International Research Journal of Innovations in Engineering and Technology (IRJIET)
ISSN (online): 2581-3048
Volume 8, Issue 9, pp 194-197, September-2024
https://doi.org/10.47001/IRJIET/2024.809024

Enhancing Drug Safety: AIs Role in Pharmacovigilance and Adverse Event Reporting

Hannah Alex

School of Pharmacy, University of Pittsburgh, USA

***Abstract* - The role of pharmacovigilance (PV) in healthcare is to optimize the safety and efficacy of the delivery of pharmaceutical drugs and medical equipment. The increasingly dynamic nature of adverse drug reactions and pharmacovigilance has rendered traditional approaches susceptible to the underreporting of ADRs. Subsequently, the integration of Artificial intelligence in adverse drug reaction reporting is an outstanding technological advancement in pharmacovigilance. Therefore, this critical analysis applied a systematic literature review to comprehend the extensive role of AI in Pharmacovigilance. The research findings acknowledged that AI technologies such as machine learning, deep learning, and natural learning processing (NLP) have automated PV, leading to enhanced signal detection, analysis of unstructured data, risk assessment, and regulatory compliance.**

Keywords: Pharmacovigilance (PV), natural learning processing, adverse drug reactions (ADR), signal detection, deep learning, Artificial intelligence, and machine learning.

I. INTRODUCTION

In a field as complex as medicine, the role of AI is inevitable. Pharmacovigilance (PV) and Adverse Event Reporting (AER) are meant to help physicians “do no harm” (Bate and Stegmann 20). These concepts are dedicated to monitoring the impacts of pharmacological drugs after licensure and involve continuous surveillance of the side effects, besides analyzing voluminous scopes of data to find existing and developing unknown side effects (Vickers-Smith et al. 203). Therefore, the voluminous scope of data, high degree of uncertainty, and need to learn from data justify the relevance and applicability of AI in PV and AER. Subsequently, this analysis applies a systematic literature methodology to extensively and critically evaluate the role of AI in Pharmacovigilance and Adverse Event Reporting (AER).

II. LITERATURE REVIEW

Existing studies have also compared the effectiveness of AI-based and traditional approaches in PV, monitoring and reporting of Adverse drug reactions. For example, in predictive analytics tasks such as identifying complex patterns in Symptoms data and pharmacoepidemiology, AI-based approaches were more reliable than traditional PV methods (Bate and Stegmann 23). Notably, a systematic review of 44 studies was undertaken by Sessa et al. to compare the application of AI and traditional approaches for tasks such as predicting the occurrence or severity of Adverse drug responses and propensity scores (p.121). For instance, despite not performing quality assessments for studies, AI outperformed traditional mechanisms in 50% of the studies

Multiple studies have also attempted to demonstrate the complexity and costs involved in individual case safety reports (ICSRs) to justify the implementation of AI in PV and AER. For example, a 2021 GSK study concluded that the estimated average cost of processing an individual case report was $33 and even higher across pharmaceutical companies (Beninger et al. 1229; Stergiopoulos et al. 506). In 2021, Navitaspvnet and pvconnect also conducted an annual survey of pharmaceutical companies' cost per ICSR processing (Bate and Stegmann 23). The findings showed the median was US$86 for Pvnet and $345 in Pvconnect’s survey (Bate and Stegmann 24). Consequently, such processing costs have increased the allure of AI automation regardless of the high initial implementation costs.

Besides, the evolving nature of the pharmaceutical landscape is characterized by the increased volume and complexity of the new drugs and therapeutics available annually. The continuous introduction of different drugs has also increased the scope of advanced events reported, prompting the need for technological integration for quality, real-time, convenient and automated drug safety monitoring. For example, Patel et al. point out a 300% increase in the adverse events reported by the FDA Adverse Event Reporting System (FAERS) between 2009 and 2019, further increasing to 2.2 million AE reports by 2021.

III. PROPOSED METHODOLOGY

The proposed research methodology was a systematic literature review of research articles published between 2010 and 2024. This proposed methodology has also been previously adopted in similar studies examining the role of AI in PV, such as those by Sessa et al. and Bate and Stegmann.

ISSN (online): 2581-3048
Volume 8, Issue 9, pp 194-197, September-2024
https://doi.org/10.47001/IRJIET/2024.809024

The literature review applied in the systematic review was obtained from multiple online medical databases like PubMed, Cochrane Library, CINAHL, Scopus, Web of Science and Google Scholar in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines as summarized in the illustration below. Subsequently, seventeen (17) articles were identified for the systematic literature review.

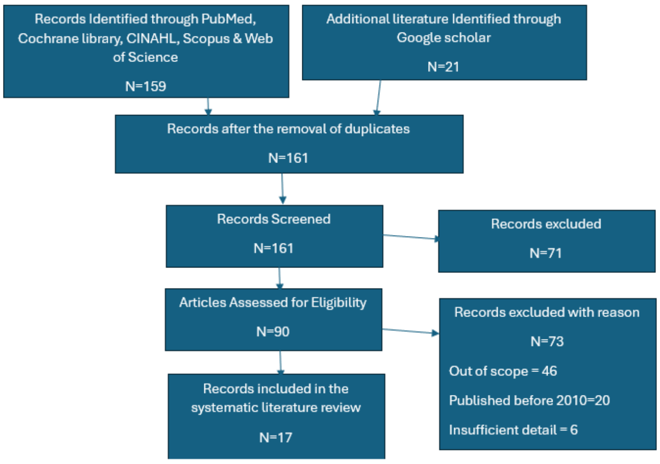

Figure 1: Proposed Methodology Block Diagram

IV. RESULT ANALYSIS AND DISCUSSION

Various aspects necessitate and justify the essence of AI in PV and AER. Primarily, the heterogeneity and comprehensiveness of PV data make manual analytics complicated and challenging. Notably, the scope of PV data is derived from different medicines and vaccines and describes a vast scope of adverse reactions that manifest differently due to dynamic mechanisms involved (Bate and Stegmann 24). Additionally, AI is essential in multiple aspects of data ingestion, which involves case intake and processing. Such aspects include the deletion of duplicates, ensuring quality assurance through anomaly detection and evaluating reported causality in individual case safety reports (ICSRs) (Bate and Stegmann 23). Besides, the Head of Case Processing Automation and Intelligence with Pfizer Worldwide Safety, Bhavin Patel, also agrees that AI not only alleviated the case processing time but also enabled effective management of voluminous reports, enabling scientists and professionals to derive and communicate essential insights to patients, health care providers and regulators (Silver).

Moreover, other forms of AI, such as machine learning are applicable in disproportionality analysis to enable signal detection and analysis. Machine learning techniques such as Lasso regression shrinkages, Bayesian borrowing algorithm and temporal scan statistics have been adopted for quantitative signal detection (Caster et al. 201; Crooks et al. 64). Notably, organizations like Pfizer have utilized AI since 2014 in categorizing and sorting case reports due to its ability to automate repetitive tasks while enabling the collection and analysis of unlimited volumes of data (Silver). However, Bate and Stegmann agree that the overall performance features of such advanced AI-based approaches have been reported to lack the requisite transparency and usability compared to simpler signal detection methods (26). As richer training data sets are available, such performance features and capabilities are likely to improve.

In addition, through AI-based technologies such as Natural language processing (NLP), AI also enables PV and AER through its ability to derive pharmacological safety insights from informal data sources such as social media posts and payment services (Comfort et al. 587). However, despite the potential to improve the ability to identify and understand safety signals, (Jokinen et al. 741; Lee et al. 1363) also acknowledge that despite the additional complex process involved in deriving insights from unconventional sources such as social media, the results might be ineffective. Therefore, Powell et al. (229) recommend that analyzing such emerging sources should consider stream-specific strengths and weaknesses besides overcoming the temptation of treating such sources as similar to traditional data sources.

Harerimana et al. and Luo et al. also point out that NLP, deep learning and data analytics can ease the extraction of PV information and data from clinical narrative repositories in Electronic Health Records (p.1081). An example is Pfizer's application of data analytics in collecting anonymized, de-identified and secure data from the EMRs of nearly 80 million individuals in real-time (Silver). According to the head of safety surveillance research at Pfizer, Heather Rubino, accessing such voluminous data enables the entity to derive insights and monitor safety en masse (Silver). Upadhyay et al. also note that besides electronic health records, Algorithms also analyze extensive unstructured data from medical literature and real-time ADR data, which collectively facilitates early detection of ADRs (p.354). Despite such potential benefits, Upadhyay et al. also ascertain that the optimal integration of AI in PV is undermined by challenges related to the poor quality of data, regulatory compliance, transparency and bias (p.355)

Consequently, it enables acquiring and consolidating PV and AER data from multiple integrated data sources while implementing advanced analytical methods. Nonetheless, Wang et al. also opined that AI has enabled the development of rapid query real-world data across distributed networks to avail a comprehensive data network for the generation of real-world evidence. An example is Pfizer's AI-enabled COVAES online adverse reporting event reporting portal, translated into multiple languages, that enables patients to report advanced

ISSN (online): 2581-3048
Volume 8, Issue 9, pp 194-197, September-2024
https://doi.org/10.47001/IRJIET/2024.809024

incidences and experiences with Pfizer vaccines. This leads to the collection and analysis of real-time ADR and PV data. (Silver). Hence, combining integrated data sources and advanced analytical methods leads to developing richer PV and AER insights that support safe and optimal healthcare delivery.

Despite the ability to eliminate irrelevant low-cost PV tasks, the implementation of AI might also exacerbate additional complexities, expenditure, and questionable implications for PV. For instance, Mouffak et al. acknowledge that the application of machine learning enabled data mining to enable systematic detection and analysis of safety signals, which also exhibits unintended consequences such as the over interpretation of quantitative statistical alerts as suspected causality (p.76). Hence, to alleviate this over interpretation, some of the recommended measures include availing guidance on evidence-based signal detection practices and implementing data mining technologies to alleviate inappropriate data mining analyses.

Lastly, the effective and optimal implementation of AI in PV to realize improved reporting and monitoring of adverse drug reactions (ADRs) also relies on the harmonized interplay between market authorization holders and regulatory entities. Whereas market Authorization holders are pharmaceuticals responsible for marketing the product, regulatory entities include the US Food and Drug Administration (Bate and Stegmann 33). Subsequently, Bate and Stegmann (33) agree that the absence of harmonization of PV requirements by regulatory organizations in different jurisdictions has become a challenge for organizations using AI to collect and analyze safety and ADR data relevant to patients and other stakeholders regardless of their geographical location. Therefore, a harmonized and inter-jurisdictional PV regulatory framework is required to guide the cross-jurisdictional safety data collection, analysis and reporting to optimize inter-jurisdictional applications and benefits.

V. CONCLUSION

The role of AI in PV and reporting ADRs is exceptional due to its ability to perform repetitive tasks and advanced data collection and analysis capabilities. According to the existing scope of literature, the integration of AI technologies such as deep learning, machine learning, and NLP in PV and ADR has improved signal detection, risk assessment, regulatory compliance and analysis of unstructured data, contributing to comprehensive PV insights. However, the full realization of these benefits has also been undermined by regulatory inconsistencies, transparency, bias, poor data quality, and complexities associated with AI integrations. Ultimately, critical analysis not only identified the role of AI in PV but also critically assessed weak points and pointed out recommendations. Such recommendations can be leveraged to optimize the role and impact of AI in improving essential tenets of PV, such as signal detection.

REFERENCES

[1] Bate, Andrew, and Jens-Ulrich Stegmann. "Artificial intelligence and pharmacovigilance: What is happening, what could happen and what should happen?" Health Policy and Technology 12.2, (2023): 100743.

[2] Beninger, Paul, et al. "Effects of the Covid-19 pandemic on pharmacovigilance strategy, systems, and processes of large, medium, and small companies: An industry survey." Clinical Therapeutics 44.9 (2022): 1225-1236.

[3] Caster, Ola, et al. "Large-scale regression-based pattern discovery: The example of screening the WHO global drug safety database." Statistical Analysis and Data Mining: The ASA Data Science Journal 3.4 (2010): 197-208.

[4] Comfort, Shaun, et al. "Sorting through the safety data haystack: using machine learning to identify individual case safety reports in social-digital media." Drug Safety 41 (2018): 579-590.

[5] Crooks, Colin John, David Prieto-Merino, and Stephen JW Evans. "Identifying adverse events of vaccines using a Bayesian method of medically guided information sharing." Drug Safety 35 (2012): 61-78.

[6] Harerimana, Gaspard, et al. "Deep learning for electronic health records analytics." IEEE Access 7 (2019): 101245-101259.

[7] Jokinen, Jeremy, et al. "Industry assessment of the contribution of patient support programs, market research programs, and social media to patient safety." Therapeutic Innovation & Regulatory Science 53.6 (2019): 736-745.

[8] Lee, Inyoung, et al. "Impact of adverse event reports from marketing authorization holder-sponsored patient support programs on the performance of signal detection in pharmacovigilance." Expert Opinion on Drug Safety 19.10 (2020): 1357-1366.

[9] Luo, Yuan, et al. "Natural language processing for EHR-based pharmacovigilance: a structured review." Drug Safety 40 (2017): 1075-1089.

[10] Mouffak, Amelle, et al. "High prevalence of spin was found in pharmacovigilance studies using disproportionality analyses to detect safety signals: A meta-epidemiological study." Journal of Clinical Epidemiology, 138 (2021): 73–79.

[11] Patel K, et al. "Artificial intelligence is changing the face of Pharmacovigilance." Pharmacy Times, 17 Oct.

ISSN (online): 2581-3048
Volume 8, Issue 9, pp 194-197, September-2024
https://doi.org/10.47001/IRJIET/2024.809024

2022, www.pharmacytimes.com/view/artificial-intelligence-is-changing-the-face-of-pharmacovigilance.

[12] Powell, Greg, et al. "Engaging patients via online healthcare fora: Three pharmacovigilance use cases." Frontiers in Pharmacology 13 2022: 901355.

[13] Sessa, Maurizio, et al. "Artificial intelligence in pharmacoepidemiology: A systematic review. part 2–comparison of the performance of artificial intelligence and traditional pharmacoepidemiological techniques." Frontiers in Pharmacology 11 (2021): 568659.

[14] Stergiopoulos, Stella, et al. "Adverse drug reaction case safety practices in large biopharmaceutical organizations from 2007 to 2017: An industry survey." Pharmaceutical Medicine 33.6 (2019): 499-510.

[15] Silver K. "The future of Pharmacovigilance: Applying AI and other tech to monitor medicine and vaccine safety | Pfizer." Pfizer: One of the world's premier biopharmaceutical companies, 2024, www.pfizer.com/news/articles/the_future_of_pharmacovigilance_monitoring_medicine_and_vaccine_safety_using_ai_and_other_tech.

[16] Upadhyay, Jyoti, Mukesh Nandave, and Anoop Kumar. "Role of Artificial Intelligence in Pharmacovigilance." Pharmacovigilance Essentials: Advances, Challenges and Global Perspectives. Singapore: Springer Nature Singapore, 2024. 347-363.

[17] Vickers-Smith, Rachel, et al. "Gabapentin drug misuse signals: A pharmacovigilance assessment using the FDA adverse event reporting system." Drug and Alcohol Dependence, 206 (2020): 107709.

[18] Wang, Shirley V., Sushama Kattinakere Sreedhara, and Sebastian Schneeweiss. "Reproducibility of real-world evidence studies using clinical practice data to inform regulatory and coverage decisions." Nature Communications 13.1 (2022): 5126.

AUTHOR'S BIOGRAPHY

Hannah Alex,
School of Pharmacy, University of Pittsburgh, USA.

Citation of this Article:

Hannah Alex. (2024). Enhancing Drug Safety: AIs Role in Pharmacovigilance and Adverse Event Reporting. *International Research Journal of Innovations in Engineering and Technology - IRJIET*, 8(9), 194-197. Article DOI https://doi.org/10.47001/IRJIET/2024.809024

****