World Journal of Pharmaceutical and Life Sciences
WJPLS
www.wjpls.org
SJIF Impact Factor: 7.409

ADVERSE DRUG REACTION: A PHARMACEUTICAL REVIEW OF MECHANISM, RISK FACTORS, AND EMERGING DETECTION STRATEGIES

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DOI: https://doi.org/10.5281/zenodo.17223438

Article Received on 29/07/2025 **Article Revised on 19/08/2025** **Article Accepted on 09/09/2025**

ABSTRACT
Adverse drug reactions (ADRs) are unexpected and adverse reactions to drugs that jeopardize patient safety and raise healthcare expenditures. They are a major cause of morbidity and mortality, especially among hospitalized patients, with children being more vulnerable than adults. ADRs are divided into Type A (predictable, dose-dependent) and Type B (idiosyncratic, dose-independent) reactions based on hereditary variables, drug-drug interactions, and patient-specific situations. ADR symptoms vary significantly, affecting numerous body systems and ranging from mild to life-threatening. Effective ADR diagnosis and management need the use of standard reporting systems as well as modern machine learning approaches for detection. Artificial intelligence and knowledge graphs have emerged as effective techniques for forecasting ADRs, hence improving pharmacovigilance efforts. Aiming to finally improve patient safety and lower healthcare burdens, the integration of several evidence sources and creative models such as the Knowledge Graph Deep Neural Network (KGDNN) offers promise in enhancing ADR diagnosis and management.

KEYWORDS: ADR- Adverse Drug Reaction, ALS- Automatic laboratory signal, KG- Knowledge graph.

INTRODUCTION
An unpleasant and unanticipated reaction that happens at standard levels of medication used for prevention, identification, or treatment is known as an adverse drug reaction.[1] It is regarded as a major cause of death for hospitalized patients and one of the most important factors in determining drug safety.[2] ADRs are linked to higher rates of morbidity, death, and medical expenses and can have mild to severe impacts on patients. ADRs are more common in children and infants than in adults, and they are usually more severe. It's interesting to note that many adverse drug reactions (ADRs) are only identified following extensive post-marketing monitoring of medication use, rather than during the few pre-marketing clinical trials.[1] ADRs frequently occur when a medication or its metabolites interact with protein targets that are essential for regular cellular activity.[3] ADRs have an impact on medication development and patient safety, making them a serious public health issue. Improving medication safety and healthcare requires the identification and reporting of adverse drug reactions (ADRs). ADRs are identified and analysed using a variety of methodologies, such as data mining tools and spontaneous reporting systems.[2] An undesirable reaction to a medication is known as an adverse drug reaction (ADR). ADRs are prevalent and represent a substantial cost to healthcare. The Adverse Event Reporting System (FAERS) of the U.S. Food and Drug Administration is the most comprehensive database of adverse drug reactions that is currently accessible. Nearly 175,000 deaths and more than 1.25 million major adverse events were reported in 2022.[4] For diagnostic and nontherapeutic pharmaceutical hazards, there are six ED visits for every 1,000 patients, and around 38% of these visits result in hospitalization.[5]

Types of ADR
Based on their processes and traits, adverse drug reactions (ADRs) can be divided into a few categories. The most common ADRs are Type A and Type B reactions, while Type C, D, and E reactions are less common. Type A reactions are predictable and dose dependent, while Type B responses are peculiar and independent to dosage.[6] It's interesting to note that both Type A responses and Type B allergic reactions are significantly influenced by hereditary variables.[7] For example, genetic testing can assist in preventing adverse drug reactions (ADRs) associated with thiopurines and warfarin. ADRs can also be categorized according to their consequences, including pharmacokinetic effects, molecularly based side effects, and drug-drug interactions that do not have known ADRs.[8] In

summary, successful pharmaceutical surveillance and patient safety depend on an understanding of the different kinds of adverse drug reactions. Although algorithms and computational techniques have been created to identify and categorize ADRs, it is crucial to remember that additional expert research is frequently required to verify these findings.[9]

Type of ADRs	Characteristics	Example
Type A	- Dosage in relation to drug's pharmacological aetivity that is preidicable based on established pharmacology	- The nephrotoxicity that aminoglycosides cause - Penicillin-induced urticaria
Type B	- Non dose-dependent - Uncommon - No relation to a a pharmacological action of drug	- Penicillin-induced urticaria - Anti-conwlsant hypersensitivity Syndrome reach
Type C	- Uncommon - Long term exposure of a drug	- Hypothalamic-pitu-tary-adrenal axis suppression
Type D	- Termination of treatment.	- Bladder Carcinoma after treatment with Cyclophoshmide.

Figure no. 1.

- **Reasons for ADR**

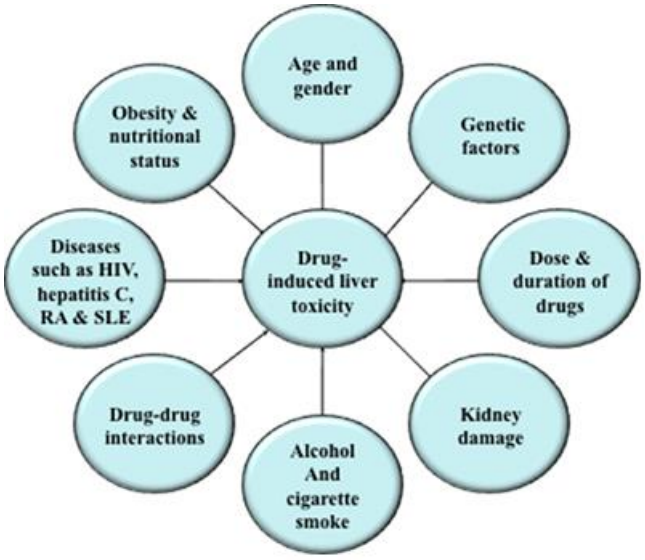

Figure no. 2.

Numerous factors might contribute to the development and severity of adverse drug reactions (ADRs), which can occur for a variety of causes.[7]

People are predisposed to both types A and B adverse reaction in large part due to genetic factors. The importance of taking genetic risk factors into account when trying to foresee and avoid adverse reactions is highlighted by the fact that the overall impact of genomics is contingent on the medication and specific ADR. Drug-drug interactions based on metabolism are also essential for the emergence of ADRs.[10] The occurrence and severity of afterwards adverse drug reactions (ADRs) can also be greatly influenced by pharmacogenetics, metabolism, and the impact of physiological and pathophysiologic conditions on a medicinal product's clinical effect.

It's interesting to note that some of the most common causes of adverse drug reactions are routinely used medications like narcotics diuretics, and anticoagulants.[11] This defies the widespread belief that the only medications that have serious dangers are those that are more recent or poorly researched. Furthermore,

the idea that fixed drug combinations (FDCs) invariably increase prescription compliance and decrease side effects is called into question because both logical and irrational FDCs significantly contribute to the pool of all ADRs.[12] In summary, a variety of factors, including genetic makeup, drug-drug interactions, metabolic considerations, and the intrinsic qualities of both older and more recent drugs, contribute to ADRs. In conclusion, enhancing medication security and patient outcomes requires an awareness of the causes causing adverse drug reactions. Comorbidities, polypharmacy, genetic susceptibility, and certain patient populations (such as those with HIV) are important contributors. Standardized reporting mechanisms are necessary to improve ADR management and prevention, analysis based on sex and gender, and predictive genotype for high-risk ADRs are necessary to improve ADR prevention and management.[13] Individual susceptibility to dose-dependent and dose-independent adverse medication reactions is largely determined by genetic factors, including polymorphisms in drug targets and enzymes that metabolize drugs.[14]

- **Signs and symptoms**

Different body systems can be affected by adverse drug reactions (ADRs), which can take many different forms. The most reported symptoms of ADRs are changes to the nervous system and the stomach, with the former accounting for 60% of ADR cases and the latter for 24.6% of cases.[15] In clinical settings, skin and ancillary damage is a common sign of adverse drug reactions.[16] Sometimes ADRs can be fatal, leading to prolonged hospital stays or hospitalisation. ADRs can range in severity from minor discomfort to life-threatening events.[17] Medication side effects typically begin minutes after the drug is administered. Individual differences may exist in the severity of the symptoms. The following could be signs of a mild drug allergy.

1. Skin that is red, flaky, itching, or swollen.
2. A red, flat spot on your skin with a few tiny pimples.
3. Bees.
4. Blisters or peeling skin.
5. Issues with vision.
6. Itching.
7. eye watering (epiphora).
8. Skinrash.
9. Hives.
10. Runny nose.
11. Inflammation (angioedema).

Anaphylaxis is one of the severe signs of a medication allergy. If treatment is delayed, anaphylaxis, a severe allergic reaction, can be fatal. Among the severe symptoms are.

12. Dysphagia, or difficulty swallowing.
13. Having trouble breathing.
14. Light headedness or dizziness.
15. Low blood pressure.
16. Elevated heart rate.
17. Feeling anxious or perplexed.
18. Unconsciousness.

Rarely, up to a week after taking a medication, you could experience a gradual allergic reaction. Additionally, the effect may continue for decades after you stop using the Drug.

These responses could consist of

1. Fever.
2. Rashes on the skin.
3. Joint Edema or discomfort.
4. Low platelets (thrombocytopenia) or red blood cells (anaemia).
5. Either an abnormal eosinophil count (eosinophilia) or a white blood cell count.(leucocytosis or leukopenia).
6. A decline in liver function (hepatitis) or kidney function (nephritis).
7. Swelling in the lymph nodes.

- **Diagnosis of ADR**

To ensure patient safety and comprehend drug safety profiles, adverse drug reaction (ADR) monitoring is essential. ADR detection has been enhanced by a few strategies, from conventional methods to sophisticated machine learning algorithms. Prescription event monitoring (PEM), volunteer reporting initiatives, and spontaneous reporting are examples of traditional techniques.[18] These approaches, however, have shortcomings in treatment inspection and underreporting. Researchers have investigated more advanced methods to deal with these problems. In ADR detection, machine learning methods including ensemble models that combine support vector machines, choice trees, random woodlands, and adaptive boosting have demonstrated encouraging outcomes.[19] Bi-LSTM with mechanisms for attention is one deep learning technique that has been used to extract complicated contextual knowledge from unstructured textual input.[20] Some research has investigated new methods for detecting ADRs. For example, to take advantage of quantum computing's concurrent processing powers for ADR detection from social media large data, a quantum Bi-LSTM with attention (QBi-LSTMA) paradigm has been developed.[21] To enhance ADR detection capabilities on tiny target corpora, antagonistic transfer learning has also been developed.[22]

- **AI Tools**

The recognition of adverse drug reactions (ADRs) has greatly improved thanks to artificial intelligence (AI) and machine learning approaches, which also provide strong tools for post marketing surveillance and preclinical drug safety.[23] These strategies are especially helpful in tackling the problems of growing patient diversity and polypharmacy.

Deep Neural Networks (DNN) in conjunction with Knowledge Graph (KG) anchoring have demonstrated encouraging outcomes in ADR prediction. The KGDNN model outperformed current techniques with an

exceptional AUROC score of 0.917. It embeds items such as medicines, ADRs, and proteins using the Node2Vec algorithm.[24] An ensemble model that combines decision trees, random forests, support vector machines, and adaptive boosting is another successful strategy; on benchmark datasets, it obtained an F-measure of 89%.[19] Successful use of deep learning techniques has also been documented; one study found that 14 models that predicted for different ADRs had an average validation precision of 89.4%.[25] Furthermore, even before they are formally published, web search log analysis has demonstrated promise for early ADR detection.[26] Interestingly, 65.8% of ADR-positive admissions have been found by automated laboratory data analysis employing automatic laboratory signals (ALS), which may increase the probability of identification of undiscovered ADRs in clinical settings.[28] To sum up, AI solutions for ADR detection cover a broad spectrum of methods, including data mining, deep neural networks, and machine learning algorithms.

Knowledge Graph

To improve the effectiveness of machine learning models, knowledge graph embedding's are currently used in the identification of adverse reactions to medications (ADRs). The combination of DBpedia knowledge graph embedding's with an RNN, or recurrent neural network, transducer for ADR detection in social media messages is specifically described by Stanovsky et al. (2017). With a score of F1 of 93.4% within the CADEC corpus, this method produced a very accurate model.[29] Curiously, other research has used a variety of graph-based techniques for ADR detection, even though knowledge graphs are only specifically referenced in one of the publications that were sent., for example, describe the creation of a novel graph-based system that builds a drug-disease graph using healthcare claims data. Graph Neural Networks are used in this method to forecast ADR signals, and it performs better than other methods. In conclusion, graph-based techniques generally seem to be gaining popularity in this field, even though knowledge graph embeddings have demonstrated promise in ADR detection, as demonstrated by the high accuracy attained in social media text analysis. These methods enhance ADR detection capabilities by taking advantage of the intricate connections among medications, illnesses, and adverse responses.

- **Drug disease graph**

Globally, adverse drug reactions, or ADRs, are a serious public health hazard. Several graph-based techniques have been used to predict adverse drug reactions (ADRs) at pre-marketing stages using biological graphs. In post-market surveillance, ADR identification is just as crucial as pre-marketing evaluation, and in recent years, there has been a lot of interest in ADR detection using extensive clinical data. Studies that use graph structures using clinical data to identify an ADR signal—a pair of prescribed medications and a diagnostic that may represent a possible ADR—are scarce, nevertheless. In this work, we use data from healthcare claims to create an original graph-based structure for ADR signal recognition. The medical codes are represented by nodes in a drug-disease graph that we create. The model efficiently generates node representations expressive of those associations, as evidenced by its enhanced AUROC and AUPRC effectiveness of 0.795 and 0.775 when compared to other techniques. Additionally, our model demonstrates its capacity to complement the ADR database by predicting ADR pairs that are not present in the known ADR database.

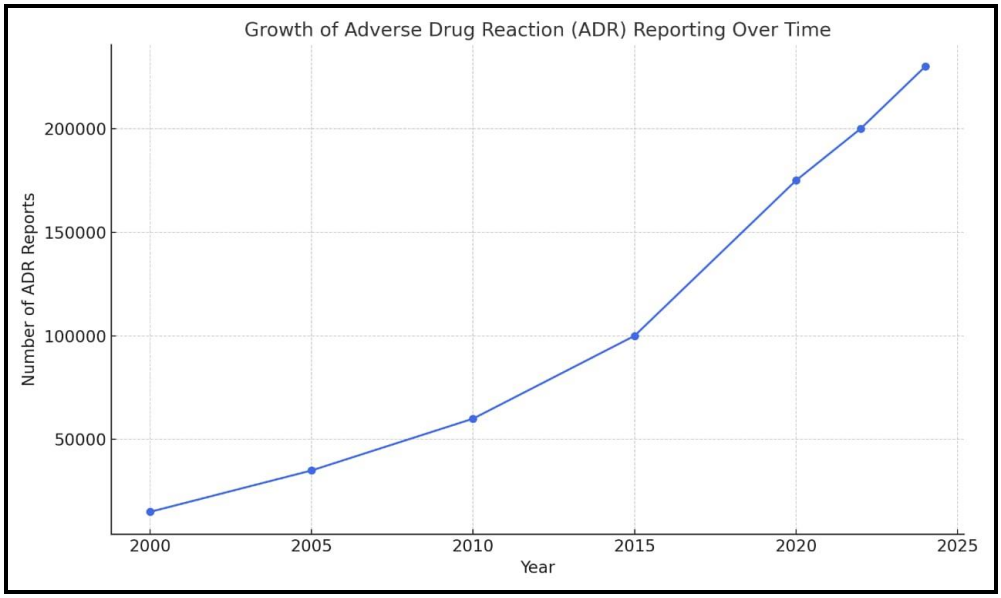

Figure no 3.

- **Knowledge Graph Deep Neural Network (KGDNN)**

A new method for forecasting adverse drug reactions (ADRs) utilizing Knowledge Graph (KG) embedding is the KGDNN model. This approach uses a KG built with six different types of entities: medicines, ADRs, protein targets, evidence, pathways, and genes. This helps to overcome the problem of generating fewer cases reported for ADR prediction. Every node in the KG is embedded into a feature space using the KGDNN model using the Node2Vec algorithm. A specially designed Deep Neural Network is subsequently trained using these embedding's to classify ADRs. The suggested approach has outperformed current approaches by a wide margin, attaining an AUROC score of 0.917.[24] Interestingly, several studies have investigated alternative methods for ADR detection, even though the KGDNN model concentrates on KG embedding. For example, with an F-measure of 89%, ensemble models that combine support vector machines, decision trees, random woodlands, and adaptive boost techniques have demonstrated potential.[19] Furthermore, to enhance ADR identification in hospital settings, machine learning models utilizing ICD-10 codes have been created.[30] In summary, by utilizing deep learning and Knowledge Graph embedding, the KGDNN model offers a novel method for ADR prediction. It is a useful instrument in the field of pharmaceutical security and pharmacovigilance because of its excellent performance and capacity to manage the problem of limited reports.

- **Multiple evidence fusion**

Multiple evidence fusion (MEF) is a promising simultaneous method for predicting adverse drug reactions (ADRs) that can handle both approved drugs and novel molecules. With this method, probable unknown ADRs are predicted by combining drug-related and ADR-related data at various levels, including network structural data created by established drug-ADR relationships. MEF has outperformed current techniques that use one or a small number of data types in cross-validation, exhibiting high sensitivity and specificity.[31] It's interesting to note that other strategies make use of diverse information sources, whereas MEF concentrates on integrating disparate data kinds. For example, information on pharmaceuticals and adverse reactions has been extracted from aggregated search data from large populations of Internet users, and these data have been correlated over time to detect probable ADRs.[32] Furthermore, an ensemble model with an F-measure of 89% on benchmark datasets that combines decision trees, support vector machines, random forests, and adaptive boosting has demonstrated potential in enhancing ADR detection.[33] In conclusion, improved computational tools and a variety of data sources are being incorporated into simultaneous systems for ADR detection. Although MEF provides a thorough strategy by combining many data kinds, other techniques like web search query analysis and ensemble models also show promise. These methods supplement conventional pharmacovigilance efforts and may result in the early identification of adverse drug reactions, which would eventually enhance patient safety and lower medical expenses.[34]

- **Management of ADR**

Effective management techniques are necessary to guarantee patient safety in the face of adverse drug reactions (ADRs), a serious worldwide health concern.[35] ADRs have a direct influence on patient care, and pharmacists are essential in tracking and reporting them. Studies indicate that up to 98% of ADRs may be undetected in spontaneous reporting systems, indicating that under-reporting of ADRs is still a significant problem.[36] It's interesting to note that the reporting patterns in various healthcare settings differ from one another. In Saudi Arabia, just 10.2% of community pharmacists and 26.8% of hospital pharmacists admitted ever reporting an ADR, but pharmacists in Australia were found to be a major source of ADR reporting, making up 16% of complaints in 2016. This demonstrates that to increase ADR reporting rates, context-specific interventions are required.[37] Many tactics have been put forth to improve ADR management. These include the introduction of established tracking of medication schedules.[38] The development of Bayesian estimation algorithms to identify the drugs responsible[39] and the use of automated systems for monitoring that produce signals associated with changes in laboratory results. Furthermore, hospital-based ADR reporting has improved in the short to medium term when educational initiatives are paired with prescription card reports and reminders.[40] In the end, raising awareness and enhancing reporting of allergic reactions among healthcare professionals—especially pharmacists—requires a multi-stakeholder, multifaceted strategies.

- **Comparative Analysis**

Method	Data Source	Technique Used	Accuracy / AUROC / F1	Advantages	Limitations
Spontaneous Reporting (e.g., FAERS)	Clinical Case Reports	Manual reporting	Moderate (Variable)	Real-world data; cost-effective	Underreporting; lacks standardization
Ensemble Machine Learning	Clinical Texts / Reports	SVM + Decision Tree + Random Forest + AdaBoost	F1 Score ~89%	High predictive power; robust to noise	Requires labelled data; limited interpretability
Bi-LSTM + Attention	Unstructured Text (EHR,	Deep learning (RNN with attention)	~88-90% Precision	Captures contextual patterns; works with	Needs large, labelled corpora; computationally

	Social Media)			free text	expensive
QBi-LSTM + Attention	Social media + Quantum Encoding	Quantum Bi-LSTM	Improved over Bi-LSTM	Handles large-scale real-time data	Still experimental; limited hardware support
Knowledge Graph + RNN (CADEC)	Social Media (CADEC Corpus)	Knowledge Graph + RNN	F1 Score 93.4%	Incorporates semantic relationships; accurate	Corpus-specific; less generalizable
KGDNN (Node2Vec + DNN)	Drugs, Targets, Genes, Pathways (KG)	Knowledge Graph Embedding + Deep Neural Net	AUROC 0.917	Structured representation; handles sparse data well	Needs KG construction; harder to explain to clinicians
Drug-Disease Graph (GNN)	Healthcare Claims	Graph Neural Network	AUROC 0.795 / AUPRC 0.775	Can detect unknown ADRs; complements known databases	Depends on coding accuracy; not all ADRs are claim-based
Multiple Evidence Fusion (MEF)	Literature, Networks, Drug-ADR pairs	Multi-source integration	High Sensitivity & Specificity	Holistic view; works for novel drugs	Requires harmonization of data; model complexity increases
Web Search Log Analysis	Search Engine Logs	Temporal pattern mining	65% early detection rate	Early signals; non-invasive	Privacy issues; false positives due to unrelated queries
Automatic Laboratory Signal (ALS)	Hospital Lab Data	Rule-based thresholds	Detects 65.8% of true ADRs	Effective for lab-measurable ADRs	Misses' non-lab ADRs; limited to hospital settings

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