

Factors Impacting Prescription Practice in Primary Healthcare Setting in India: A Case Study in Rajasthan

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Abstract

Objective: To assess the prescription practices in the Indian state of Rajasthan with a view to demonstrate the effect of provider and system level factors, and their interactions on good prescription practices. The study analysed two major dimensions of good prescription practice; first, the completeness of prescription, a measure of adequacy; and second, the appropriateness of prescription, a measure of quality of care.

Design: A retrospective cross-sectional study with a mixed method approach

Setting: 24 rural and 7 urban government Primary Health Centres of Rajasthan, India

Participants: Audit of 2801 prescriptions from health facility and the service providers in these facilities, including doctors, and nurses

Primary and Secondary Outcomes: The study outcome testified the study objective that provider level factor is critical to assure adequacy and appropriateness of good prescription practice. The secondary level outcome revealed that the system level factors are equally important to ensure compliance to good prescription practice

Result: We found that the documentation of patient complaint, examination findings largely depended on system level factors, such as availability of space in the piece of paper used for writing prescription; because for the doctor documenting diagnosis, and prescribing medicines and investigations were of greater importance. Ownership compliance of doctors, measured in terms of their signature on the prescriptions, emerged as an important factor determining both adequacy and accuracy of prescriptions. Further, the treatment appropriateness, measured in terms of QoC, depends on both provider & system level factors.

Conclusion: There is a need to focus on provider and system level factors to improve prescription practices in primary health care. We recommend that institutional strengthening at systemic & provider level using innovative ways; such as task shifting to nurses as 'physician assistants', and reducing administrative activities of physicians to enhance focus on clinical work can propel better prescription practice.

Keywords: Prescription practice, appropriateness, compliance, comprehensiveness, disease burden, primary health, signs and symptoms.

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Contributorship Statement:

AKD and SN conceptualized and prepared outlined of the paper in consultation with other authors. AKD provided the analytical approach, conducted the data analysis and

drafted the result section. SN conducted literature review and prepared the draft manuscript review with support from RB, RRS, AKS and AD. Final draft is prepared by SN and AKD in consultation with other authors. The final draft was approved by all authors.

Strengths and limitations of this study:

- The study is unique as it uses prescription data to generate indices to measure the quality of care and appropriateness of treatment; to understand the health system perspective-the provider and system-level factors impacting prescribing practices, which is first of its kind in the context of primary health care services in LMICs.
- The evidence-based prescription practices will be pivotal to assure quality of care, guide policy reform around primary care, especially for digital health and avoid legal battles around medical negligence.
- The study has used a mixed-method approach to summarize the statistical inferences derived from prescription data.
- However, the study was limited by the fact that it wasn't multi-locational and purposefully selecting PHCs of Rajasthan; hence generalizing findings across India can be inappropriate.

Data availability statement: All datasets available are used in the study and included in the manuscript. The datasets can be made available on appropriate request to author by e-mailing to Dr Arup Kumar Das at adas@wishfoundationindia.org

Patient and Public Involvement statement: Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research

Introduction

Rational medicine use requires patients to receive medication appropriate to their clinical needs, in doses that meet their requirements, for an adequate period of time, and at a cost affordable to the community.^{1,2,3} Unfortunately, WHO report, 2002 on rational drug use reports that more than 50% of all medicines prescribed, dispensed, or sold on a global basis are inappropriate; and around 50% of inappropriateness is contributed by patients in terms of their failure to take medicines as prescribed.⁴ Bhatnagar and Mishra have reported that overuse of medicines stimulates inappropriate patient

demand and leads to medicine stock-outs and loss of patient confidence in the health system.⁵ Inappropriate (over or underutilization) use of medicines increases antimicrobial resistance, contributes to poor clinical outcomes, and manifests as avoidable adverse drug reactions.⁴ Inappropriate usage is also a wastage of scarce economic resources.⁵ Overall, 25%–70% health expenditure in developing countries is contributed by expenditure on medicines, as against 10% in high-income countries.⁶ The situation as regards drug use is no different in India from rest of the world. One third of world's population living in India lacks access to essential medicine, which makes it up to 65% in India alone.^{7,8} With out-of-pocket expenditure on health at 82%, 62% is spent on medicines; large percentage of which is rendered waste because of irrational prescription of non-essential medicines, and brands instead of generics.⁹ A study by Kasabiet.al. in Karnataka with 200 prescriptions, in 15 PHCs in a district, reported more than 45% use of antibiotics at primary level.⁹

The WHO good prescription practice indicates % of medicine usage per encounter (<2), % of encounter with antibiotics (<30 %), % of encounter with an injection prescribed (<20 %), and % of medicines prescribed in generic name (100 %) from a defined Essential Drug List (EDL) as an objective measure.^{10,11}

WHO apart, The Medical Code of Ethics prescribed by the Medical Council of India (MCI) in 2002, amended in 2016 regulates prescription practice in India; to foster rational drug use. The prescription in India is thus a legally admissible evidence to care process, generated by doctors to assure completeness of prescribed care plan to ensure patient safety.¹²

While there are some studies, they are far and few elaborating barriers to good prescription practice, its correlation to confounding factors; to draw sustainable solutions in a PHC setting. Under this backdrop, we conducted the study in Rajasthan to identify factors associated with adequacy and appropriateness of prescribing practices at primary level. For the purposes of study:

- 'Adequacy' means, compliance to completeness and comprehensiveness of prescription practices as per WHO norms and MCI Guidelines;
- 'Appropriateness' means, the extent of 'reasonableness' in practice towards quality of care (QoC) that can be justified.¹³ Reasonableness

to QoC, stems from variation in qualification (knowledge gained as a medical graduate or postgraduate in specific speciality) and experience (years of relevant patient care service provision).

Method

A sequential mixed-method approach was adopted to evaluate the prescribing practices in the 31 PHCs in 11 districts of Rajasthan as shown in the flow diagram in Figure-1. Prescriptions for a period of two years from September 2016-August 2018 were reviewed.

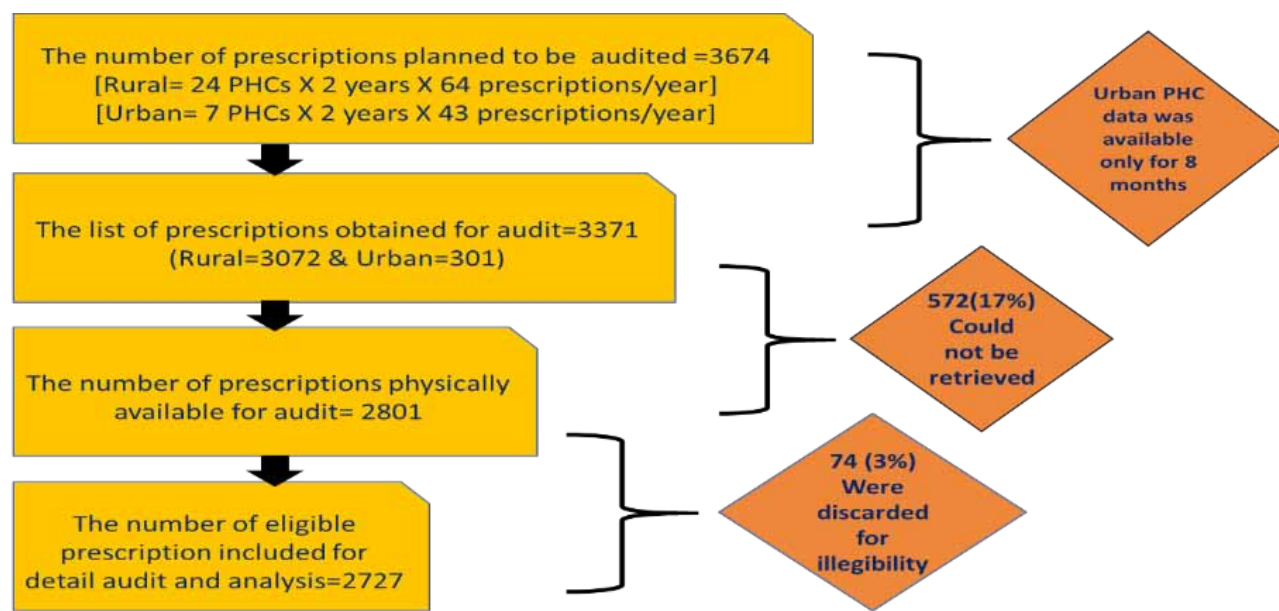


Figure 1: Targeted vs actual number of prescriptions included in the study

In-depth interviews (IDI) with PHCs' service providers were conducted to capture their profile. Subsequently a focused group discussion (FGD) was held to share findings of the quantitative study, and deliberate on barriers and facilitators to good prescription practice; to recommend possible improvements.

A total of 3698 prescriptions @ 64 per year from 24 rural and 43 per year from 7 urban PHCs each were selected. As urban PHCs were operationalised late, from January 2018, only 8-month of prescriptions could be collected. Out of 3698 selected entries, 572 prescriptions (17%) could not be retrieved as they were physically damaged because of compromised storage conditions in PHCs that were operating out of make shift buildings. Of the total 2801 prescriptions physically retrieved, 2727 (97%) were defined as legible for further analysis and remaining 3(%) were discarded as illegible.¹⁴

To ensure adequate representation of the disease profile samples from different patient categories were picked; namely (i) maternal (M), women who availed

maternity services, (ii) paediatrics (P), sub-divided into under-five (P1) and children between 5-15 years (P2); (iii) Adults (A), male and female of age between 18-59 years of age with conditions other than maternity; (iv) old age over 60yrs (O); and (v) emergency (E), to capture emergencies and trauma.

To capture seasonal variation in disease, the calendar year was split into four quarters (i) Winter—November to January, (ii) Spring—February to April, (iii) Summer—May to July, (iv) and Rainy—August to October.

Further, it was ensured that all six working days of a week has equal probability of being selected twice every season. To avoid investigator bias, serial number wise first occurrence/s for every patient category in the OP register was chosen to collect desired number (2-4) of prescriptions.

Semi-structured interviews were conducted to profile the providers @ one doctor, one nurse and one

pharmacist per facility. In all we profiled 23 doctors, 31 nurses and 28 pharmacists based on their availability during the study period. Finally, 15 medical officers, 6 GNMs/pharmacists participated in the FGD for the qualitative study to provide feedback on findings of quantitative study around barriers to good prescription practice.

The quantitative study was aimed at estimating the percentage compliance to WHO indicators and MCI requirements as follows:

- a. **Completeness of prescription**—This was assessed on the seven elements of completion, as per the MCI guidelines.
 - **Demographic compliance**--%of Prescription with complete demographic information; such as Name, Age, Sex, Date of visit, Contact Details.
 - **Registration process compliance**--% of Prescription with details on unique id to support identification of patient throughout the care process.
 - **Patient compliant compliance**--% of Prescription with complete in terms of recording of signs, symptoms presented by the patients.
 - **Doctor examination compliance**--%of Prescription with complete recording of weight, BP, Provisional Diagnosis, and investigation ordered.
 - **Treatment compliance**--% of Prescription with complete recording of final diagnosis, prescription of medication (completeness refers to information on Name of the drug, dose, strength and Number of days to be consumed) and care plan. This also includes % of prescription with Drugs written in capital letters as per MCI requirement
 - **Continuum of care compliance**--% of Prescription with complete recording of requisite conditions for a follow-up, and referral
 - **Ownership compliance**--% of Prescription with complete signature of the treating clinician.
- b. **Appropriateness of prescription**—refers to analysis of prescription on quality of care in terms of diagnosis, investigation and treatment prescribed. Appropriateness was analysed at two levels:
 - **Facility level** to understand the systemic issues impacting appropriateness;
 - **Clinical level** to understand the clinical issues as

regards patients' complaints, doctor's findings, investigation advised, care plan designed and treatment offered.

We used bi-variate and multivariate analysis to correlate factors associated with good prescription practices. Multilevel logistic analysis, random slope model was used to understand the role of facility or provider level factors affecting prescription practices. The model comparison was carried out using Akaike Information Criteria (AIC) and Bayesian Information Criteria (BIC), a lower value of these statistic indicates best fit model.

Results and Discussion

The findings of the study as revealed were:

1. **Completeness of prescription:** Completeness evaluated on seven broad sections as under.
 - a. **Demographic Details:** The *first compliance* was documenting of basic demographics in the prescription; meaning noting of name, age, gender, address and contact details of the patients. While name and age of patient was recorded in all eligible prescriptions; sex was not recorded in 65 (2.3%) prescriptions. Highest compliance level was seen in prescriptions for elderly (29%); and lowest being that for maternity and emergency cases, at 5%. While MCI mandates capturing of data on occupation and place of living, the same was not captured in any of the audited prescriptions. These socio-economic indicators have significant bearing on the disease manifestation, its recurrence/chronicity. For instance, recurrence of dermatitis and staining of tooth in some PHCs was attributed to high fluoride content in ground water by the staff. Repeated treatment of such conditions without documentation of living condition, reduces the probability of escalating issues with relevant state authorities to systematically address the public health hazard.
 - b. **Registration Process Details:** The *second compliance*, includes assigning registration number to each patient and recording visit dates, tot rack patient progress during follow ups, and referrals to other/specialised services. The study reveals that while assigning registration number was almost universal; there was no inter or intra facility standard followed. Each year, the registration number began with serial number '1'; thereby creating new registration number on each patient visit including

that for follow-up visit/s. In the absence of unique identification number, a mechanism to identify new and repeat/follow-up cases doesn't exist; except for the informal facial recognition by the hospital staff. Audited prescriptions revealed 1-8% duplication of registration numbers in 8 of 31 facilities; except for one PHC that had 56% duplication. Overall, 16% of the eligible prescriptions did not have the date recorded.

- c. **Patient complaint details:** *The third compliance is towards recording of patient complaints.* Herein patient's narrative of chief complaints (symptoms) and provider's interpretation of these complaints (signs) are recorded. These signs and symptoms with clinical examination findings as noted by the doctor, enables the clinician to arrive at provisional diagnosis to decide on the investigations required to clinch the final diagnosis, design the treatment & care plan and decide referral, if required. Our study revealed that signs & symptoms were recorded in only 28% of eligible prescriptions. A substantial difference was noted in recording symptoms across 31 PHCs, ranging from zero to 100%, with SD 28%, skewed (0.696) & leptokurtic (2.28) distribution. It was noted that 'signs' and 'symptoms' were used synonymously, and handwriting was hard to decipher in all prescriptions. The terminology used for writing signs and symptoms were either incomplete or not adhered to as per the prescribed textbooks. For instance, itching or skin allergy was mentioned in 2.2 % cases as 'skin'. This was attributed to the documentation of prescriptions by the nurses or paramedics; who while were untrained and ineligible, substituted in absentia of the doctor, to respond to patient needs. Among the eligible prescriptions, majority had only one symptom recorded (19.7%) and 8.6% had more than one symptom recorded. Most frequently mentioned signs and symptoms were fever (14.7%), pain (4.7%), diarrhoea (4.1%), injury (3%), pregnancy and delivery (2.2 %). Interestingly, a clustering of symptoms around patient categories was recorded. For example, fever, diarrhoea and skin allergy was clustered around paediatric (P2), adults and old age population.

Based on the proportion of prescriptions that had recorded signs & symptoms, we classified the PHCs into five quintiles to compare their patient profiles with provider experience and facility, system level factors.¹⁰

No substantial difference in patient profile in the PHCs, except that the facilities under high quintile had higher load of maternity cases. However, substantial difference was noted across quintiles in terms of provider and facility, system level factors. The cluster of 6 PHCs, that had high recording of symptoms (76 %) had providers with longer work experience with our PHCs, had relatively infrequent drug stock-out, more accountable providers (measured on proportion of prescription signed), with higher provider focus on service delivery as against administrative work. **Contrary to the common belief, high OPD load was not a hindrance to recording signs and symptoms.** This was corroborated during the FGD, and doctors recommended reducing their administrative work that consumed 50% of their time, and training AYUSH practitioners and GNMs for documenting findings in the prescription, to save doctor's time for patient examination and writing the care plan.

Qualitative finding revealed that protocolled treatment for maternity cases had rendered documentation of signs and symptoms redundant. However, in emergency, paediatric and old age patients since non-documentation of signs and symptoms had the potential for medication error, the compliance was higher at 2.6 (1.6 – 4.0), 1.5 (0.9 – 2.15) and 1.5 (1.1 – 2.3) respectively, as necessitated.

- d. **Examination Finding Details:** *The fourth compliance on recording of doctor's examination findings,* includes noting of patient vitals (Blood Pressure-BP, pulse, weight), investigations required, and provisional diagnosis. The compliance was low across facilities and was limited only to maternity cases. BP was recorded in 4% prescriptions and 18% of maternity cases. Weight and investigations were recorded in 2% and 6% of the total, 11% and 23% of maternity cases, respectively. The major investigations documented for maternity cases were Haemoglobin (15 %), HIV/ELISA (6%), Random Blood Sugar (5%), Urine albumin and STI (4% in each), which were a part of protocolled treatment to be followed. Provisional diagnosis was recorded in 24% of total and 86% of maternity cases.

Three logistic regression model has been compared to identify the effect of recording symptom & investigations, their interaction on reported diagnosis and a multilevel model to identify the role of system level variations. It was evident from the best fit multilevel

model that almost 39% variations in reporting diagnosis can be attributed to system level factors. The fixed part of the model revealed that diagnosis was more likely to be written in maternal health prescriptions. The predicted

probabilities of interaction suggest that a prescription that had symptom & signs recorded and investigations/ tests prescribed, had 8 and 5 times higher likelihood of diagnosis being documented respectively (Table-1).

Table 1: Facility level factors impacting compliance to documentation of examination findings

| Diagnosis | M1: Logistic | | | | M2: Logistic with interaction | | | | M3: Multilevel logistic with interactions | | | |
|--------------------|--------------|-------|----------------------|--------|-------------------------------|-------|----------------------|--------|---|-------|----------------------|--------|
| | Odds Ratio | P>z | [95% Conf. Interval] | | Odds Ratio | P>z | [95% Conf. Interval] | | Odds | P>z | [95% Conf. Interval] | |
| Fixed part | | | | | | | | | | | | |
| Patient category | | | | | | | | | | | | |
| Maternal | 1.000 | | | | 1.000 | | | | 1.000 | | | |
| Emergency | 0.054 | 0.000 | 0.034 | 0.085 | 0.060 | 0.000 | 0.037 | 0.095 | 0.042 | 0.000 | 0.024 | 0.072 |
| Pediatric <5 yrs | 0.019 | 0.000 | 0.012 | 0.030 | 0.021 | 0.000 | 0.013 | 0.033 | 0.007 | 0.000 | 0.004 | 0.013 |
| Pediatric 5-15 yrs | 0.014 | 0.000 | 0.009 | 0.021 | 0.014 | 0.000 | 0.009 | 0.023 | 0.005 | 0.000 | 0.003 | 0.008 |
| Adult (16-59 yrs) | 0.017 | 0.000 | 0.011 | 0.026 | 0.018 | 0.000 | 0.012 | 0.028 | 0.008 | 0.000 | 0.005 | 0.014 |
| Old age(>60 yrs) | 0.017 | 0.000 | 0.011 | 0.027 | 0.019 | 0.000 | 0.012 | 0.029 | 0.008 | 0.000 | 0.004 | 0.014 |
| Symptom recorded | | | | | | | | | | | | |
| no | 1.000 | | | | 1.000 | | | | 1.000 | | | |
| yes | 8.418 | 0.000 | 6.634 | 10.683 | 9.894 | 0.000 | 7.729 | 12.666 | 7.709 | 0.000 | 5.516 | 10.772 |
| Test recorded | | | | | | | | | | | | |
| no | 1.000 | | | | 1.000 | | | | 1.000 | | | |
| yes | 1.537 | 0.041 | 1.017 | 2.323 | 6.624 | 0.000 | 3.454 | 12.706 | 5.285 | 0.000 | 2.482 | 11.256 |
| Symptom X Test | | | | | | | | | | | | |
| yes#yes | | | | | 0.097 | 0.000 | 0.042 | 0.227 | 0.169 | 0.000 | 0.062 | 0.458 |
| _cons | 4.075 | 0.000 | 2.895 | 5.735 | 3.484 | 0.000 | 2.476 | 4.903 | 4.996 | 0.000 | 2.581 | 9.671 |
| Random Part | | | | | | | | | | | | |
| var(_cons) | | | | | | | | | 2.067 | | 1.163 | 3.675 |
| ICC | | | | | | | | | 0.386 | | 0.261 | 0.528 |
| Model Comparison | | | | | | | | | | | | |
| AIC | 2037.676 | | | | 2010.757 | | | | 1580.959 | | | |
| BIC | 2084.964 | | | | 2063.955 | | | | 1640.069 | | | |

During the FGD, providers iterated on the non-essentiality of recording vitals for all clinically stable patients; except for old-age patients who could potentially deteriorate quickly and maternity cases that had protocol to monitor progress.

- e. **Treatment:** The *fifth compliance* towards *treatment* dealt with polypharmacy, prescription of antibiotic and injections. The mean polypharmacy rate was 2.8 per prescription, median being 3; slightly higher than the WHO recommended reference value. Overall, 63% prescription had more than 2

drugs prescribed; highest recorded among the old age at 75% with a mean of 3.15 per prescription; and lowest in maternity cases (51%) with mean 2.6 per prescription. Polypharmacy in maternity was attributed to prescription of nutrients, such as iron and folic acid. Across PHCs, polypharmacy varied from 24% to 80%.

As for antibiotics in prescription, 63% of the patient encounters had an antibiotic prescribed, which was double the WHO reference value(<30 %); and 9% had more than one antibiotic. The prescription of antibiotics

was highest among paediatric (P1-77 %) and lowest in maternity (31%). Since maternity is not a disease, such a high volume of antibiotic usage needs further investigation. Urban PHCs had more antibiotics (68%) per prescription, than in the Rural (62%).

Injection prescription also varied across PHCs, ranging from 0 to 46%, with an average of 15%, within WHO reference indicator. However, prescriptions for maternity and emergency cases had higher proportion of injection/s prescribed, with 23% and 25% respectively. This was attributed to the protocolled routine immunization of pregnant women with TT, and injections for pain relief during emergency. Unlike antibiotics, injection prescribed was substantially low for Urban PHCs (5%) vis-à-vis rural (16%).

Multilevel logistic model (table-2) revealed that polypharmacy and prescription of antibiotic depends largely on patient's profile. An old patient was 3.3

times more likely to experience polypharmacy than others, in the form of increased nutritional and mineral supplements. However, 8-9 times increase in polypharmacy in paediatric patients was linked to use of antibiotics. Interestingly provider or system level factors did not contribute to polypharmacy (8%) and increased antibiotic prescription (7%). However, in case of injections, the system level factors accounted for 14% variation. As for provider level factors, patients that had symptom/s recorded had 1.6 times more likely to receive an injection. Second generation aminoglycosides or broad-spectrum antibiotics were the most commonly prescribed antibiotics in the encounters wherein antibiotics were prescribed. Amoxicillin was prescribed in 28% of encounters, Ciprofloxacin on 17%, and Cephalexin was the least prescribed antibiotic. The other most frequently prescribed drugs were Analgesics, Anti-allergens, Multivitamins, Gastroenterology and respiratory drugs.

Table 2: Factors associated with treatment compliance

| | Prescription with polypharmacy | | | | Antibiotic prescribed | | | | Injections given | | | |
|-------------------------------|--------------------------------|-------|------------|----------|-----------------------|-------|------------|----------|------------------|-------|------------|----------|
| | Odds Ratio | P>z | [95% Conf. | Interval | Odds Ratio | P>z | [95% Conf. | Interval | Odds Ratio | P>z | [95% Conf. | Interval |
| Patient category | | | | | | | | | | | | |
| Maternal | 1.000 | | | | 1.000 | | | | 1.000 | | | |
| Emergency | 1.228 | 0.302 | 0.831 | 1.815 | 5.066 | 0.000 | 3.360 | 7.638 | 1.167 | 0.510 | 0.737 | 1.848 |
| Pediatric <5 yrs | 1.116 | 0.549 | 0.779 | 1.598 | 9.922 | 0.000 | 6.680 | 14.739 | 0.633 | 0.054 | 0.398 | 1.009 |
| Pediatric 5-15 yrs | 1.719 | 0.004 | 1.194 | 2.474 | 8.283 | 0.000 | 5.602 | 12.247 | 0.517 | 0.007 | 0.321 | 0.835 |
| Adult (16-59 yrs) | 2.181 | 0.000 | 1.541 | 3.087 | 5.535 | 0.000 | 3.841 | 7.974 | 0.562 | 0.011 | 0.361 | 0.876 |
| Old age(>60 yrs) | 3.237 | 0.000 | 2.246 | 4.665 | 3.532 | 0.000 | 2.443 | 5.105 | 0.725 | 0.157 | 0.464 | 1.131 |
| Type of resident | | | | | | | | | | | | |
| Urban | 1.000 | | | | 1.000 | | | | 1.000 | | | |
| Rural | 1.208 | 0.501 | 0.697 | 2.093 | 0.886 | 0.657 | 0.520 | 1.511 | 4.256 | 0.003 | 1.636 | 11.072 |
| Symptom recorded | | | | | | | | | | | | |
| No | 1.000 | | | | 1.000 | | | | 1.000 | | | |
| Yes | 1.085 | 0.499 | 0.857 | 1.374 | 0.816 | 0.109 | 0.637 | 1.046 | 1.589 | 0.002 | 1.180 | 2.139 |
| Test recorded | | | | | | | | | | | | |
| No | 1.000 | | | | 1.000 | | | | 1.000 | | | |
| Yes | 0.815 | 0.406 | 0.503 | 1.320 | 0.799 | 0.376 | 0.486 | 1.313 | 0.937 | 0.840 | 0.497 | 1.765 |
| Symptom X Test | | | | | | | | | | | | |
| Yes | 2.202 | 0.036 | 1.053 | 4.604 | 1.622 | 0.187 | 0.791 | 3.329 | 1.226 | 0.626 | 0.541 | 2.779 |
| Doctor Signed | | | | | | | | | | | | |
| No | 1.000 | | | | 1.000 | | | | 1.000 | | | |
| Yes | 0.910 | 0.491 | 0.695 | 1.191 | 1.190 | 0.221 | 0.901 | 1.570 | 1.223 | 0.230 | 0.881 | 1.698 |
| Random Part (PHC name) | | | | | | | | | | | | |
| var(_cons) | 0.294 | | 0.157 | 0.548 | 0.256 | | 0.128 | 0.513 | 0.535 | | 0.261 | 1.096 |
| ICC | 0.082 | | 0.046 | 0.143 | 0.072 | | 0.037 | 0.135 | 0.140 | | 0.074 | 0.250 |

As regards documentation of drug related information, 99.9% drugs were written by their generic names from the Essential Drug List (EDL) as approved by the state; 21% drugs were indicated with their strength; 79% with dose; and 92% was documented with duration of treatment. During the qualitative study, doctors explained that documentation of drug strength was irrelevant, because of availability of limited strength/s of drugs at the PHCs.

f. Continuum of care (follow up and referral):

Referral and follow up, the two major components of primary care, had poor compliance across all facilities at 1%. While all the respondents during the qualitative study agreed on the importance of documenting follow up and referral to ensure continuum of care; the reasons for abysmal documentation was attributed to:

- The practice of dispensing medicine for 3 days forcing patient's revisit within 72 hours for a follow-up. Providers explained that in a low literacy setting, it's important to impress upon the need & incentivise follow up, rather than documenting it; because patients hardly refer to prescription for compliance.
- Inadequate space in the existing prescription format
- Self-motivation of the chronic patients (TB, typhoid, diabetes, dermatitis etc.)
- Disincentive for providers to prescribe referral, owing to absence of a system at higher centres to entertain referrals from PHCs.

g. Ownership compliance: Ownership compliance was measured by the proportion of prescription with documented doctor's signature. Overall 58% prescriptions had documented doctor's signature; higher in urban (78%) against rural (56%) PHCs. Contrary to the common belief that high patient

footfall leads to poor completeness of prescription; a high level of correlation was witnessed between proportion of prescriptions signed by the doctors and its completeness. The several logistic regressions drawn to understand factors associated to ownership compliance revealed that the system level factors accounted for 30% of the variations in the best fit model. Prescriptions at urban PHCs had 5 times more potential of being signed by a doctor than a rural one. Similarly, maternity cases had 1.5–2 times higher likelihood of receiving signed prescription. The logistic regression model suggests that provider's age, experience, availability of medicine and ability of the clinicians to accord time for clinical practice enhances ownership compliance. The FGD corroborated our quantitative findings that lesser the doctor's engagement in administrative activities, greater was focus on clinical care and completeness of prescription.

Appropriateness of prescription (QoC): We used dual approach to understand the QoC dimension. First, a latent measure of quality was computed by considering the five important indicators of prescription practice and explored factors attributable to QoC. Second, we evaluated appropriateness of investigation & treatment from the clinical stand point.

a. Appropriateness as a measure of facility level variation in Quality of care (QoC): The QoC index was computed using a latent variable comprising of indicators: (i) % of prescriptions wherein sign &/or symptoms were recorded, (ii) % of prescriptions that had diagnosis (final or provisional) documented, (iii) % of prescriptions wherein diagnostic tests (investigation) were recommended, (iv) % of prescription wherein treatments were recorded (antibiotic and injection), (v) and % of prescriptions wherein follow-up/referral was documented.

Table 3: Variation across facilities on QoC indicators

| Indicators | N | Mean | St. Dev | Min | Pctl(25) | Pctl(75) | Max |
|---|----|------|---------|------|----------|----------|------|
| % of pres. sign/symptom mentioned | 31 | 30.4 | 28.5 | 0.0 | 5.2 | 53.6 | 98.1 |
| % of pres. diagnosis mentioned | 31 | 22.6 | 21.5 | 0.0 | 7.0 | 29.5 | 93.0 |
| % of pres. tests recommended | 31 | 5.9 | 7.0 | 0.0 | 0.8 | 6.8 | 33.0 |
| % of pres. <2 medicine prescribed | 31 | 11.9 | 6.9 | 0.0 | 6.8 | 16.3 | 28.2 |
| % of pres. antibiotic prescribed | 31 | 65.3 | 11.5 | 43.1 | 56.4 | 74.7 | 90.1 |
| % of pres. injection prescribed | 31 | 13.9 | 11.2 | 0.0 | 5.0 | 19.4 | 44.6 |
| % of pres. Referral/follow up mentioned | 31 | 2.6 | 6.8 | 0.0 | 0.0 | 1.7 | 35.7 |

We noted substantial variation in all indicators across PHCs (refer table-3 and figure-4). In order to compute a latent variable, we adjusted the variables by taking deviations from WHO reference value and computed a summative score. The score was further divided into five quintiles to create an ordered variable – QoC index. Comparison of system and provider level factors across

quintiles of QoC (table-4) revealed that facilities very good on QoC, had young nurses with doctors either less than 35 yrs or over 65 years of age, spending less time in administrative tasks, and experienced nurses. The facilities that were better on QoC were well-stocked with drugs.

Table 4: Profile of facilities with different level of quality of care in terms of prescribing practices

| | V.Low | Low | Moderate | Good | V.Good | Total |
|---------------------------------------|-------|------|----------|------|--------|-------|
| Age of doctors | | | | | | |
| <35 years | 42.9 | 14.3 | 20.0 | 28.6 | 60.0 | 32.3 |
| 35-65 years | 14.3 | 42.9 | 20.0 | 28.6 | 0.0 | 22.6 |
| 65+ years | 28.6 | 28.6 | 60.0 | 28.6 | 40.0 | 35.5 |
| Less time (<50%) spent on admin task | 42.9 | 28.6 | 80.0 | 71.4 | 80.0 | 58.1 |
| % of prescription signs by the doctor | 51.9 | 58.1 | 64.0 | 50.1 | 75.0 | 58.3 |
| Medicine was available (%) | 42.9 | 14.3 | 60.0 | 57.1 | 60.0 | 45.2 |
| Stock out in past 6 months (%) | 28.6 | 28.6 | 20.0 | 28.6 | 60.0 | 32.3 |
| Age of GNM <27 yrs (%) | 71.4 | 42.9 | 0.0 | 85.7 | 40.0 | 51.6 |
| Work experience of GNM (35+ months) | 28.6 | 85.7 | 80.0 | 85.7 | 80.0 | 71.0 |
| Average OPD per day | 41.0 | 52.8 | 27.4 | 42.1 | 57.1 | 45.7 |
| % Urban | 28.6 | 14.3 | 20.0 | 28.6 | 20.0 | 22.6 |
| No of PHCs | 7 | 7 | 5 | 7 | 5 | 31 |

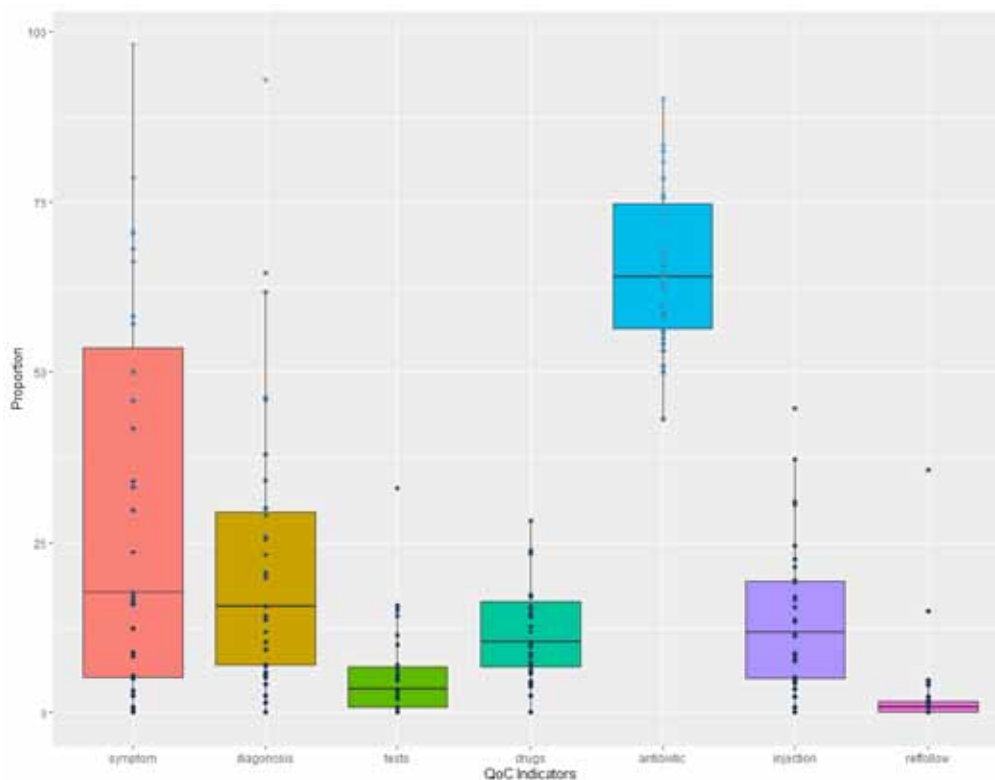


Figure 2: Box plot of QoC indicators

b. Appropriateness as a measure of Quality of care from clinical stand point: The appropriateness of drug use stems from the Standard Treatment Guidelines (STGs) and best practices to treat certain disease/s. Further, as signs and symptoms are sine-quo-non to patient complaints, from which the clinician draws provisional and differential diagnosis; we analysed 783 prescriptions that had symptoms and signs documented to evaluate appropriateness of drug use, using STGs recommended by government of India and WHO. As the study focused on completeness and compliance of prescription, the diagnosis made by the clinician and the treatment thereof was not questioned. Therefore, a documented justification on investigation advised, treatment given, follow up & referrals advised for such a diagnosis vis-à-vis the documented signs and symptoms was considered relevant, and hence evaluated.

Nearly 36 % of prescription were found inappropriate in terms of its documented justification for the treatment advised. The commonest inappropriateness in treatment were non-documentation of rationale for:

- Prescription of one or more antibiotics/3rd Generation Antibiotic/Anti-fungal, steroids and NSAIDs, Anti-Rabies vaccine without documentation of signs and symptoms or investigation;
- Using both Gram negative and Gram positive antibiotics for the same event;
- Prescribing Azithromycin in prescription reporting diarrhoea;
- Prescribing steroids for fever and cough in child under five without relevant clinical findings;
- Treatment of dehydration or prescription of fluids in old age without investigating for electrolyte imbalance;
- Not prescribing anti-hypertensive or not advising referral/follow-up for hypertension in pregnancy.

Commonest prescription with limited error on appropriateness were for maternity cases, wherein STG was well defined and adequately communicated to the staff.

While weight is an important criterion for calculation of drug dose, especially in case of children; only in 43 prescriptions weight was documented, which included

6 children under the age group of 5 years. Similarly, Blood pressure was documented only in 4% of cases; commonest of them being: pregnancy and all cases of gastritis, hypertension, weakness, diarrhoea, and body ache in old age patients.

Conclusion

PHCs are the first point of doctor-patient interaction in the public healthcare delivery system. It is not only an entry to the continuum of care cycle in terms of provision of diagnosis, treatment and appropriate referrals and follow-ups; but also echoes with universalization of health care as was envisaged for the first time at Alma-Ata Declaration. Therefore, early diagnosis of disease, its timely treatment and referral if the primary role of a PHC; served through a complete and comprehensive prescription. In order to improve compliance and comprehensiveness of prescription practice at PHCs, our study revealed the need for following system and provider level strengthening efforts:

- **System level Strengthening**
- **Creating facility level enabling environment by ensuring availability of:** (i) drugs and supplies, test kits at all times; (ii) prescription pad with sufficient space for recording details; (iii) unique identifier for maintaining continuum of care for each patient; (iv) referral practice to higher centres and back to be streamlined (documented, standardised, and communicated across).
- Policy reform to rationalise polypharmacy beyond WHO definition, considering Indian realities; thereby including multivitamins as nutritional supplements to all vulnerable sections of the population instead of categorising it as “Drug” in a prescription.
- Provider level strengthening
- Empowering staff nurse/GNM as “Physician Assistant” by protocolled task shifting to treat select diseases with limited allowable prescription & sign off by “Nurse Practitioner” to increase accountability of the system.
- Stakeholder buy-in to influence behaviour change management, to: (i) improve legibility of prescriptions, and documentation of justification for the treatment offered; (ii) implement Anti-Microbial Stewardship Program to build capacity of care providers on rational drug use.

Ethical Clearance: Taken from IIMR, Delhi Ethics board

Patients Involvement: No patients were involved during the research

Source of Funding: Self

Conflict of Interest: Nil

Units of Measurement: Nil

Abbreviations and Symbols:

AIC: Akaike Information Criteria

AYUSH: Ayurveda Yoga Unani Siddha and Homeopathy system of Indian Medicine

BIC: Bayesian Information Criteria

EDL: Essential Drug List

FGD: Focus Group Discussion

GNM: General Nursing and Midwifery

IDI: In-depth Interviews

MCI: Medical Council of India

OP: Outpatient

OPD: Outpatient Department

PHC: Primary Healthcare Centre

QoC: Quality of Care

SD: Standard Deviation

STG: Standard Treatment Guidelines

WHO: World Health Organization

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13. Collins Dictionary of Law. S.v. “duty of care.” Retrieved July 27 2020 from <https://legal-dictionary.thefreedictionary.com/duty+of+care>; a duty of care is a legal obligation which is imposed on an individual requiring adherence to a standard of reasonable care while performing any act/s that could foreseeably harm others
14. For the purpose of the study, legibility of prescription was defined as the effortless ability of reader/data entry expert to read and copy the contents of the prescription in the content analysis sheet