

Evaluating Regulatory Compliance and WHO Prescribing Indicators in Uttar Pradesh: A Cross-Sectional Audit of Ground-Level Prescription Practices

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ABSTRACT

Background: Incomplete documentation, poor legibility, excessive drug use, and preference for brand names may increase medication-related problems and compromise rational drug use. This study examined prescription writing and prescribing practices in healthcare settings in Uttar Pradesh. **Objectives:** To assess prescription writing practices and rational drug use according to WHO prescribing indicators and the prescription-related requirements of the NMC Registered Medical Practitioner (Professional Conduct) Regulations, 2023. **Materials and Methods:** A retrospective, cross-sectional observational prescription audit was conducted on 100 prescriptions collected from retail, hospital, and community pharmacy settings across Uttar Pradesh between January and April 2026. First-encounter outpatient prescriptions containing at least one medicine were included. Prescriptions were assessed using a structured checklist covering patient and prescriber details, diagnosis, allergy history, legibility, drug nomenclature, dosage, route, duration, and WHO prescribing indicators. **Results:** Important gaps were observed in prescription practices. Diagnosis and allergy history were documented in 34% and 12% of prescriptions, respectively. Only 42% were clearly legible, 79% included the prescriber's registration number, and 14% used capitalized drug names. The mean number of medicines was 4.1 ± 1.2 per prescription. Generic prescribing was 11.1%, while antibiotics, injections, and NLEM/EML medicines accounted for 18.8%, 5.3%, and 10.7%, respectively. **Conclusion:** The audit identified substantial gaps in prescription documentation, legibility, generic prescribing, and rational medicine use. Regular prescription audits, prescriber training, pharmacist involvement, and electronic prescribing may improve prescription quality and patient safety.

Keywords: Generic prescribing, NMC 2023, Polypharmacy, Prescription audit, Prescription writing, Rational drug use, WHO prescribing indicators.

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INTRODUCTION

Prescription writing is one of the most fundamental responsibilities of a registered medical practitioner and serves as a critical link between the prescriber, pharmacist, and patient. Beyond being a clinical instruction, a prescription is also a legal and medico-legal document that reflects the quality of healthcare delivered to the patient. A well-constructed prescription provides comprehensive and precise information regarding pharmacotherapy, including drug name, dosage, frequency, route of administration, and duration of treatment (World Health

Organization, 1994). Accurate prescription writing is essential to ensure the “five rights” of medication use—right patient, right drug, right dose, right route, and right time—thereby optimizing therapeutic outcomes while minimizing medication errors and enhancing patient safety (Aronson, 2009).

Medication errors associated with inappropriate prescribing practices remain a major public health concern worldwide. Illegible handwriting, incomplete prescriptions, irrational Fixed-Dose Combinations (FDCs), polypharmacy, omission of essential patient information, and inappropriate use of antimicrobials contribute significantly to preventable adverse drug events (World Health Organization, 2012). According to the World Health Organization (WHO), rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate duration, and at the lowest possible cost to them and the community (NMC Registered Medical, 2023).



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Over the past decade, many developed healthcare systems have implemented standardized prescription formats and electronic prescribing systems to reduce prescribing errors and improve medication safety (World Health Organization, 2006; National Institute for Health and Care Excellence, 2015). Countries such as the United States and the United Kingdom have integrated electronic prescribing with clinical decision-support systems capable of identifying dosing errors, drug interactions, allergies, and duplication of therapy (Institute of Medicine, 2007; Ministry of Health and Family Welfare, 2017; Kaur *et al.*, 2009). These systems have demonstrated substantial reductions in medication errors and improvements in prescription legibility and traceability (Dean *et al.*, 2002).

However, handwritten prescriptions are still widely used in many healthcare settings in developing nations like India (National Institute for Health and Care Excellence, 2015). Medication safety is still jeopardized by uneven compliance with legal requirements, insufficient use of logical prescribing concepts and variations in prescription writing procedures. Concerns about cost, adverse medication reactions, therapeutic duplication, and antimicrobial resistance, have also been brought up by the growing use of illogical fixed-dose combos and brand-name prescribing (Institute of Medicine, 2007; Ministry of Health and Family Welfare, 2017; Kaur *et al.*, 2009).

The Registered Medical Practitioner (Professional Conduct) Regulations, 2023 were enacted by the National Medical Commission (NMC) in honor of the need for increased accountability and uniformity. These statutes emphasize the need for readable prescriptions, the use of generic names, the inclusion of prescriber registration numbers, and comprehensive reporting of patient and treatment information. The guidelines are intended to improve patient safety in all Indian healthcare settings and to reinforce ethical prescribing practices (National Medical Commission, 2023).

The crucial quality assurance technique for assessing prescribing trends and spotting departures from accepted practice and legal requirements is the prescription audit. Irrational prescribing patterns, polypharmacy, excessive antibiotic usage, improper injectable use, and poor adherence to lists of necessary medications can all be found with the use of systematic prescription auditing. In emerging healthcare systems, where prescription standardization is still in its early stages, these assessments are especially crucial (Kumar *et al.*, 2025).

Thus, the present research used a cross-sectional audit of 100 prescriptions gathered from healthcare facilities in Uttar Pradesh, India, to analyse prescription writing methods and rational medication usage. The study examined problems with generic prescribing, polypharmacy, unreasonable fixed-dose combinations, documentation quality, and prescription readability in addition to evaluating adherence to NMC 2023

prescription guidelines and WHO prescribing indicators. The results of this study might be used to pinpoint deficiencies in the present prescription processes and aid in the creation of safer, more uniform, and more logical prescription systems in India.

Why Prescription Writing Standards Matter

Prescription writing standards are crucial to ensuring the safe and effective use of drugs (World Health Organization, 1994). These recommendations are meant to reduce errors, improve professional communication, and protect patients from possible harm. One of the primary arguments in favour of standardized prescription writing is patient safety (Aronson, 2009). Inaccurate medicine names, illegible handwriting, or missing dosage instructions can all lead to serious prescription errors (World Health Organization, 2002). For example, a badly written prescription might result in a pharmacist giving the incorrect medication or dosage, which could cause adverse drug reactions (Dean *et al.*, 2002; Institute of Medicine, 2007). Another crucial element is legal protection. A prescription is a legal document, and both the pharmacist and the prescriber are covered by the proper documentation in the case of disputes or claims of medical malpractice (Medical Council of India, 2002). Additionally, prescription guidelines support antibiotic stewardship, which lessens the overuse and abuse of antibiotics (Dyar *et al.*, 2017). When prescriptions are clearly written, antibiotics are only given when necessary and in the appropriate amounts (World Health Organization, 2014). Standardization also helps reduce pharmaceutical errors. Properly structured prescriptions eliminate confusion regarding medication names, abbreviations, or dose recommendations (National Institute for Health and Care Excellence, 2015). Finally, prescription guidelines ensure accurate medication delivery and sufficient treatment counseling for patients by improving communication between doctors and pharmacists (World Health Organization, 2002; Avery *et al.*, 2012).

Global Regulatory Frameworks and Clinical Standards in Prescription Writing

The foundation of the healthcare system's architectural integrity is the uniformity and strictness of prescription-writing criteria. A medical prescription is a complicated legal document that allows the transmission of therapeutic intent from the doctor to the dispenser and ultimately to the patient. It is not only a clinical order (Navadia *et al.*, 2023; Abdullahi *et al.*, 2023). These standards have evolved in accordance with a global trend toward patient safety, economic rationalization, and a decrease in the forensic risks related to drug mistakes in all jurisdictions (Chandran, 2024). This transition has intensified in recent years due to the digital revolution of health data and the urgent need to address public health crises like the opioid epidemic and the rising burden of chronic non-communicable illnesses (Muthukumarana and Ranatunga, 2025).

Regulatory Transformation and Standardization of Prescription Practices in India

With the National Medical Commission (NMC) replacing the Medical Council of India, India's prescription regulatory framework underwent a dramatic change, creating a more responsible and legally binding medical practice system (Drugs and Cosmetics Act, 1940). The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945, and the NMC Registered Medical Practitioner (Professional Conduct) Regulations, 2023, which together seek to harmonize prescription practices with patient safety and the constitutional right to health, are the main laws governing this framework (National Medical Commission, 2023; Government of India, 1940; Government of India, 1945). The legal emphasis on prescription legibility under the 2023 standards is a significant development. Judicial acknowledgment of clear prescription writing as a component of patient safety has resulted from the widespread correlation between illegible prescriptions and avoidable drug mistakes. In order to reduce mistakes associated with look-alike and sound-alike drugs, the NMC requires that prescriptions be written legibly, ideally in capital letters (National Medical Commission, 2023). This guideline, which reflects a move toward quality assurance in prescribing procedures, is strengthened by institutional control, including monitoring by Drugs and Therapeutics Committees (Raja *et al.*, 2019). By requiring crucial elements like prescriber identification (with registration number), patient demographics, clinical diagnosis, and comprehensive treatment data (drug name, dosage, route, frequency, and duration), the NMC further standardizes prescription structure. These specifications provide medico-legal validity, rational prescription, and traceability in all healthcare settings (Ministry of Health and Family Welfare, 2016; Gupta and Nayak, 2014). The promotion of generic prescription is a key component of the present reform. Brand names are only allowed under certain clinical explanations, such as narrow therapeutic index pharmaceuticals, and doctors must give medications under non-proprietary (generic) names (National Medical Commission, 2023; Mahato *et al.*, 2023). The goals of this strategy are to lessen the impact of pharmaceutical promotion, increase affordability, and encourage sensible medication usage. Research indicates that, when bioequivalency requirements are satisfied, generic prescription practices can dramatically save healthcare expenditures without sacrificing therapeutic efficacy (Mahato *et al.*, 2023). Furthermore, the NMC 2023 laws establish strict ethical guidelines that forbid financial or promotional connections between pharmaceutical companies and healthcare workers (National Medical Commission, 2023). Professional responsibility is strengthened by addressing non-compliance through a systematic disciplinary mechanism that ranges from warnings to license suspension or termination. Notably, a progressive approach to restorative regulation is seen in the inclusion of remedial measures like community service (Vejdani *et al.*, 2022). All things considered, India's changing prescription

system reflects a move toward uniform, open, and patient-focused prescription procedures. Enforcement, prescriber education, and connection with digital health systems are still necessary for successful deployment (Osmani *et al.*, 2023).

The United States: Federal Rigor and the Electronic Mandate

Prescription writing is a highly regulated business in the United States of America that falls under the concurrent authority of federal and state authorities. The licensure of practitioners is supervised by state boards of pharmacy and medicine. The federal government sets national standards for the prescription of banned drugs and the technical infrastructure for electronic transmission through the Drug Enforcement Administration (DEA) and the Centers for Medicare and Medicaid Services (CMS) (Drug Enforcement Administration, 2020).

The Anatomical Standard for Prescriptions, 21 CFR 1306.05

The final set of conditions for any prescription for a restricted drug is found in CFR (Code of Federal Regulations) Title 21, Section 1306.05. While permitting the prescription to be granted for a "legitimate medical purpose" in the regular course of professional practice, the legislation aims to create a strong audit trail to avoid diversion. The major mandatory components of controlled substance prescriptions under the US regulatory framework are summarized in Table 1.

The Support Act and the Rise of EPCS

The SUPPORT for Patients and Communities Act of 2018 significantly changed the prescription landscape in the United States. This law's Section 2003 required all drugs covered by Medicare Part D to be prescribed via Electronic Prescribing for Controlled Substances (EPCS) (CMS to Require Electronic, n.d.). CMS, which set a 70% compliance level for the 2023 measurement year, is responsible for enforcing this obligation (EPCS, n.d.). By lowering the possibility of faked or changed paper prescriptions and offering real-time notifications for possible drug-drug interactions or "doctor shopping" behavior, the switch to EPCS is seen as a crucial public health tool to address the opioid problem (Drug Enforcement Administration, 2010).

United Kingdom: Integrated Prescribing and Digital Governance

The Human Medicines Regulations 2012, which combined earlier laws to simplify the regulation of pharmaceuticals and prescribing procedures, control the highly organized and integrated prescribing system in the United Kingdom (UK Government, 2012). By explicitly recognizing non-medical prescribers-such as nurses, pharmacists, and allied health professionals-who are permitted to prescribe within specified competences as either independent or supplemental prescribers, this framework

promotes a multidisciplinary model of treatment (Cope, 2022). This strategy improves access to care, especially in primary care and chronic illness management settings.

One distinguishing characteristic of the UK system is the extensive use of the Electronic Prescription Service (EPS), which allows for safe, direct delivery of prescriptions to licensed pharmacies. EPS increases prescription efficiency, minimizes transcribing mistakes, and connects prescribing with the National Health Service's (NHS) overall digital infrastructure (Garfield *et al.*, 2013). Furthermore, by allowing prescribers to authorize repeat prescriptions for stable patients for up to 12 months, electronic Repeat Dispensing (e-RD) reduces clinical effort while improving therapeutic continuity (Garfield *et al.*, 2013; Harvey *et al.*, 2012).

The validity and distribution of prescriptions are rigorously monitored under the Misuse of Medications Regulations, especially for prohibited medications. Standard prescriptions are valid for six months, however Schedule 2 and 3 regulated medications are only valid for 28 days and require extra protections, such as specifying the complete quantity in words and numbers and verifying at the moment of dispensing (UK Government, 2012; Royal Pharmaceutical Society, 2015). These safeguards are intended to reduce abuse, prevent prescription counterfeiting, and assure responsibility for high-risk drugs (Morecroft *et al.*, 2015).

Overall, the UK prescription model exemplifies a mature combination of legal legislation, digital health systems, and interdisciplinary practice, which leads to better drug safety, operational efficiency, and patient-centered care (Jani *et al.*, 2020). However, ongoing review is required to address developing issues such as digital system mistakes and prescription safety in complicated patient groups (Knai *et al.*, 2014).

Australia

The Therapeutic Goods Administration (TGA) and state laws control prescription writing rules in Australia (Australian Government Department of Health, 2000). Detailed information on the patient, the physician, and the drug must be included in prescriptions (Pharmaceutical Society of Australia, n.d.). Additionally, Australia has embraced electronic prescribing technology that enable digital prescription transmission (Australian Digital Health Agency, 2020). Controlled substances are subject to strict rules, and pharmacists are crucial in confirming the legitimacy of prescriptions before they are filled (Therapeutic Goods Administration, n.d., Pharmaceutical Society of Australia, n.d.).

Comparative Analysis

The major differences in prescription-writing regulations across India, the United States, the United Kingdom, and Australia are summarized in Table 2.

The comparison reveals that industrialized nations use digital prescribing systems more frequently and have more standardized prescription forms. India, on the other hand, is still working on national standards.

Study Objectives

This study was designed to:

- Systematically audit and quantify the baseline compliance rate of clinical prescriptions against the statutory mandates of the NMC 2023 regulations and World Health Organization (WHO) prescribing indicators within the state of Uttar Pradesh.
- Identify and evaluate structural gaps in everyday prescribing habits, focusing on handwriting legibility, generic nomenclature adoption, and the prevalence of irrational Fixed-Dose Combinations (FDCs).

MATERIALS AND METHODS

Design and setting of the study

A cross-sectional, retrospective, observational prescription audit study was conducted to evaluate prescription writing practices and rational drug use patterns in accordance with World Health Organization (WHO) prescribing indicators and the National Medical Commission (NMC) Registered Medical Practitioner (Professional Conduct) Regulations, 2023.

The study was carried out using prescriptions collected from retail pharmacies, hospital pharmacies, and community pharmacies in different parts of Uttar Pradesh, the most populous state in India. The parameters used for prescription evaluation are summarized in Table 3.

Sampling Procedure

A total of 100 prescriptions were randomly collected from different patients that have visited retail or community pharmacies during the period of 1 Jan 2026 to 30th April 2026. All first-encounter prescriptions issued to adult and paediatric patients during the study period were included. Prescriptions for vaccines, inpatient treatment charts and those from external institutions were excluded to standardize the audit of the primary care prescribing process.

Inclusion Criteria

- Prescriptions issued to adult and paediatric patients.
- First-encounter outpatient prescriptions.
- Prescriptions containing at least one prescribed medication.
- Handwritten and digital prescriptions.

Exclusion Criteria

- Inpatient medication charts.
- Vaccine-only prescriptions.
- Follow-up prescriptions without fresh clinical evaluation.
- Prescriptions from external or unidentified healthcare institutions.
- Incomplete or damaged prescriptions unsuitable for analysis.

Data extraction was done using structured Prescription Audit Checklist validated against WHO and NMC 2023 guidelines. The review of each prescription was done on the below mentioned evaluation parameters.

Legibility and Professional Conduct Analysis

Handwriting legibility was assessed subjectively by three independent investigators and categorized as "Clear/Legible," "Difficult to Read," or "Illegible". For digital/telemedicine prescriptions, compliance with the mandatory display of the prescriber's registration number on all electronic communication platforms was recorded.

Ethical Considerations

The study protocol was designed to maintain strict patient confidentiality. No patient or prescriber names were disclosed in the final report, and data were anonymized at the point of collection. Ethical oversight was maintained in accordance with institutional Quality Improvement Project (QIP) guidelines.

Statistical Analysis

The collected data were compiled and analyzed using descriptive statistical methods. The data were presented as frequencies, percentages, and mean values when suitable. To evaluate rational prescribing practices and prescription quality, WHO prescribing indicators were compared with standard prescribed values.

RESULTS AND DISCUSSION

To analyze prescription writing quality, rational prescribing practices, and adherence to National Medical Commission (NMC) 2023 standards and WHO prescribing indicators, a total of 100 prescriptions were examined. Significant variation in prescription completeness, prescribing practices, and adherence to the rational pharmacotherapy concept was found during the audit.

Structural and Demographic Integrity (NMC 2023 Compliance)

The following describes the baseline documentation rates for required structural fields:

Patient Identity and Clinical Demographics

In 96% ($n=96$) of the prescriptions, the patient's name was documented, and in 88% ($n=88$) of the sample, age and gender were correctly recorded. Importantly, just 34% ($n=34$) of the audited cases had a baseline clinical diagnosis or preliminary diagnostic note, meaning that 66% of the cases had no clinical background at all. Just 12% ($n=12$) of the records had complete clinical history and medication allergy profiles.

A solid baseline adherence to basic clerical identification is demonstrated by the fact that patient names and age/gender data were entered in the majority of prescriptions (96% and 88%, respectively). However, there is a significant clinical risk associated with the remaining gaps, where 12% of patients did not have their age or gender specified. Age and gender are not only administrative inputs in clinical pharmacy; they are essential factors needed for precise weight-based dosing in pediatric populations, renal or hepatic dose adjustments in elderly patients, and assessing teratogenic hazards in women of childbearing age.

The widespread lack of a recorded diagnosis (66% left entirely blank) represents a significantly more serious failure in therapeutic communication. A prescription without a clinical diagnosis loses context from the perspective of a hospital and clinical pharmacy,

Table 1: Federal Mandatory Components for Controlled Substance Prescriptions (US).

Requirement Category	Specific Element	Legal Reference
Date of Issuance	Must be dated and signed on the day of issue	21 CFR 1306.05(a)
Patient Identification	Full Name and Physical Address	21 CFR 1306.05(a)
Drug Specifications	Drug Name, Strength and Dosage Form	21 CFR 1306.05(a)
Dispensing Details	Quantity prescribed and specific directions for use	21 CFR 1306.05(a)
Prescriber Identify	Name, Address and DEA Registration Number	21 CFR 1306.05(a)
Verification	Manual signature (for paper) or Electronic Signature (for EPCS)	21 CFR 1306.05(d, e)
Special Notation	Medical necessity for Gamma-hydroxybutyric acid (GHB)	21 CFR 1306.05(c)

Table 2: Global Prescription Writing Frameworks-Expert Comparative Analysis.

Dimension	India (NMC Framework)	United States (DEA / CMS)	United Kingdom (NHS)	Australia (TGA / PBS)
Generic / Nomenclature Policy	Mandatory generic prescribing in CAPITAL letters Aims to curb branded generics and reduce costs in a largely self-pay market.	Generic prescribing encouraged Substitution governed by state laws and payer policies Strong market-driving influence.	Generic prescribing is the default and widely adopted Supports cost-efficiency and sustainability of NHS.	Mandatory Active Ingredient Prescribing (A-Z) Promotes patient recognition, safety and health literacy.
E-Prescribing Maturity	Emerging; telemedicine driving adoption Mixture of digital platforms and manual practices.	Mandatory EPCS for Medicare Part D (controlled drugs) 21 CFR Part 1311 compliant.	Electronic Prescription Service (EPS) is standard across NHS Smartcards used for secure authentication.	Widely adopted Integrated with My Health Record for real-time access and continuity.
Controlled Drugs Regulation	High forensic focus; manual record keeping Governed by the NDPS Act and State Rules.	Strict digital audit trail DEA Schedules I-V EPCS ensure traceability and accountability.	CDs valid for 28 days (shorter for some) Governed under the Misuse of Drugs Act.	S4 and S8 medicines under strict regulation Authority scripts and quantity limits apply.
Prescriber Base	Registered Medical Practitioners (MBBS, MD/MS) only RMP-based model.	Broad prescriber base: MD, DO, NP, PA Scope of practice varies by state.	Extensive non-medical Prescribing (NMP) Includes pharmacists, nurses, allied health professionals.	Growing Nurse Practitioner (NP) autonomy Expanding scope under strict governance.
Legibility and Prescription Format	High emphasis on legibility; CAPITAL letters mandated Judicial and regulatory expectation.	Digital systems reduce handwriting issues EPCS ensures clarity and integrity.	System-generated EPS prescriptions Legibility ensured by system design.	Software-driven AIP (A-Z) reduces ambiguity and improves safety.
Dispensing Duration and Refills	Generally short durations Conservative refill approach Patient safety prioritized.	Refills per insurance plan: Typically, 30-90 days' supply, depending on payer.	Up to 12 months' repeat dispensing (e-RD) supports adherence in chronic care.	Up to 60 days' dispensing for chronic medicines Balances access with safety.
Legal and Forensic Accountability	Registration No. mandatory Capital letters and manual records create accountability Forensic trail (manual + digital).	Immutable digital audit trail 2-factor authentication Prescriber intent is legally protected.	Smartcards and NHS systems create robust audit logs Prescription is a system data point.	My Health Record ensures traceability across the continuum of care High data integrity.

turning the pharmacist from an essential safety checkpoint into a blind dispenser.

The audit's most concerning discovery is that a pitiful 12% of patients had comprehensive clinical histories and medication allergy profiles. Ignoring a patient's allergy history poses an

immediate risk to patient safety in a setting where polypharmacy is prevalent. Globally, preventable Adverse Drug Events (ADEs) are a significant contributor to hospital readmissions and death.

The healthcare system is largely depending on the patient's recollection at the pharmacy counter since 88% of prescriptions

do not record medication allergies. The risk of a severe allergic response or anaphylaxis increases significantly if a patient is unable to convey their medical history because of a language barrier, limited health literacy, or an acute sickness.

A carefully recorded allergy section is a major defense mechanism for clinical pharmacists to intercept cross-reactivities (for example, avoiding cephalosporins in patients with known severe penicillin allergies). Failure to document this information jeopardizes fundamental patient safety practices.

Prescriber Traceability and Legibility

The prescriber's entire name and institutional qualifications were found in 89% ($n=89$) of cases. However, the legally required Unique Medical Registration Number was absent from 21% of the prescriptions, resulting in a 79% compliance rate ($n=79$). Out of 42 handwriting samples, only 42% were classified as "Clear/Legible". The remaining 58% ($n=58$) were classified as "difficult to read" or "illegible," which directly increased dispensing hazards.

It is very serious matter that 58% of prescriptions were identified as "difficult to read" or "illegible." More than 50% of medical documentation is vulnerable to misinterpretation, which creates a danger to patient safety. When prescriptions are unclear, dispensing becomes an act of guessing rather than a systematic procedure. This notably raises the possibilities of Look-Alike/Sound-Alike (LASA) mistakes, which happen when entirely different drugs with identical names are misread (for example, misidentifying a high-risk antidiabetic for a common

gastrointestinal treatment). The potential pathway linking illegible handwriting with Look-Alike/Sound-Alike (LASA) medication errors and subsequent clinical consequences is illustrated in Figure 1.

Having pharmacists interrupt operations to understand confusing handwriting or seek verbal explanation from doctors reduces institutional efficiency significantly. Disrupting workflows can lead to longer wait times for patients and hinder inter-professional communication, which is crucial for an efficient healthcare system.

Pharmacological Prescribing Integrity

Out of the 100 prescriptions analyzed, only 14% ($n=14$) conformed with the NMC guideline to write medication nomenclature only in capital letters. Explicit instructions regarding the route of administration were detailed in 62% ($n=62$) of the samples, while the total duration of the intended therapy was recorded in 74% ($n=74$) of cases.

These findings reinforce the critical importance of the NMC's directive requiring all handwritten drug names to be spelled out in BLOCK CAPITAL LETTERS. Writing in block letters provides an immediate, low-cost safety buffer against poor penmanship, improving clarity across the board.

Manual safeguards, on the other hand, have a limited range. These recurrent handwriting and traceability problems underline the urgent necessity to abandon paper scripts completely.

Table 3: Evaluation Criteria for Prescription Audit ($n=100$).

Category	Parameter	Evaluation Criteria / Requirement
Demographics	Patient Name	Full name must be mentioned
	Age/Gender	Essential for dosage and clinical context
	Unique ID/Reg. No	OPD/IPD or Hospital registration number
Prescriber Info	Name and Qualification	Printed or stamped details of the doctor
	Registration No	Unique NMC/State Medical Council ID
	Signature/Stamp	Handwritten signature or verified digital sign
Clinical Context	Date	Mandatory day of issuance
	Diagnosis	Provisional or definitive diagnosis mentioned
	History/Allergies	Documentation of known drug allergies
Pharmacological	Generic Name	Use of non-proprietary names
	Capital Letters	Drug names written in all CAPS (NMC 2023)
	Dose/Frequency	Clearly specified dosage and timing
	Route/Duration	Mode of admin and total treatment length
WHO Indicators	Polypharmacy	Average number of drugs per prescription
	Antibiotics	Percentage of encounters with antimicrobial agents
	Injections	Percentage of encounters with injectable drugs
	Essential Meds	Percentage of drugs from the EML/NLEM
	Generic drugs	Percentage of drugs prescribed by generic name

The most consistent way to automate professional verification, establish a secure, error-free dispensing environment and to eliminate legibility issues to switch to Computerized Physician Order Entry (CPOE) and electronic prescribing (e Rx) systems, which are integrated with a centralized registration database.

WHO Core Prescribing Indicators Assessment

The quantitative data collected from the field sample were benchmarked against the globally accepted ideal criteria specified by the WHO. The observed WHO prescribing indicators and their comparison with the corresponding WHO reference values are presented in Table 4.

Polypharmacy and the Average Number of Drugs Used Per Encounter

The audit discovered an average of 4.1 medications per prescription, much beyond the WHO's optimum guideline of 1.6-1.8. This high average clearly indicates polypharmacy, which raises the risk of treatment duplications, adverse medication events, and complicated drug-drug interactions. A large quantity of medications per contact in many developing healthcare settings may indicate a "weaker health system".

This tendency, according to clinical pharmacists, implies defensive prescription behaviors and a systemic dependence on empirical medicine. Instead of waiting for lab-supported diagnostic proof, clinicians frequently mix various structural classes (for example, dual NSAIDs or empirical antimicrobials) to meet a wide range of clinical profiles. This technique imposes an additional metabolic strain on the patient.

Generic Prescribing and Economic Rationalization

The generic prescribing rate of 11.1% is significantly lower than the WHO ideal standard of 100% and the NMC 2023 guidelines.

Over 88.9% of all registered drugs were administered using proprietary brand names.

Generic prescribing is an essential component of rational pharmacotherapy because it ensures that patients receive medications that are appropriate for their clinical needs at the lowest possible cost to both them and the community. The deviation from this standard-with 98.9% of drugs prescribed by brand names suggests a continued reliance on proprietary nomenclature. Despite regulatory emphasis on generic medicines, low rates of prescription remain a major concern in India. Brand-name prescribing correlates to increasing treatment costs and may limit pharmaceutical affordability, particularly among economically needy patient populations.

Factors including pharmaceutical marketing, physician preferences, bioequivalence concerns, and patient familiarity with branded medications may contribute to the low rate of generic prescribing in this research. The study recommends improving institutional monitoring, educating prescribers, and implementing generic prescription procedures.

Antibiotic Utilization and Antimicrobial Stewardship

The audit found that antimicrobials were prescribed in 18.8% of contacts, which is within the WHO's recommended range of 20.0%-26.8%. This was the only favorable finding we obtained.

Antibiotic stewardship programs need rational prescription to reduce Antimicrobial Resistance (AMR). Antibiotic overuse and misuse are key contributors to the evolution of multidrug-resistant pathogens, treatment failure, and increasing healthcare burden.

A rate of 18.8% suggests a high degree of "judicious antibiotic use," which is consistent with the goals of the WHO Global Action Plan on Antimicrobial Resistance (2015), which stresses the optimization of antimicrobial treatments to avoid

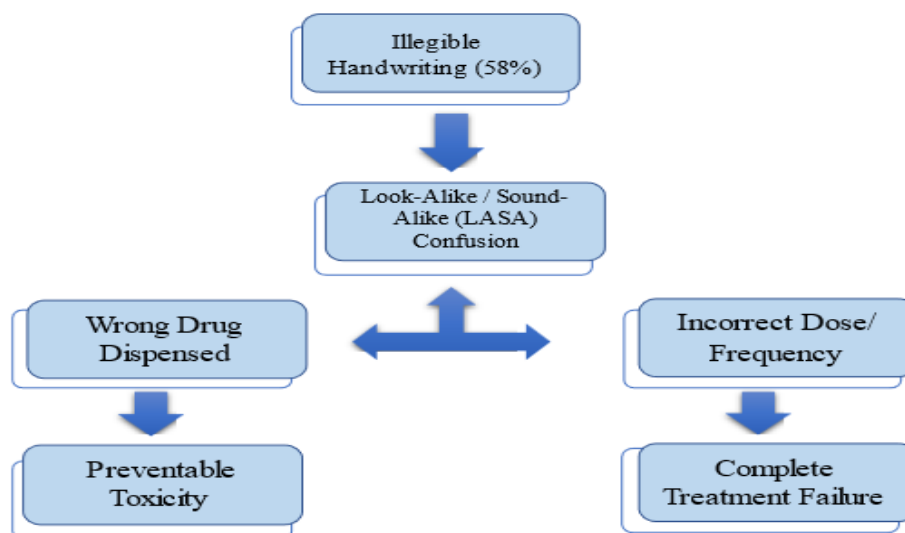


Figure 1: Medication Error Pathway: Illegible Handwriting, LASA Confusion, and Clinical Consequences.

Table 4: A comparison of study findings (n=100) with WHO optimal standards.

Indicator	Observed Value (n=100)	Optimal Value as per WHO	Compliance Status
Avg. Drugs per Encounter	4.1±1.2	1.6-1.8	Non-Compliant
% Prescribed by Generic Name	11.1%	100%	Non-Compliant
% with Antibiotics	18.8%	20.0%-26.8%	Compliant
% with Injections	5.3%	13.4%-24.1%	Compliant
% from NLEM/EML	7.7%	100%	Non-Compliant

a "post-antibiotic era." Adherence to this criterion shows that doctors are likely using antibiotics largely for bacterial etiologies rather for presumed therapy of viral illnesses, thus maximizing therapeutic benefit while reducing drug-related toxicity.

Furthermore, the results reflect a "rational pharmacotherapy" strategy in which patients obtain drugs that are suitable for their clinical requirements for an adequate amount of time, helping to promote patient safety and public health generally.

Injection Usage and Patient Safety

Surprisingly, the percentage of interactions with injections was 5.3%, significantly below the WHO criterion of 13.4%-24.1%. Although some standards recommend a dosage as low as $\leq 10\%$, the current audit results show a prudent usage of intrusive administration. Oral drugs are often safer and more cost-effective than injections, making this a favorable conclusion for patient safety.

Adherence to the Essential Medicines List (EML/ NLEM)

Adherence to the National List of Essential Medicines (NLEM) was very low at 10.7%, much below the WHO target of 100%. This indicator assesses a facility's adherence to a national drug policy meant to encourage the use of well-known, cost-effective, and evidence-based medications.

This difference is clinically and economically important. Out-of-Pocket Health Expenditure (OOPHE) in India makes up 48.2% of overall health spending, with non-EML prescriptions leading to "medical impoverishment" for households.

To solve this issue, hospitals must strengthen the function of their Drugs and Therapeutics Committees (DTC). These committees must regularly monitor prescription variations and enforce hospital-specific formularies firmly established in the NLEM.

Expert study identifies numerous problems preventing uniform adherence:

Clinician Skepticism

Some practitioners opt for non-EML alternatives due to concerns about the bioequivalence and quality of some generic formulations in comparison to recognized brands.

NLEM Omissions

A recent review of the NLEM 2022 revealed gaps in which particular required dosage forms-such as parenteral preparations for severe migraine or certain heart failure medications-were excluded, forcing the usage of non-listed pharmaceuticals.

Institutional Monitoring

To close this gap, the NMC now requires that each medical college form a Sub-Committee under the Drugs and Therapeutics Committee (DTC) to rigorously monitor and enhance EML compliance.

Market Proliferation of Irrational Fixed-Dose Combinations (FDCs)

A key hurdle to WHO metrics in India is the unprecedented market dominance of FDCs, which account for 40% of the pharmaceutical industry. While rational FDCs are essential for conditions like Tuberculosis or HIV to improve adherence, the Indian market is saturated with over 6,000 FDCs, many of which lack therapeutic rationale or evidence-based indications. Data reveals that 94-95% of these combinations are prescribed by brand names, often by senior specialists like cardiologists and consulting physicians. Examples of potentially irrational drug combinations identified in the audit and their associated clinical risks are summarized in Table 5.

KEY ISSUES, CHALLENGES, AND OPPORTUNITIES

The successful adoption of standardized prescription procedures in India is hampered by a number of issues (Chaturvedi *et al.*, 2012). The inadequate training that healthcare practitioners get about appropriate prescription writing standards is a significant obstacle. Non-standard acronyms and insufficient paperwork are still used by many prescribers (Velo and Minuz, 2009). The lack of a nationally defined prescription format that is accepted by all healthcare facilities is another problem (Government of India, 1940).

Nonetheless, there are a lot of advantages to the growing trend of digital healthcare systems (Raja *et al.*, 2019). Prescription accuracy may be significantly increased and drug mistakes can be decreased with the development of electronic health records and e-prescribing systems. Additionally, pharmacists are essential

Table 5: Clinical Risks Associated with Irrational Drug Combination Therapy.

Irrational Combination Example	Therapeutic Class	Specific Clinical Rationale Deficiency	Reported Clinical Risk
Dual NSAIDs (e.g., Nimesulide + Paracetamol)	Analgesic	Nimesulide alone is a superior antipyretic; addition of Paracetamol offers no efficacy gain	6-fold increased risk of severe liver injury (Hepatotoxicity)
Glimepiride + Metformin	Anti-diabetic	Conflict in administration timing: Glimepiride is pre-meal while Metformin is post-meal	Sub-optimal glycemic control and unpredictable pharmacokinetics
Expectorant + Antitussive (e.g., Guaifenesin + Dextromethorphan)	Respi Acute	Contradictory action: expectorants loosen mucus while antitussives suppress the clearing cough reflex	Retained secretions, worsened congestion, and increased infection risk
Quinolone + Nitroimidazole (e.g., Norfloxacin + Tinidazole)	Antimicrobial	Broad-spectrum “cover-up” for poor diagnosis; not recommended in standard texts	Accelerated development of multidrug-resistant bacteria (e.g., <i>S. typhi</i>)

in spotting possible prescription problems and guaranteeing the safe delivery of medications (World Health Organization, 2016; World Health Organization, 1994).

CONCLUSION

This prescription audit highlights substantial gaps between everyday prescribing habits in Uttar Pradesh and the clinical standards set by the NMC and WHO. High levels of brand-name selection, handwritten readability issues, and the usage of illogical FDCs highlight the need for institutional improvements.

To increase patient safety and prescription quality, the following actions are suggested

Transition to Electronic Prescribing (CPOE/e-Rx)

Eliminating handwritten prescriptions in favor of Computerized Physician Order Entry (CPOE) systems with built-in decision assistance can improve readability and greatly minimize dosage and interaction mistakes.

Enforce NLEM and Generic Mandates

Healthcare institutions should use stringent institutional formularies based on the NLEM. Regular pharmacy-led audits should be conducted to monitor prescribing of generic names in block capital letters.

Strengthen Hospital Pharmacy Interventions

Clinical pharmacists (M. Pharm pharmacy practice/Pharm. D graduates) should be incorporated into the care team to undertake prospective prescription reviews, identify illogical FDCs, monitor medication interactions, and support antimicrobial stewardship initiatives.

Strict Regulations

The government, with the assistance of the NMC, CDSCO, and PCI, should establish strong laws and correct norms, as well as provide a legal framework and penalties for violations.

ABBREVIATIONS

ADE: Adverse Drug Event; **AMR:** Antimicrobial Resistance; **CHX:** Chlorhexidine; **CMS:** Centers for Medicare and Medicaid Services; **CPOE:** Computerized Physician Order Entry; **CPC:** Cetylpyridinium Chloride; **DEA:** Drug Enforcement Administration; **DTC:** Drugs and Therapeutics Committee; **e-Rx:** Electronic Prescribing; **EPCS:** Electronic Prescribing for Controlled Substances; **EML:** Essential Medicines List; **FDC:** Fixed-Dose Combination; **HPLC:** High-Performance Liquid Chromatography; **HPTLC:** High-Performance Thin-Layer Chromatography; **LASA:** Look-Alike/Sound-Alike; **NHS:** National Health Service; **NLEM:** National List of Essential Medicines; **OOPHE:** Out-of-Pocket Health Expenditure; **QIP:** Quality Improvement Project; **RCT:** Randomized Controlled Trial; **TGA:** Therapeutic Goods Administration; **WHO:** World Health Organization.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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