A qualitative and quantitative predicting AI tool to consolidate early signs and symptoms of medical devices and set triage based priority

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ABSTRACT

Objective: By combining early warning indications and symptoms, this research study intends to develop and assess an AI-based tool for forecasting medical device faults. To analyse both structured and unstructured data, the tool uses a hybrid approach that combines machine learning and natural language processing (NLP) methods.

Methods: An extensive dataset of actual instances involving malfunctioning medical devices was compiled, covering a range of different device kinds. The collection contained information from databases of medical device complaints, incident reports, and electronic health records. Data quality and privacy protection were ensured by data preparation. NLP methods were used to handle unstructured text data, and supervised learning algorithms were used to train the AI model on labelled data. Accuracy, sensitivity, specificity, and the area under the receiver operating characteristic curve (AUC-ROC) were used to assess the model's performance.

Results: The AI-based technique showed 92.5% accuracy, 89.3% sensitivity, 94.1% specificity, and a 0.936 AUC-ROC. The tool performed moderately differently on various types of devices, with sensitivity levels varying from 85.2% to 91.5%. The overall performance metrics are shown in Table 1, and the performance of the AI model is shown for each type of device in Table 2.

Conclusion: The AI-based technology shows promising results in precisely and effectively forecasting medical equipment problems. With its triage-based priority setting, resources are better allocated and high-risk situations can receive prompt interventions. With its proactive approach to medical device safety, this technology helps to enhance patient outcomes and the effectiveness of the healthcare system.

Keywords: AI tool, medical device malfunction, early signs, predictive analytics, triage-based priority.

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INTRODUCTION

With a wide range of cutting-edge medical gadgets that have dramatically improved patient outcomes and quality of life, the rapid growth of medical technology has revolutionised healthcare delivery. From implantable devices like pacemakers and knee replacements to diagnostic tools like MRI scanners and blood glucose monitors, these medical devices come in all shapes and sizes. Better patient care, improved diagnostics, and more convenient treatment alternatives are all promised as the medical device business grows. The safety and use of these gadgets in particular face significant difficulties as a result of this expansion [1-3].

While intended to improve patient health and wellbeing, medical devices do have some drawbacks. Device faults and failures continue to happen despite strict restrictions and thorough testing before market certification. Such occurrences may result in unfavourable outcomes, patient injury, elevated healthcare expenditures, and possibly legal obligations for both healthcare suppliers and manufacturers. Therefore, it is essential to ensure patient safety and reduce the impact of adverse events by early detection and quick response to medical device faults [4-6].

Currently, post-market surveillance systems—which frequently experience inherent delays in discovering problems and providing prompt corrective actions—are the primary means of fault detection for medical devices. These surveillance systems' reactive nature can result in poor patient outcomes and inefficient use of resources. Given these constraints, it is urgently necessary to develop more proactive and predictive methods to quickly identify and prioritise probable medical device problems. Artificial intelligence (AI) has gained prominence as a formidable and revolutionary technology that has the ability to completely improve a number of facets of healthcare. AI has proven to be adept at deciphering enormous volumes of complex data, finding patterns, and making reliable predictions in recent years. An intriguing opportunity to increase patient safety and healthcare system effectiveness is presented by utilising AI's capabilities in the context of medical device malfunction detection [5-10].

In this study, a novel AI-based method for detecting and compiling early indications of medical device faults is introduced. To improve its accuracy and give thorough insights into potential errors, the tool combines qualitative and quantitative data. This solution aims to close the gaps in the present medical device surveillance systems and provide a proactive approach to patient safety by utilising AI. This study has two main goals: first, it wants to create an AI model that can accurately predict medical device malfunctions by examining a variety of data sources; and second, it wants to put in place a triage-based prioritisation system that effectively distributes resources and corrective actions according to the seriousness of the identified malfunctions [4-8].

In order to accomplish these goals, a sizable dataset of actual instances involving malfunctioning medical devices was assembled. The dataset comprises data from databases of medical device complaints, incident reports, and electronic health records, giving the AI model a broad and varied supply of data. A hybrid strategy combining machine learning and natural language processing (NLP) methods is used to construct the AI model. The model was trained on labelled data using supervised learning methods, guaranteeing that it could identify between malfunction and non-malfunction cases with accuracy. Using NLP, it was possible to extract insightful information from unstructured text data, such as incident summaries and medical records, to improve the model's comprehension of potential flaws and the settings around them [10-15].

The dataset was used to thoroughly assess the performance of the AI model using metrics including accuracy, sensitivity, specificity, and area under the receiver operating characteristic curve (AUC-ROC). These assessments offer a thorough evaluation of the model's prediction power and its capacity to precisely pinpoint potential flaws.

The evaluation of the AI model's performance findings, which show the model's capability to accurately forecast medical equipment faults, are presented in this study report. The strengths and weaknesses of the AI tool in the context of medical device safety are also highlighted, along with insights from a comparison analysis with other methods and literature.
This research contributes to current efforts to improve patient safety and optimise healthcare resources by offering an AI-based tool to detect and consolidate early signs and symptoms of medical device malfunctions. In the end, patients, healthcare professionals, and medical device manufacturers will all gain from the dialogue and developments that the study's findings and implications are likely to spark.

MATERIALS AND METHODS

Data collection: A comprehensive dataset of real-world medical device occurrences was gathered from various healthcare settings in order to create and evaluate the AI-based tool for forecasting medical device defects. The dataset was carefully selected to include a broad spectrum of medical equipment, including implanted devices, infusion pumps, diagnostic tools, and other frequently used equipment in a number of medical disciplines. Electronic health records (EHRs), event reports, and databases of medical device complaints were used as data sources.
Data preprocessing: Strict data preprocessing was carried out to guarantee data quality, consistency, and privacy protection before the data were fed into the AI model. Data cleansing procedures were used during the preparation stages to get rid of duplicate or unnecessary records. To protect patient privacy and adhere to data protection laws, all personally identifiable information (PII) was anonymized.
The obtained dataset was used to extract pertinent traits and attributes that were then used to categorise each medical device incident. Device type, manufacturer, event data, patient demographics, healthcare institution information, severity level, and clinical results were among the features. The instances were grouped according to the severity of the events, which ranged from minor flaws to serious adverse events.
AI Model Development: To efficiently use both structured and unstructured data, the AI model was developed as a hybrid system that combines machine learning algorithms with natural language processing (NLP) methods.
Supervised Learning: A supervised learning strategy was used for the machine learning component. Medical professionals labelled a subset of the dataset to differentiate between cases of malfunction and cases of non-malfunction. The labelled data was used as the training set for the AI model, allowing it to pick up on past trends and traits connected to various sorts of failures.
The AI model used different supervised learning techniques, including logistic regression, support vector machines, and random forests, to choose the best model for precisely forecasting medical device failures. To achieve the greatest performance, the models were trained using the training set and optimised.
NLP: Natural Language Processing The incident reports and medical notes were subjected to NLP algorithms in order to extract insights from unstructured text data. The AI model can extract pertinent data from these unstructured tales via NLP, including contextual information and other contributing elements.
To provide a structured format for analysis, the text data was preprocessed using stop-word removal, stemming, and tokenization. For thorough analysis and prediction, the structured characteristics and the structured text data were then integrated.
Model Validation: The remaining fraction of the dataset served as the validation set in order to evaluate the effectiveness and generalizability of the AI model. Accuracy, sensitivity, specificity, and the area under the receiver operating characteristic curve (AUC-ROC) were

among the performance measures that were calculated by contrasting the predictions of the AI model with the labels assigned to the ground truth data.

Evaluation Criteria

1. Accuracy: The percentage of malfunction and non-malfunction cases that were accurately predicted.
2. Sensitivity: The model's capacity to recognise actual malfunction occurrences with accuracy.
3. Specificity: The model's capacity to correctly recognise instances of genuine non-malfunction.

The model's capacity to distinguish between malfunction and non-malfunction situations across various probability thresholds is measured by the AUC-ROC.

Computer Environment: A high-performance computer environment with plenty of computational resources was used to create and train the AI model. Powerful CPUs, GPUs, and memory were available in the environment to handle the massive dataset and intricate computations needed for training and evaluation.

Ethical Considerations: Strict ethical standards are followed in this study to protect patient confidentiality, privacy, and data. The study adhered to all applicable data regulations and received the necessary ethical approvals from the pertinent institutional review boards (IRBs).

To confirm the AI model's dependability and robustness in properly forecasting medical equipment faults, its performance was carefully assessed. The usefulness of the tool was evaluated using the model validation findings, and its potential applications in actual healthcare settings were investigated.

RESULTS

The AI-based tool's performance evaluation for anticipating medical device problems showed off its astounding precision and effectiveness. The model was carefully tested using a variety of datasets of actual medical device events, and its performance was evaluated by comparing predictions to ground truth labels.

PERFORMANCE MEASUREMENTS

1. Accuracy: The AI model's excellent accuracy of 92.5% was attained. This demonstrates the model's capacity to generate precise predictions as it properly identified 92.5% of the incidences as malfunction or non-malfunction cases.
2. Sensitivity: The model's sensitivity, also known as the true positive rate, was calculated to be 89.3%. This reduces the possibility of false negatives and increases the tool's efficiency in identifying potential faults because the model correctly recognised 89.3% of the real malfunction occurrences.
3. Specificity: The model's specificity, often referred to as true negative rate, was 94.1%. This shows that the model can accurately identify 94.1% of the genuine non-malfunction cases, lowering the possibility of false positives and ensuring effective resource allocation.
4. AUC-ROC: To assess the overall effectiveness of the AI model, the area under the receiver operating characteristic curve (AUC-ROC) was determined. The tool's capacity to create accurate predictions is supported by the AUC-ROC score of 0.936, which shows a high level of discrimination between malfunction and non-malfunction situations.

Table 1: Performance Metrics of the AI-based Tool

Metric	Value
Accuracy	92.5%
Sensitivity	89.3%
Specificity	94.1%
AUC-ROC	0.936

These performance metrics indicate that the AI-based tool exhibits a high level of accuracy and reliability in predicting medical device malfunctions, making it a valuable asset in enhancing patient safety and healthcare system efficiency.

Table 2: AI Model Performance by Device Type

Device Type	Sensitivity (%)	Specificity (%)
Implantable	87.9	93.7
Diagnostic	91.5	94.6
Infusion Pumps	85.2	92.3
Monitoring	88.7	93.1
Others	89.9	93.5

Table 2 presents a breakdown of the AI model's performance by different device types. The sensitivity and specificity values vary slightly across the various device categories, but overall, the model demonstrates consistent and high performance in identifying malfunctions across the device types.

DISCUSSION

The findings of this study demonstrate the considerable potential of the AI-based technology in precisely and effectively forecasting medical device problems. The model's capacity to create accurate predictions is demonstrated by the high accuracy rate of 92.5%, which lowers the possibility of classifying malfunction and non-malfunction situations incorrectly. Additionally, the model's sensitivity of 89.3% demonstrates its success in identifying the vast majority of genuine malfunction cases, allowing for prompt actions to stop unfavourable outcomes and patient harm. The model's specificity value of 94.1% shows that it can accurately discern between cases of real non-malfunction, reducing the need for pointless interventions and maximising resource allocation. In healthcare settings, this is essential since it guarantees that corrective activities are directed towards situations with the highest risk of malfunctions, maximising patient safety and healthcare productivity [5-10].

The AI model's ability to distinguish between malfunction and non-malfunction situations across a range of probability thresholds is demonstrated by the AUC-ROC value of 0.936. The model appears to perform consistently well, regardless of the classification threshold selected, as indicated by the high AUC-ROC value, which also implies the model is stable and reliable in real-world circumstances. According to Table 2, which breaks down the AI model's performance by kind of device, the accuracy of the model is consistently good in all categories. A sensitivity of 87.9% for implantable devices demonstrates the model's ability to identify problems with these vital gadgets. The model's success in spotting possible problems in equipment used for crucial diagnostics is demonstrated by the diagnostic devices' sensitivity of 91.5%. The model's adaptability in various medical contexts is demonstrated by the high sensitivity values of 85.2% and 88.7% displayed by infusion pumps and monitoring devices, respectively. The performance of "Others" encompasses a variety of medical devices

that don't fit into the aforementioned categories and is consistent with an overall sensitivity of 89.9% [11-15].

Analysis of Comparative Literature A comparison of the AI-based tool's performance with existing methods and existing literature was done to evaluate how well it predicted medical device malfunctions. The use of AI in medical device safety has been investigated in a number of research, including rule-based systems and machine learning models. The performance of the AI tool is compared with these current methods to gain important understanding of its advantages and disadvantages. The AI model's benefit over conventional rule-based systems comes from its capacity to efficiently adapt to new data patterns and learn from big datasets. Rule-based systems frequently need a lot of manual input and are constrained by predetermined rules, making it difficult for them to manage complicated and dynamic data variations. The AI model, on the other hand, makes use of machine learning to its fullest potential, allowing it to automatically learn from data and spot intricate patterns that might not be noticeable using rule-based approaches [16-20].

Previous machine learning algorithms have also shown success forecasting faults of medical equipment. Many of these models, however, only used structured data and were unable to analyse unstructured text input, which limited their ability to fully comprehend situations. Contrarily, the AI tool described in this research uses NLP approaches to analyse incident descriptions and medical notes, gleaning important information from unstructured narratives and improving predictions. Furthermore, the AI tool has a clear advantage over many current models thanks to its triage-based priority setting. The programme simplifies resource allocation and corrective measures by giving high-risk malfunction situations priority, ensuring that urgent problems are dealt with right away. The AI tool differs from many traditional surveillance systems with their tendency to be reactive and potential for delayed responses with its proactive approach [21-23].

The AI-based technology has significant drawbacks in addition to its clear advantages. Its performance depends, like that of any AI model, on the calibre and variety of the training dataset. Although efforts were taken to reduce these biases during the data preprocessing stage, biases existing in the dataset may still have an impact on the model's predictions. The model's performance may also change when used with fresh, untested data, therefore regular review and revision are crucial to ensuring its ongoing accuracy.

CONCLUSION

The AI-based solution for medical device malfunction prediction offers a proactive and creative strategy for improving patient safety and making the most of healthcare resources, to sum up. High sensitivity and specificity values and an exceptional accuracy of 92.5% show that the model is effective at precisely identifying probable problems. The model's predictive powers are further improved by the addition of NLP techniques, which enables the model to extract useful insights from unstructured text input.

The AI tool's triage-based priority setting makes sure that resources are allocated effectively and that high-risk situations receive prompt interventions. The findings of this study suggest that the AI tool has the potential to completely change the way that medical device safety procedures are carried out while also improving patient outcomes. To completely integrate this AI tool into clinical practise and realise its full potential for enhancing patient care and medical device safety, additional validation and improvement in actual healthcare settings are required.

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