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Review on Artificial Intelligence in Pharmacovigilance: Opportunities and Challenges

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Abstract: *Due to the clever gathering and reporting of individual case safety reports, as well as the increased awareness and involvement of patients and healthcare professionals, the number of suspected adverse event reports in the PV database has grown exponentially. The PV case processing cycle starts with data collection, data entry, initial checking completeness and validity, coding, medical assessment for causality expectedness, severity, and seriousness, subsequently submitting report, quality checking followed by data storage and maintenance. Artificial intelligence (AI) in health care has been very impressive in specialties that rely heavily on the interpretation of medical images. The focus should be a collaborative approach of technical expertise (people) combined with intelligent technology (processes) to augment human talent that meets the objective of the PV system and benefit all stakeholders. AI technology should enhance human intelligence rather than substitute human experts. This review describes the benefits and the outstanding scientific, technological, and policy issues, and the maturity of AI tools for full automation in the context to the Indian health-care system.*

Keywords: Artificial Intelligence, Individual case safety reports processing, Pharmacovigilance

I. INTRODUCTION

Pharmacovigilance (PV) is fundamentally a data-driven field as it requires the collection, management, and analysis of a large amount of data gathered from a wide range of disparate sources[1]. The primary type of data used in PV are individual case safety reports (ICSRs), which are records of suspected adverse events collected via multiple channels, aggregated and organized into large databases, and constantly monitored to detect safety signals[2] . Electronic health records (EHRs), published research, patient registries, chatbot interactions, patient support programs, and even direct patient communications via social media are some of the many sources of ICSRs[3]. Reports are col- lected worldwide and characterized by heterogeneity in format, language, and unique characteristics of the underlying healthcare systems. Adverse events must be identified and analyzed in order to find potential emerging safety issues in medicines and vaccines. The central challenge of PV is how to make sense of these large and heterogeneous data to quickly and reliably find the 'needles in the haystack,' which are safety signals that require escalation and triage[4]. Given the rise of artificial intelligence (AI) powered by new advancements in machine learning (ML) across many fields of science and medicine over the last decade, many have speculated that these same technologies could be brought to bear on the core problems of PV[5]. The use of these methods for human safety data first appeared in the early 1990s and has steadily increased since the 2000s. The goal of this review is to systematically identify works that use ML, broadly defined, for safety data to characterize the current state of ML in PV, and to provide clarity on ways that recent advances in AI and ML can be translated to improve various components of PV[6-7].

Artificial Intelligence in Pharmacovigilance

Artificial intelligence (AI) is being increasingly used in Pharmacovigilance (PV). On the basis of a MEDLINE search for the terms artificial intelligence and Pharmacovigilance, the field of artificial intelligence in Pharmacovigilance (AIPV) is rapidly growing Although the recent increase shown in this figure is only a crude signal of the magnitude of increasing interest, it aligns with observations of scientific meeting agendas and initiatives in this area[8]. For instance, Al is the focus of a subgroup under the recently established Drug Safety Research Unit International Working Group on Signal Detection and Evaluation.

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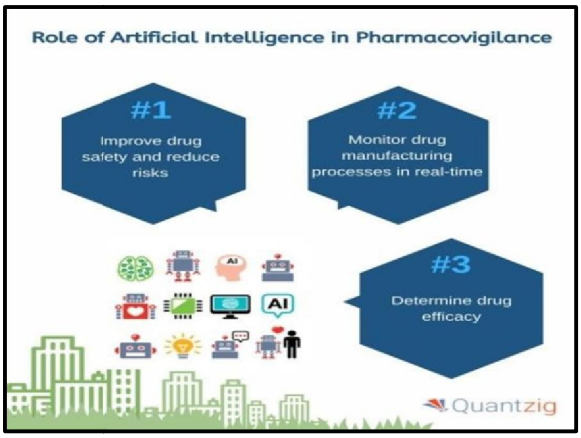

Fig.1. Role of Artificial Intelligence in Pharmacovigilance

A dictionary definition of Al is different from a working definition of Al. An insufficient understanding of the scope of AIPV, for example, which terms, methods, tasks, and data sets are ordinarily considered to be included in the application of AIPV, will likely hamper efficient and consistent execution of various activities for which decisions about what is and is not AIPV must be made. Such activities potentially adversely affected would include, for example, conducting systematic reviews or planning scientific meetings or working groups. AIPV scoping is even more essential given the nested and overlapping fields of Al, machine learning (ML), deep learning (DL), data mining and cognitive computing. In addition, AIPV stakeholders are a diverse range of scientific and policymaking disciplines with variable baseline knowledge[9-10].

The availability of healthcare data has been tremendously increasing over the last years and will further increase in the near future thanks to massive marketing of digitaltools collecting patient-derived Huge amounts of electronic data present an opportunity to apply artificial intelligence (AI) techniques to improve drug safety assessment. In clinical research, information extraction—the process of extracting pertinent ideas from readily available, primarily unstructured sources utilizing text mining and natural language processing (NLP) techniques—has been becoming more and more significant[11]. As regards Pharmacovigilance, text mining and NLP methods can be very useful together information on adverse drug reactions (ADRs) and drug drug interactions from various textual sources, supporting researchers and clinicians in monitoring drug safety. Indeed, both public and private entities are currently trying to develop Al tools that can allow to automatically process ADRs[12]. Artificial intelligence and machine learning may also be useful in Pharmacovigilance for The automatic execution of tasks associated with case report entry and processing.

- The identification of clusters of adverse events representing symptoms of syndromes.
- The conduction of pharmacoepidemiological studies
- Data linkage, through the conduction of probabilistic 8 of 13 matching within datasets.
- The prediction and prevention of adverse events through specific models using real-world data[13].

Need of Artificial Intelligence in Pharmacovigilance

There has been exponential growth in the number of suspected adverse event (AE) reports in the PV database. For important stakeholders including pharmaceutical companies, regulatory bodies, medical and PV specialists, and managers of the National Pharmacovigilance Program, processing the vast amount and diversity of data sources, putting it to sound use, and sorting "needles from baystack," is a challenge. Conventionally, the case processing of ICSR needs essential elements (details of patient, reporter, adverse reaction, suspected and concomitant medications, and outcome). In addition, ICSR case processing is evaluated for the expectedness of AE as per the prescribing information leaflet, the likelihood of causal relationship, determine severity and seriousness criteria, and finally scrutinize for completeness and validity for regulatory submission. Importantly, it encompasses manual tasks along with human cognition. Essentially, it needs a workforce and technical expertise and, therefore, is expensive and time consuming To cope with this increased workload, there has been a lot of excitement and enthusiasm to adopt Al technology to automate PV[14-15].

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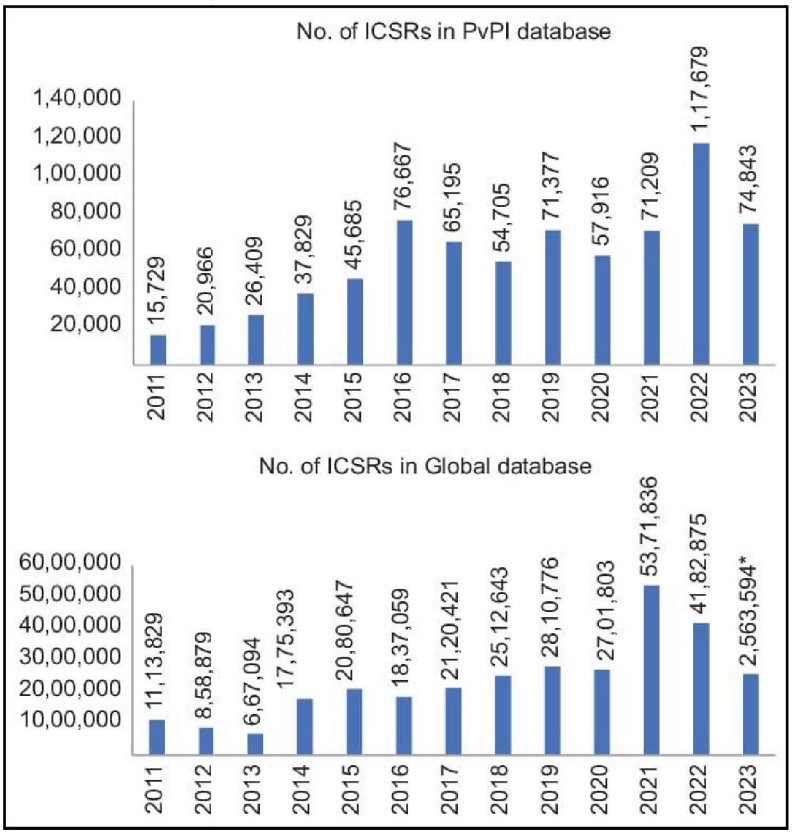

Fig.2. Individual case safety reports received by the Pharmacovigilance Program of India (PvPI) and the WHO Global database has increased dramatically in the past several years. Source: PvPI, IPC, MoHFW. *Data as on October 10, 2023. PvPI = Pharmacovigilance Program of India, ICSR = Individual case safety report, IPC = Indian pharmacopoeia commission, MoHFW = Ministry of Health and Family Welfare.

Opportunities and Challenges for Artificial Intelligence in Pharmacovigilance

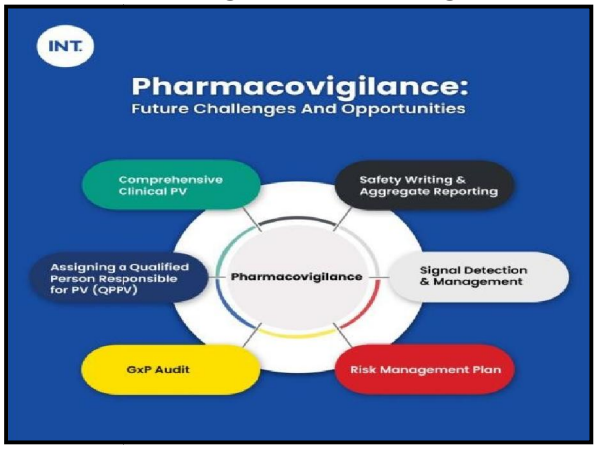

Fig.3. Future Challenges and Opportunities in Pharmacovigilance

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Opportunities for Artificial Intelligence in Pharmacovigilance:-

The manual repetitive and routine tasks of data input, AE identification, drug-drug interactions, subtle data patterns, and single case evaluation have all been suggested to benefit from the Al tool. AI is also capable of transforming handwritten documents and unstructured, free-text drug safety data into a machine-readable format. Further, the tool can automate the Medical Dictionary for Regulatory Activities coding, check duplicate reports, categorize reports into physician or consumer reports, identify serious reports, and exclude non serious reports. Interestingly, the Al platform can also analyze unstructured data, extract the text, and identify relevant information to build clinically robust auto-narratives and identify patterns within structured and unstructured narratives, refuting the need for routine review of single cases and manual identification and validation of signals[16]. Further more, it can extract ICSR information from various published documents such as medical literature, case reports, medication reviews in social media, free-text clinical notes in electronic health records, and discharge summaries. A recent survey reports that the use of AI tools processes the data very fast, speeds up computations that were not previously feasible, and saves scientists time and money With the large amount of drug safety data being stored in an electronic manner, the adoption of AI tools will reduce the efforts, time, and cost of case processing, improve data quality, and possibly be a game changer for PV activities[17].

Challenges of Using AI in Pharmacovigilance

Pharmacovigilance is a critical and essential function in healthcare. However, the use of artificial intelligence (Al) in this field is still a relatively new and developing field. One of the main challenges in adopting to Al is availability of structured and curated data for training the software to identify potential drug safety issues. Additionally, there are privacy concerns with using Al for pharmacovigilance, as data could potentially be used for other purposes without consent from individuals involved. Some other issues that need to be considered when deploying Al in drug safety monitoring are data quality, machine learning algorithms and data processing. Processes for data quality assurance and data management oversight can enhance the quality of data. Adding a human intelligence module to the system can enhance machine learning algorithms. Using a machine learning technique that is resilient to missing data can enhance data processing. Pharmacovigilance will probably rely more on Al in the upcoming years as a result of Al's continuing development and the development of data-driven algorithms[18]

1. Scientific Challenges

Interpretation and prediction

Processing AE cases in PV is a complicated procedure that includes several adjudication and decision-making points inside a system that is regulated and audited. For determining causality and detecting signals, clinical evaluation and the viewpoint of the doctor have played a significant role. The evaluation of AE's causality primarily relies on professional opinion and reflection. 112,13] The medical science and therapeutics arc complex and ever-changing The assessment of ICSRS is not a standardized or homogenous process that can be computerized. In fact, variations in the clinical presentation of the patients and adverse effects typically require human intervention and clinical evaluation for decision-making. The central question is whether the current Al tool is strong enough to determine temporality, causal association, predict potential drug-drug interaction and flag safety alerts in real-world data processing, and ensure generalizability and quality performance. According to Huysentruyt et al., complete AI automation of PV is still being developed for best practices and harmonization. It is improper and dangerous to fully automate heterogeneous complicated data using AI tools. It might be deceptive and erroneous to fully automate the PV system in order to identify these intricate patterns. This raises even another accountability issue. If an Al tool makes a mistake in spite of being thoroughly validated, who will be held responsible: developer, technology firm, or regulator? Importantly, AI technology must be flexible and recognize the need for expert judgment for the assessment of complex difficult case scenarios[18-19].

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2. Technological challenges

Training datasets and validation

The fundamental key to this impressive technology is training datasets used for the generation of Al algorithms. The dataset has to be vast and diverse, from different sources, covering all types of reports, representing the world's population to make the algorithm valid and robust in real-world settings. Datasets must be integrated, linked, annotated, labeled, and maintained in order to teach and train the computers from conception to deployment. Before being used on actual data, the training model must then be examined and verified. India has a well-established PV system and database. However, it does not represent the actual AEs happening in the real world due to underreporting and selective reporting. In order to provide high-quality evidence for causal association and signal detection, spontaneous adverse event reports must be connected to public and private hospitals' electronic health records, general practice records for patients outside of the hospital, disease registries, and published medical literature[20].

II.CONCLUSION

AI in health care has been very impressive for a well-defined, discrete task like the interpretation of medical images; however, its application to heterogeneous data is complicated. There may be advantages to using AI tools in PV systems to reduce manual labor and increase productivity. However, it cannot replace or overtake the importance of medical review and judgment of trained PV professionals for final adjudication of causality and signal detection. To date, full automation of PV system comes at risks and several challenges. It requires more testing, validation, and approval from medical professionals and regulators. Neither AI experts appreciate the intricacy and complexity of the interpretation of medical data nor do medical professionals comprehend the operations of AI technology. AI technology should enhance human intelligence rather than substitute human experts. What is important is to emphasize and ensure that AI brings more benefits to PV rather than challenges.

REFERENCES

[1]. Mann RD, Andrews EB. Pharmacovigilance. John Wiley & Sons; 2007.
[2]. Office of the Commissioner. Individual Case Safety Reports. 2019. Available at: https://www.fda.gov/industry/fda- resources-data- standards/individual-case-safety-reports
[3]. Ratain et al. (2016). Electronic Health Records and Pharmacovigilance. Journal of Clinical Pharmacology, 56(11), 1339-1345. DOI: 10.1002/jcph.760
[4]. Edwards RI. Adverse drug reactions: finding the needle in the haystack. BMJ. 1997;315:500.
[5]. Liu, J., et al. (2021). "Artificial Intelligence in Solar Energy: Current Status and Future Prospects." Renewable and Sustainable Energy Reviews, 143, 110915.
[6]. Li, S., & Zhang, H. (2020). "A Review of Machine Learning in Photovoltaic Systems: Modeling, Optimization, and Applications." Energy Reports, 6, 1237-1251.
[7]. Zhao, Z., & Liu, X. (2022). "Machine Learning Techniques in Solar Energy Systems: Applications in Safety, Fault Detection, and Predictive Maintenance." Energy and Buildings, 267, 112206.
[8]. Article: "Artificial Intelligence in Pharmacovigilance: An Emerging Approach to Safety Monitoring." https://link.springer.com/journal/.
[9]. European Medicines Agency (EMA). (2020). Artificial Intelligence and Machine Learning in Pharmacovigilance: A Regulatory Perspective. Retrieved from https://www.ema.europa.eu
[10]. Brown, A., & Zhang, L. (2022). Artificial Intelligence in Pharmacovigilance: Scope, Challenges, and Future Prospects. Journal of Pharmacovigilance, 45(2), 101-113.
[11]. Zhang, Y., et al. (2021). "Artificial intelligence in pharmacovigilance: Opportunities and challenges." Journal of Pharmacovigilance and Drug Safety, 12(4), 125-134.
[12]. Wang, J., et al. (2020). "Text mining and machine learning for pharmacovigilance: A review." Journal of Pharmaceutical Sciences, 109(9), 2860-2872.
[13]. Harper, C., & Lee, J. (2022). "Using natural language processing to identify adverse drug reactions: A systematic review." Pharmacoepidemiology and Drug Safety, 31(5), 675-687.

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[14]. European Medicines Agency (EMA). (2021). "Artificial intelligence in pharmacovigilance: Regulatory considerations and framework." European Medicines Agency. Available at: https://www.ema.europa.eu

[15]. U.S. Food and Drug Administration (FDA). (2023). "Pharmacovigilance and AI: Strengthening post-market safety surveillance." FDA Guidance Documents. Available at: https://www.fda.gov

[16]. Bates, D. W., & Singh, H. (2022). "Artificial intelligence in pharmacovigilance: Transforming drug safety monitoring." Pharmacoepidemiology and Drug Safety, 31(6), 653-664. Available at: https://onlinelibrary.wiley.com

[17]. Vargas, M. R., & Medina, M. (2021). "Artificial intelligence in pharmacovigilance: Impact, challenges, and future perspectives." Pharmaceutical Safety Journal, 12(4), 212-227. Available at: https://www.pharmasafetyjournal.com

[18]. Sarker et al. (2020). Human-in-the-Loop Machine Learning for Pharmacovigilance. Journal of Medical Systems, 44(10), 2108.

[19]. Agbabiaka TB Savović), Ernst E. Methods for causality assessmentof adverse drug reactions: A systematic review. Drug Saf 2008;31:21-37.

[20]. 13. Ralph Edwards I. Causality assessment in pharmacovigilance: Still a challenge. Drug Saf 2017;40:365-72