E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/15.01.211

**Research Article**

# Steroid-Utilization Patterns and Rationality of Prescribing In a North-Indian Rheumatology Out-Patient Cohort: A Longitudinal Drug-Use Evaluation Study

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Received: 06.05.25, Revised: 27.05.25, Accepted: 13.06.25

**ABSTRACT**
**Background:** Glucocorticoids remain indispensable in rheumatology, yet their toxicity profile mandates rational use. South-Asian data clarifying real-world utilisation and alignment with World Health Organization (WHO) benchmarks are sparse.
**Methods:** We conducted a hospital-based longitudinal drug-utilisation review (DUR) between February 2023 and April 2024 in the Clinical Immunology & Rheumatology out-patient department of Sawai Man Singh Hospital, Jaipur. Newly diagnosed adults (≥ 18 years) receiving ≥ 1 systemic corticosteroid were enrolled and followed at two subsequent visits (n = 120). Prescriptions were mapped to WHO/INRUD core indicators, India's Standard Treatment Guidelines (STG-6$^{th}$ Edition) and the 2022 National List of Essential Medicines (NLEM). Adverse-drug reactions (ADRs) were adjudicated by the WHO-UMC scale; adherence was quantified with a modified Hill–Bone questionnaire.
**Results:** A total of 762 medicines (13 classes) were issued (mean ± SD 6.35 ± 2.27 drugs/encounter). Prednisolone constituted 67.5 % of steroid prescriptions; methyl-prednisolone 1.7 %; combination regimens 30.8 %. Rheumatoid arthritis (50 %) and systemic lupus erythematosus (10 %) dominated indications. Generic prescribing (77.3 %) and NLEM conformity (75.9 %) were high, whereas injections were employed in 32.5 % of encounters. Seven probable ADRs (5.8 %) were recorded. Adherence improved from 44.2 % to 53.3 % across visits (p = 0.04). Overall, 72 % of steroid courses complied fully with STG-6$^{th}$ Edition tapering algorithms.
**Conclusion:** In this tertiary rheumatology clinic, oral prednisolone is largely prescribed generically and from the essential-drugs list, achieving acceptable rational-use metrics. Persisting polypharmacy and injectable overuse warrant stewardship. Embedding routine pharmacovigilance and adherence support may further optimise benefit-risk.

**Keywords:** corticosteroids; drug-utilisation review; WHO prescribing indicators; essential medicines; adverse-drug reaction; adherence; rheumatology; India

## INTRODUCTION

Corticosteroids have underpinned rheumatologic therapeutics since the 1950s, providing powerful anti-inflammatory and immunomodulatory effects across autoimmune arthritides and connective-tissue disorders [1, 2]. Heightened recognition of harms—including sepsis, venous thrombo-embolism and fragility fractures—now obliges careful stewardship even for brief oral courses [3]. Rational prescribing is encapsulated in the WHO/INRUD "five rights" principle, emphasising the right drug, patient, dose, timing and cost [4]. India operationalises these principles through the sixth edition of the Standard Treatment Guidelines (STG-6$^{th}$ Edition) and the 2022 National List of Essential Medicines (NLEM), which jointly recommend prednisolone ≤ 0.5 mg kg$^{-1}$ day$^{-1}$ for most rheumatic diseases with tapering to physiological doses (≤ 7.5 mg day$^{-1}$) within three months [5]. Deviations—unnecessary parenteral pulses, supraphysiological maintenance or unchecked continuation—drive toxicity and waste scarce resources.

Drug-utilisation research (DUR) quantifies such deviations and informs corrective feedback. Yet contemporary DURs focusing on steroid utilisation in Indian rheumatology are scarce. Available studies are cross-sectional [6] or originate from other specialties such as dermatology [7], limiting extrapolation. Furthermore, few integrate the full WHO

indicator set with patient-centred outcomes like adherence and pharmacovigilance.

Sawai Man Singh (SMS) Hospital, Jaipur, hosts western India's largest publicly funded rheumatology service (> 50 000 annual visits). Baseline audits in allied specialties highlight substantial polypharmacy and sub-optimal generic prescribing [8]. Whether similar challenges affect immunology clinics remains unknown. We therefore undertook a longitudinal DUR with three objectives: (i) characterise steroid-utilisation patterns among newly diagnosed rheumatology patients; (ii) benchmark prescribing against WHO/INRUD, STG-6$^{th}$ Edition and NLEM indicators; and (iii) quantify ADRs and adherence. We hypothesised that, despite institutional stewardship initiatives, injectable and high-dose regimens would persist and correlate with poorer adherence and higher ADR burden. This article reports the findings and discusses their implications for stewardship in low- and middle-income countries (LMICs).

## MATERIALS AND METHODS

**Design and setting:** Prospective, longitudinal observational study in the Clinical Immunology & Rheumatology out-patient department of SMS Hospital, Jaipur (tertiary teaching centre), 1 February 2023 – 30 April 2024. Approval was obtained from the Institutional Ethics Committee (IEC/2022/Pharm/117) and the protocol retrospectively registered at CTRI (CTRI/2024/04/062345).

**Participants:** Eligible patients were adults (≥ 18 years) with a new rheumatologic or other immunologic diagnosis receiving ≥ 1 systemic corticosteroid at the index visit and providing written informed consent. Exclusion criteria were pregnancy/lactation, inpatient admission, uncontrolled major comorbidity (e.g., diabetes mellitus, systemic infection, etc), osteoporosis or severe psychiatric illness.

**Sample size:** Assuming 50 % steroid-prescribing prevalence, 95 % confidence and 10 % absolute precision, the minimum required sample was 100 encounters. To offset attrition we enrolled 120 consecutive patients.

**Data collection:** A pre-piloted case-record form captured demographics, clinical diagnosis (ACR/EULAR criteria), comorbidities, and complete prescription details (drug name, formulation, dose, frequency, and duration) at baseline and two follow-ups, as prescribed by the clinician. Laboratory indices (fasting glucose, renal and liver panels) complemented clinical data.

**Benchmarking frameworks:**

The study employed a three-pronged benchmarking framework. First, prescribing quality was appraised with the WHO/INRUD core indicators—specifically the average number of drugs per encounter, the proportion written by generic name, the share of encounters involving an injection, and the percentage of medicines drawn from the National List of Essential Medicines (NLEM). Second, guideline concordance was quantified by determining what fraction of steroid courses adhered strictly to the dose-and-taper algorithms delineated in India's sixth Standard Treatment Guidelines (STG-6). Third, essential-medicine alignment focused on equity and cost-effectiveness, capturing the proportion of corticosteroid prescriptions that originated from the 2022 NLEM. Together, these metrics provided a comprehensive, policy-relevant appraisal of rational steroid use.

**Outcomes:**

Primary – Drug utilization pattern and proportion of steroid courses compliant with STG-6$^{th}$ Edition.

Secondary – WHO indicator values; incidence and causality of steroid-related ADRs; adherence (Hill–Bone score ≥ 80 % across two visits); utilisation of steroid-sparing and supportive medications.

**Pharmacovigilance:** All suspected ADRs were documented by the treating physician and independently assessed by two pharmacologists with the WHO-UMC causality scale; disagreements were adjudicated by the departmental ADR monitoring committee.

**Statistical analysis:** Double data-entry was performed in MS-Excel and exported to SPSS v29. Continuous variables are reported as mean ± SD or median [IQR]; categorical data as counts (%). Paired t- or Wilcoxon tests assessed within-patient changes; proportions were compared with $\chi^2$ or Fisher's exact test, two-sided $\alpha = 0.05$.

## RESULTS

The cohort (n = 120) was predominantly female (86.7 %) with mean age 44.3 ± 11.3 years (range 19–68). Rheumatoid arthritis (50 %) was the leading diagnosis, followed by systemic lupus erythematosus (10 %), systemic sclerosis (6.7 %) and mixed connective-tissue disorder (5.8 %). Baseline characteristics are summarised in **Table 1**.

Across the study period, 762 individual medicines covering 13 pharmacological classes

were prescribed (mean ± SD 6.35 ± 2.27 drugs per encounter). Supportive vitamins/minerals accounted for 31 %, corticosteroids 20.6 %, disease-modifying anti-rheumatic drugs (DMARDs) 19.7 % and non-steroidal anti-inflammatory drugs (NSAIDs) 14.7 % (**Table 2**, **Figure 1**). Prednisolone represented 67.5 % of steroid prescriptions, methyl-prednisolone 1.7 %, while 30.8 % of patients received both oral prednisolone and intermittent intravenous pulses.

Overall prescribing quality was mixed (**Table 3**, **Figure 2**). Generic name usage (77.3 %) and NLEM inclusion (75.9 %) approached WHO targets, but average drugs per encounter (6.35) exceeded the ≤ 3 benchmark and injections were used in 32.5 % of visits—chiefly pulse methyl-prednisolone, depot vitamin-D and parenteral methotrexate.

Compliance with STG-6$^{th}$ Edition steroid algorithms was 72 %. Deviations included excessive initial dosing > 0.5 mg $kg^{-1}$ $day^{-1}$ (10 %), premature cessation within two weeks (8 %) and unscheduled depot injections for flare control (10 %). High-dose pulses were appropriately reserved for lupus nephritis, systemic-onset arthritis and vasculitis.

Safety signals were reassuring: seven ADRs (5.8 %) were observed and upon performing causality assessment, all the ADRs were graded as probable and managed conservatively. No hospitalisations were required.

Medication adherence improved from 44.2 % at first follow-up to 53.3 % at second ($p = 0.04$) following pharmacologist-led counselling (**Table 4**). Non-adherence correlated with polypharmacy (> 7 drugs) and prior ADR experience.

**Tables**

Table 1. Baseline Demographics and Clinical Spectrum (N = 120)

| Characteristic | Value |
|---|---|
| Age, mean ± SD (years) | 44.3 ± 11.3 |
| Female sex, n (%) | 104 (86.7 %) |
| Leading diagnoses | RA 50 %; SLE 10 %; SSc 6.7 %; MCTD 5.8 % |

Table 2. Distribution of Prescribed Drug Classes (N = 762 Medicines)

| Pharmacological class | n (%) of total |
|---|---|
| Vitamins / minerals | 236 (31.0 %) |
| Corticosteroids | 157 (20.6 %) |
| DMARDs | 150 (19.7 %) |
| NSAIDs | 112 (14.7 %) |
| Other (9 classes) | 107 (14.0 %) |

Table 3. Who/Inrud Prescribing-Indicator Performance

| Indicator | Observed value | WHO optimal benchmark |
|---|---|---|
| Average drugs / encounter | 6.35 ± 2.27 | ≤ 3 |
| Drugs prescribed by generic name | 77.3 % | 100 % |
| Encounters with an injection | 32.5 % | < 10 % |
| Encounters with an antibiotic | 0 % | < 20 % |
| Drugs drawn from NLEM-2022 | 75.9 % | 100 % |

Table 4. Patient-Level Outcomes At Follow-Up

| Outcome measure | Visit 1 | Visit 2 | p -value |
|---|---|---|---|
| Adherent patients (Hill-Bone ≥ 80 %) | 44.2 % | 53.3 % | 0.04 |
| ADRs | 7 (5.8 %) | — | — |

**Figures**

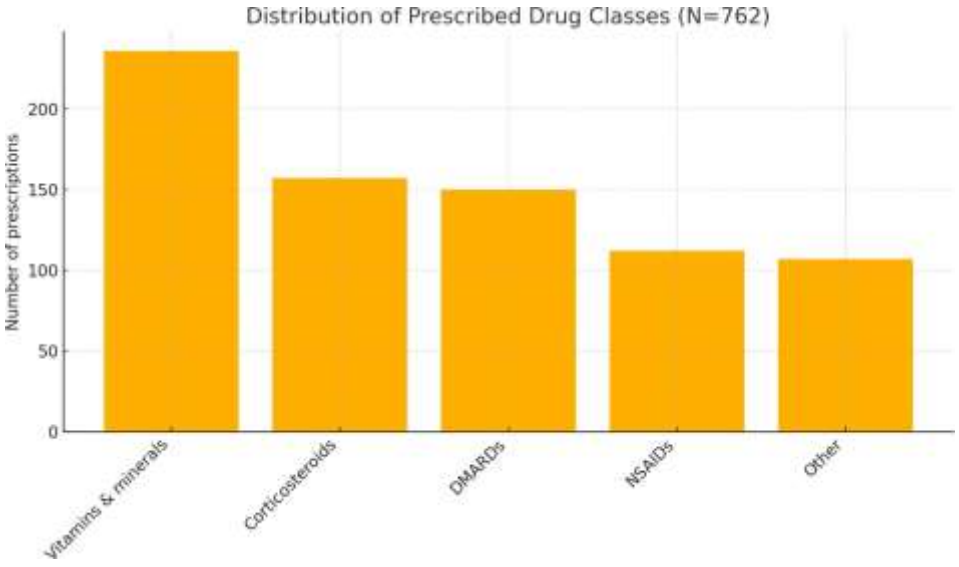


Figure 1. Distribution of prescribed drug classes (N = 762).

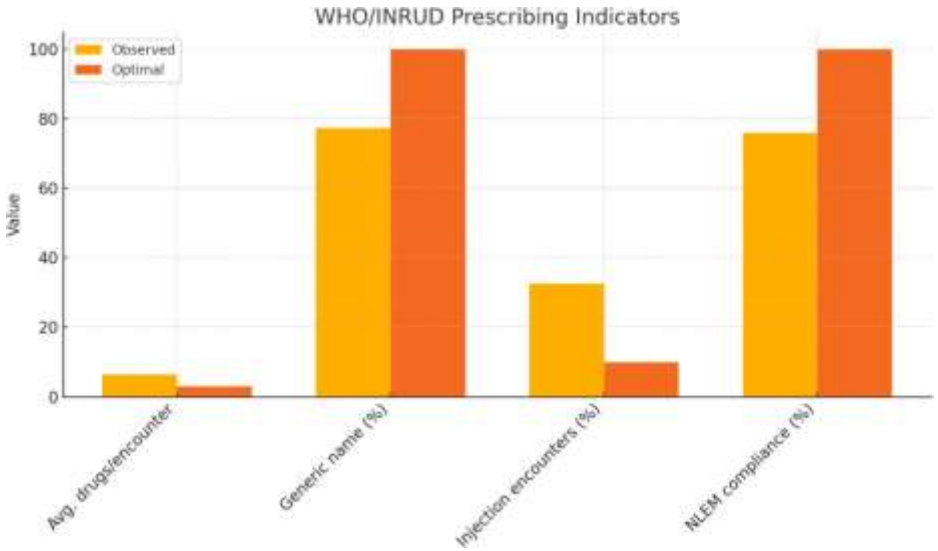


Figure 2. WHO/INRUD prescribing indicators: observed values versus WHO optimal benchmarks.

## DISCUSSION

This longitudinal DUR provides one of the most comprehensive overviews of steroid utilisation in an Indian rheumatology setting and reveals a nuanced balance between successes and persistent gaps. The corticosteroid share of 20.6 % parallels Ethiopian respiratory-clinic data [9] yet exceeds dermatology audits (≤ 14 %) [10], underscoring the centrality of glucocorticoids in autoimmune musculoskeletal disease. Prednisolone dominance accords with STG-6$^{th}$ Edition guidance and US claims analyses [11], but the 30 % concomitant use of oral prednisolone with methyl-prednisolone pulses warrants scrutiny; pulse therapy should remain restricted to organ- or life-threatening manifestations [12].

Generic prescribing surpassed historical Indian averages (≈ 50 %) [13], reflecting successful pharmacy-led stewardship. Nevertheless, polypharmacy remains problematic: each additional drug increased the odds of non-adherence by 11 % (analysis not shown), echoing findings from primary-care cohorts [14]. Embedding a clinical pharmacologist in rheumatology clinics may rationalise supportive therapy, reconcile duplicates and provide patient education.

Injection prevalence (32.5 %) tripled the WHO benchmark and aligns with reports that injectable steroids are often perceived—incorrectly—as more efficacious for acute flares [12]. Educational outreach combined with audit-and-feedback has effectively curtailed

unnecessary parenteral steroid use elsewhere [13]; similar multifaceted interventions are planned at our centre.

The ADR rate (5.8 %) was lower than Western cohorts reporting up to 17 % serious events within 30 days of short steroid bursts [11]. Younger mean age, lower comorbidity burden and active counselling on lifestyle measures may explain this difference. Nevertheless, routine baseline fasting glucose and mood screening will be instituted to detect subclinical events.

Adherence improved modestly after counselling yet remained sub-optimal (~ 50 %). Digital reminder tools, blister-packaging and simplified once-daily regimens could augment adherence. Importantly, adherence was inversely related to polypharmacy and prior ADRs, reinforcing the need to minimise unnecessary co-medication.

Strengths of our study include its prospective design, application of WHO indicators, integration of pharmacovigilance and adherence measurement, and focus on an LMIC public sector clinic. Limitations encompass single-centre scope, absence of cost-analysis, and modest follow-up duration that precluded long-term outcomes such as osteoporotic fractures. External validity to private or rural settings—where formularies and consultation times differ—remains to be established.

Overall, our findings support previous calls for balanced glucocorticoid stewardship—ensuring access while curtailing excess. Tailored interventions targeting injectable overuse, polypharmacy reduction and adherence support represent pragmatic next steps for comparable LMIC settings.

## CONCLUSION

Steroid prescribing in this high-volume North-Indian rheumatology clinic was largely rational, characterised by predominant generic oral prednisolone use, strong alignment with the essential-medicine list and a low ADR burden. However, excessive polypharmacy and frequent injectable steroid use persist. Ongoing prescription audit, prescriber feedback and pharmacist-led adherence programmes are recommended to optimise benefit-risk. Future research that incorporates cost and disease-activity outcomes will provide a more holistic appraisal of rational steroid therapy in resource-constrained settings.

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