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Research Article

Prescribing quality in patients with chronic diseases at primary and secondary health care facilities using prescription quality index tool

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ABSTRACT

Background: Prescribing quality is a matter of major concern worldwide. This study was carried out to determine the quality of prescribing in chronic diseases at primary health care (PHC) and secondary health care (SHC) settings using the new prescription quality index (PQI) tool.

Methods: A cross-sectional observational study was carried out at four PHC and two SHC facilities in Anand district of India. Patients attending these facilities for at least 3 months were included. Complete medical history and prescriptions received were noted. Total and criteria wise PQI scores were derived for each prescription. Prescriptions were categorized as poor (score of ≤31), medium (score 32-33), and high quality (score 34-43) based on PQI total score. The internal consistency of PQI was measured using item total correlation and Cronbach's α so as to validate it in our settings. Data were analyzed using Statistical Package for Social Science 20.

Results: A total of 134 prescriptions were collected and evaluated for quality of prescribing. Mean age of patients was 60.6 ± 13.5 years. Mean PQI score was 23.60 ± 9.3 with 71.6% prescriptions being of poor quality. Quality of prescribing did not differ at PHC and SHC ($P>0.05$). Of 22 criteria, PQI score was strongly correlated with drug indication, drug effectiveness, evidence-based prescribing, unnecessary duplication, duration of therapy, and cost ($P<0.01$). PQI total score was negatively correlated to the number of drugs per prescription. Cronbach's α for the entire 22 criteria were 0.90.

Conclusion: PQI was found to be a reliable tool for assessment of prescribing quality in chronic diseases.

Keywords: Rational drug use, Prescription quality index, Quality of prescribing

INTRODUCTION

Prescription is a written document that engages the medical and legal responsibility not only of the physician, but of all those subsequently involved in its execution.[1] A good prescription is one that is rational, evidence based, clear, complete, and able to improve the health outcomes of the patient treated. Good prescription quality reflects good prescribing process and thus good quality health care in general. Prescribing without an acceptable indication, correct dose, frequency, route of administration, schedule or duration of treatment, duplicating therapeutic agents and prescribing drugs without adequate regard to potential interactions or adverse reactions are all forms of inappropriate prescribing[2-4] and contribute to poor quality of prescribing.

Several tools have been developed based on expert judgment of practitioners or consensus.[5-9]

These tools are intended for measurement of quality of care in general,[10] specific population,[11,12] overall drug use,[13] specific areas of drug use,[14] for specific disease[15] or specific drug or groups of drugs.[15,16] The World Health Organization has derived indicators to describe key areas of outpatient and in-patient drug use in developing countries.[13] These indicators are intended to be objective measures of prescribing behavior allowing comparison between prescribers or units over time. The medication appropriateness index (MAI) developed by Hanlon et al.[17,18] at Duke University Medical Center (Durham, NC, USA) is an instrument to evaluate the appropriateness of medication

use in individual patients and has been found to be reliable and valid in a number of clinical settings. However, the MAI is not designed to measure prescription quality and does not address several important issues, such as adverse drug reactions (ADRs), evidence-based prescribing, compliance, and patient outcomes. Thus, there is a lack of a single measure that will capture all facets of prescription quality and which is applicable for measurement of prescription quality in chronic diseases, especially those with multiple comorbidities.

The first step in improvement of prescribing practices would be evaluating the quality of prescribing and any tool, which would evaluate all aspects of prescription right from the selection of the drug to complete prescribing instructions, would be most appropriate. Prescription quality index (PQI) developed by Hassan et al. in 2010,[19] is the tool intended for health care providers to evaluate the quality of drug prescribing in chronic diseases. It contains 22 criteria in question form. The PQI has been claimed to be an ideal tool applicable to a broad variety of medications and clinical conditions and easily be adopted for application in different settings and limited availability of data. The criteria in the PQI are specifically chosen to measure the common problems related to prescription quality in clinical practice.

This observational cross-sectional study was conducted to determine the quality of prescribing in patients with chronic diseases attending primary health care (PHC) and secondary health care (SHC) facilities near Anand district in Gujarat state of India using PQI tool[19] and to assess the reliability of this tool.

Ethical approval

The study was approved by the Institutional Human Ethics Committee. Formal permission of chief medical officer of each health center was obtained. Each participant's informed consent was obtained before collecting his/her data and any other relevant information.

METHODS

Observational cross-sectional study was carried out from April 2012 to September 2012 - spread over 6 months at four PHC and two SHC facilities - one community health center and one civil hospital.

Inclusion criteria

Patients of all ages suffering from chronic illnesses such as hypertension, bronchial asthma and any joint disorder with or without comorbidities and attending the outpatient department of PHC or SHC facilities for at least 3 months or greater and ready to give consent were included in the study.

Data collection

Data were collected for a period of 4 weeks (3 days in a week) at each facility. Patient's complete medical history was obtained by personal interview and other relevant information including prescription was recorded in the case record form. Compliance of patient for medicines was evaluated using patient's self-report.

Calculating PQI scores using the PQI tool

Drug indication and dosage were rated as very important and given the highest weighted scale of '0' to '4'. Fifteen criteria: evidence-based, effectiveness, correct directions, practical directions, drug-drug interactions, drug-disease interactions, ADR, duration, compliance, legibility, prescriber's information, patient's information, medication's name, diagnosis, and patient's improvement were considered as important and assigned the medium score of '0' to '2'. Five criteria: unnecessary duplication, cost, generic prescribing, formulary or essential drug list, and requirement for drug therapy were rated as least important and assigned the lowest score of '0' to '1'.[19]

As described in PQI, if the prescription consisted of more than one drug, each drug was rated individually. Similarly, if patients suffered from more than one disease, each disease state was rated separately. The minimum score was then selected for the PQI summation. If a drug was not indicated, criterion 1 was scored as '0'. Subsequently, criterion 2 (dosage), criterion 13 (duration) and criterion 14 (cost minimization) were all scored as '0'. The PQI total score was obtained by summing up all the minimum scores for the 22 criteria for all drugs in a prescription. The possible maximum score of the PQI was '43'. Prescription with the PQI total score of ≤31 was interpreted as poor quality, scores 32 to 33 as medium quality and scores 34 to 43 as high quality as described in PQI tool.[19]

To evaluate different items in the questionnaire, standard references, or publications were used. The primary references were PQI manual, pharmaceutical/pharmacological texts or credible clinical journals or established online websites. Examples are A to Z drug facts,[20] USPDI, MedLine, PubMed, Martindale's complete drug reference,[21] WHO essential drug list 2011,[22] National list of Essential medicines of India 2011,[23] National Formulary of India 2011[24] and British National Formulary 2011.[25] For the cost of the therapy current issues of commercial sources such as CIMS, MIMS, and Indian Drug Review were reviewed. Hospital formularies were used if available.

Statistical analyses

Data were analyzed using Statistical Package for Social Science version 20. Descriptive statistics were used to describe the samples. Mean and standard deviation were

used to describe numerical and variables and frequency (%) was used for categorical variables. To check the normality of data Kolmogrov-Smirnov test was applied. Non-parametric tests were applied due to skewed distribution of our data. To validate the PQI internal consistency (reliability) was measured using item total correlation and Cronbach's α. These two properties reflect the extent to which items correlate with the total score and how well items measure the same construct. Correlation of criteria should be between 0.2 and 0.8.[19] Floor effects (percentage of prescriptions with the minimum possible score) and ceiling effects (percentage of prescriptions with a maximum possible score) were also assessed. Factor analysis[26] was performed to explore common dimensions between the PQI criteria. Majority of factor analysis use more than one criterion. Hence, both Kaiser's criteria (eigenvalue > 1 rule) and the Scree test were employed to assess the construct validity of the tool.[27] p<0.05 was considered significant.

RESULTS

Characteristics of the patients

A total of 134 prescriptions were collected from four PHCs (66) and two SHCs (68) during the study period. The mean age of patients was 60.6 ± 13.5 years. The number of drugs in the prescriptions ranged from one to 10 with the mean value of 3.9 ± 1.8. The mean number of chronic medical illnesses per prescription at both the facilities was 1.5 ± 0.6. The most common medical conditions were hypertension (55%), bronchial asthma (37.3%), diabetes mellitus (8%), and others (13.4%). Male patients formed 55% of patients attending health care facility. The demographical and clinical features of patients are shown in Table 1.

The PQI

The PQI could be evaluated in about 15-20 mins, depending on the number of drugs in the prescription.

Psychometric properties of the PQI in patient with chronic diseases

The mean PQI total score was 23.60 ± 9.3. While the PQI score can range from '0' to '43', there were four (2.99%) prescriptions with a minimum score of '11', whereas two (1.49%) prescriptions scored maximum '43'. However, no prescription scored 0, indicating the absence of floor effects. The total PQI scores were not normally distributed. There was no significant difference in quality of prescribing between PHC and SHC as shown in Table 2.

Table 3 shows criteria wise mean PQI score compared with the previous study, which shows that about 60% of criteria have scores comparable with the previous study. In addition,

criteria such as cost, compliance and prescriber's information scored higher than in the previous study.

Exploratory principal components analysis of the PQI total scores revealed a six-factor solution using the minimum Eigenvalue criteria of ≥1. These six accounted for 71.2% of the total variance (Figure 1).

As criterion 7 (drug-drug interactions) was a constant value, it was neglected in the analysis. For both the facilities none of the 22 criteria were normally distributed. All showed a skewed distribution as verified using Kolmogrov-Smirnov test (for all P<0.001). Cronbach's α for the entire 22 criteria were 0.90.

As shown in Table 4, PQI total scores were strongly correlated with drug indication, drug effectiveness, evidence-based prescribing, unnecessary duplication, duration of therapy and cost (P<0.01). The criteria including dosage, practical directions, drug-disease interaction, generic prescribing, medication's name, requirement for drug therapy and patient's improvement showed moderate correlation. There was a weak correlation with remaining criteria.

The PQI total score was positively correlated with age (correlation coefficient 0.28, P=0.001), number of diseases/conditions per prescription (correlation coefficient 0.42, P<0.001) and negatively correlated with the number of drugs in the prescriptions (correlation coefficient −0.33, P<0.001).

DISCUSSION

This study was planned to evaluate the quality of prescribing for chronic conditions in an outpatient setting of PHC and SHC facilities in the western part of India with the help of PQI tool developed by Hassan et al. in 2010.[19] The PQI tool is already validated and claimed to be reliable and hence, it was selected for assessment of prescribing quality in Indian setting.
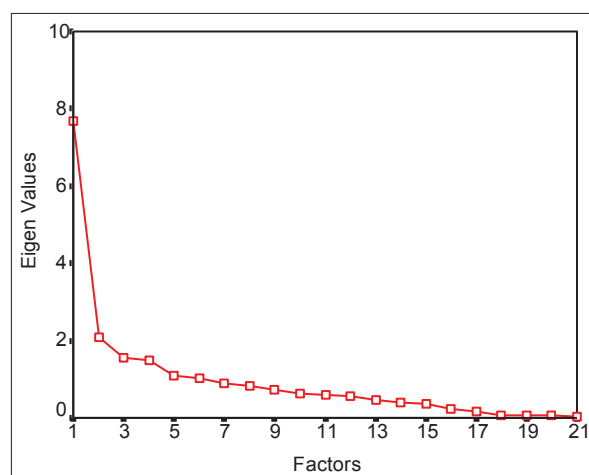

Figure 1: Scree plot showing components of Prescription Quality Index total score in patients with chronic diseases.

Table 1: Demographical and clinical features of patients at PHC and SHC facilities (n=134).

Parameters	PHC facility n (%)	Mean±SD	SHC facility n (%)	Mean±SD	Total n (%)
Age group		62.1±15.6 years		57.2±13.8 years	
≥65 years	35 (53)		24 (35.3)		59 (44.03)
<65	31 (47)		44 (64.7)		80 (59.7)
Sex					
Male	42 (63.6)		31 (45.6)		73 (54.5)
Female	24 (36.4)		37 (54.4)		61 (45.5)
Number of drugs in the prescription		2.9±1.2		4.8±1.7	
1 drug	7 (10.6)		0		7 (5.2)
2 drugs	18 (27.3)		02 (2.9)		20 (14.9)
3 drugs	26 (39.4)		05 (7.4)		31 (23.1)
4 drugs	8 (12.1)		07 (10.3)		15 (11.2)
5 drugs	5 (7.6)		11 (16.2)		16 (11.9)
≥6 drugs	2 (3.0)		19 (27.9)		21 (15.7)
Number of diseases or conditions per prescription		1.5±0.6		1.5±0.5	
1	41 (62.1)		38 (55.9)		79 (59)
2	20 (30.3)		24 (35.3)		44 (32.8)
3	5 (7.6)		1 (1.5)		6 (4.5)
4	0		0		0
Compliance status					
Compliant	41 (62.1)		41 (60.3)		82 (61.2)
Noncompliant	25 (37.9)		27 (39.7)		52 (38.8)
Total patients	66		68		134

SD: Standard deviation, PHC: Primary health care, SHC: Secondary health care

Table 2: Prescription quality index score and prescribing quality at PHC and SHC facilities (n=134).

Quality	PQI score	PHC facility (n=66) n (%)	SHC facility (n=66) n (%)	Chi-square test *P* value
Poor	≤31	46 (69.69)	50 (73.53)	0.6064
Medium	32-33	2 (14.28)	1 (4.17)	0.7235
High	34-43	18 (27.27)	17 (25)	0.6429

P<0.05 shows significant difference, PQI: Prescription quality index, PHC: Primary health care, SHC: Secondary health care

Prescribing quality in terms of PQI score showed no significant difference between PHC and SHC. At PHC and SHC quality of prescribing is poor as evident by approximately 70 % of prescriptions being of poor quality with PQI score ≤31. There could be certain factors that may affect the quality of prescribing like; patient's illness status including comorbidities, number of drugs prescribed, patient flow at health care center, etc. At PHC the majority of patients have simple problems without/with minimum complications or comorbidities. Polypharmacy was less frequent at PHC as compared to SHC. The number of drugs per prescription at PHC was 2.9 ± 1.2 and at SHC 4.8 ± 1.7. Kumari et al.

have reported that polypharmacy (>2 drugs) was evident in a majority of the prescriptions, at all the public health facilities in India.[28] Factors like patients with more complex conditions and availability of the greater number of drugs as well as doctors at SHC may lead to polypharmacy. Moreover, larger turnover of patients may make prescribing complex and varied at SHC. To some extent these influences can be attenuated by higher qualifications of prescribers at SHC, which would improve the prescribing quality. Absence of significant difference in quality of prescribing between PHC and SHC is suggestive of no impact of the differences in prescribers' qualifications on prescribing behavior.

The PQI total scores were not normally distributed. There were four (2.98%) prescriptions with a minimum score of '11', whereas two (1.49%) prescriptions scored a maximal of '43', indicating the absence of floor effects. These finding differs from that of Hassan et al., who reported that the two criteria (generic prescribing and diagnosis) were normally distributed, while the other criteria displayed skewed distribution with the absence of floor or ceiling effects.[19]

The instruments that have been tested in the same population might not need further testing, but further psychometric testing is necessary if differences exist between the study population and the population sampled when the instrument

Table 3: Comparison of Criteria wise mean PQI score with previous study.[19]

Criterion	Maximum score for criterion	Obtained score (Mean±SD)	Score Hassan et al. (Mean±SD)
Is there an indication for the drug?	4	1.30±1.7	2.8±1.5
Is the dosage correct?	4	1.39±1.8	3.0±1.7
Is the medication effective for the condition?	2	0.71±0.9	1.8±0.5
Is the usage of the drug for the indication supported by evidence?	2	0.66±0.8	2.0±0.2
Are the directions for administration correct?	2	1.18±0.6	0.2±0.5
Are the directions for administration practical?	2	1.03±0.8	1.8±0.6
Are there clinically significant drug-drug interactions?	2	1.97±0.2	1.6±0.6
Are there clinically significant drug-disease/condition interactions?	2	1.67±0.7	1.8±0.7
Does the patient experience any adverse drug reaction (s)?	2	1.52±0.6	1.8±0.5
Is there unnecessary duplication with other drug (s)?	1	0.35±0.5	1.0±0.1
Is the duration of therapy acceptable?	2	0.78±0.9	1.3±0.8
Is this drug the cheapest compared to other alternatives for the same indication?	1	0.43±0.5	0.2±0.4
Is the medication being prescribed by generic name?	1	0.37±0.5	0.6±0.5
Is the medication available in the formulary or essential drug list?	1	0.89±0.3	1.0±0.2
Does the patient comply with the drug treatment?	2	0.88±1	0.6±0.9
Is the medication's name on the prescription clearly written?	2	1.27±0.5	1.8±0.4
Is the prescriber's name on the prescription legible?	2	1.99±0.1	2.0±0.2
Is the prescriber's information on the prescription adequate?	2	2.00±0	1.5±0.9
Is the patient's information on the prescription adequate?	2	1.03±0.3	1.0±0.3
Is the diagnosis on the prescription clearly written?	2	0.94±0.7	0.9±0.5
Does the prescription fulfil the patient's requirement for drug therapy?	1	0.61±0.5	1.0±0.2
Has the patient's condition (s) improved with treatment?	2	0.61±0.8	0.7±0.9
Total score	43	23.60±9.3	31±5.2

PQI: Prescription quality index, SD: Standard deviation

was developed and tested. Psychometric properties of tools used in the current study are necessary to report because they are specific to the sample of participants.[29] In this study, the exploratory principal components analysis of the PQI total scores exposed a six factor solution using the minimum Eigen value criteria of ≥1. These six factors accounted for 71.2% of the total variance. Hassan et al. have reported an eight-factor solution and these eight factors accounted for 66% of the total variance. Cronbach's α for the entire 22 criteria was 0.90 in this study, while Cronbach's α for the entire 22 criteria were reported as 0.60 in the previous study.[19] This finding suggests that the PQI tool is reliable for use in our setting also.

This study has demonstrated weak positive correlation of PQI total score with patient's age and number of associated illness/diseases. This finding is unexpected and in contrast with the results of Hassan et al.[19] and a study of prescription database, which stated that as age increases there is a higher risk of complications and more drugs required for treatment.[30] However, the inverse correlation of PQI score with patient's age in the study by Hassan et al. was weak. The numbers of comorbidities in our study did not exceed three, which could be the probable reason for weak positive correlation with

associated illnesses. An inverse correlation of prescription quality with the number of drugs in the prescriptions was observed. The higher the number of drugs prescribed in a prescription, the lower the prescription quality. This finding is in accordance with Hassan et al.[19] and another study, which reported that inappropriate prescribing was significantly correlated with polypharmacy.[31]

The PQI total scores for both the facilities were strongly correlated with drug indication, drug effectiveness, evidence-based prescribing, unnecessary duplication, duration of therapy and cost (*P*<0.01). Hassan et al. have reported that the PQI total scores were strongly correlated with drug indication and drug dosage. There was no correlation between the PQI total scores and four criteria: unnecessary duplication, formulary/essential drug, medication's name, and adequate patient information. Although these four criteria did not meet the selection criteria, these criteria were still retained in the PQI for content validity, clinical and legal significance.[19] Two of these criteria–unnecessary duplication and medication's name correlated with total PQI score in our study proving that their retention by the developers was appropriate. Overall the differences are indicative of regional variations in prescribing behavior.

Table 4: PQI total score correlation with 22 criteria.

Criterion	Correlation with PQI total score* (N=134)	
	Correlation coefficient	*P* value
Indication	0.881	<0.001
Dosage	0.656	<0.001
Effectiveness	0.872	<0.001
Evidence-based	0.890	<0.001
Correct directions	0.759	<0.001
Practical directions	0.640	<0.001
Drug-drug interactions	1	-
Drug-disease/condition interactions	0.613	<0.001
Adverse drug reaction	0.262	0.024
Unnecessary duplication	0.853	<0.001
Duration of therapy	0.856	<0.001
Cost	0.809	<0.001
Generic prescribing	0.542	<0.001
Formulary or essential drug list	−0.028	0.809
Compliance	0.334	0.027
Medication's name	0.539	<0.001
Legibility	−0.042	0.718
Prescriber's information	0.003	0.982
Patient's information	0.076	0.515
Diagnosis	0.438	<0.001
Requirement for drug therapy	0.551	<0.001
Patient's improvement	0.699	<0.001

*Correlation significant at 0.05 level (two-tailed), Spearman's correlation, PQI: Prescription quality index

The results suggest poor quality of prescribing at PHC and SHC facilities of national health system of India in the region under study. The first four criteria - correct indication for drug, correct dosage, effectiveness and evidence-base, which contribute to 12 points out of maximum 43 points in PQI, scored lower compared to the previous study.[19] The other criteria - unnecessary duplication, adequate duration and prescribing by generic names also exhibited lower score compared to Hassan et al.[19] Low scores in these seven criteria contribute to poorer quality prescribing in our setup.

Strength and limitations of this study

As the data were collected prospectively there are no chances of missing any information relevant to prescribing quality assessment unlike in retrospective studies. Moreover, rather than selecting one facility per health care level, data were collected from more than one facilities to incorporate any inter-facility differences in the prescribing behavior. We have not included tertiary health care facility in this study. Inclusion of tertiary care facility would have allowed a complete overview of quality of prescribing at different levels of health care.

CONCLUSION

The overall quality of prescribing at PHC and SHC is poor with no inter facility differences. The PQI is a comprehensive valid and reliable instrument for measuring quality of prescribing in chronic diseases in Indian settings and can be useful for assessment and comparison of quality of prescribing in different clinical settings at different health care levels.

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