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Review Article

AI in Pharmacovigilance: Automated Detection of Adverse Drug Reactions

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Abstract

Pharmacovigilance (PV) is essential for the surveillance of drug safety; however, existing forms of PV are based on passive reporting systems. Problems of under-reporting, data volume, manual processing bottlenecks and delayed signal detection prevent timely identification of Adverse Drug Reactions (ADRs). The automation of ADR detection are in various ways in which Artificial Intelligence (AI), and specifically Machine Learning (ML) and Natural Language Processing (NLP) can potentially transform the area. Artificial intelligence (AI) also boosts the efficiency, agility, and sensitivity of pharmacovigilance activities by leveraging real-world data sources such as Electronic Health Records (EHRs), academic publications, or social media. The benefits include quicker case treatment, early signal identification, and new adverse drug reaction detection. Certainly, there are data quality issues to address, interpretation ("black box"), how it can be integrated into workflows that already exist and the negation of biases in algorithms, which should still be something that is tested. The application of AI to pharmacovigilance has the potential to transform it from a reactive and passive, into a predictive, proactive, robust and efficient tool benefiting patient safety through early intervention and more comprehensive safety surveillance.

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KEYWORDS: Pharmacovigilance (PV), artificial intelligence (AI), machine learning (ML), adverse drug reactions (ADR) etc.

1. INTRODUCTION

Pharmacovigilance (PV) guarantees drug safety following market clearance since negative drug reactions (ADRs) present a serious public health issue (WHO, 2023). Traditionally, PV depended on voluntary reporting systems including FDA databases and VigiBase; nevertheless, under-reporting, inconsistent data quality, and big unstructured datasets restrict efficient signal detection (Bate & Edwards, 2006; Harpaz et al., 2013). Including natural language processing and machine learning, artificial intelligence provides better methods for automated ADR detection (Yang et al., 2017).

2. Traditional Pharmacovigilance Methods and Limitations

Using MedDRA coding, manual data entry, and WHO–UMC causality assessment, conventional pharmacovigilance often entails time-consuming report reviews (e.g., vertigo after amlodipine use), therefore delaying signal detection and incomplete ADR reporting (Sarker et al., 2015).

3. AI Approaches for Automated ADR Detection

AI identifies adverse drug reactions using diverse data sources.

3.1. Natural Language Processing (NLP): NLP helps find knowledge in unorganized text. RE (Relation Extraction) identifies relationships (Liu et al., 2016), while NER (named entity recognition) finds important entities like medicines. Deep learning methods like BERT enhance the accuracy of these tasks (Devlin et al., 2019).

3.2. Machine Learning (ML) and Deep Learning (DL): Through supervised or unsupervised models, machine learning finds ADR signals by noting patterns in huge datasets. Deep learning improves NLP activities and ADR prediction (Pawar et al., 2017).

4. Data Sources Used by AI

Artificial intelligence uses many data sources for drug safety analysis. Electronic Health Records provide detailed patient information to link drugs with side effects (Gurulingappa et al., 2012).AI also looks at scientific literature for side effect reports and collects patient experiences from social media(Sarker et al., 2015). Insurance claims and clinical trial results further improve AI's drug safety capabilities (Coloma et al., 2011).

5. Advantages of AI in Drug Safety Monitoring

AI offers several advantages in drug safety monitoring:

- Enhanced efficiency: Automation of data entry, coding, and report review reduces processing time and enables early signal detection (Yang et al., 2017).
- Improved signal detection: AI identifies subtle and complex safety patterns earlier than conventional methods.
- Handling large datasets: AI effectively processes diverse structured and unstructured data sources.
- Signal prioritization: AI ranks potential signals by severity or novelty, supporting focused expert review (Liu & Chen, 2013).
- Detection of novel ADRs: Integrated data analysis helps identify new adverse effects and drug interactions (Tatonetti et al., 2012).

6. Difficulties and Constraints

Data quality issues can lead to inaccuracies and bias in AI models. Successful AI integration requires careful planning (Obermeyer et al., 2019). AI must be safe and reliable for regulatory compliance, especially in pharmacovigilance (Bate & Hobbiger, 2021, FDA, 2021). Ethical concerns include privacy, transparency, and accountability when using social media and health data.

7. Future Directions

Multimodal data integration, sophisticated models such BERT, explainable AI, real-world evidence, predictive safety with clinical and genetic data, and worldwide cooperation for standard models (WHO, 2023) define future research in AI pharmacovigilance.

8. CONCLUSION

By employing large data for proactive safety inspections, artificial intelligence increases drug safety monitoring. By examining several data sources, it enables quick detection of safety issues. But questions like data quality and system compatibility have to be handled. Overcoming these obstacles requires continuous study and cooperation, therefore guaranteeing safe medicine usage everywhere.

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