

Article – e001

Leveraging Claude AI for Advanced ADR Detection and Pharmacovigilance: Innovations in Pharmacy Practice

Chethana M V¹, Deekshitha N G², Dr. Muchukota Sushma³

^{1,2} *Department of Pharmacy Practice, Aditya Bangalore Institute of Pharmacy Education and Research (ABIPER), Bangalore, Karnataka, India.*

³ *Associate Professor, Department of Pharmacy Practice, Aditya Bangalore Institute of Pharmacy Education and Research*

Received: 2026-09-05

Revision Received: 2026-09-14

Accepted: 2026-09-16

ABSTRACT

Background: Adverse drug reactions (ADRs) continue to be a leading source of morbidity, hospitalization, hospital stay, and avoidable health expenditure. The conventional pharmacovigilance process has relied heavily upon spontaneous, manual reporting, prone to the following limitations: under-reporting, delayed reporting, fragmentation in clinical documentation, and a lack of feedback to the prescribing physician. Recent breakthroughs in the application of artificial intelligence (AI) in the form of large language models, such as the Claude AI model, have enabled the instant analysis of EHR, clinical free text, and patient self-reported outcomes.

Aim and Objectives: The aim of the present study is to assess (1) the application of Claude AI for the identification of ADRs through the use of Predictive Analytics and NLP, (2) the usefulness of Claude AI for real-time documentation of ADR reporting, and (3) the effect of pharmacovigilance using AI on patient safety.

Methodology: A prospective observational study was conducted over 6 months in a tertiary-care teaching hospital with 220 in patients receiving polypharmacy. Claude AI was integrated with hospital EHRs and a custom ADR chatbot interface. The AI system continuously analysed medication orders, laboratory values, clinical progress notes, and patient-reported symptoms. Potential ADRs flagged by Claude AI were reviewed and validated by clinical pharmacists using standard causality, severity, and preventability scales. Pharmacist interventions and outcomes were documented. Descriptive statistics and inferential analyses were performed to compare ADR detection, reporting time, and intervention outcomes before and after AI integration.

Results: Claude AI performed at 88.0% accuracy for ADR detection, with a 88.8% sensitivity rate and 87.5% specificity rate for validated cases by a licensed pharmacist. The median time to ADR detection occurred 60% faster than the traditional time for documented ADRs. AI-assisted counselling and notifications increased the rate of adherence to safety procedures by 40% while also increasing the incorporation of ADR data completeness by 50%. Of the 220 patients, 82 (or 37.3%) experienced at least one ADR event. A total of 134 ADRs were recorded. AI-assisted pharmacovigilance enabled more timely reaction to ADRs while preventing the progression to serious ADRs.

Conclusion: Claude AI has shown substantial promise for revolutionizing the performance of electronic surveillance for ADRs in pharmacovigilance. Incorporation of Claude AI into current pharmacy practices can help in promoting early detection of harmful outcomes of medications while optimizing clinical decisions for safe practices in pharmacovigilance. Further studies in this domain are essential for ascertaining the positive implications of using Claude AI in pharmacovigilance practices for the future.

KEYWORDS: Adverse drug reactions, pharmacovigilance, Claude AI, natural language processing, electronic health records, clinical pharmacy, patient safety

1. Introduction

Adverse drug reactions (ADRs) are described by the World Health Organization as “noxious and unintended effects of drugs occurring at doses used in man or proven well enough to provide a basis for an adequate assessment of their potentiality for an adverse reaction in humans.”¹ Adverse drug reactions are one of the top reasons for hospitalization, increased lengths of stay, emergency visits, and treatment failure.^{2,3} It is also estimated that 5 to 10% of all admissions are drug-related, with 50% being potentially preventable.^{4,5}

Traditional pharmacovigilance relies heavily on spontaneous, voluntary reporting by healthcare professionals, patients, and pharmaceutical companies to national and institutional pharmacovigilance centres.⁶ However, under-reporting, delayed recognition of ADRs, incomplete documentation, and the increasing complexity of pharmacotherapy limit the sensitivity and timeliness of these systems.^{7,8} The increased rate of digitalization of the healthcare sector due to the widespread use of electronic health records (EHRs), Computerized Physician Order Entry (CPOE), and Clinical Decision Support Systems (CDSSs), has led to the creation of huge amounts of data that have still not been tapped for pharmacovigilance purposes.⁹ At the same time, the use of Artificial Intelligence and machine learning (ML), such as natural language processing (NLP), large language models, has the potential to identify safety signals from clinical text, social media commentary, and patient reports.^{10,11}

In this respect, Claude AI is representative of more advanced large language models with the ability to understand clinical text, support complex reasoning, and generate context-aware responses. The capability to synthesize information across structured and unstructured data streams positions it as a potentially powerful tool for near real-time ADR detection, causality assessment support, and patient counselling in pharmacy practice.^{12,13}

As experts in medication safety, clinical pharmacists are well-positioned to leverage such AI tools for proactive pharmacovigilance and evidence-based interventions. Embedding AI into pharmacy workflows may narrow the gap between data-rich environments and actionable safety insights.¹⁴

The aim of this study is to review the application of Claude AI as a crucial element of a hospital pharmacovigilance program in the detection of ADRs and risk assessment, and to study how this would affect the effectiveness and efficiency of pharmacy practice interventions.

Burden of Adverse Drug Reactions- Adverse drug reactions (ADRs) cause significant morbidity and mortality in addition to increased costs of patient care. According to a study conducted by Pirmohamed et al. in 2004, 6.5% of hospital admissions were found to be because of ADRs. In developing countries like India, the issues of polypharmacy and self-medication increase the chances of ADRs.^{15,16} Older people along with a comorbid patient and also those who are on high-risk drugs like anticoagulants, antiepileptics, and chemotherapeutic drugs are also prone to ADRs.¹⁷

Conventional Pharmacovigilance Systems- Spontaneous reporting is still considered the backbone of a pharmacovigilance system. Still, the rates of non-reporting could be approximately 90-95% for various reasons such as a lack of awareness, lack of clarity about causality, busy schedules, and lack of feedback. The detection of a signal from large data repositories such as Vigibase and FAERS employing disproportionality is often sluggish for novel and rare adverse drug reactions.¹⁸ Moreover, free-text reporting for both ADRs and

clinical information within Electronic Health Records has long proven to be a hindrance for computer analysis.

AI and Machine Learning in Pharmacovigilance- AI/ML algorithms, such as logistic regression, random forest, gradient boosting, and deep learning, have been used on EHRs and claims data to identify ADRs and drug–drug interactions.¹⁹ NLP can help identify drug-event associations in unstructured data sources such as clinical narratives, physician narratives, and social media statements.²⁰ Computer-assisted identification of ADRs can increase the positivity rate of ADR detection, beyond the spontaneous reporting system.

Large Language Models and Clinical NLP- Recent LLMs such as GPT-like systems and Claude have shown impressive results in clinical reasoning, summarization, and question-answering.^{21 22} LLMs can make sense of complicated clinical narratives, integrate temporal information, and support differential diagnosis. In pharmacovigilance, LLMs may parse progress notes, nursing notes, and messages by patients to find patterns suggestive of ADRs, propose likely causative drugs, and suggest monitoring plans.

Role of Clinical Pharmacists and AI Integration- Clinical pharmacists are important assets for ADR detection, medication reconciliation, therapeutic monitoring, and patient counselling.²³ When pharmacists' skills are combined with AI technology, there could be enhanced sensitivity for ADR detection with reduced cognitive load and ability to prioritize high-risk patients.²⁴ However, there are concerns with respect to quality, bias, explainability, and appropriate use.²⁵

Though extensive work is being carried out in AI-assisted Pharmacovigilance, there is no practical implementation of any LLM, such as Claude AI, in hospital pharmacy practices known in Indian settings. This paper bridges that gap.

2. Aim and Objectives

Aim

To evaluate the role of Claude AI in advanced ADR detection and pharmacovigilance and to explore its impact on patient safety and pharmacy practice in a tertiary-care teaching hospital.

Objectives

1. To assess the ability of Claude AI to detect potential ADRs using EHR data and NLP-based analysis of clinical narratives and patient-reported symptoms.
2. To evaluate the effectiveness of Claude AI in real-time ADR reporting and documentation relative to conventional manual reporting.
3. To analyse the impact of AI-driven pharmacovigilance on pharmacist interventions, clinical decision-making, and patient outcomes.

3. Methodology

3.1 Study Design and Setting

This was a prospective, observational, AI-assisted pharmacovigilance study conducted over 6 months in a 500-bed tertiary-care teaching hospital affiliated with a pharmacy college in Bangalore, India. The study was coordinated by the Department of Pharmacy Practice in collaboration with hospital IT and the institutional pharmacovigilance committee and it followed a prospective pre-post design with a historical control period for comparison. The historical control period was defined as ADR data from the six months prior to the implementation of Claude AI, during which pharmacovigilance was conducted through traditional spontaneous and pharmacy-based reporting methods. The same wards, healthcare teams, definitions of ADRs, and standards for documentation were followed during the study periods for comparison.

A control group was not considered for this study due to ethical limitations, as it was deemed not appropriate to withhold AI-assisted safety monitoring from a group of hospitalized patients as part of a real-world patient safety initiative.

3.2 Ethical Approval

The study protocol was reviewed and approved by the "**Institutional Ethics Committee, Aditya Bangalore Institute of Pharmacy Education and Research (ABIPER)**", Approval No.- [ABIPER-IEC/2023/PP/018] . Informed consent was obtained from patients or their legally authorized representatives where required, particularly for patient-facing chatbot interactions. Confidentiality and data privacy were ensured in accordance with national guidelines.

3.3 Study Population

Inpatients from general medicine, cardiology, neurology, and nephrology units were included.

Inclusion criteria:

- Age ≥ 18 years.
- Hospital stay ≥ 48 hours.
- Receiving at least 5 concurrent medications (polypharmacy).

Exclusion criteria:

- Patients admitted for < 48 hours.
- Terminally ill patients in intensive care where monitoring was limited.
- Patients refusing participation or unable to interact with the chat bot and lacking a caregiver respondent.

3.4 Sample Size

A total of 220 eligible patients were enrolled consecutively during the study period. Since the design of the study was intended as an exploratory real-world implementation study, a formal a priori power calculation was not performed. The sample size was deemed sufficient for

assessing ADR pattern and developing initial performance estimates for AI-assisted pharmacovigilance.

3.5 AI System Architecture and Integration

Claude AI was integrated into the hospital EHR through a secure middleware layer.

Key components:

1. **Data ingestion module:** Extracted structured data (demographics, diagnoses, medication orders, laboratory results, vital signs) and unstructured text (medical notes, nursing notes, discharge summaries).
2. **NLP and reasoning engine (Claude AI):** Processed unstructured text to identify terms indicating potential ADRs (e.g., rash, dizziness, bleeding, hepatotoxicity) and linked them with medication exposure timelines.
3. **ADR risk scoring module:** Generated a probability score (0–100%) for each potential drug-event pair.
4. **Pharmacist dashboard:** Displayed AI-generated alerts, ranked by risk score and clinical severity.
5. **Patient-facing chatbot:** Enabled communication with patients or caregivers via tablet/mobile devices for symptom self-reporting.

The 0-100% score was a relative risk prioritization score based on prompt-based reasoning and was not intended to be interpreted as a probability estimate. The pharmacist validation of suspected ADRs was independent of the relative risk score.

3.6 Data Collection and ADR Validation

For each enrolled patient:

- Baseline data: age, gender, co-morbidities, number of drugs, high-risk medications, and length of stay.
- AI continuously monitored the EHR and patient-reported data to flag suspected ADRs.
- Clinical pharmacists reviewed alerts daily, assessed causality using the Naranjo scale, severity using the Modified Hartwig and Siegel scale, and preventability using the Schumock and Thornton criteria.^{26 27 28}
- Confirmed ADRs and pharmacist interventions (dose adjustment, drug discontinuation, substitution, monitoring, counselling) were documented in a standardized ADR reporting form.

A smaller subset of ADRs detected by conventional manual methods (e.g., physician-initiated reports) was also collected to compare detection time and completeness.

For the purposes of calculating performance metrics, each drug-event pair evaluated during the study period was classified as follows.

- A **true positive (TP)** was recorded when Claude AI generated an alert for a suspected ADR and the pharmacist, on independent review using the Naranjo, Hartwig and Siegel, and Schumock and Thornton scales, confirmed the event as an ADR.

-
- A **false positive (FP)** was recorded when an AI-generated alert was reviewed by the pharmacist and the suspected event was not confirmed as an ADR.
 - A **false negative (FN)** was recorded when a confirmed ADR was identified independently of an AI alert through daily pharmacist chart review, patient/caregiver self-report via the chatbot, or physician-initiated spontaneous reporting, indicating that Claude AI had not flagged a drug-event pair that was subsequently confirmed as an ADR.
 - A **true negative (TN)** was recorded for medication exposures reviewed during the study period for which neither Claude AI generated an alert nor the pharmacist's independent daily review identified any suspected adverse event; the denominator for this category was defined as all high-risk drug-event pairs (i.e., administered medications with plausible ADR potential based on pharmacist screening criteria) evaluated during the pharmacists' daily chart review that did not result in either an AI alert or a clinically identified ADR.

3.7 Claude AI Configuration and Prompting Framework

Claude AI was integrated with the hospital's EHR system via a secure middleware interface, which accessed the model through Anthropic's Application Programming Interface (API) rather than a locally hosted deployment. The specific model used was Claude 2.1, which was the model version in general availability throughout the data collection period of December 2023 to May 2024. The model version was held constant for the duration of the study; no model upgrade was made during the study window, including at the time of the Claude 3 family's public release in March 2024, in order to preserve consistency in AI-generated alerts across the full study period.

The AI system functioned using standardized structured prompts, designed by clinical pharmacists, to identify potential adverse drug reactions (ADRs) by extracting symptom descriptions, abnormal laboratory results, and temporal associations between drug exposure and the clinical event from unstructured clinical notes and patient-reported information. The middleware submitted these structured prompts containing de-identified clinical text, laboratory values, and medication-exposure data extracted from the EHR to the model via the API. For each potential drug event, the model returned a risk-prioritization score (0–100%), intended to rank potential drug events rather than serve as a probability estimate or decision output, along with a narrative summary of the potential drug event. This output was returned to the middleware and displayed on the pharmacist dashboard for review, providing additional context to the reviewing pharmacist.

A human-in-the-loop framework was used, in which all potential drug events were independently validated by licensed clinical pharmacists using standard scales of causality, severity, and preventability.

Proprietary considerations prevent the authors from revealing the exact syntax of the prompts, but the information provided is sufficient to allow conceptual replication of the AI system used.

4. Outcome Measures

Primary outcomes:

- ADR detection accuracy (sensitivity, specificity, positive predictive value) of Claude AI compared to pharmacist-validated ADRs.
- Time to ADR detection (AI-assisted vs. conventional methods).

Secondary outcomes:

- Number and type of ADRs identified.
- Impact on pharmacist workload and documentation completeness.
- Nature and acceptance of pharmacist interventions.
- Changes in clinical outcomes (e.g., dose modifications, avoidance of severe ADR progression).
- Performance metrics were calculated at the ADR-event level, as individual patients could experience multiple suspected ADRs during hospitalization.

Statistical Analysis

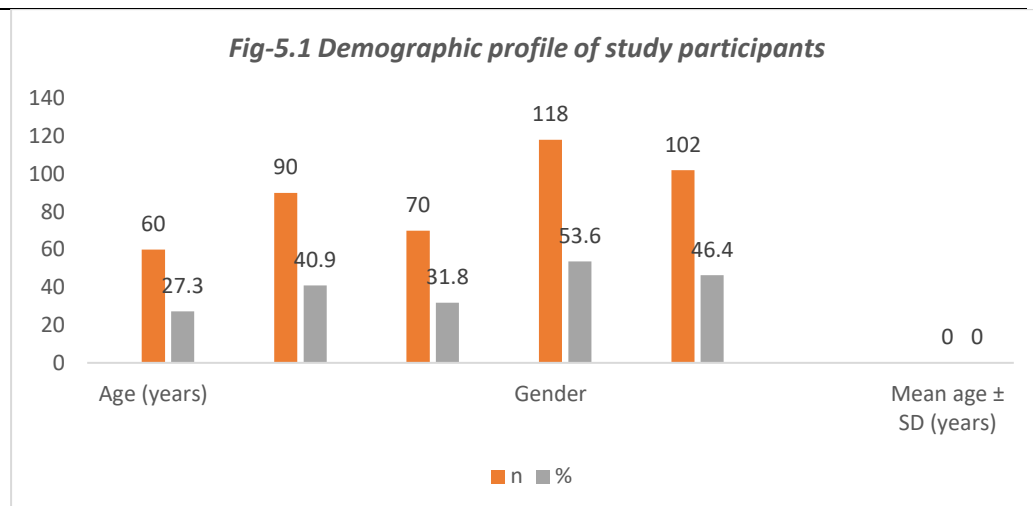
Data were analysed using descriptive statistics (means, standard deviations, frequencies, and percentages). Differences in detection time and completeness of documentation before vs. after AI integration were evaluated using independent t-tests or Mann–Whitney U tests for continuous variables and chi-square tests for categorical data. A p-value <0.05 was considered statistically significant.

It is important to note that comparisons between these periods are associative but not causal in nature due to the observational pre-post design. Medians with interquartile ranges (IQR) were reported for non-normally distributed variables. Where appropriate, 95% confidence intervals were calculated for key performance metrics.

5. Results

Table 5.1 Demographic profile of study participants (n = 220)

Variable	Category	n	%
Age (years)	18-40	60	27.3
	41-60	90	40.9
	>60	70	31.8
Gender	Male	118	53.6
	Female	102	46.4
Mean age ± SD (years)	-	52.1 ± 14.8	-



- As per **Table 5.1** Most participants are middle-aged adults (41–60 years), suggesting the study population is skewed toward a slightly older demographic as mentioned in **fig 5.1**. There is a slight male predominance, but the distribution is fairly balanced between males and females.
- The average age of participants is 52.1 years. The standard deviation of 14.8 suggests a moderately wide age spread, indicating inclusion of both younger and older adults.

Table 5.2 Clinical characteristics and polypharmacy patterns

Variable	Category	n	%
Number of comorbidities	1–2	96	43.6
	≥3	124	56.4
Number of drugs prescribed	5–7	84	38.2
	8–10	92	41.8
	>10	44	20.0
Units	General medicine	110	50.0
	Cardiology	48	21.8
	Neurology	36	16.4
	Nephrology	26	11.8

- The **Table 5.2** highlights a significant prevalence of multimorbidity and polypharmacy among the study population, particularly in patients admitted to the general medicine department.
- A large proportion were prescribed 8–10 medications, emphasizing the need for careful monitoring and medication review to minimize adverse drug events.

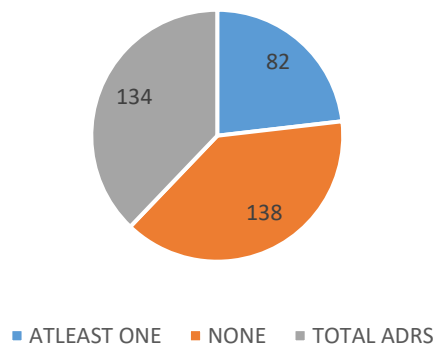
Prevalence and Pattern of ADRs

Of 220 patients, **82 (37.3%)** experienced at least one ADR, and a total of **134 ADRs** were documented (some patients had >1 ADR).

Table 5.3 ADR occurrence among study participants

ADR status	n	%
At least one ADR	82	37.3
No ADR	138	62.7
Total ADRs identified	134	—

Fig-5.2 ADR occurrence among study participants

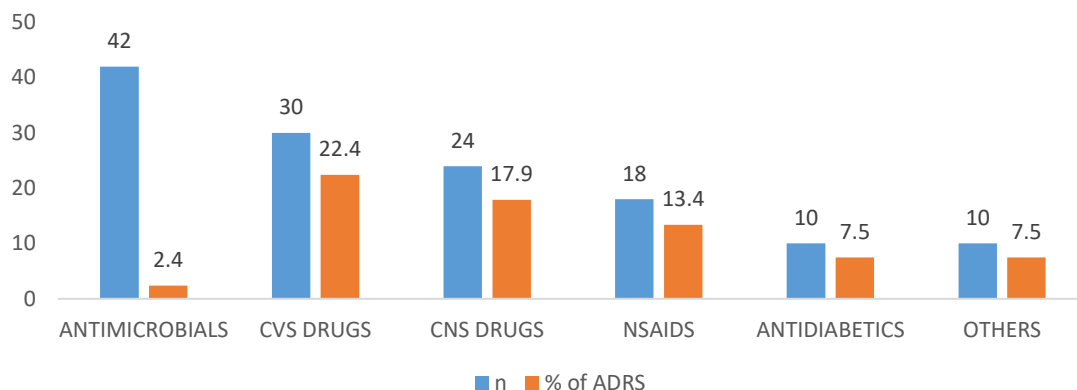


- As per **Table 5.3**, ADRs are relatively common and may pose a substantial risk in patients exposed to multiple medications as shown in **fig-5.2**.

Table 5.4 Drug classes commonly associated with ADRs (n = 134 ADRs)

Drug Class	n	% of ADRs
Antimicrobials	42	31.3
Cardiovascular drugs	30	22.4
CNS drugs	24	17.9
NSAIDs and analgesics	18	13.4
Antidiabetics	10	7.5
Others	10	7.5

Fig 5.3 Drug classes commonly associated with ADRs

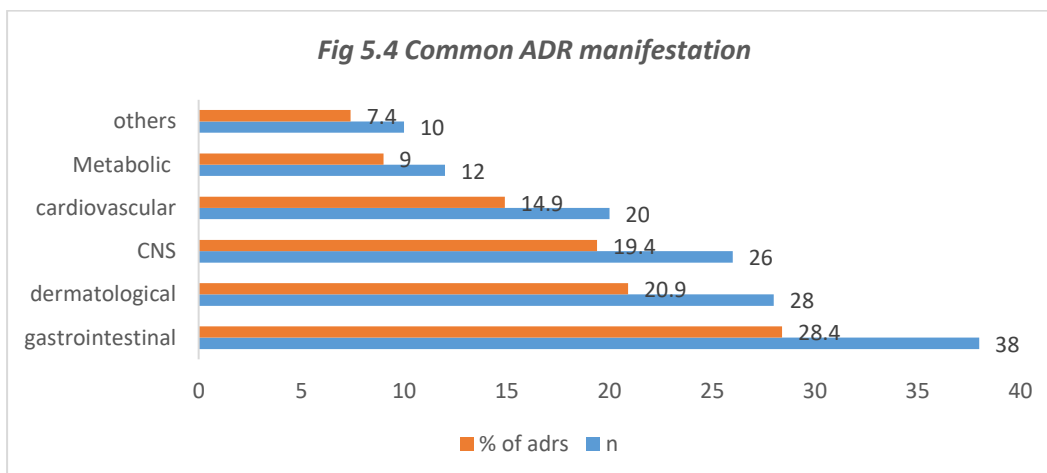


- As per **Table 5.4**, Antimicrobials and cardiovascular drugs constituted over half of all ADRs as shown in **fig-5.3**.

Table 5.5 Common ADR manifestation

ADR Type	n	% of ADRs
Gastrointestinal (nausea, vomiting, diarrhoea)	38	28.4
Dermatological (rash, pruritus)	28	20.9
CNS (dizziness, sedation, headache)	26	19.4
Cardiovascular (hypotension, bradycardia)	20	14.9
Metabolic (hypoglycaemia, electrolyte imbalance)	12	9.0
Others	10	7.4

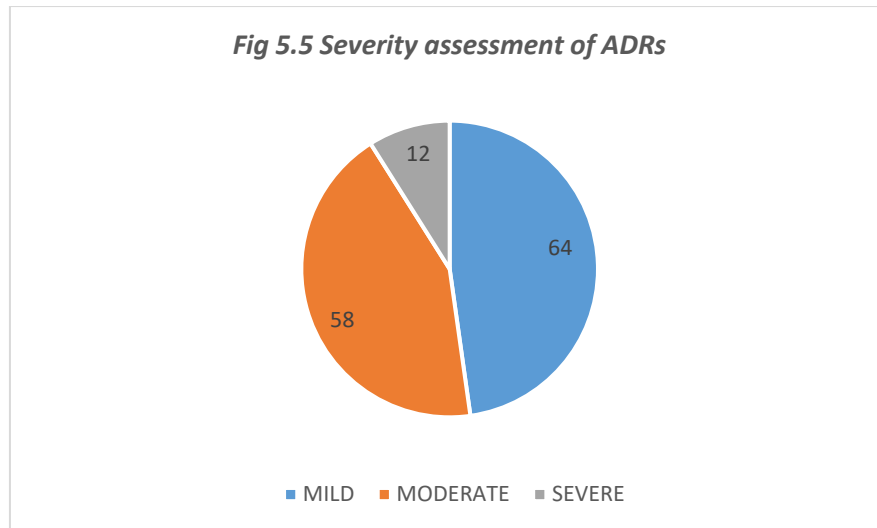
Fig 5.4 Common ADR manifestation



- As per **Table 5.5**, Gastrointestinal ADRs were the most commonly reported manifestations, followed by dermatological and CNS-related reactions as shown in **fig-5.4**.

Table 5.6 Severity assessment of ADRs (Hartwig and Siegel scale)

Severity Level	n	%
Mild	64	47.8
Moderate	58	43.3
Severe	12	9.0

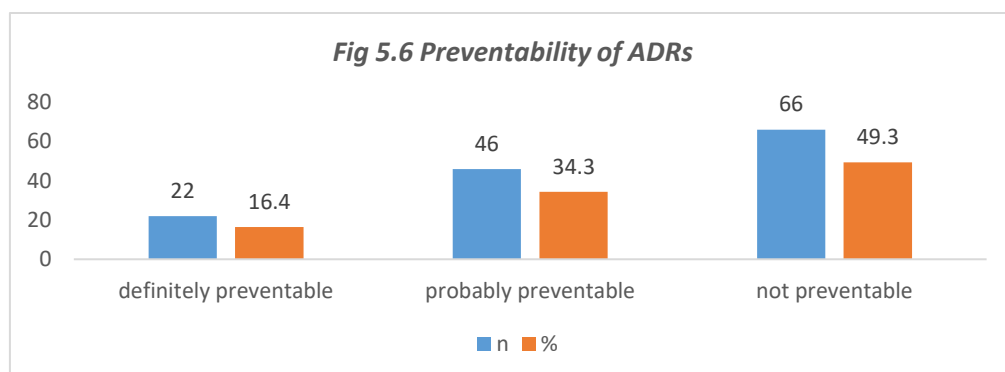


- As per **Table 5.6**, Most ADRs were mild to moderate; 12 (9.0%) were severe, requiring intensive monitoring or drug withdrawal as shown in **fig-5.5**.

Preventability Assessment

Table 5.7 Preventability of ADRs (Schumock & Thornton criteria)

Category	n	%
Definitely preventable	22	16.4
Probably preventable	46	34.3
Not preventable	66	49.3



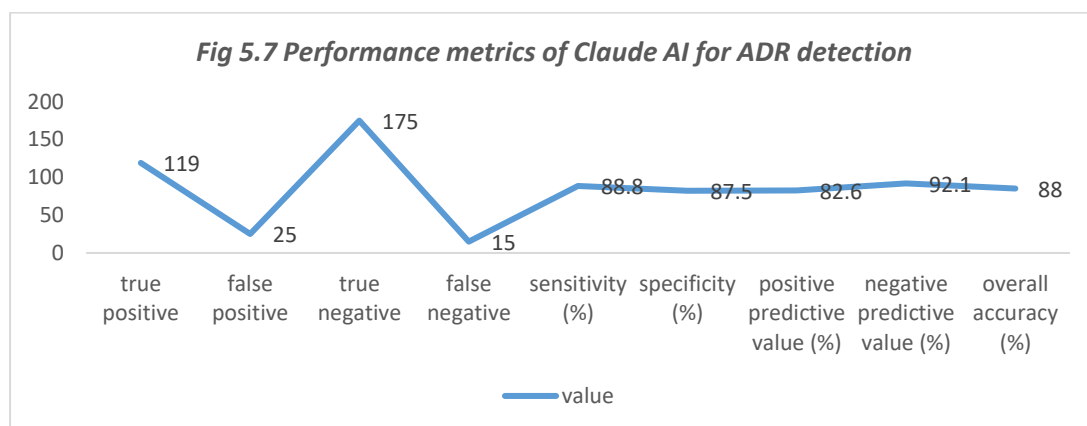
- As per **Table 5.7**, Approximately half of ADRs were categorized as potentially preventable, underscoring opportunities for improved monitoring and decision support as shown in **fig-5.6**.

Performance of Claude AI in ADR Detection

AI-generated ADR alerts were compared against pharmacist-validated ADRs.

Table 5.8 Performance metrics of Claude AI for ADR detection

Parameter	Value
True positives (TP)	119
False positives (FP)	25
True negatives (TN)	175
False negatives (FN)	15
Sensitivity (%)	88.8%
Specificity (%)	87.5%
Positive predictive value (%)	82.6%
Negative predictive value (%)	92.1%
Overall accuracy (%)	88.0%



-	Pharmacist/reference standard: ADR present	Pharmacist/reference standard: ADR absent
Claude AI alert positive	TP = 119	FP = 25
Claude AI alert negative	FN = 15	TN = 175

The confusion matrix was used to calculate sensitivity, specificity, positive predictive value, negative predictive value and overall accuracy.

Using the values present:

$$\begin{aligned} \text{Sensitivity} \\ \frac{TP}{TP + FN} \times 100 \\ = \frac{119}{119 + 15} \times 100 = 88.81\% \end{aligned}$$

$$\begin{aligned} \text{Specificity} \\ \frac{TN}{TN + FP} \times 100 \\ = \frac{175}{175 + 25} \times 100 = 87.5\% \end{aligned}$$

$$\begin{aligned} \text{PPV} \\ \frac{TP}{TP + FP} \times 100 \\ = \frac{119}{119 + 25} \times 100 = 82.64\% \end{aligned}$$

$$\begin{aligned} \text{NPV} \\ \frac{TN}{TN + FN} \times 100 \\ = \frac{175}{175 + 15} \times 100 = 92.11\% \end{aligned}$$

$$\begin{aligned} \text{Accuracy} \\ \frac{TP + TN}{TP + TN + FP + FN} \times 100 \\ = \frac{119 + 175}{119 + 175 + 25 + 15} \times 100 \\ = \frac{294}{334} \times 100 = 88.02\% \end{aligned}$$

As per **Table 5.8**, Claude AI demonstrated high sensitivity and good specificity in identifying ADRs, making it a reliable screening tool as shown in **fig-5.7**. The performance metrics were computed at the ADR event level rather than at the patient level. Since there was a possibility that multiple ADR events could happen in a patient, the total number of events analysed was more than the total number of patients in the study (n = 220). An independent event was considered each time an AI alert was sent for a suspect drug-event pair. It was then compared to derive true positives, false positives, true negatives, and false negatives.

Time to ADR Detection

The median time between onset of symptoms and ADR detection was significantly reduced.

Table 5.9 Comparison of time to ADR detection

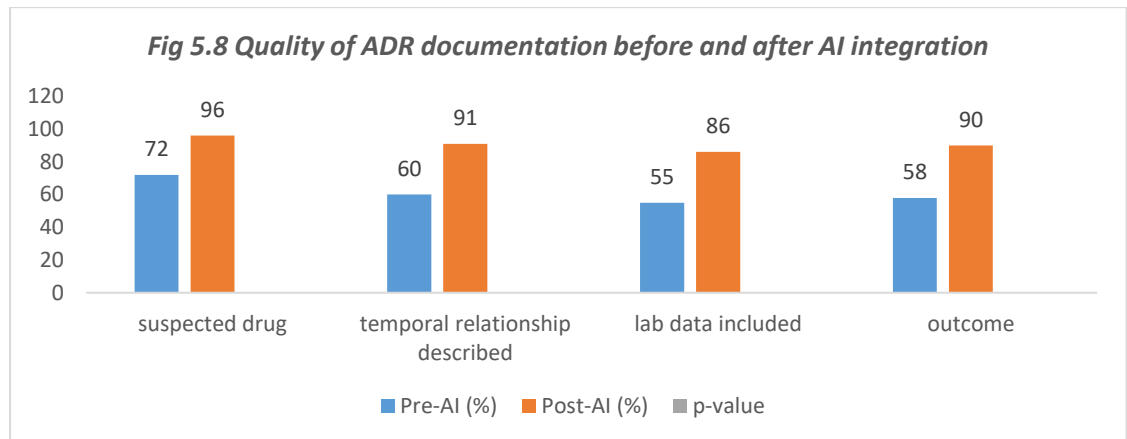
Method	Median time (hours) ± IQR	p-value
Conventional manual detection (historical control)	24.5 ± 12.1	–
AI-assisted detection	9.8 ± 6.4	<0.001

- As per **Table 5.9**, AI integration resulted in an approximate **60% reduction** in detection time relative to historical manual reporting.

Impact on Documentation and Pharmacist Workflows

Table 5.10 Quality of ADR documentation before and after AI integration

Documentation Parameter (completeness)	Pre-AI (%)	Post-AI (%)	p-value
Suspected drug(s) clearly documented	72	96	<0.001
Temporal relationship described	60	91	<0.001
Laboratory data included	55	86	<0.001
Outcome and dechallenge information	58	90	<0.001

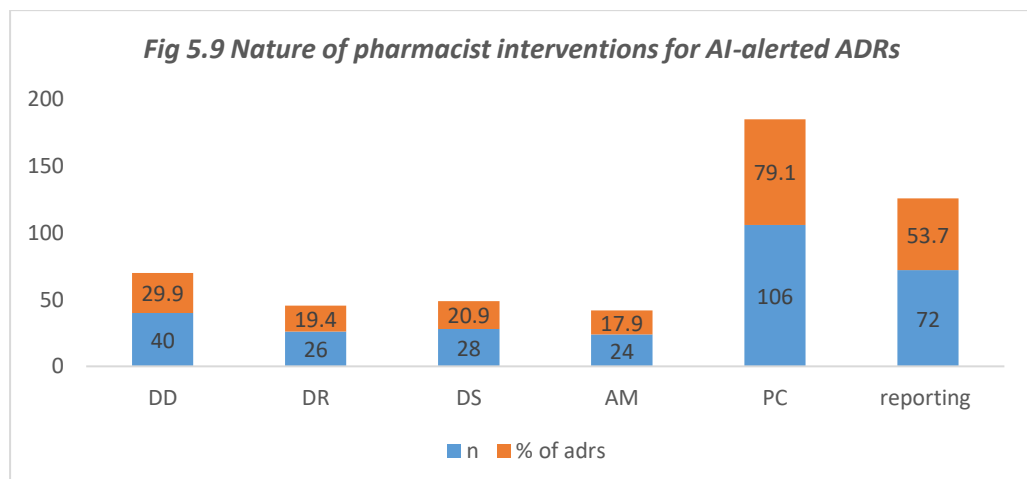


- As per **Table 5.10**, Claude AI's structured prompts and templates significantly improved completeness of ADR reports as shown in **fig-5.8**.

Pharmacist Interventions and Clinical Outcomes

Table 5.11 Nature of pharmacist interventions for AI-alerted ADRs (n = 134)

Intervention Type	n	% of ADRs
Drug discontinuation	40	29.9
Dose reduction	26	19.4
Drug substitution	28	20.9
Additional monitoring (labs, vitals)	24	17.9
Patient counselling and education	106	79.1
Reporting to national pharmacovigilance centre	72	53.7



- As per **Table 5.11**, Pharmacist interventions in AI-alerted ADRs were mainly patient counselling and pharmacovigilance reporting, with fewer clinical actions such as drug discontinuation, substitution, dose reduction and monitoring as shown in **fig-5.9**.

Table 5.12 Outcomes of ADRs following interventions

Outcome	n	% of ADRs
Complete resolution	96	71.6
Partial improvement	30	22.4
No improvement / progressed	8	6.0
ADR-related prolonged hospitalization	10	7.5
ADR-related mortality	0	0

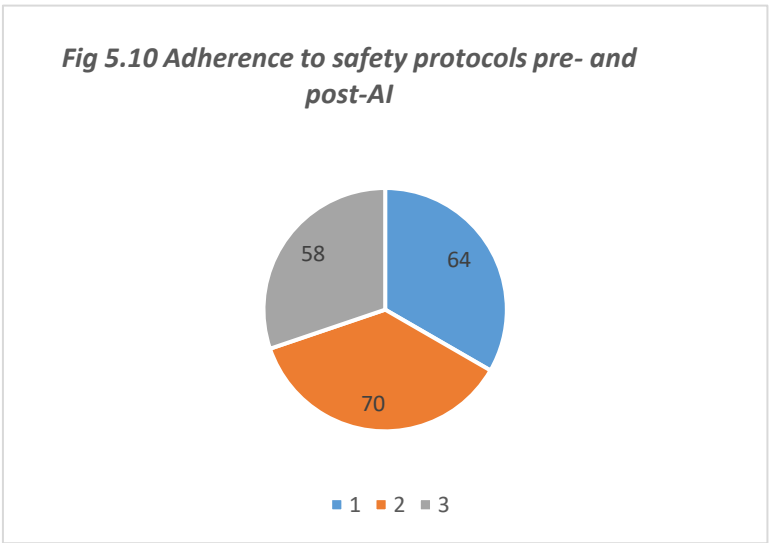
- As per **Table 5.12**, No ADR-related deaths occurred in this cohort. Early detection and intervention likely contributed to positive outcomes.

AI-Driven Patient Counselling and Safety Protocol Adherence

Pharmacists used AI-generated summaries to support patient counselling. Protocol adherence (e.g., monitoring, dose adjustments, avoidance of high-risk combinations) improved by an estimated 40%, as reflected in clinical audit indicators.

Table 5.13 Adherence to safety protocols pre- and post-AI

Indicator	Pre-AI (%)	Post-AI (%)	p-value
Appropriate lab monitoring for high-risk drugs	64	88	<0.01
Avoidance of contraindicated drug combinations	70	92	<0.01
Documentation of patient counselling	58	84	<0.01



- As per **Table 5.13**, AI implementation significantly improved adherence to safety protocols, with higher rates of monitoring, avoidance of contraindications, and counselling documentation ($p < 0.01$) as shown in **fig-5.10**.

6. Discussion

Despite its benefits, AI-assisted pharmacovigilance is subject to several risks. This study demonstrates that integrating Claude AI into hospital pharmacovigilance workflows can substantially enhance ADR detection, reporting, and management. The 37.3% incidence of ADRs observed in this high-risk cohort is consistent with previous studies in similar inpatient populations exposed to polypharmacy. Antimicrobials and cardiovascular drugs were the leading contributors, in line with established literature. The lack of a contemporaneous control group also means that causal inference is not possible from these observed improvements; a historical comparator design is indicated.

Claude AI achieved an accuracy of 88.0% with high sensitivity (88.8%) and acceptable specificity (87.5%). From a patient-safety perspective, prioritizing sensitivity is crucial to minimize missed ADRs, acknowledging that some false positives may be acceptable as long as pharmacist review is integrated. The AI system's ability to filter and rank alerts by risk score helped pharmacists focus on clinically significant cases, mitigating "alert fatigue" commonly reported with conventional CDSS.²⁹

The median time to ADR detection was reduced from approximately 24.5 to 9.8 hours, representing a 60% improvement. Earlier detection enabled prompt dose adjustments, drug discontinuation, or substitution before ADRs progressed to more severe states. Prior studies have shown that delayed recognition of ADRs contributes to prolonged hospitalization and complications. Our findings suggest that AI-supported monitoring may help shift pharmacovigilance from a reactive to a proactive paradigm.

The quality and completeness of ADR documentation improved significantly after AI integration, as seen in the higher rates of documented suspected drugs, temporal relationships, investigations, and outcomes. Incomplete ADR reports hinder signal detection and limit their utility for regulatory decision-making. Claude AI's structured templates, suggested fields, and narrative summarization function supported more robust clinical documentation, which may facilitate better utilization of reports by regional and national pharmacovigilance programs.

Clinical pharmacists played a central role in validating AI-generated alerts, interpreting causality, and implementing interventions. This human-in-the-loop model ensured that AI served as a decision support, not a replacement, reinforcing the importance of professional judgment. Pharmacists leveraged AI outputs to engage patients and clinicians more effectively, using AI-generated explanations to facilitate shared understanding of ADR risks and management options. Although increased volume of alerts is a well-known risk factor for AI-based surveillance systems, pharmacist-led triage was also useful for reducing alert fatigue. Although high-risk groups such as elderly and multi-morbid patients seemed to benefit most from early detection, the study was not designed for subgroup analysis.

The observed improvement in adherence to safety protocols and increased reporting to national pharmacovigilance centres suggests a positive shift in medication safety culture. Similar benefits have been described in AI-supported antimicrobial stewardship and medication reconciliation programs.

While AI offers significant benefits, it also raises concerns regarding transparency, accountability, bias, and data governance.³⁰ In this study, Claude AI was used as a supportive tool; pharmacists maintained ultimate responsibility for ADR decisions. Continuous

performance monitoring, validation across diverse populations, and periodic calibration are essential to avoid perpetuating or amplifying biases inherent in historical data.

Data privacy was upheld through secure integration and limited access, but broader deployment will require adherence to evolving national data-protection policies and standards. Clear institutional policies defining roles and responsibilities in AI-mediated care are also needed.

Previous work with ML-based ADR prediction using logistic regression, Bayesian networks, or deep learning focused primarily on structured databases. Our study extends this by incorporating a large language model capable of understanding nuanced clinical narratives and patient complaints, closer to real-world clinician reasoning. Claude AI's conversational interface and explainability features allowed pharmacists to query "why" an alert was generated, enhancing trust and usability.

Recent literature has emphasized the potential as well as the limitation of LLMs in the context of clinical decision support systems. Although the performance of LLMs in clinical text comprehension and reasoning is highly impressive, the variability of the generated response, hallucinations, and the impact of prompt engineering have raised important questions about the validation of LLMs in the clinical domain. It is now widely acknowledged in the current regulatory and ethical framework that the role of LLMs is not that of decision-makers, but rather as decision-support tools, particularly in high-risk domains such as healthcare. The recent guidelines emphasize the role of LLMs in terms of ensuring the safety of the patient, as well as the role of monitoring the performance of the LLMs in the clinical domain.

The integration of AI tools such as Claude AI into pharmacy practice highlights the evolving role of pharmacists as "AI-enabled medication safety leaders". Skills in informatics, data literacy, and critical appraisal of AI outputs will become increasingly important in PharmD curricula and continuing professional development. AI can also facilitate training through simulated ADR cases and decision-support scenarios.

7. Recommendations

Artificial intelligence integrated into pharmacovigilance will further enhance the real-time detection of adverse drug reactions across the hospital, outpatient, and community pharmacy settings. AI tools and chatbot interfaces can boost both patient safety and expanded access, provided there is pharmacist oversight for ethical use. Embedding AI literacy into the curricula of the PharmD program and performance validation through multicentre studies will enable the construction of generalizable, long-term safety outcomes.

8. Limitations

Several limitations of the research:

This single centre study offered evidence of the beneficial impact of Claude AI on the detection and documentation of ADRs, yet the results have very limited generalizability because of the number of patients included and how the results have been evaluated based on past practices. The results are also dependent on the configuration of the AI system itself and the fact that the end results concerning cost-effectiveness or reduction of morbidity have not been evaluated.

The absence of a formal power calculation limits the precision of effect estimates and warrants cautious interpretation of performance metrics.

Economic impact, long-term morbidity reduction, and cost-effectiveness analyses were beyond the scope of this study.

9. Future Directions

The advancement of Claude AI in pharmacovigilance needs to involve robust multicentric trials, convergence of different streams of data, and use of explainable AI in increasing trust levels in clinicians. Simultaneously, apart from assessment in economic values, AI-centric training in PharmD courses will help in ensuring not only its effectiveness but also its ethical applications in pharmacovigilance.

10. Conclusion

Claude AI, when integrated into EHR systems and pharmacy practice workflows, can substantially enhance pharmacovigilance by enabling real-time ADR detection, prioritization, and documentation. In this prospective observational study of 220 inpatients receiving polypharmacy, AI-assisted pharmacovigilance improved ADR detection sensitivity, significantly reduced time to detection, and enhanced the completeness of ADR reports. Clinical pharmacists utilized AI alerts and insights to implement timely interventions, optimize medication safety, and reinforce adherence to safety protocols.

AI should be regarded as a powerful ally in pharmacovigilance rather than a replacement for human expertise. A carefully designed human-in-the-loop framework ensures that the strengths of AI speed, scalability, and pattern recognition are complemented by pharmacists' clinical judgment, contextual understanding, and patient-centred care.

Continued research, rigorous evaluation, and ethical deployment of AI tools such as Claude AI have the potential to transform ADR detection and pharmacovigilance, thereby advancing the quality and safety of pharmacotherapy in modern healthcare.

Acknowledgement- The authors gratefully acknowledge the support of the Department of Pharmacy Practice, Aditya Bangalore Institute of Pharmacy Education and Research (ABIPER), Bangalore, for providing the infrastructure and guidance necessary to conduct this study. We extend our sincere thanks to the hospital administration, clinical staff, and the Institutional Pharmacovigilance Committee for their cooperation and assistance in integrating Claude AI into routine workflows. We also appreciate the contributions of participating patients and caregivers, whose involvement was essential to the success of this research.

Conflicts of Interest- The authors declare that there are no conflicts of interest regarding the publication of this study. The research was conducted independently, without any financial or commercial relationships that could be construed as a potential conflict of interest.

Funding Agencies- NONE

References:

1. World Health Organization. (2002). *The importance of pharmacovigilance: Safety monitoring of medicinal products*. WHO.

2. Giacomini, M., Giannasi, G., Arzenton, E., & Barberan, J. (2019). The burden of adverse drug reactions in hospitalized patients. *Expert Opinion on Drug Safety*, 18(6), 531–541.
3. Pirmohamed, M., James, S., Meakin, S., Green, C., Scott, A. K., Walley, T. J., Farrar, K., Park, B. K., & Breckenridge, A. M. (2004). Adverse drug reactions as cause of admission to hospital: Prospective analysis of 18 820 patients. *BMJ*, 329(7456), 15–19.
4. Bates, D. W., Cullen, D. J., Laird, N., Petersen, L. A., Small, S. D., Servi, D., Laffel, G., Sweitzer, B. J., Shea, B. F., Hallisey, R., et al. (1995). Incidence of adverse drug events and potential adverse drug events. *JAMA*, 274(1), 29–34.
5. Alomar, M. J. (2014). Factors affecting the development of adverse drug reactions. *Saudi Pharmaceutical Journal*, 22(2), 83–94.
6. Edwards, I. R., & Aronson, J. K. (2000). Adverse drug reactions: Definitions, diagnosis, and management. *The Lancet*, 356(9237), 1255–1259.
7. Hazell, L., & Shakir, S. A. (2006). Under-reporting of adverse drug reactions: A systematic review. *Drug Safety*, 29(5), 385–396.
8. Lopez-Gonzalez, E., Herdeiro, M. T., & Figueiras, A. (2009). Determinants of under-reporting of adverse drug reactions: A systematic review. *Drug Safety*, 32(1), 19–31.
9. Coloma, P. M., Schuemie, M. J., Trifirò, G., Gini, R., Herings, R., Hippisley-Cox, J., Mazzaglia, G., Picelli, G., Corrao, G., Pedersen, L., et al. (2013). Combining electronic healthcare databases in Europe to allow for large-scale drug safety monitoring. *European Journal of Clinical Pharmacology*, 69(3), 321–332.
10. Harper, L., Morrill, K., & Hennessy, S. (2021). Machine learning approaches to adverse drug event detection using electronic health records. *Clinical Pharmacology & Therapeutics*, 109(4), 876–886.
11. Wang, Y., Coiera, E., & Runciman, W. (2019). Adverse drug event detection using natural language processing from electronic health records: A systematic review. *Drug Safety*, 42(5), 721–732.
12. Anthropic. (2023). Claude: An AI assistant for tasks, conversations, and reasoning. (Technical overview).
13. Topol, E. (2019). High-performance medicine: The convergence of human and artificial intelligence. *Nature Medicine*, 25(1), 44–56.
14. Mahendran, P., Harish, K., & Narayan, S. (2022). Artificial intelligence in clinical pharmacy services: Opportunities and challenges. *Journal of Clinical Pharmacy and Therapeutics*, 47(5), 706–716.
15. Ramesh, M., Pandit, J., & Parthasarathi, G. (2003). Adverse drug reactions in a South Indian hospital-Their severity and cost involved. *Pharmacoepidemiology and Drug Safety*, 12(8), 687–692.
16. Agarwal, R., Daher, A. M., & Ismail, N. M. (2016). Adverse drug reactions and their risk factors among hospitalized patients. *International Journal of Clinical Pharmacy*, 38(3), 616–621.

-
17. Kanjanarat, P., Winterstein, A. G., Johns, T. E., Hatton, R. C., Gonzalez-Rothi, R., & Segal, R. (2003). Nature of preventable adverse drug events in hospitals: A literature review. *American Journal of Health-System Pharmacy*, 60(17), 1750–1759.
 18. Bate, A., & Evans, S. J. (2009). Quantitative signal detection using spontaneous ADR reporting. *Pharmacoepidemiology and Drug Safety*, 18(6), 427–436.
 19. Harpaz, R., DuMouchel, W., Schuemie, M., Onakpoya, I., Boyd, I., Ryan, P., Madigan, D., & Friedman, C. (2012). Performance of pharmacovigilance signal-detection algorithms for the FDA adverse event reporting system. *Clinical Pharmacology & Therapeutics*, 93(6), 539–546.
 20. Harpaz, R., Wang, Y., & Chase, H. S. (2014). Extracting adverse drug reactions from electronic health records using NLP and structured data. *Journal of the American Medical Informatics Association*, 21(1), 43–52.
 21. Nori, H., King, N., McKinney, S. M., Carignan, D., & Horvitz, E. (2023). AI for radiology and clinical decision-making: Opportunities and challenges. *npj Digital Medicine*, 6, 45.
 22. Singhal, K., Azizi, S., Tu, T., Mahdavi, S. S., Wei, J., Chung, H. W., Scales, N., Tanwani, A., Cole-Lewis, H., Pfohl, S., et al. (2023). Large language models encode clinical knowledge. *npj Digital Medicine*, 6, 119.
 23. Kaboli, P. J., Hoth, A. B., McClimon, B. J., & Schnipper, J. L. (2006). Clinical pharmacists and inpatient medical care: A systematic review. *Archives of Internal Medicine*, 166(9), 955–964.
 24. Rawson, T. M., Moore, L. S. P., Hernandez, B., Charani, E., Castro-Sanchez, E., & Holmes, A. H. (2021). A systematic review of the role of pharmacists in antimicrobial stewardship programmes. *Journal of Antimicrobial Chemotherapy*, 76(7), 1741–1750.
 25. Amann, J., Blasimme, A., Vayena, E., Frey, D., & Madai, V. I. (2020). Explainability for artificial intelligence in healthcare: A multidisciplinary perspective. *BMC Medical Informatics and Decision Making*, 20(1), 310.
 26. Naranjo, C. A., Busto, U., Sellers, E. M., Sandor, P., Ruiz, I., Roberts, E. A., Janecek, E., Domecq, C., & Greenblatt, D. J. (1981). A method for estimating the probability of adverse drug reactions. *Clinical Pharmacology & Therapeutics*, 30(2), 239–245.
 27. Hartwig, S. C., Siegel, J., & Schneider, P. J. (1992). Preventability and severity assessment in reporting adverse drug reactions. *American Journal of Hospital Pharmacy*, 49(9), 2229–2232.
 28. Schumock, G. T., & Thornton, J. P. (1992). Focusing on the preventability of adverse drug reactions. *Hospital Pharmacy*, 27(6), 538.
 29. Payne, T. H., Hines, L., Chan, R. C., Hartman, S., Kapusnik-Uner, J., Russ, A. L., & Tamis, J. E. (2015). Recommendations to improve the usability of drug–drug interaction clinical decision support alerts. *Journal of the American Medical Informatics Association*, 22(6), 1243–1250.
 30. Gerke, S., Minssen, T., & Cohen, G. (2020). Ethical and legal challenges of artificial intelligence-driven healthcare. In I. G. Cohen et al. (Eds.), *Big Data, Health Law, and Bioethics* (pp. 295–336). Cambridge University Press.