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Role of Prescription Practice in Ensuring Patient Safety in the Primary Health-Care Settings in India

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Summary

“Completeness (a measure of adequacy)” and the “appropriateness (a measure of the quality of care)” are two dimensions of good prescription practice. The study assessed the prescription practices at the primary health centers (PHCs); to demonstrate the effect of individual and system-level factors, on adequacy and appropriateness of prescription practices, with special reference to e-prescription over manual prescription given the rising acceptance of teleconsultation in health care. A total of 600 manual and 1000 e-prescriptions were randomized using a probability-proportional-to-size sampling method to distribute/allocate samples across manual and e-prescriptions. Findings revealed that while adequacy and appropriateness of prescriptions depend on individual training and clinical practice; adequacy of prescription, especially the manual was compromised by systemic factors, such as nonavailability of space in a prescription, forcing doctors to prioritize documentation of diagnosis, advising tests, and prescribing medicines, over other details (chief complaints and examination findings).

Key words: Adequacy, appropriateness, effectiveness of quality of care

“Rational use of medicine” means patients receive medication appropriate to their clinical condition, in doses that meet their requirements, for an adequate period of time, and at a cost affordable to the community.^[1] Globally, over 50% of all medicines are prescribed, dispensed, or sold inappropriately.^[2] Common types of inappropriate medicine use include polypharmacy (use of too many medicines per patient), overuse of injections, inappropriate use of antimicrobials, failure to prescribe in accordance with clinical guidelines, irrational prescription of nonessential medicines, and costlier brands instead of generic drugs and inappropriate self-medication.^[3-5]

The medical practice in India is guided by the World Health Organization (WHO) and its own Medical Council like the rest of the world. While the *WHO provides for core prescribing practices on rational drug use*, i.e., on poly-pharmacy, antibiotic, and/or injection use, prescribing generics, and adherence to the Essential Drug List (EDL), the *Medical Code of Ethics by the Medical Council of India (MCI) in 2002*, the *current day National Medical Council (NMC), amended in Section 1.5 of 2016 regulates clinician prescribing practice in terms of documentation*.^[6,7]

A retrospective cross-sectional quantitative and qualitative study was undertaken at 31 Primary Health Centers (PHCs) in Rajasthan and Madhya Pradesh to evaluate the prescribing practices. A probability-proportional-to-size sampling method was adopted to pick samples across manual and e-prescriptions from outpatient clinics of these PHCs; and allocated equally across gender and patient age group during the period of 2 years, from September 2018 to August 2020. 1000 e-prescriptions from a total of 54,532 completed teleconsultation entries across disease types and patient categories were selected at the rate of a 60:40 ratio for general and specialist consultations, respectively. Further to compare the benefits and strengths of e-prescription over manual, 600 manual prescriptions were randomized from the matching facilities during the same

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period. The following patient groups were covered for the assessment: maternity, emergency, pediatrics under 5 years of age, pediatrics age between 5 and 15 years, adult (male and female of age between 18 and 59 years of age with conditions other than maternity), and old age (≥ 60 years).

The quantitative analysis estimated the percentage compliance with the WHO indicators and the MCI/NMC requirements. The *Adequacy, i.e., Completeness of the Prescription* includes the assessment of documentation of demographics (name, age, gender, date, and time of visit); patient complaints; examination findings (weight, vitals, signs, and symptoms); doctor’s diagnosis, tests advised to clinch the diagnosis; treatment prescribed; instruction to maintain continuity of care (follow-up and referral advice); documentation of medication in capital letters (as per MCI on the name of drug, dose, strength, and number of days to be consumed); and signature of doctor, to testify prescription ownership by the prescriber. The *Appropriateness, i.e., “Prescription justifies itself in terms of the care provided to meet patient’s requirement.”*

India stands signatory to the Global Antibiotic Resistance Partnership (GARP) established in 2009 to foster antimicrobial stewardship. The GARP India Strategy, the ICMR guidelines 2017 prescribes 2 antibiotics for acute diseases and defines the use of >3 antibiotics for >3 days as an alert to review antimicrobial use.^[8,9]

Some of the study findings were quite revealing and unique about prescription practices, especially in terms of their adequacy, appropriateness, and effectiveness on quality of care (QoC).

In terms of adequacy, the study revealed that over 50%–90% of patients across age groups were handled by a generalist/medical officer with an MBBS degree in the PHCs. However, the disease burden of the community could not be identified, as 73% of the prescriptions treated patients against their signs and symptoms, with no documented diagnosis. Clinical diagnosis was captured only in 27% of prescriptions, whereas no manual prescriptions were complete, 77% of e-prescriptions were found to be complete or adequate. Of the completed e-prescriptions, 78% were generalists and 75% were specialist consults. Furthermore, compliance to completeness was at its best in clinicians between 20 and 30 years of clinical experience, *i.e.*, at the peak of their careers, which dipped to suboptimal levels with the advancing age beyond 30 years of experience.

Almost all e-prescriptions (98.2%) had a treatment plan documented; symptoms and/or signs including vitals (except for weight) were recorded in 100% of cases, but diagnosis even in e-prescriptions was mentioned only in 55% of cases. In manual prescriptions, while there was 100% compliance with the documentation of the treatment plan, the elements of the treatment plan (signs and symptoms, diagnosis, and vitals) were inadequately documented, which is a critical omission

compromising prescription practice, especially in children, wherein the weight is an important criterion for calculating drug dose.

While nondocumentation of clinical diagnosis, justification for treatment, and documenting specific nature/region of pain or injury were the most common noncompliance to adequacy in e-prescription; nondocumentation of diagnosis, referrals (only 3%), and signs/symptoms were the most common inadequacies in manual prescription.

The 31 clinicians interviewed voiced that adequacy of prescribing pattern is an element of clinical training and practice, rather than being a mere factor of systemic constraint. The most common reasons for this noncompliance were (i) lack of formal spacing or appointment system to regulate patient visits leading to overcrowding at select times of the day, (ii) involvement of doctors in nonclinical activities, (iii) lack of peer pressure in PHCs unlike that in an academic environment, (iv) patient’s contribution to nonadherence to positive health-seeking behavior, and (v) restricted size of manual prescription pads forces them to prioritize documenting only necessary elements of a prescription to ensure care provision.

In terms of appropriateness, 78% of e-prescriptions and 4% of manual prescriptions were found appropriate. The appropriateness for e-prescription was the highest for maternity cases at 83%. The elderly and pediatric (under 5) account for 24% of appropriateness in manual prescriptions, followed by the adults and the pediatric 5–14 age group [Figure 1].

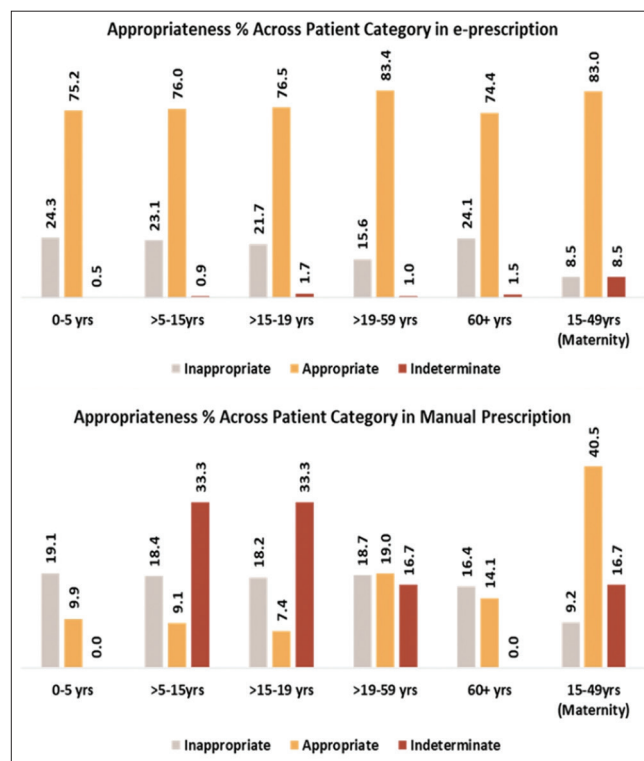


Figure 1: Appropriateness % across patient categories in manual and E-prescription.

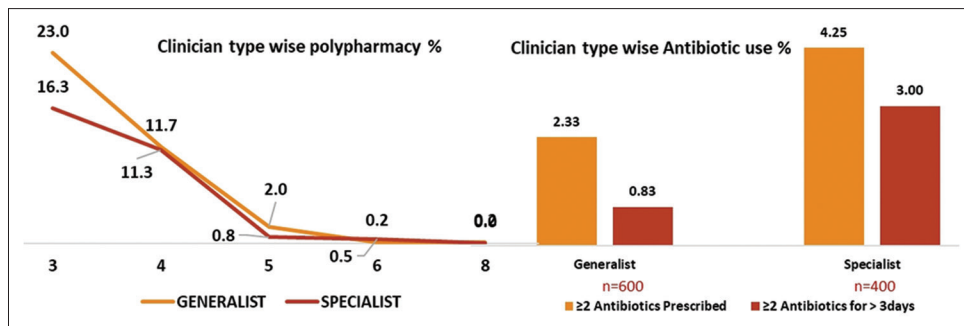


Figure 2: Clinician type wise % of polypharmacy and antibiotic use.

The most common reason for inappropriateness in over 98.5% of prescriptions was around nondocumentation of justification for the use of antibiotics. Antibiotic usage was justified only in 2.6% of analyzed manual prescriptions and 18.3% of e-prescriptions. Clinical findings to support the prescription of antihypertensives, antibiotics, antimalarials, and steroids were documented only on 3.2% of occasions. Further, documentation to justify antibiotic use was better with general practitioners (not specialists) with 20–30 years of experience.

The effectiveness of QoC, as against WHO's definition of rational drug/antimicrobial use and polypharmacy, revealed 100% prescription by generic names from the EDL across manual and e-prescriptions. The average number of drugs prescribed was 2.3 per episode, with better compliance in e-prescription, around the WHO reference range of <2 per episode. Prescriptions of antibiotics were out of reference range in both manual and e-prescription, but antibiotic usage was 2 times lower for e-prescriptions. While the use of injectables was much below the WHO reference range of <20% of episodes for both manual (7.8%) and e-prescriptions (0.9%), the usage of injectables was 7 times lower in e-prescriptions. This reduced use of injectables in primary care was attributed to the prescription practice of sticking to oral drugs in outpatient consults and restricting the use of injectables primarily to hospitalization to ensure better compliance and patient safety.

Further, polypharmacy (prescription of 3–5 drugs per episode) was higher in specialists (2%) than in generalists (0.8%), and in patients over 60+ years; with the lowest in children under 5 years [Figure 2]. The polypharmacy of the use of ≥5 drugs per episode, too was 4.5 times lower in e-prescription than the manual prescription.

Polypharmacy apart, the use of antimicrobials too varied across patient categories and prescription types (manual and e-prescription). The highest antibiotic use was seen in old age (18.6%) and adolescents (18%), followed by children between 5 and 18 years (15%), adults (13.9%), and children under 5 years (10.5%), and the lowest being that for maternity cases (2.1%). Further, polypharmacy in terms of the use of ≥2 antibiotics per episode for >3 days was 2.5–3 times more rampant with the specialists than with generalists [Figure 2].

Increased use of antibiotics/antimicrobials and polypharmacy with advanced ages were attributed to comorbidities and compromised immunity with advanced age, lower socioeconomic background coupled with illiteracy, unhygienic habits, and living conditions in the community.

“Adequacy” and “appropriateness” of prescription are factors of individual clinical practice and training of a clinician that cuts across geographies. It is hardly impacted by local facility-level factors or the use of digital tools such as teleconsultation. However, “Effectiveness of Quality of Care” (rational drug use in all its forms of administration and types of drugs across patient categories and facilities), as is a manifestation of both adequacy and appropriateness of the prescription, improves with digitization because of improved levels of completeness of a prescription. Therefore, e-prescription assists in making prescriptions effective from QoC standpoint. Further, as adequacy and appropriateness are a factor of individual clinical practice, compliance is better with practitioners at the peak of their career and dips with age over 60 and beyond, because of changing priorities.

Therefore, impacting clinical practice needs a multidisciplinary approach both at the organizational and individual levels. The Global Association of Risk Professionals (GARPs) India Strategy, 2017, elaborates on this multidisciplinary approach to rationalizing antibiotic use; which can be extended to improve the adequacy and appropriateness of prescription; thereby impacting the overall effectiveness of QoC. The GARP guidelines recommend in-service training for physicians, especially on legal aspects of prescription writing, monitoring, and incentivizing delivery of effective QoC.

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Conflicts of interest

There are no conflicts of interest.

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