

Letter to Editor

How to cite this article:

B S, B M. Reporting AI-associated Medication Errors in Oncology Pharmacovigilance. *Advanced Pharmaceutical Bulletin*, doi: 10.34172/apb.47632

Reporting AI-associated Medication Errors in Oncology Pharmacovigilance

Srinivasa B ^{1*}, Madhusudhan B ¹¹Department of Pharmacology, Saveetha Medical College and Hospital, Saveetha Institute of Medical and Technical Sciences (SIMATS), Saveetha University, Chennai – 602105, Tamil Nadu, India.***Corresponding Author**

Srinivasa B, E-mail: srinivasab.smc@saveetha.com, ORCID: 0000-0002-7512-0555

Received: June 26, 2026 **Revised:** August 14, 2026 **Accepted:** October 15, 2026 **epublished:** October 24, 2026**To Editor,**

Artificial intelligence (AI) tools built on large language models (LLMs) are increasingly used by patients and healthcare professionals to obtain information about cancer diagnosis, treatment, adverse effects and supportive care. Recent clinical pharmacology literature has emphasized the expanding role of AI in medicines management, pharmacovigilance and therapeutic decision-making.¹ In oncology specifically, AI applications are evolving rapidly, with potential roles in clinical decision support, health information extraction and patient management.^{2,3} As these technologies become embedded in routine care, an important medication-safety question warrants attention: how should pharmacovigilance systems address medication errors that arise from AI-generated recommendations?

Current pharmacovigilance frameworks have evolved to identify and minimize harm associated with medicines across their life cycle, and traditional medication-error classifications encompass prescribing, dispensing, administration and monitoring errors.⁴ These frameworks, however, were developed before generative AI systems became capable of delivering medication-related recommendations directly to clinicians, patients and caregivers. The source of medication-related misinformation is therefore changing in ways that existing reporting systems may not adequately capture.

AI systems can provide clinically useful information while also exhibiting important limitations. In an evaluation of ChatGPT's performance on questions relating to cirrhosis and hepatocellular carcinoma, the model demonstrated substantial knowledge but struggled to provide specific decision-making cut-offs and treatment durations; the authors concluded that such systems may serve as adjunct informational tools rather than substitutes for clinical judgement.⁵ Comparable concerns about the limitations of AI in oncology have been raised elsewhere.⁶ The increasing use of AI in oncology further underscores the need for accurate interpretation of complex diagnostic and therapeutic information and appropriate integration of AI outputs with clinical reasoning.⁷ These limitations are particularly consequential in oncology because treatment frequently involves narrow therapeutic margins, complex protocols, individualized dose adjustments based on renal or hepatic function, clinically important drug-drug interactions and multiple supportive-care medicines. An error in interpreting any of these factors may therefore affect treatment selection, dosing, scheduling or supportive care

and may have clinically significant consequences. For example, an AI system could recommend an inappropriate methotrexate dose without accounting for impaired renal function or fail to identify a clinically important interaction, such as the increased risk of methotrexate toxicity with concomitant trimethoprim-sulfamethoxazole. It could also suggest an incorrect chemotherapy cycle interval or overlook a required dose adjustment. Such errors may appear clinically plausible while remaining inappropriate for the individual patient. AI-associated medication events should distinguish between errors that result in patient harm, errors intercepted before reaching the patient and near misses in which an unsafe recommendation is identified before any medication-related action is initiated. A minimum reporting dataset should capture the AI system and model or software version, clinical setting and task, relevant input and generated output, clinical context, human verification, action taken, error type, patient consequence and corrective action. AI involvement should be assessed according to its role in the event and classified as a direct cause, a contributing factor or an incidental exposure, with the level of attribution recorded where possible.

Reporting should also indicate whether the AI output was incorporated into the medical record, reviewed by a clinician and used while relevant institutional safeguards were active.

The reporting framework should also address privacy and reproducibility.⁸ Prompts and AI-generated outputs may contain identifiable clinical information and therefore require appropriate protection, while sufficient contextual information should be retained to support reconstruction of the event. Reports should also reach healthcare institutions, software developers, regulators and clinicians, as appropriate, so that identified problems can inform corrective action and system improvement. Potential underreporting, uncertain denominators, changing model versions and the stochastic nature of some AI outputs may complicate signal interpretation and should be considered when evaluating reported events.

Equally important is the risk of AI hallucination, whereby models generate plausible but inaccurate information. Kumar and colleagues described instances in which an LLM produced fabricated citations and incorrect responses delivered with apparent confidence.⁹ While such inaccuracies may seem benign in academic settings, their implications in oncology are more serious: inaccurate AI-generated advice on anticancer drug dosing, treatment schedules, supportive-care medicines or interaction management could influence medication decisions before professional verification occurs.

Pharmacovigilance has long served as a cornerstone of medication safety in oncology by identifying, evaluating and preventing medicine-related harm.¹⁰ As AI-assisted tools are increasingly evaluated and incorporated into oncology workflows, it may therefore be appropriate to consider whether AI-associated medication errors should also be systematically documented and evaluated within existing pharmacovigilance frameworks.¹¹

The concern becomes acute when AI-generated recommendations contribute to medication errors. An AI-associated medication error may be understood as an incorrect or potentially harmful medication-related recommendation in which an AI system has a direct or contributory role. This may include an erroneous AI-generated recommendation, an error introduced while translating or implementing the output, a problem arising from the system or its interface, or use of the tool beyond its intended clinical context. The nature of the AI system involved may also influence how such an event is interpreted and reported. Regulated clinical decision-support and electronic-prescribing systems differ from general-purpose language models and patient-facing chatbots, while locally developed or modified models may present additional implementation and governance

considerations. Although these events may resemble conventional prescribing errors in their consequences, they may involve both AI-related and human factors in the pathway leading to the error.

An AI-associated medication error may not necessarily fall within pharmacovigilance alone. While pharmacovigilance primarily addresses adverse drug reactions and medicine-related safety concerns, medication errors may also be captured through dedicated medication-safety or national reporting systems.¹² When an AI-enabled clinical or prescribing system contributes to an error, reporting may therefore need to involve linked pharmacovigilance, medication-error, software or medical-device vigilance and institutional safety pathways, depending on the nature of the event. Such coordination could help ensure that an event reaches not only those responsible for medicine-related risk assessment but also the healthcare institution, software developer or regulator best placed to address the underlying system-level problem.

Conclusion: We propose systematic reporting of AI-associated medication errors and near misses through a standardized reporting framework. The framework should capture key details including the AI system or software version, clinical context, error type, patient consequence and corrective action. Reports should be linked, where appropriate, with pharmacovigilance, medication-error and institutional safety systems. A formal consensus process involving clinicians, pharmacovigilance experts, regulators and AI developers could establish and periodically refine these reporting standards.

Competing Interests: The authors declare no competing interests.

Ethical Approval: Not Applicable

Sources of Funding: None Declared

References

1. Ryan DK, Maclean RH, Balston A, Scourfield A, Shah AD, Ross J. Artificial intelligence and machine learning for clinical pharmacology. *Br J Clin Pharmacol*. 2024;90(3):629-639. doi: 10.1111/bcp.15930.
2. Chen D, Alnassar SA, Avison KE, Huang RS, Raman S. Large language model applications for health information extraction in oncology: scoping review. *JMIR Cancer*. 2025;11: e65984. doi: 10.2196/65984.
3. Annamalai A, Dhanes V, Jayalakshmi L, Shanmugam R, Ravi S. Artificial intelligence in oral oncology: current advances and future potential in diagnosis, prognosis and therapeutic decision-making. *Cancer Treat Res Commun*. 2026; 47:101193. doi: 10.1016/j.ctarc.2026.101193.
4. Song H, Pei X, Liu Z, Shen C, Sun J, Liu Y, et al. Pharmacovigilance in China: evolution and future challenges. *Br J Clin Pharmacol*. 2023;89(2):510-522. doi: 10.1111/bcp.15277.
5. Yeo YH, Samaan JS, Ng WH, Ting PS, Trivedi H, Vipani A, et al. Assessing the performance of ChatGPT in answering questions regarding cirrhosis and hepatocellular carcinoma. *Clin Mol Hepatol*. 2023;29(3):721-732. doi: 10.3350/cmh.2023.0089.
6. Kolla L, Parikh RB. Uses and limitations of artificial intelligence for oncology. *Cancer*. 2024;130(12):2101-2107. doi: 10.1002/cnccr.35307.

7. Ardila CM, Vivares-Builes AM, Pineda-Vélez E. Integrating artificial intelligence with human reasoning in oncology: questions on real-world implementation and patient-centric evidence. *Mil Med Res.* 2025;12(1):75. doi: 10.1186/s40779-025-00663-7.
8. Goodman KW, Litewka SG, Malpani R, Pujari S, Reis AA. Global health and big data: The WHO's artificial intelligence guidance. *S Afr J Sci.* 2023;119(5-6):14725. doi: 10.17159/sajs.2023/14725.
9. Kumar M, Mani UA, Tripathi P, Saalim M, Roy S. Artificial hallucinations by Google Bard: think before you leap. *Cureus.* 2023;15(8): e43313. doi: 10.7759/cureus.43313.
10. Baldo P, Fornasier G, Ciolfi L, Sartor I, Francescon S. Pharmacovigilance in oncology. *Int J Clin Pharm.* 2018;40(4):832-841. doi: 10.1007/s11096-018-0706-9.
11. Donaldson LJ, Kelley ET, Dhingra-Kumar N, Kieny MP, Sheikh A. Medication Without Harm: WHO's Third Global Patient Safety Challenge. *Lancet.* 2017;389(10080):1680-1681. doi: 10.1016/S0140-6736(17)31047-4.
12. Kumar A, Bhatnagar A, Desai NN, Paul JR, Padhi S. Comment on "Uncovering Medication Errors Leading to Hospital Admissions in the Emergency Department: An External, Prospective Validation of Clinical Decision Rules". *Pharmacoepidemiol Drug Saf.* 2026;35(1): e70314. doi: 10.1002/pds.70314.