Review Article

Artificial Intelligence in Pediatric Medication Safety: Opportunities for Detecting Dosing Errors and Adverse Drug Reactions

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ABSTRACT

Medication safety in children remains difficult because prescribing and administration depend on age, body weight, developmental physiology, indication, formulation, route, organ function, and frequently changing clinical status. Errors can occur during prescribing, transcription, dispensing, preparation, administration, reconciliation, and monitoring. Computerized physician order entry and clinical decision support can reduce some pediatric medication errors, but conventional systems may also generate inappropriate alerts, omit clinically important context, or create workflow-related problems. Artificial intelligence (AI), including machine learning and natural language processing, may extend these systems by learning from structured and unstructured clinical data. Potential applications include identification of unusual doses, prioritization of high-risk prescriptions, medication reconciliation, extraction of adverse drug events (ADEs) from clinical notes, and pharmacovigilance signal detection. Pediatric evidence specifically evaluating AI remains limited, and much of the available AI literature is based on adult or mixed-age datasets. Existing pediatric studies nevertheless demonstrate the value of electronic dosing calculators, computerized prescribing, prospective pharmacovigilance, and electronic health-record data for medication safety. The most appropriate near-term role for AI is therefore as an additional safety layer that prioritizes cases for pharmacist or clinician review rather than as an autonomous prescribing system. Future studies should emphasize pediatric and neonatal datasets, multicenter external validation, clinically meaningful outcomes, explainability, subgroup performance, human factors, cybersecurity, and prospective evaluation of whether AI reduces preventable medication harm.

Key words: Artificial intelligence, Pediatrics, Medication safety, Dosing errors, Adverse drug events, Machine learning, Natural language processing, Clinical decision support, Pharmacovigilance.

Medication-related harm is a persistent patient-safety problem, and children have several characteristics that increase the risk of error. Pediatric prescriptions commonly require weight- or body-surface-area-based calculations, age-specific dose selection, concentration conversions, and adjustment for renal or hepatic function. Neonates and critically ill children add rapidly changing physiology and complex drug disposition. Errors can therefore arise even when the medication itself is appropriate. Earlier pediatric studies have shown that medication errors occur across prescribing, dispensing, administration, and monitoring, and that pharmacists frequently intercept potentially harmful orders [1,2]. Digital prescribing has reduced some categories of error but has not eliminated the problem. Pediatric computerized order-entry systems can introduce new errors through incomplete weight information, inappropriate dose alerts, duplicate-therapy warnings, selection menus, or system configurations that do not adequately represent pediatric practice [3]. In a pediatric hospital, implementation of computerized physician order entry reduced some serious prescribing problems, but subsequent studies have continued to identify clinically important errors after implementation [4,5]. More recent evaluations suggest that the benefit of computerized prescribing depends strongly on the design and usability of the associated decision-support functions [6,7]. Despite growing interest in AI-assisted healthcare, evidence specifically addressing AI for pediatric medication safety remains limited. Important challenges include the relatively small size and heterogeneity of pediatric datasets, differences between neonatal and older pediatric populations, incomplete clinical data, variations in prescribing practices between institutions, model interpretability, external validation, alert fatigue, bias, cybersecurity, and the risk of inappropriate reliance on automated recommendations.

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Therefore, AI should currently be considered an augmentation tool that supports, rather than replaces, pediatric clinical judgment and pharmacist oversight. This mini-review summarizes the current evidence and potential applications of AI in pediatric medication safety, with particular emphasis on detection of dosing errors and ADEs. It also discusses the role of AI in clinical decision support and medication reconciliation, implementation and human-factor considerations, ethical and governance issues, and priorities for future prospective and multicenter research.

2. PEDIATRIC MEDICATION SAFETY AS A TARGET FOR AI

The pediatric medication-use process contains several structured variables that are suitable for computational checking. A prescription may include age, weight, dose, dose unit, concentration, frequency, route, duration, and maximum-dose limits. Additional variables such as indication, renal function, interacting medicines, and previously tolerated doses can change the clinical interpretation of an order. An AI-supported system could therefore identify an order that is statistically unusual while allowing deterministic rules to enforce non-negotiable safety constraints. Evidence from non-AI pediatric decision-support interventions supports this general architecture. Electronic dosing calculators have reduced ordering errors, and a randomized simulation study of the PEDeDose system found substantially fewer dose-calculation errors and shorter calculation time when clinicians used an integrated calculator rather than a prescribing reference with a pocket calculator [8,9]. A pediatric opioid-dosing study similarly found that a dedicated decision-support application reduced calculation errors compared with conventional calculators [10]. These studies do not demonstrate that machine learning is superior to rules or calculators; rather, they show that well-designed computational support can address a real source of pediatric risk.

An important design issue is distinguishing an unusual dose from an erroneous dose. Pediatric dosing is indication-specific, and a dose outside a common range may be clinically justified. Models trained only on historical prescribing patterns may therefore learn local practice rather than clinical correctness. Expert-adjudicated labels, indication-specific reference data, and explicit representation of patient context are needed. The system should also avoid simply increasing the number of warnings. Pediatric CPOE studies have documented errors caused by inadequate alerts as well as by inappropriate alerts and system-design limitations [3,6].

3. AI APPROACHES RELEVANT TO DOSING-ERROR DETECTION

Supervised machine learning can classify medication orders as potentially erroneous or estimate the probability of a medication-related event. Candidate variables include dose deviation from a reference range, patient weight, age, renal function, medication class, frequency, route, recent laboratory values, and concurrent medicines. Tree-based methods can handle nonlinear relationships and mixed clinical variables, while more complex neural models can represent high-dimensional temporal data. For a high-risk clinical application, however, a slightly less complex model with reliable calibration and interpretable outputs may be preferable to a black-box model with marginally better discrimination.

Unsupervised methods may identify unusual prescribing patterns without requiring a predefined error label. This may be useful for detecting local prescribing changes, concentration mismatches, or rare combinations of medicines. Yet anomaly detection can generate many clinically legitimate outliers. Human review and a mechanism for learning from adjudicated alerts are therefore essential. Generative and large language models may assist with medication-history summarization, extraction of dose instructions, comparison of medication lists, and identification of inconsistencies across clinical notes. Their role should remain bounded by validated knowledge sources because generative systems can produce plausible but incorrect statements. For high-risk pediatric orders, an LLM should not independently authorize or modify a prescription.

4. AI AND DETECTION OF PEDIATRIC ADVERSE DRUG EVENTS

Adverse drug event surveillance is another area in which AI may add value. Pediatric pharmacovigilance traditionally relies on spontaneous reports, chart review, laboratory triggers, clinician recognition, and prospective pharmacy surveillance. These methods are complementary but incomplete. A pediatric study of adverse-reaction documentation found that a substantial proportion of clinically identified reactions were not appropriately recorded in the electronic medical record before discharge, while the presence of pharmacovigilance oversight improved documentation [11]. Another pediatric study showed that retrospective electronic record triggers could identify additional adverse drug reactions beyond voluntary reporting [12].

NLP can make greater use of the narrative information contained in clinical notes. In the broader pharmacovigilance literature, deep-learning systems have successfully extracted medications and ADEs and linked them through relation-extraction models [13-16]. These studies demonstrate technical feasibility, but most are not pediatric-specific and often use benchmark datasets enriched for particular clinical domains. Their results should therefore not be interpreted as evidence that the same performance will occur in children. Recent work also highlights the importance of external validation. Machine-learning methods for ADE detection may perform well within the development dataset but degrade when applied to notes

from another institution because terminology, documentation style, patient mix, and EHR configuration differ [17]. A recent transformer-based system showed that ADE detection could be achieved across datasets, but performance was lower on an external institutional dataset than on the development benchmark [18].

This is directly relevant to pediatrics, where data volume is smaller and age-specific terminology is heterogeneous.AI-generated ADE signals should be treated as potential signals rather than confirmed causal relationships. A child may receive several medications while also having infection, organ dysfunction, or other conditions that can produce the same symptoms or laboratory abnormalities. Temporal association, dechallenge or rechallenge information when available, alternative explanations, and clinician assessment remain necessary before an AI signal is treated as an ADR.

5. MEDICATION RECONCILIATION AND PHARMACIST WORKFLOW

Medication reconciliation is a practical application because discrepancies are often distributed across multiple sources: home medication lists, admission orders, discharge prescriptions, pharmacy records, and clinical notes. NLP and machine learning could compare these sources, identify likely discrepancies, and prioritize high-risk cases for pharmacist review. Pediatric electronic medication-reconciliation programs have demonstrated that systematic electronic workflows can improve reconciliation processes, providing a foundation for future AI-assisted prioritization [19].

AI may also support prospective pharmacy review by ranking orders according to risk factors such as age, weight, medication class, dose deviation, renal function, polypharmacy, and previous medication-related events. This approach is preferable to replacing pharmacist review because the output can be framed as a queue of cases requiring attention. It also creates an opportunity for continuous monitoring of model performance: pharmacists can document whether a flag was clinically useful, irrelevant, or harmful.

6. IMPLEMENTATION, HUMAN FACTORS, AND SAFETY RISKS

Data quality is a major limitation. Pediatric records may contain missing or outdated weights, inconsistent units, incomplete allergy information, medication-list discrepancies, and documentation errors. A model trained on these records can learn artifacts rather than clinically meaningful relationships. In addition, a model trained in one hospital may encounter different formularies, prescribing conventions, laboratory ranges, and EHR workflows elsewhere. External validation should therefore be performed across institutions and across pediatric age groups, including neonates when neonatal use is intended. Alert fatigue is equally important. If an AI system generates frequent low-value warnings, clinicians may override or ignore them. The relevant outcome is not simply area under the receiver-operating-characteristic curve. Evaluation should include clinically meaningful measures such as preventable medication errors, pharmacist interventions, ADEs, alert-override rates, time burden, and patient outcomes. Pediatric studies of CPOE have shown that implementation can reduce some errors while leaving important residual risks, reinforcing the need to evaluate the complete sociotechnical system rather than the algorithm alone [4-7].

Human factors should be incorporated from the beginning. The interface should state why an order was flagged, identify the patient variables that influenced the result, distinguish hard safety constraints from probabilistic suggestions, and provide a rapid path for expert review. Cybersecurity, auditability, version control, and monitoring for model drift are also required. A model that performs well at deployment may become unreliable when prescribing patterns, formularies, clinical guidelines, or patient populations change.

7. ETHICAL AND GOVERNANCE CONSIDERATIONS

Pediatric AI systems process sensitive health information and may affect children who cannot independently consent to many aspects of data use. Governance should therefore address data minimization, access control, security, accountability, and appropriate secondary use of clinical data. Bias is another concern. A model may perform well overall but poorly in smaller age groups, rare diseases, or populations that are underrepresented in the training dataset. Performance should be reported by clinically meaningful subgroups and should include calibration as well as discrimination. Transparency is particularly important when AI influences medication decisions. Clinicians should be able to distinguish a validated rule from a probabilistic prediction and understand the basis of a warning. International guidance emphasizes human oversight, transparency, accountability, safety monitoring, and attention to bias and equity when AI is used in health care [20].

These principles are especially important for generative AI and multimodal models, for which plausible but incorrect outputs can be difficult to recognize [21].

8. FUTURE DIRECTIONS AND RESEARCH PRIORITIES

The next phase of pediatric medication-safety AI should move from retrospective proof-of-concept studies toward prospective, multicenter evaluation. Priority areas include standardized pediatric medication-error definitions, expert-adjudicated datasets, age- and indication-specific dosing references, neonatal and critically ill populations, and integration of pharmacokinetic and pharmacodynamic information. Studies should compare AI with established rule-based decision support and pharmacist review rather than

assuming that greater algorithmic complexity is automatically safer. Research should also examine implementation outcomes. A model may have good discrimination yet fail to improve patient safety if its alerts are poorly timed, difficult to interpret, or disconnected from clinical workflow. Prospective trials should measure whether AI reduces preventable medication errors or ADEs without increasing unnecessary interventions, clinician workload, or inequity. AI-assisted pharmacovigilance studies in broader populations show that machine-learning approaches can identify candidate signals, but they also illustrate the need for prospective validation before routine use [22].

CONCLUSION

AI has a plausible role in pediatric medication safety because pediatric prescribing generates structured, patient-specific data and because important safety information is also embedded in clinical narratives. The most practical applications are dose-risk prioritization, medication reconciliation, ADE extraction, and pharmacovigilance signal detection. Current evidence supports the usefulness of computational decision support in pediatrics, while the AI-specific evidence remains less mature and is often derived from non-pediatric datasets. AI should therefore be implemented as an additional safety layer rather than an autonomous prescribing authority. High-quality pediatric datasets, external validation, transparent model outputs, prospective clinical evaluation, human oversight, and continuous monitoring will be necessary before AI can be relied upon for high-stakes medication decisions.

REFERENCES

1. Wang JK, Herzog NS, Kaushal R, Park C, Mochizuki C, Weingarten SR. Prevention of pediatric medication errors by hospital pharmacists and the potential benefit of computerized physician order entry. Pediatrics. 2007;119(1):e77-e85. doi:10.1542/peds.2006-0034. PMID:17200262.
2. Hardmeier A, Tsourounis C, Moore M, Abbott WE, Guglielmo BJ. Pediatric medication administration errors and workflow following implementation of a bar code medication administration system. J Healthc Qual. 2014;36(4):54-61. doi:10.1111/jhq.12071. PMID:25041604.
3. Walsh KE, Adams WG, Bauchner H, Vinci RJ, Chessare JB, Cooper MR, et al. Medication errors related to computerized order entry for children. Pediatrics. 2006;118(5):1872-1879. PMID:17079557.
4. Upperman JS, Staley P, Friend K, Neches W, Kazimer D, Benes J, et al. The impact of hospitalwide computerized physician order entry on medical errors in a pediatric hospital. J Pediatr Surg. 2005;40(5):857-859. doi:10.1016/j.jpedsurg.2004.09.024. PMID:15868559.
5. Jani YH, Barber N, Wong ICK. Paediatric dosing errors before and after electronic prescribing. Qual Saf Health Care. 2010;19(4):337-340. doi:10.1136/qshc.2009.033068. PMID:20693222.
6. Alhanout K, Bun SS, Retornaz K, Chiche L, Colombini N. Prescription errors related to the use of computerized provider order-entry system for pediatric patients. Int J Med Inform. 2017;103:15-19. doi:10.1016/j.ijmedinf.2017.04.005. PMID:28550997.
7. Liang MQ, Thibault M, Jouvet P, Lebel D, Schuster T, Moreault MP, et al. Improving medication safety in a paediatric hospital: a mixed-methods evaluation of a newly implemented computerised provider order entry system. BMJ Health Care Inform. 2023;30(1):e100622. doi:10.1136/bmjhci-2022-100622. PMID:36787953.
8. Higi L, Käser K, Wälti M, Grotzer M, Vonbach P. Description of a clinical decision support tool with integrated dose calculator for paediatrics. Eur J Pediatr. 2022;181(2):679-689. doi:10.1007/s00431-021-04261-2. PMID:34524516.
9. Higi L, Schmitt R, Käser K, Wälti M, Grotzer M, Vonbach P. Impact of a clinical decision support system on paediatric drug dose prescribing: a randomised within-subject simulation trial. BMJ Paediatr Open. 2023;7(1):e001726. doi:10.1136/bmjpo-2022-001726. PMID:36697035.
10. Matava CT, Bordini M, Jasudavisius A, Santos C, Caldeira-Kulbakas M. Comparing the effectiveness of a clinical decision support tool in reducing pediatric opioid dose calculation errors: PediPain App vs. traditional calculators - a simulation-based randomised controlled study. J Med Syst. 2024;48(1):43. doi:10.1007/s10916-024-02060-4. PMID:38630157.
11. Kocmanova P, et al. Enhancing pediatric adverse drug reaction documentation in the electronic medical record. J Clin Pharmacol. 2020;60(12):1588-1594. PMID:32776356.
12. Joyner LM, et al. Methods for detecting pediatric adverse drug reactions from the electronic medical record. J Clin Pharmacol. 2021;61(11):1479-1484. doi:10.1002/jcph.1916. PMID:34031886.
13. Jagannatha A, Liu F, Liu W, Yu H. Overview of the first natural language processing challenge for extracting medication, indication, and adverse drug events from electronic health record notes (MADE 1.0). Drug Saf. 2019;42(1):99-111. doi:10.1007/s40264-018-0762-z. PMID:30649735.
14. Dandala B, Joopudi V, Devarakonda MV. Adverse drug events detection in clinical notes by jointly modeling entities and relations using neural networks. Drug Saf. 2019;42(1):135-146. doi:10.1007/s40264-018-0764-x. PMID:30649738.
15. Wei Q, Ji Z, Li Z, Du J, Wang J, Xu J, et al. A study of deep learning approaches for medication and adverse drug event extraction from clinical text. J Am Med Inform Assoc. 2020;27(1):13-21. doi:10.1093/jamia/ocz063. PMID:31135882.
16. Chen L, Gu Y, Ji X, Sun Z, Li H, Gao Y, Huang Y. Extracting medications and associated adverse drug events using a natural language processing system combining knowledge base and deep learning. J Am Med Inform Assoc. 2020;27(1):56-64. doi:10.1093/jamia/ocz141. PMID:31591641.
17. Zitu MM, Zhang S, Owen DH, Chiang C, Li L. Generalizability of machine learning methods in detecting adverse drug events from clinical narratives in electronic medical records. Front Pharmacol. 2023;14:1218679. doi:10.3389/fphar.2023.1218679. PMID:37502211.
18. Wu J, Ruan X, McNeer E, Rossow KM, Choi L. Developing a natural language processing system using transformer-based models for adverse drug event detection in electronic health records. PLoS One. 2026;21(7):e0350516. doi:10.1371/journal.pone.0350516. PMID:42384713.

19. Rappaport DI, Collins B, Koster A, Mercado A, Greenspan J, Lawless S, et al. Implementing medication reconciliation in outpatient pediatrics. Pediatrics. 2011;128(6):e1600-e1607. doi:10.1542/peds.2011-0993. PMID:22123872.
20. WHO. Ethics and governance of artificial intelligence for health. www.who.int. June 28, 2021. Accessed September 21, 2026. https://www.who.int/publications/i/item/9789240029200.
21. WHO. Ethics and governance of artificial intelligence for health: guidance on large multi-modal models. www.who.int. March 25, 2025. Accessed September 21, 2026. https://www.who.int/publications/i/item/9789240084759
22. De Abreu Ferreira R, Zhong S, Moureaud C, Le MT, Rothstein A, Li X, Wang L, Patwardhan M. A pilot predictive surveillance model in pharmacovigilance using machine learning approaches. Adv Ther. 2024;41(6):2435-2445. doi:10.1007/s12325-024-02870-5. PMID:38704799.

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