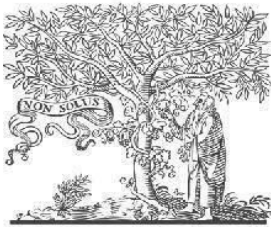


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Title: " EXPLAINABLE ARTIFICIAL INTELLIGENCE FOR PATIENT SAFETY A REVIEW OF APPLICATION IN PHARMACOVIGILANCE"

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EXPLAINABLE ARTIFICIAL INTELLIGENCE FOR PATIENT SAFETY A REVIEW OF APPLICATION IN PHARMACOVIGILANCE

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ABSTRACT

Explainable AI (XAI) is a methodology designed to enhance the transparency of AI models. Often referred to as black boxes. Its importance has been increasingly recognized across various fields, including pharmacovigilance, which monitors drug safety and adverse effects. This research aimed to review studies applying XAI in pharmacovigilance, identifying only 25 relevant papers out of an initial 781. The study highlights the potential of XAI in analyzing clinical, registry, and knowledge data to assess drug treatments, side effects, and interactions using models like decision trees, and NN, and graph models. While AI is widely used for drug surveillance and patient safety, XAI's role remains underutilized.

INTRODUCTION

costly and time-consuming and can result in adverse drug reactions (ADRs) that go unreported to healthcare professionals.

Artificial intelligence (AI) can improve PV, but its use in PV is still in the early stages of research. Various machine learning (ML) techniques, together with natural language processing and data mining, can be applied to electronic health

records, claims databases and social media data to improve the characterization of known drug side effects and reactions, and to detect new signals [2], [3].

AI-based technologies have been criticized for their inexplicable algorithms, despite their high predictive power. In critical decision areas such as healthcare, the reasoning behind a decision is as important as the decision itself, which is why there is growing interest in and research and development around Explainable Artificial Intelligence (XAI).

XAI was developed to improve the transparency of AI systems and generate explanations for them, and seeks to increase trust and understanding by assessing the strengths and limitations of existing models [4], [5], [6]. Approaches that extract information from a model's decision-making process, such as post-hoc explanations, can provide useful information for practitioners and users interested in case-by-case explanations rather than the internal workings of a model [7].

XAI increases the explain ability and transparency of AI algorithms by making it possible to interpret the variables that influence decisions, complex internal features, and learned decision paths within a decision process [8], [9]. I.R. Ward et al. successfully quantified the importance of features using an XAI algorithm, further demonstrating the potential contribution of XAI to PV monitoring [10].

The importance of PV in medicine is relevant to all species affected by medical interventions, and ensuring medical safety requires attention and research into approaches such as drug safety reporting and the exchange of reliable and timely information on PV activities [11]. The global pharma covigilance and drug safety

software market size was valued at USD 6.9 billion in 2021 and is estimated to expand at a compound annual growth rate (CAGR) of 10.5% between 2022 and 2030 (Source: www.grandviewresearch.com).

The aim of this study was to review the literature on the use of XAI in PV by identifying publications related to ML/AI and drugs and the rationale for the reported findings. From the perspective of AI and XAI usage, these studies were analyzed, and the findings were summarized, in which the use of XAI in the field of PV is referred to as “PV XAI”. The main contributions are highlighted and discussed below:

- This study is clearly an early attempt to review XAI research in PV. Unlike other fields, we found that XAI research in PV is at an early stage of development, limited to a few articles and some methodologies.
- Nevertheless, we have identified the positive potential of PV XAI for drug therapy, ADRs, poly pharmacy and drug repurposing.
- While safety issues in real-world healthcare settings may limit the growth of the field, we expect PV XAI research to expand as it has in other areas, and we encourage collaboration and ongoing research discussions with experts in the field.

II.EXISTING SYSTEM

In this study, the trend of XAI in the field of PV was examined. However, the trend was

also explored broadly to more diverse aspects, including interpretable artificial intelligence. Although there is a clear difference between Explainable AI (knowledge about what different nodes represent and their importance to model performance) and Interpretable AI (ability to determine cause and effect in a machine learning model), based on the same aim, they were comprehensively reviewed.

There has been a surge in XAI studies in drug-related applications since 2019, with relatively few studies from 2013 to 2018 (Fig. 1). The limited number of publications indicates a demand for more research on XAI in PV applications.

The selection of appropriate search terms for the exploration of XAI-related research in PV was not easy; we started manually with broad keywords. The following five searches were performed: pharmacovigilance XAI (47), pharmacovigilance “explainable artificial intelligence” (76), pharmacovigilance explainable AI (230), pharmacovigilance explainable ML (181), and pharmacovigilance explainable machine learning (213). These search terms were used in a Google Scholar search on 22 June 2022, and the numbers in parentheses are the number of articles returned from each search. Retrieved articles were first screened for titles and abstracts to exclude duplicates,

then articles were added through a first full-text review for relevance and a second full-text review based on a selective methodology, resulting in a final selection of 25 unique publications

Disadvantages

- The complexity of data: Most of the existing machine learning models must be able to accurately interpret large and complex datasets to detect Patient Safety.
- Data availability: Most machine learning models require large amounts of data to create accurate predictions. If data is unavailable in sufficient quantities, then model accuracy may suffer.
- Incorrect labeling: The existing machine learning models are only as accurate as the data trained using the input dataset. If the data has been incorrectly labeled, the model cannot make accurate predictions.

III. PROPOSED SYSTEM

The aim of this study was to review the literature on the use of XAI in PV by identifying publications related to ML/AI and drugs and the rationale for the reported findings. From the perspective of AI and XAI usage, these studies were analyzed, and the findings were summarized, in which the use of XAI in the field of PV is referred to as “PV XAI”. The main contributions are highlighted and discussed below:

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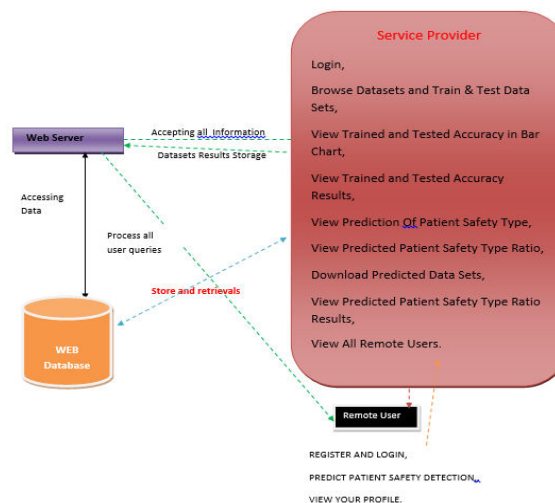
- While safety issues in real-world healthcare settings may limit the growth of the field, we expect PV XAI research to expand as it has in other areas, and we

encourage collaboration and ongoing research discussions with experts in the field.

Advantages

1) We propose Deep neural networks (DNNs) are the foundation of modern AI models.

2) The proposed system implemented Tree-based algorithms in which conceptually simple but powerful ML methods that are effective on small and large datasets to solve linear and nonlinear modeling problems..



IV.Modules

Service Provider

In this module, the Service Provider has to login by using valid user name and password. After login successful he can do some operations such as Browse Datasets and Train & Test Data Sets, View Trained and Tested Accuracy in Bar Chart, View

Trained and Tested Accuracy Results, View Prediction Of Patient Safety Type, View Predicted Patient Safety Type Ratio, Download Predicted Data Sets, View Predicted Patient Safety Type Ratio Results, View All Remote Users.

View and Authorize Users

In this module, the admin can view the list of users who all registered. In this, the admin can view the user's details such as, user name, email, address and admin authorizes the users.

Remote User

In this module, there are n numbers of users are present. User should register before doing any operations. Once user registers, their details will be stored to the database. After registration successful, he has to log :: by using authorized user name and password. Once Login is successful user will do some operations like register and login, predict patient safety detection, view your profile.

V.CONCLUSION

In this study, we reviewed PV XAI papers and discussed recent research trends and the need for XAI research. Unlike other areas where XAI and AI are developing together, PV XAI research is still in its infancy. There are not many papers on PV XAI and the methodology is limited to a few models. However, studies are slowly beginning to show the potential of XAI research for medication monitoring and patient safety, collecting ADR and ADE information, extracting drug-drug interactions, and predicting drug treatment effects.

As in other areas, as awareness of XAI methods grows, we expect to see AI used in pharmacyvigilance and patient safety in many more ways in the coming years than those identified in this review, and the positive potential of XAI for drug therapy, ADRs and interactions is very promising. However, it is clear that the growth of this field may be limited by the lack of validated and established uses of XAI in real-world healthcare settings, and this is an area that requires further investigation. Therefore, the challenges and future prospects of XAIs in pharmacovigilance should be discussed with continued interest.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

VI. REFERENCE

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