Indian Journal of Pharmacy Practice., 2026; 19(1):137-138.
https://www.ijopp.org

Letter to the Editor

A Need for Pharmacovigilance in OTC Steroid Misuse: Real-World Insights

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ABSTRACT

Over-the-Counter (OTC) corticosteroid misuse remains a pressing yet underreported issue in rural India. This letter presents a case of a 70-year-old male who developed iatrogenic Cushing's syndrome complicated by urosepsis and septic shock after prolonged self-medication with dexamethasone. The case underscores the urgent need for enhanced pharmacovigilance systems at the community level, stricter enforcement of Schedule H regulations, and the active involvement of pharmacists in identifying and preventing such adverse drug reactions. Strengthening public awareness and pharmacist-led interventions are vital to curb the inappropriate use of potent corticosteroids.

Keywords: Over-the-counter drugs, Corticosteroids, Pharmacovigilance, Schedule H violations, Rural healthcare.

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Received: 14-04-2025;
Revised: 02-06-2025;
Accepted: 28-08-2025.

INTRODUCTION

Over-the-Counter (OTC) misuse of corticosteroids is an under-recognized public health threat in India, particularly in rural and semi-urban areas where community pharmacies often serve as the first point of care. Despite being classified under schedule H, drugs like dexamethasone are frequently dispensed without a prescription, contributing to delayed adverse outcomes.[1,2] The need to extend pharmacovigilance efforts beyond hospitals into community and outpatient settings has become urgent, especially with rising cases of steroid-induced complications.[3] This report aims to underscore the importance of real-world pharmacovigilance in addressing such misuse.

CASE SUMMARY

A 70-year-old male from a rural background presented with complaints of breathlessness, fever, and abdominal pain. On further inquiry, it was found that he had been self-medicating with dexamethasone 0.5 mg daily for nearly 10 years to manage joint pain. Examination revealed classical Cushingoid features including moon facies, central obesity, and skin thinning. Laboratory investigations indicated severe hyperglycemia, elevated white blood cell count, impaired renal function, and a urinary tract infection. He was admitted to the intensive care unit and managed with intravenous antibiotics, insulin infusion, and vasopressors.

The patient improved with appropriate treatment and was discharged after 12 days. Who-UMC causality assessment classified the reaction as "Probable," and the Naranjo ADR Probability Scale score was 6, confirming a "Probable" Adverse Drug Reaction (ADR) due to prolonged corticosteroid use.[4,5]

DISCUSSION

This case represents the real-world dangers of unsupervised corticosteroid use, especially in geriatric patients with multiple comorbidities.[6] In rural India, the lack of awareness about prescription-only medications, limited healthcare access, and informal medical advice contribute significantly to the chronic misuse of steroids.[7] Prolonged use can lead to suppression of the hypothalamic-pituitary-adrenal axis, metabolic derangements like steroid-induced diabetes, and immunosuppression, which predispose patients to serious infections.[8]

While pharmacovigilance efforts in tertiary hospitals have improved in recent years, ADR reporting in outpatient and pharmacy-level interactions remains negligible.[3] Cases like this rarely enter national databases because they originate outside institutional settings. This incident also highlights the consequences of inadequate pharmacist involvement in community-level medication counseling and monitoring.[9] Despite the presence of national programs like PvPI (Pharmacovigilance Programme of India), their reach into smaller towns and villages is still limited.[10]

DOI: 10.5530/ijopp.20260450

Schedule H violations, such as OTC availability of potent corticosteroids, continue unchecked due to poor enforcement, creating a pharmacotherapeutic blind spot. A stronger pharmacovigilance culture at the retail and primary care level, combined with public education campaigns, is vital to preventing such adverse outcomes.[11]

Role of the Pharmacist

Pharmacists are the first and most accessible healthcare professionals in many communities. Their proactive engagement is essential for early identification of inappropriate drug use.[7] In this case, pharmacist intervention could have identified the prolonged unsupervised use of dexamethasone and prevented complications. Pharmacists, especially PharmD graduates, are trained to assess drug therapy, counsel patients, and report ADRs.[9]

Enhancing the involvement of PharmD professionals in rural pharmacovigilance initiatives could significantly reduce the incidence of drug-induced complications. Training programs, continuing education, and integration of pharmacists into national PV systems like PvPI can ensure better community surveillance.[10] Additionally, encouraging pharmacists to act as educators in local settings can improve public understanding of drug risks and reduce misuse.

CONCLUSION

The chronic misuse of over-the-counter corticosteroids like dexamethasone poses a severe risk to public health, especially in rural areas where access to regulated healthcare is limited. This case highlights the urgent need for strengthened pharmacovigilance systems that extend into community settings. Pharmacists must be empowered and actively involved in patient education, medication counseling, and adverse drug reaction reporting. Comprehensive regulatory enforcement and public awareness campaigns are essential to prevent similar adverse outcomes in the future

ACKNOWLEDGEMENT

The author sincerely thanks Dr. V. Vijay Ram, MBBS, MD, Assistant Professor, Department of General Medicine, Government Medical College and Hospital, Orathur-Nagapattinam, for his clinical guidance and support in documenting this case. The author also acknowledges the faculty of E.G.S. Pillay College of Pharmacy for their academic and ethical supervision throughout the study.

CONFLICT OF INTEREST

The author declares no conflict of interest.

ABBREVIATIONS

ADR: Adverse Drug Reaction; **OTC:** Over the Counter; **PV:** Pharmacovigilance; **ICU:** Intensive Care Unit; **PVPI:** Pharmacovigilance Programme of India.

ETHICAL APPROVAL

The case was approved by the institutional ethics committee (E.G.S. Pillay College of Pharmacy), IEC No: EGS/IEC/PharmD/03/2025.

SUMMARY

A case of dexamethasone-induced Cushing's syndrome with urosepsis in a rural elderly patient underscores the dire need for community-based pharmacovigilance. Strengthening pharmacist roles and enforcing schedule H compliance are essential to mitigating similar events.

REFERENCES

1. Chopra, A., Choudhary, N., and Saroha, S. Community-level challenges in controlling OTC steroid misuse. Journal of Family Medicine and Primary Care, 2021; 10(2): 678-83.
2. Gupta, S., Sharma, R., and Patel, N. Role of community pharmacists in adverse drug reaction reporting: An Indian perspective. International Journal of Pharmacy Practice, 2021; 29(3): 210-5.
3. Kalaiselvan, V., Srivastava, S., and Singh, A. Enhancing the scope of pharmacovigilance: Community-level practices. Indian Journal of Pharmacology, 2020; 52(1): 7-12.
4. Mohan, V., Unnikrishnan, R., and Ranjani, H. Glucocorticoid-induced diabetes mellitus. Diabetes and Metabolic Syndrome: Clinical Research and Reviews, 2019; 13(3): 1705-10.
5. Mukherjee, S., Das, R., and Kumar, A. Steroid misuse in elderly: An underreported menace. Geriatric Pharmacotherapy, 2020; 8(2): 145-50.
6. Naranjo, C. A., Busto, U., Sellers, E. M., Sandor, P., Ruiz, I., Roberts, E. A., *et al.* A method for estimating the probability of adverse drug reactions. Clinical Pharmacology and Therapeutics, 1981; 30(2): 239-45.
7. Pharmacovigilance Programme of India (PvPI). Annual report and updates. Indian Pharmacopoeia Commission. 2023. Retrieved from https://www.ipc.gov.in
8. Raut, A. A., Singh, J., and Kale, M. S. OTC steroid sales in India: Regulatory gaps and health outcomes. Indian Journal of Public Health, 2019; 63(4): 289-93.
9. Sathvik, B. S., and Keshava, B. S. Pharmacists' role in rural health: Opportunities in India. Indian Journal of Pharmacy Practice, 2018; 11(1): 5-9.
10. Sharma, R., Kalra, B., and Mehta, R. Schedule H and OTC drug violations: A retail-level analysis. Indian Journal of Regulatory Affairs, 2017; 5(1): 32-6.
11. World Health Organization-Uppsala Monitoring Centre (WHO-UMC). (2022). WHO-UMC system for standardized case causality assessment. Retrieved from https ://www.who-umc.org.

Cite this article: Karthikesan J. A Need for Pharmacovigilance in OTC Steroid Misuse: Real-World Insights. Indian J Pharmacy Practice. 2026;19(1):137-8.