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Machine Learning for Antidiabetic Drug Safety: Data Sources, Explainability and Methodological Challenges

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ABSTRACT: Long-term treatment of type 2 diabetes mellitus exposes patients to adverse drug reactions (ADRs), creating a need for better pharmacovigilance. This narrative review examines machine-learning (ML) approaches relevant to antidiabetic drug safety across electronic health records (EHRs), spontaneous reporting systems, social media, and drug–target and in vitro pharmacology datasets. The manuscript reports a literature search through March 2025. Diabetes-specific evidence is distinguished from methodological examples involving other therapeutic areas. A small metformin-related Twitter study reported 94% classification accuracy, but its engagement-based labelling and inconsistent performance statistics limit clinical interpretation. Broader studies illustrate the use of ensemble methods for signal detection, hybrid language models for extracting ADR-related entities, and target-based random forests for mechanistic association analysis. These tasks are distinct: text extraction does not establish causality, signal detection does not estimate incidence, and retrospective discrimination does not establish clinical benefit. Major limitations include class imbalance, reporting and selection biases, outcome heterogeneity, data leakage, limited external validation and insufficient assessment of calibration and clinical utility. Explainable models may help prioritise hypotheses, but feature importance alone does not establish a biological mechanism. Future research should develop and externally validate drug-class-specific models in diabetes populations and prospectively evaluate their effects on medication safety and clinical workload.

1. INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a major global health problem associated with increasing treatment complexity (Chen et al., 2012). Long-term exposure to multiple antidiabetic agents can create safety problems, particularly in older people with comorbidity and polypharmacy (Scheen, 2021; Labib et al., 2019). In this review, adverse drug events (ADEs) refer to medication-related harm, including harm associated with medication errors; adverse drug reactions (ADRs) refer more specifically to harmful, unintended responses attributed to a medicine. A temporal association or a positive safety signal alone does not establish drug causation (Hu et al., 2024; Jiao et al., 2024). Electronic health records (EHRs), spontaneous reports and patient-generated content provide complementary information for computational safety assessment (Kim et al., 2022). Diabetes-related blogs and patient-generated behavioural data can add patient perspectives, although these sources do not

necessarily provide clinically adjudicated ADR outcomes (Lenzi et al., 2019; Nagpal et al., 2021). ML-based pharmacovigilance could support risk stratification and signal prioritisation, but applications require validation for the intended population and task. This review examines data sources, algorithm choices, explainability and limitations relevant to antidiabetic therapy. Studies involving other drug classes are included as methodological examples, not as evidence of established effectiveness in diabetes care.

2. REVIEW METHODOLOGY

Literature was identified through a literature search of PubMed, Scopus, Web of Science and Google Scholar up to March 2025. Search strings combined terms for type 2 diabetes and antidiabetic therapy with pharmacovigilance and safety concepts like adverse drug reaction, adverse drug event and drug safety, and ML terminologies like machine learning, deep learning, artificial intelligence. Full texts of potentially relevant articles were assessed, and reference lists were hand-searched to identify additional studies. The studies were eligible if they reported AI or ML methods applied to ADR or ADE detection, pharmacovigilance signal management or drug-safety prediction in humans; we excluded purely preclinical work unrelated to human drug-safety evidence, non-ML statistical analyses, non-drug-related ADEs and non-English publications. Disagreements on eligibility were resolved by discussion. Mechanistic studies linking *in vitro* pharmacology to human ADR reports were considered methodological evidence rather than clinical diabetes studies. This section gives a structured overview of anti-diabetic pharmacotherapy, relevant pharmacovigilance data sources and the spectrum of ML algorithms applied to ADR and ADE detection in diabetes and related settings, forming the basis for the subsequent methodological critique.

2.1 Anti-diabetic therapy and ADR burden

Antidiabetic pharmacotherapy includes insulin, metformin, sulfonylureas, thiazolidinediones, dipeptidyl peptidase-4 (DPP-4) inhibitors, sodium–glucose cotransporter-2 (SGLT-2) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists (Mahgoub et al., 2023; Yin et al., 2022). Their safety profiles differ, making drug class, dose, concomitant treatment and patient characteristics important when defining an ML prediction task. Metformin tolerability and the risk of hypoglycaemia with sulfonylureas require attention, particularly in older patients; a head-to-head meta-analysis examined sulfonylureas against agents with lower hypoglycaemia risk (Scheen, 2021; Volke et al., 2022). Evidence on combining GLP-1 receptor agonists with SGLT-2 inhibitors should be interpreted as evidence for that combination and its comparators, not as proof that every adverse outcome applies equally to both classes (Li et al., 2022). Polypharmacy is associated with adverse health consequences in older people with T2DM, underscoring the importance of concomitant medicines and multimorbidity in safety modelling (Labib et al., 2019). Models should therefore specify the medicine, exposure window, outcome definition and intended clinical decision rather than combine all antidiabetic ADRs into an undifferentiated endpoint.

2.2 Data sources for ML-based ADR detection

ML-based pharmacovigilance uses several complementary data streams (Kim et al., 2022). EHRs provide medication histories, laboratory measurements, diagnoses and clinical outcomes for patient-level ADE prediction, but require explicit timing of predictors and outcomes (Yasrebi-de Kom et al., 2023; Hu et al., 2024). Continuous glucose-monitoring data are relevant to hypoglycaemia detection and prediction; these tasks should be distinguished from adjudicating a drug-induced reaction (Diouri et al., 2021). Spontaneous reporting systems support signal detection, but their selected reports do not provide an exposed-population denominator for estimating incidence (Jiao et al., 2024). Social media and web-based patient reports offer complementary perspectives while raising concerns about representativeness, privacy, clinical verification and consent (Banerjee and Ingate, 2012; Bulcock et al., 2021). *In vitro* drug–target profiles can be linked to human ADR reports for association modelling (Ietswaart et al., 2020). Integrating spontaneous reporting and EHR information is also relevant to detecting clinically plausible drug–drug interactions, although this does not establish that multimodal ML necessarily outperforms every single-source approach (Jeong et al., 2024). Data-source selection should follow the safety question, with provenance and harmonisation documented.

2.3 Machine learning algorithms used in ADR detection

ML applications differ in their targets: patient-level ADE prediction, drug–event signal prioritisation, extraction of ADR-related text, and mechanism-oriented association modelling are separate tasks (Kim et al., 2022; Hu et al., 2024). Classical classifiers and ensemble methods have been used across these settings. EHR-based research frequently uses random forests, support

vector machines and boosting algorithms, with substantial variation in outcomes and validation methods (Hu et al., 2024). In one Korean spontaneous-reporting study of nivolumab and docetaxel, gradient boosting and random forests outperformed reporting odds ratios and information component methods within the study design; this finding does not demonstrate universal superiority or diabetes-specific effectiveness (Bae et al., 2021). Transformer models have also been evaluated for ADR extraction from biomedical and social-media text (Elbiach et al., 2025). A BERT–bidirectional LSTM–conditional random field model extracted ADR-related entities from Chinese reports, illustrating a text-processing application rather than independent confirmation of causal ADRs (Wu et al., 2021). Target-based random forests provide another approach by associating pharmacology profiles with human safety reports (Ietswaart et al., 2020). Table 1 separates these endpoints and their relevance to antidiabetic therapy.

Table 1. Selected ML applications relevant to pharmacovigilance: task-specific results and limitations.

Study	Data source and population	Drugs	ML algorithms	Endpoint	Key performance (AUC, F1 score)	Reference
Metformin Twitter study	176 tweets; 123 training, 53 test	Metformin	GSO + NB/KNN/SVM	Exploratory tweet classification; engagement-based labels	Source-reported accuracy: SVM 94%, KNN 92%, NB 91%; inconsistent precision/recall/F1 omitted	Priya and Devapriya (2020)
EHR systematic review and meta-analysis	59 studies; quantitative synthesis of 33 studies	15 drug categories; not a diabetes-specific cohort	38 algorithms across reviewed studies	Specific ADE prediction	Pooled sensitivity 0.65; specificity 0.89; SROC AUC 0.8069; very high heterogeneity	Hu et al. (2024)
Korean spontaneous-reporting study	Korean national reports, 2009–2018	Nivolumab; docetaxel (oncology)	GBM/RF versus ROR/IC	Signal classification against study reference standard	AUC GBM 0.97/0.93; RF 0.95/0.92; ROR 0.55/0.51; IC 0.49/0.48	Bae et al. (2021)
Chinese ADR-report text extraction	24,890 annotated ADR reports; external evaluation on 2,479 hospital reports	Mixed medicines; not diabetes-specific	Fine-tuned BERT + bi-LSTM + CRF + radical features	Named entity recognition, not causal signal confirmation	Internal precision 96.4%, recall 96.0%, F1 96.2%; external model F1 86.4%	Wu et al. (2021)
Target-based pharmacology analysis	*In vitro* profiles for 2,134 marketed drugs linked to FDA reports	Marketed drugs; not diabetes-specific	Random forests	Target–ADR association modelling	221 target–ADR associations; literature corroboration; not a clinical safety-effect estimate	Ietswaart et al. (2020)

Abbreviations: ADR, adverse drug reaction; ADE, adverse drug event; ML, machine learning; GSO, glowworm swarm optimisation; NB, naïve Bayes; KNN, k-nearest neighbours; SVM, support vector machine; GBM, gradient boosting machine; RF, random forest; ROR, reporting odds ratio; IC, information component; AUC, area under the receiver operating characteristic curve; EHR, electronic health record; SROC, summary receiver operating characteristic; BERT, Bidirectional

Encoder Representations from Transformers; bi-LSTM, bidirectional long short-term memory; CRF, conditional random field. Results across different endpoints and datasets are not directly comparable. Except for the metformin Twitter example, these rows provide broader methodological evidence rather than diabetes-specific validation.

2.4 Social-media-based ADR detection in anti-diabetic therapy

Social media can complement formal reporting by capturing patient descriptions of treatment experiences, but reported experiences require careful interpretation and clinical verification (Bulcock et al., 2021; Oyebode and Orji, 2023). Priya and Devapriya (2020) analysed 176 metformin-related Twitter messages, using 123 for training and 53 for testing. They combined GSO feature selection with NB, KNN and SVM classifiers and reported accuracies of 91%, 92% and 94%, respectively. Importantly, the source describes labelling rules involving favourites and retweets; these engagement measures are not equivalent to independent clinical ADR adjudication. The paper also reports SVM precision and recall of 1.00 alongside an F1 score of 0.96, an internally inconsistent combination. Consequently, the reported accuracy is presented as a source-reported exploratory result, while the inconsistent precision, recall and F1 figures are not treated as reliable estimates. The small sample, limited outcome verification and absence of demonstrated multicentre clinical validation prevent conclusions about treatment safety or continuation decisions for individual patients (Priya and Devapriya, 2020). Broader transformer-based work demonstrates methodological interest in ADR extraction, but performance depends on the corpus, annotation scheme and evaluation task (Elbiach et al., 2025). Figure 1 summarises the proposed relationship between data sources and ML-enabled pharmacovigilance; it is a conceptual illustration, not evidence of clinical effectiveness.

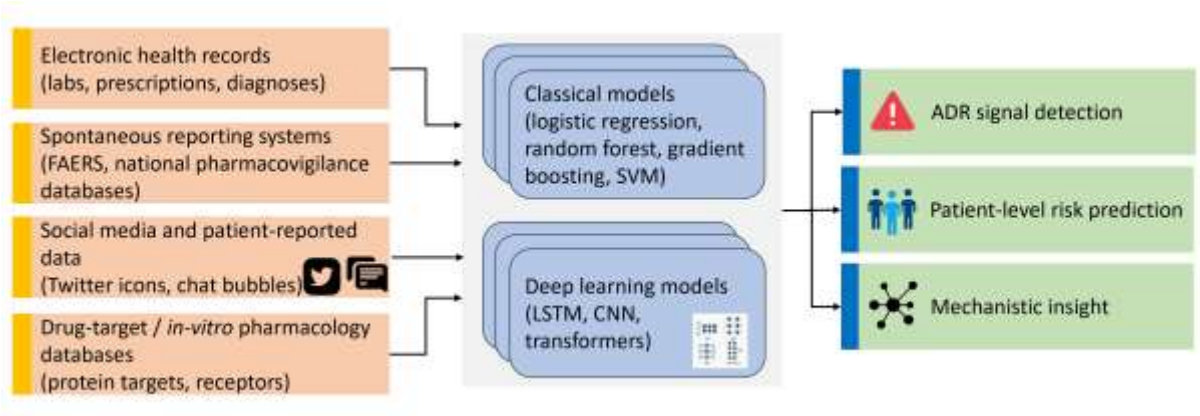

Figure 1. Machine-learning-enabled pharmacovigilance in anti-diabetic therapy. LSTM: long short-term memory, CNN: convolutional neural network, SVM: support vector machine.

2.5 EHR- and clinical-data-based ADE prediction

EHR-based models can predict ADEs using patient characteristics, medication exposure and clinical measurements, but their clinical value depends on outcome definition, timing and validation (Yasrebi-de Kom et al., 2023). Hu et al. (2024) included 59 studies covering 15 drug categories and 15 ADE categories in a systematic review. Their quantitative synthesis used 33 studies with extractable contingency tables and reported pooled sensitivity of 0.65, specificity of 0.89 and SROC AUC of 0.8069. These are broad ADE-prediction results, not hypoglycaemia-specific estimates or a benchmark validated for antidiabetic drugs. The review reported very high heterogeneity, so its pooled estimates should not be transferred directly to an individual drug, hospital or patient population. For diabetes-related hypoglycaemia, a separate review addresses detection and prediction technologies, including glucose-monitoring approaches (Diouri et al., 2021). Prediction of a prescription, glycaemic outcome or future glucose value is not equivalent to predicting a causal ADR. Any antidiabetic safety application should explicitly specify the exposure, prediction horizon, baseline comparator and clinical action. Broader observational-health-data reviews support evaluating calibration, generalisability and deployment rather than relying solely on retrospective discrimination (Denck et al., 2023).

2.6 Spontaneous reporting system-based signal detection

Spontaneous reporting systems support postmarketing safety surveillance, with disproportionality analyses commonly used to prioritise drug–event associations for assessment (Jiao et al., 2024). Bae et al. (2021) evaluated ML using Korean national

spontaneous reports from 2009–2018 for nivolumab and docetaxel. Reported test-set AUCs were approximately 0.97 and 0.93 for GBM, 0.95 and 0.92 for RF, 0.55 and 0.51 for ROR, and 0.49 and 0.48 for IC, respectively. These figures describe performance against the study reference standard and must not be interpreted as prospective detection accuracy or confirmation of new causal ADRs. The drugs are anticancer agents, so the example supplies a possible analytic template rather than direct evidence for insulin, metformin or newer antidiabetic therapies. More candidate signals can also increase follow-up workload; their number alone is not a measure of clinical benefit. Reporting biases, coding heterogeneity and reference-standard construction can affect both statistical and ML methods (Candore et al., 2015; Noguchi et al., 2021). Applying a similar framework to antidiabetic drugs would require class-specific reference standards, temporal and external validation, and expert assessment of newly generated signals.

2.7 Drug-target and mechanism-based safety prediction

Mechanism-oriented prediction links drug–target profiles to human safety observations. Ietswaart et al. (2020) analysed *in vitro* secondary pharmacology for 2,134 marketed drugs and developed random-forest models using FDA adverse-event reports. They identified 221 target–ADR associations and assessed literature support, including established relationships between hERG binding and cardiac arrhythmias. This analysis illustrates how pharmacology can help prioritise plausible hypotheses, but association predictions and feature-importance scores do not independently establish causation. Pharmacological mechanism-based assessment remains complementary to clinical evidence and expert interpretation (Abernethy et al., 2011). For antidiabetic medicines, linking targets to cardiovascular, renal or hepatic outcomes is a research direction rather than an already validated clinical safety tool. Any such analysis should address exposure levels, off-target activity, confounding and the possibility that correlated targets share feature importance. Human report-linked pharmacology studies are included here as methodological evidence, not as purely preclinical studies or direct diabetes-specific validation.

3. METHODOLOGICAL CHALLENGES AND LIMITATIONS

Several methodological limitations constrain routine deployment. EHR-based ADE models differ in outcome definitions, predictor availability and validation design; reviews identify a need for better data processing, standardisation and real-world evaluation (Yasrebi-de Kom et al., 2023; Hu et al., 2024). Spontaneous reports are affected by selective reporting and coding variation, while social-media language and engagement-based labels can create additional measurement and selection problems (Noguchi et al., 2021; Priya and Devapriya, 2020). Interpretation should separate patient-level prediction from population-level signal detection and text extraction. A high AUC or F1 score in one task does not establish performance in another. Explainability should include a description of input data, prediction timing, relevant uncertainty and limitations; feature importance by itself does not prove a mechanism (Ietswaart et al., 2020; European Medicines Agency, 2024).

Class imbalance warrants explicit analysis. Hu et al. (2024) describe resampling and combined over- and undersampling strategies in EHR-based ADE studies, but the reviewed evidence does not justify a universal ranking of SMOTE, focal loss, cost-sensitive learning and anomaly detection for antidiabetic pharmacovigilance. In future studies, any resampling or feature selection should be confined to training folds, with untouched evaluation data reflecting the intended clinical setting. Evaluation should include precision–recall performance, sensitivity at a clinically acceptable false-alert burden, calibration and uncertainty, as appropriate to the task. These are proposed evaluation priorities rather than comparative findings established by the present narrative review.

4. FUTURE PERSPECTIVES AND CLINICAL IMPLICATIONS

Future work should prioritise drug-class-specific analyses that directly address ADRs associated with metformin, sulfonylureas, SGLT-2 inhibitors, GLP-1 receptor agonists, and insulin analogues rather than extrapolating from oncology or mixed-drug cohorts. At present, however, dedicated ML studies on ADR detection for these anti-diabetic classes remain scarce, underscoring the need for targeted pharmacovigilance research that builds and validates models directly in diabetes populations rather than relying primarily on evidence from other therapeutic areas. Large-scale, multi-centre studies combining EHRs, pharmacovigilance databases and patient-generated data will be essential to build robust, generalisable models and to explore differential performance across demographic and clinical subgroups. Explainable-AI techniques and interpretable architectures random forests with feature importance, attention mechanisms, and generalized additive models should be emphasised so that clinicians can understand why a given regimen is flagged as high-risk for a particular patient. Integration of validated models into electronic prescribing systems could provide real-time, patient-specific ADR risk estimates at the point of care,

complementing guideline-based recommendations and shared decision-making in diabetes clinics. Prospective pragmatic trials are needed to test the impact of such tools on ADR rates, hospitalisations and clinician workload, and to refine alert thresholds that balance sensitivity with alert fatigue. Ultimately, combining mechanistic and clinical ML insights may support safer, more personalised anti-diabetic pharmacotherapy.

Regulatory interpretation should be tied to a specific document and its status. The European Medicines Agency's 2024 reflection paper addresses AI across the medicinal product lifecycle, including post-authorisation applications. It discusses data integrity, generalisability, interpretability and a risk-based approach appropriate to the context of use (European Medicines Agency, 2024). The reflection paper should not be described as binding approval of a particular ML model. For antidiabetic pharmacovigilance, these principles support transparent documentation and appropriate human oversight, with safety signals assessed alongside clinical and pharmacological evidence. Claims about specific FDA requirements or universally mandated evidence packages are not made here because the original manuscript did not identify an applicable source.

5. CONCLUSION

Across heterogeneous data sources and modelling strategies, ML approaches have begun to reshape how ADR signals are generated and prioritised for anti-diabetic therapies, yet most published evidence still comes from small, single-centre datasets or extrapolation from non-diabetes therapeutic areas. Social-media mining and transformer-based NLP show particular promise for capturing patient-reported tolerability issues, while ensemble methods and deep learning add sensitivity in EHR and spontaneous-report analyses, but concerns about class imbalance, data quality and limited external validation remain. Future work should emphasise class-specific models for metformin, sulfonylureas, SGLT-2 inhibitors, GLP-1 receptor agonists and insulin analogues, prospectively evaluate ML tools within clinical workflows, and systematically integrate explainable-AI techniques so that clinicians and regulators can understand and challenge high-impact predictions. If these methodological and governance gaps are addressed, ML-enabled pharmacovigilance has the potential to support safer and more individualised anti-diabetic pharmacotherapy across the drug-development and post-marketing continuum.

AUTHORS' CONTRIBUTIONS

All authors contributed meaningfully to the conception or design of the study and to the acquisition, analysis, or interpretation of data. Each author participated in drafting the manuscript or revising it for important intellectual content, approved the final version, and consented to submission to this journal. All authors accept responsibility for the integrity and accuracy of the work and agree to address and resolve any questions that may arise. All authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship and fulfil its recommendations in full.

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CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest for this study.

ETHICAL APPROVAL

This research did not involve any experiments related to animals or humans.

SUMMARY

ML methods may support antidiabetic pharmacovigilance by combining clinical, spontaneous-report, patient-generated and pharmacological information. Evidence remains heterogeneous, and most detailed examples in this review are not diabetes-specific clinical validations. The metformin Twitter example is exploratory and has important labelling and reporting limitations. Ensemble models, hybrid language models and target-based approaches address different endpoints and should not be ranked

using incomparable metrics. Reliable implementation requires transparent outcome definitions, suitable reference standards, robust validation, interpretable outputs and prospective evaluation of safety benefit.

DATA AVAILABILITY

No new patient-level dataset was generated for this narrative review. The evidence discussed is drawn from the cited publications. Availability of the authors' original search records and extraction materials must be confirmed by the authors before submission.

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