underreporting, reporting delays and limited capacity to handle unstructured data. Since pharmacovigilance infrastructure is still being developed in low and middle income countries (LMICs) where pharmacovigilance infrastructure is still developing.

5.2 AI Based pharmacovigilance techniques for drug safety systems have effectively incorporated AI techniques as data mining, machine learning and natural language processing (NLP).

For example:

- Machine Learning (ML) have been applied in risk prediction models and adverse event detection (e.g., FDA's Sentinel System).
- Natural Language Processing (NLP) has been applied to extract drug event correlations were extracted using natural language processing from social media and electronic health records (e.g., MedWatcher Social).
- It has been demonstrated that signal detection algorithms perform faster and more sensitively than conventional statistic techniques.

5.3 High income countries, supported by strong data systems and regulatory frameworks, such more advanced integration of AI in pharmacovigilance. In contrast, research from LMICs such as India and Indonesia highlights challenges including regulatory gaps, limited digital infrastructure and low adoption of health technologies. However, initiatives like mobile based ADR reporting applications and experimental pilot projects in these regions have shown promising results.

5.4 Recurring Themes Across Studies

- AI enhance the speed and accuracy of adverse event detection.
- Data quality and accessibility remain persistent limitations.
- Successful implementation requires collaboration between industry stakeholders and regulatory agencies.

6. Discussion

The field of drug safety monitoring is changing as a result of the incorporation of artificial intelligence into pharmacovigilance. The results of this review show that artificial intelligence technologies specifically machine learning (ML) and natural language processing (NLP) can greatly improve the detection of adverse drug reaction (ADRs) shorten reporting times and increase the overall effectiveness of pharmacovigilance systems. Despite these developments, different parts of the world continue to use AI in pharmacovigilance at different rates. Thanks to established regulatory frameworks, robust digital health infrastructure and availability to high quality data, high income countries have made significant strides in putting AI based pharmacovigilance frameworks into practice. On the other hand low and middle income nations such as Indonesia and India, have significant obstacles

such fragmented regulations, inadequate reporting systems and limited technical capability. The conversation also shows that although AI has a lot of potential and there are obstacles to overcome in its use. Recurring problems include data quality, algorithm transparency, privacy issues and the moral use of patient data. Furthermore, the inability of AI systems to produce precise and broadly applicable risk signals is hampered by the absence of standardisation in data collecting, particularly in LMICs. The regulatory readiness to accept AI driven pharmacovigilance solutions has been identified as a major need. Even while agencies such as the Food and Drug Administration (FDA) and European Medicines Agency (EMA) have started to release guidelines about AI in post-marketing surveillance and drug development, there is still a lack of harmonisation and cross border cooperation. Initiatives to increase capacity, such as infrastructure development, training and collaborations with global pharmacovigilance networks are desperately needed for LMICs. Additionally, unstructured real-world data like social media doctor's notes and customer complaints are still underutilised, whereas the majority of AI models are now concentrated on structured data like EHRs investigating NLP's and hybrid models capabilities in these situations could greatly enhance signal identification in populations that are difficult to reach. The research concludes that while AI presents pharmacovigilance with a transformative possibility its effectiveness hinges on multi stakeholder engagement, robust governance frameworks and equitable access to technology. In LMIC, in particular, future focus should be on ensuring that AI become a part of existing health systems and ethics of the data and support policy.

7. Conclusion

Artificial intelligence is rapidly transforming pharmacovigilance which makes it possible for quicker, more precise and predictive drug safety monitoring. The integration of technologies like machine learning and natural language processing into pharmacovigilance systems in various healthcare contexts is highlighted in this review. These advancements are supporting across various healthcare contexts. These advancements are supporting regulatory decision making, enhancing real time data analysis and improving the detection of adverse drug reactions (ADRs).

However, because of the obstacles including inadequate infrastructure, data accessibility and regulatory preparedness, there are still notable differences in the adoption of AI between high income, low income and middle-income countries. Governments the pharmaceutical industry, regulatory agencies and academic institutions must work together to address these issues.

Future projects would be best suited to realise the potential of AI driven pharmacovigilance on:

- Improving the accessibility and quality of pharmacovigilance data
- Promoting ethical, transparent and responsible use of AI
- Investing in infrastructure and training to build LMICs capacity
- Developing standards of regulatory framework that are internationally acceptable

AI holds a promising future for more intelligent drug development and more intelligent medication development and monitoring yet its utilization should be morally upright just and has to be according to international public health priorities.

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Akash Kishor Rokade	Medical Biotechnology University of Naples Federico II, Italy Erasmus+ Exchange Student Faculty of Pharmacy Universitas Padjadjaran, Indonesia