

PRESCRIPTION AUDITING BASED ON THE WORLD HEALTH ORGANIZATION (WHO) PRESCRIBING INDICATORS IN OUTPATIENT DEPARTMENT OF A TEACHING HOSPITAL IN KERALA

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ABSTRACT

Objectives: The objectives of the study were to study the pattern of major drug groups prescribed, assess the Rational Prescription pattern by measuring the WHO Core Prescribing Indicators and to assess the quality of the prescriptions by assessing the legibility of prescription in the outpatient department of a tertiary care hospital.

Methods: It was an analytical cross-sectional study done in Outpatient Department for a period of 6 months. Approval from Institutional Research Committee and Institutional Ethics Committee was taken before starting the study. Sample size was taken as 1020.

Results: One hundred and twenty prescriptions were analyzed. About 49% prescriptions were of males and 54% of females. Mean age of the patients were 46 years. A total of 3557 medicines were prescribed in 1020 prescriptions. Due to lack of legibility, we were unable to decode 122 medicines out of 3557 medicines prescribed. The dosage forms prescribed were; oral 87.4%, injections 1.4%, inhalational agents 0.4%, and topical agents 10.8%. Average number of medicines per prescription was 3.5. Percentage of medicines prescribed by generic name was 45%. Percentage of antibiotics per prescription was 24.8%. Percentage of injections per prescription was 4.8%. Percentage of medicines prescribed as per NATIONAL essential drugs list (EDL) was 3.2% and as per the WHO EDL was 2.6%. Percentage of fixed dose combinations (FDCs) was 6.5%.

Conclusion: It was evident that polypharmacy was present as indicated by the average number of medicines prescribed. Medicines prescribed by generic name and from Essential Medicine List were less in number. Antibiotics and injections prescribed was in conformity with the WHO recommended values, which means that there was no irrational use of antibiotics and unwanted use of injectables. Percentage of FDCs was 6.5%. Most commonly prescribed drug was Ranitidine as per our study. Hence, as per this study, prescribers did not follow prescribing core indicators of the WHO closely, except for two indicators. The quality of prescriptions with respect to legibility and clarity was found to be optimal.

Keywords: Prescription auditing, Prescribing indicators, Outpatient department.

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INTRODUCTION

Misuse of pharmaceuticals is common all over the world. Medication misuse may be due to lack of effective regulation and education, inappropriate use, and uncoordinated response from different levels of health system [1].

The WHO developed core drug use indicators to evaluate drug use practices at health care centers. It was prepared with an intention to curb irrational use of medicines. About 50% drugs are prescribed; dispensed; and sold inappropriately. Polypharmacy and irrational use of drugs affect the quality of healthcare [2-4].

Drug prescription is a medico legal document and reflects the competency of physician and his attitude toward rational prescribing. Prescribing errors can cause adverse drug reactions (ADRs) which further add to patient morbidity and mortality [5-7].

Audit was first used by Florence Nightingale in 1854 to prevent mortality after surgery. W Edward Deming characterized audit as a sequence of events, the Deming cycle (Plan- Do- Check- Act). Audit refers and monitor what we do against a reference standard [8].

Prescription audit is systematic critical analysis to assess the quality of medical care. The rational use of drugs is based on rule of right-right drug, right patient, right dose, and right cost. Medical audit collects information on drug usage, expenditure, appropriateness of prescriptions, and evidence based information.

Drug utilization studies are tools in pharmacoepidemiology and also link other areas like pharmacovigilance, pharmacoconomics, and pharmacogenetics [7-10].

This study was undertaken to create our own database, by auditing prescriptions. The objectives of the study were to study the major drug groups prescribed, assess rational prescription pattern by measuring the WHO Core Prescribing Indicators and assess quality of the prescriptions at outpatient department in a tertiary care hospital.

METHODS

It was an Analytical Cross-sectional study done in Hospital Pharmacy, Medical College Hospital, Government Medical College Thrissur for a period of 6 months with sample size taken as 1020. Data were collected every day from prescription of patients visiting various outpatient departments, by visiting hospital pharmacy after getting approval from Institutional Research Committee and Institutional Ethics Committee. Every 10th prescription was taken for collecting data. Prescriptions were numbered and data were collected using a specially designed semi-structured, pretested "Prescription Audit Check List" and were kept strictly confidential and used for the purpose of this study only. The data were presented as percentage and averages. Information filled includes; details of doctor with signature, patient details, diagnosis, allergy status of patient, drug's name, its dose, dosage form, route, and frequency of administration, and follow-up advice.

WHO core prescribing indicators assessed include

1. Average number of medicines per prescription was calculated by dividing the total number of prescribed drug products by the number of encounters surveyed. Fixed dose combination (FDC) was also counted as one drug
2. Percentage of medicines prescribed by generic name was calculated as the ratio of the number of drugs prescribed by generic name to the total number of drugs prescribed, multiplied by 100
3. Percentage of antibiotics per prescription (Antibiotics was classified based on the WHO model list for antibiotic classification) was calculated as the ratio of the number of patient encounters in which an antibiotic was prescribed to the total number of encounters surveyed, multiplied by 100
4. Percentage of injections per prescription (Vaccinations were excluded from this list) was calculated as the ratio of the number of patient encounters in which an injection was involved to the total number of encounters surveyed, multiplied by 100
5. Percentage of medicines prescribed from the essential drugs list (EDL) was calculated as the ratio of the number of products prescribed from the EDL to the total number of drugs prescribed, multiplied by 100.

Percentage of FDCs prescribed was also calculated as the ratio of the number of patient encounters in which FDCs were involved to the total number of encounters surveyed, multiplied by 100. The quality of prescriptions was evaluated by assessing the prescription legibility which was graded on a subjective scale by two independent investigators. Prescriptions were graded as: Grade 1 (legible with ease), Grade 2 (legible with difficulty), and Grade 3 (illegible). Statistical Package for the Social Science (SPSS) Version 16 was used for analysis. Descriptive statistics was used for data analysis.

RESULTS

One hundred and twenty prescriptions were analyzed. About 49% prescriptions were of males and 54% of females. Mean age of the patients were 46 years. A total of 3557 medicines were present from all the prescriptions. Due to lack of legibility of prescriptions, we were unable to decode 122 medicines out of 3557 medicines prescribed.

The dosage forms prescribed were; oral 87.4%, injections 1.4%, inhalational 0.4%, and topical agents 10.8%. Almost all prescriptions followed the mechanisms of prescription order writing such as superscription, inscription, subscription, and transcription.

Analysis of the WHO core prescribing indicators

1. Average number of medicines per prescription
Total number of prescribed drug/number of encounters surveyed
 $3557/1020 = 3.5$
2. Percentage of medicines prescribed by generic name
Ratio of the number of drugs prescribed by generic name/Total number of drugs prescribed $\times 100$
 $1605/3557 \times 100 = 4.8\%$
3. Percentage of antibiotics per prescription
Ratio of the number of patient encounters in which an antibiotic will be prescribed/total number of encounters surveyed $\times 100$
 $253/1020 \times 100 = 24.8\%$
4. Percentage of injections per prescription
Ratio of the number of patient encounters in which an injection was involved/total number of encounters surveyed $\times 100$
 $49/1020 \times 100 = 4.8\%$
5. Percentage of medicines prescribed from the EDL
Ratio of the number of products prescribed from the EDL/Total number of drugs prescribed $\times 100$
 - a. As per NATIONAL EDL $112/3557 \times 100 = 3.2\%$
 - b. As per WHO EDL $93/3557 \times 100 = 2.6\%$

Percentage of FDCs

Ratio of the number of patient encounters in which FDCs was involved/Total number of encounters surveyed $\times 100$
 $66/1020 \times 100 = 6.5\%$

The prescriptions audited in outpatient departments included around 20 departments (Table 1) in which majority of the prescriptions were from orthopedics department (21.1%), followed by general medicine (18.5%), dermatology (13.5%), and ENT (9.9%).

The most commonly prescribed group of drugs (Table 2) were miscellaneous group of drugs (21.4%) such as vitamins, minerals supplements, and drugs modulating musculoskeletal system. This was followed by drugs acting on gastrointestinal system (16.6%), drugs acting on cardiovascular system (13.7%), Nonsteroidal Anti inflammatory Drugs (NSAIDs) (13.5%), and antimicrobial agents (10.5%).

The most common diagnosis was Q00-R99 as per, International Classification of Diseases (ICD) 25.5% (Table 3), which includes not elsewhere classified diseases. As per the study since it was an audit done in outpatient setting, it included patients who presented with non-specific symptoms. The next most common diagnosis was diseases of Musculoskeletal System and connective tissue (M00-M99) 24.8%, followed by Diseases of Skin and subcutaneous tissue 14.1% (L00-L99), Diseases of Nervous System (G00-G99) 8.5%, and Diseases of Circulatory System (I00-I99) 8.3%.

Table 1: Contribution of prescription by different outpatient departments

S. No.	Specialty	Percentage
1.	Orthopedics	21.1
2.	General medicine	18.5
3.	Dermatology	13.5
4.	ENT	9.9
5.	Neurology	7.9
6.	General surgery	5.8
7.	Cardiology	3.7

ENT: Ear, nose, and throat

Table 2: Category of drugs prescribed

System	Percentage
Miscellaneous	21.4
GIT	16.6
CVS	13.7
NSAIDs	13.5
Antimicrobial agents	10.5
CNS	6.8
Antihistamines	5.4
Hormones	4.3
ANS	2.4
Endocrine	2.4
Respiratory system	2.2
Immunosuppressants	0.8

CVS: Cardiovascular system, NSAIDs: Nonsteroidal anti-inflammatory drugs, GIT: Gastrointestinal, CNS: Central nervous system, ANS: Autonomic nervous system

Table 3: Diagnosis wise distribution of prescription

S. No.	ICD code	International Classification of Diseases	Percentage
1.	Q00-R99	Not elsewhere classified	25.5
2.	M00-M99	Diseases of musculoskeletal system and connective tissue	24.8
3.	L00-L99	Diseases of skin and subcutaneous tissue	14.1
4.	G00-G99	Diseases of nervous system	8.5
5.	I00-I99	Diseases of circulatory system	8.3
6.	J00-J99	Diseases of respiratory system	3.7
7.	E00-E90	Endocrine, nutritional and metabolic diseases	3.4
8.	N00-N99	Diseases of genitourinary system	3.1

ICD: International Classification of Diseases

Regarding number of drugs per prescription (Table 4) 28.7% prescriptions had three drugs, followed by 22.8% with four drugs and 20.9% with two drugs. There were 7-9 drugs per prescription in 5.6% prescription.

Most commonly prescribed drugs were (Table 5), Ranitidine, Diclofenac, Pantoprazole, Paracetamol, Aceclofenac, Atorvastatin, Cetirizine, Omeprazole, Aspirin, Calcium, B complex, Chlorpheniramine maleate, Gabapentin, Calcium+Vitamin D3, Clotrimazole, and Folic acid.

Total number of antibiotics prescribed was 253. The most commonly prescribed antibiotic was Amoxicillin+Clavulanic acid 1.3%.

The quality of the prescriptions was evaluated by assessing the prescription legibility which was graded on a subjective scale by two independent investigators. Prescriptions were graded as: Grade 1 (legible with ease), Grade 2 (legible with difficulty), and Grade 3 (illegible). 53% prescriptions were legible and 15% prescriptions were illegible. Review date was written in 81% prescriptions. Signature of doctor was present in majority of prescriptions (92%).

DISCUSSION

Quality of medical care is assessed by medical audit. The WHO core prescribing indicators measure performance of health-care provider's appropriateness in the use of medicines. It involves encounters observed from a group of patients attending clinics at the time of data collection from the population. It measures general prescribing tendencies within a given setting. Prescribing indicators are standardized and need no adaptation for any health-care setting. Hence, comparison can be done with ease [11].

In this study, a total of 1020 prescriptions were analyzed. About 49% prescriptions were of males and 54% of females. The most common dosage form prescribed was oral 87.4%. In a study by Kusum and Prakash [7] males formed the predominant population and oral dosage

form was prescribed mostly. About 56.7% were females in a study by Hemangini *et al.* [9]. In a study by Debasis *et al.* [11] 54% were males. Similar observation on dosage form as seen in this study was observed by Uday *et al.* [12], but 59.29% were females in the study.

The first prescribing indicator, average number of medicines per prescription was 3.5. The WHO proposes an optimal value to be <2 (Table 6). Polypharmacy was assessed by this prescribing indicator. In this study, there was an increase in encounter, which indirectly point that there is an imperfection in prescriber, population, and health-care system. It can also increase the incidence of Adverse Drug Reactions (ADRs) and drug- drug interactions. There are various studies conducted with similar objectives [2,13,14]. Mishra and Sharma [3], Igbiks and Joseph [4], Maryam and Shekar [5], Sneha *et al.* [6] and Kusum and Prakash [7] concluded that, average number of drugs per encounter was 4, 3.04, 4.02, 3.5, and 3.35, respectively. Number of prescriptions audited was 250, 497, 1274, 250, and 1012, respectively.

In studies done by Hemangini *et al.* [9], Debasis *et al.* [11], Uday *et al.* [12], Patil *et al.* [15], Anjan *et al.* [16], and Naveen *et al.* [17] number of prescriptions audited were 1035, 4180, 3587, 1050, 100, and 500, respectively. Average numbers of drugs per encounter were 4.47, 4.4, 3.11, 3.31, 2.9, and 2.25, respectively. As per review of the literature, in almost all studies average number of drugs per encounter was above 2, which is an indicator of polypharmacy.

Second prescribing indicator was percentage of medicines prescribed by generic name, which were 45%. Optimal value as per the WHO was 100 (Table 6). Low percentage of generic medications may mean that there is unavailability of medicines, lack of confidence in generic medicines or patients' preference for branded products [2,13,14]. In a studies conducted by Mishra and Sharma [3], Kusum and Prakash [7] and Igbiks and Joseph [4] medicines prescribed by generic names were 9%, 29.4%, and 42.7%. Maryam and Shekar [5] in her study reported that no medicines were prescribed by generic names. But in a study by Uday *et al.* [12] medicines prescribed by generic names were 96.88%, which was near to 100% as prescribed by the WHO. In studies conducted by Sneha *et al.* [6], Hemangini *et al.* [9], Debasis *et al.* [11], Patil *et al.* [15], Anjan *et al.* [16], and Naveen *et al.* [17], the medicines prescribed by generic names were 27.4%, 75.1%, 21%, 1.5%, 93%, and 7.98%, respectively. So as per the literature majority of studies concluded that percentage of generic names were below 100%.

Percentage of antibiotics per prescription was 7.37% (Table 6). It is in conformity with the WHO optimal value which should be <30%. This highlights the point that there is no indiscriminate use of antibiotics in our setting [2,13,14]. Percentage of antibiotics per prescription in studies by Mishra and Sharma [3] was 17.48%, Igbiks and Joseph [4] was 34.4%, Maryam and Shekar [5] was 39.01%, Sneha *et al.* [6] was 1.5%, Kusum and Prakash [7] was 27.01%, Hemangini *et al.* [9] was 26.76%, Debasis *et al.* [11] 29%, Uday *et al.* [12] was 21.61%, Patil *et al.* [15] was 45%, Anjan *et al.* [16] was 0.4%, and Naveen *et al.* [17] was 12.42%. Few studies were in conformity with our study that the percentage of antibiotics per prescription was <30%.

Percentage of injections per prescription was 4.8%, as per our study for which the optimal value proposed is <20% (Table 6). This prescribing indicator is also in compliance with the WHO proposed value. It may be because this audit was done in an outpatient setting, the injectables used were less [2,13,14]. In Igbiks and Joseph [4], study injections were prescribed in 4%. In studies by Maryam and Shekar [5], 7.54% prescriptions had injections. In studies by Kusum and Prakash [7], 0.97%, Hemangini *et al.* [9], 0.56%, Debasis *et al.* [11] 29%, and Uday *et al.* [12] 2.83% had prescriptions with injections. In studies by Patil *et al.* [15], Anjan *et al.* [16], and Naveen *et al.* [17], injections were prescribed in 4.8%, 0.05%, and 3.37% prescriptions. Except for one study, all other study results were similar to our study that the percentage of injections per prescription was <20%.

Table 4: Distribution of encounters by number of drugs prescribed per prescription

Number of drugs per prescription	Number and percentage of prescriptions having number of drugs Number (n=1020), n (%)
0	5 (0.5)
1	66 (6.5)
2	213 (20.9)
3	293 (28.7)
4	232 (22.8)
5	93 (9.1)
6	61 (6)
7-9	57 (5.6)

Table 5: Distributions of commonly prescribed drugs with anatomical therapeutic chemical code

Drug	Drug group	ATC code	Number	Percentage
Ranitidine	H2 blocker	A02BA	255	7.4
Diclofenac	NSAIDs	M01AB05	192	5.6
Pantoprazole	Proton pump Inhibitors	A02BC	139	4.1
Paracetamol	NSAIDs	N02BE01	119	3.5
Aceclofenac	NSAIDs	M01AB16	108	3.1
Atorvastatin	Hypolipidemic agent	C10AA05	103	3
Cetirizine	Antihistamine	R06AE07	103	3
Omeprazole	Proton pump Inhibitors	A02BC01	102	3

ATC code: Anatomical Therapeutic Chemical code

Percentage of medicines prescribed as per National Essential Medicine List was 3.2% and the WHO EDL was 2.6% (Table 6). As per the WHO recommendations, ideally all medicines prescribed should be from the Essential Medicine List; hence, optimal value for the indicator is 100%. Lack of knowledge of Essential Medicine List and its role in cost effectiveness optimization may be the reason why the percentage was low. The outpatient radiotherapy department was not included in the study because in our setting it was a separate block. Medicines prescribed generically as well as per Essential Medicine List, throw light on the compliance with the prescribing regulations [13-15]. In the literature search, percentage of medicines prescribed as per the WHO Essential Medicine List in studies by Mishra and Sharma [3] was 53.25 %, Igbiks and Joseph [4] was 94 %, Maryam and Shekar [5] was 79.2%, Kusum and Prakash [7] was 100%, Hemangini *et al.* [9] was 64.83 %, Debasis *et al.* [11] was 60.99 %, Uday *et al.* [12] was 100%, Patil *et al.* [15] was 52.3%, Anjan *et al.* [16] was 90%, and Naveen *et al.* [17] was 97.07%. When comparing our study result with the existing data results, percentage of medicines prescribed as per Essential Medicine List was low.

Regarding percentage of FDCs, the results calculated as per our study was 6.5%, based on Essential Medicine Lists. Percentage of FDCs as per studies by Kusum and Prakash [7], Hemangini *et al.* [9], and Uday *et al.* [12] was 10.05%, 11.72%, and 33.43%, respectively.

The prescriptions audited in outpatient departments included around 20 departments (Table 1) in which majority of the prescriptions were from orthopedics department (21.1%), followed by General Medicine (18.5%), Dermatology (13.5%), and ENT (9.9%). In studies by Kusum and Prakash [7], Debasis *et al.* [11], and Uday *et al.* [12], general medicine formed the main department with 49.21%, 45.4%, and 34.54% prescriptions, respectively.

The most commonly prescribed group of drugs (Table 2) were miscellaneous group of drugs (21.4%) such as vitamins, minerals supplements, and drugs modulating musculoskeletal system. This was followed by drugs acting on gastrointestinal system (16.6%), drugs acting on cardiovascular system (13.7%), NSAIDs (13.5%), and antimicrobial agents (10.5%). The major group of drugs in various studies are; Kusum and Prakash [7] Antibiotics (27.01%), Hemangini *et al.* [9] Multivitamins (29.75%), Uday *et al.* [12] Nutritional supplements (25.83%), Patil *et al.* [15] drugs acting on GIT (20%), Debasis *et al.* [11], and Shahid *et al.* [18] antimicrobials, 28.9% and 20.87%, respectively.

The most common diagnosis was Q00-R99 as per, ICD 25.5% (Table 3), which includes not elsewhere classified diseases. As per the study since it was an audit done in outpatient setting, it included patients who presented with non-specific symptoms. The next most common diagnosis was diseases of Musculoskeletal System and connective tissue (M00-M99) 24.8%, followed by Diseases of Skin and subcutaneous tissue 14.1% (L00-L99), Diseases of Nervous System (G00-G99) 8.5%, and Diseases of Circulatory System (I00-I99) 8.3%. As per Debasis *et al.* [11], diseases of digestive system K00-K99 (12.33%) were the most common diagnosis as per, ICD.

The most commonly prescribed drug was ranitidine (7.4%) as per our study. Most commonly prescribed drug was NSAIDs by Mishra and Sharma [3], analgesics as per Igbiks and Joseph [4], antibiotics by Kusum and Prakash [7] and Debasis *et al.* [11], multivitamin by Hemangini *et al.* [9] and Naveen *et al.* [17], nutritional supplements by Uday *et al.* [12], and drugs acting on gastrointestinal system by Patil *et al.* [15].

Total number of antibiotics prescribed was 253. The most commonly prescribed antibiotic was Amoxicillin+Clavulanic acid 1.3%. In studies by Shahid *et al.* [18] 55% and Bekele *et al.* [19] 19.44%, Amoxicillin+Clavulanic acid formed the most commonly prescribed antibiotic. As per studies by Debasis *et al.* [11], fluoroquinolone (7.8 %) and Patil *et al.* [15] ceftriaxone (28.9%) were the most commonly prescribed antibiotic.

Table 6: Comparison of the World Health Organization core drug use prescribing indicators

Prescribing indicators	Optimal values	Values obtained in the audit
Average number of medicines per prescription	<2	3.5
Percentage of medicines prescribed by generic name	100%	45%
Percentage of antibiotics per prescription	<30%	7.37%
Percentage of injections per prescription	<20%	4.8%
Percentage of medicines prescribed from the essential drugs list	100%	a. NATIONAL - 3.2% b. WHO - 2.6%

WHO: World Health Organization

Regarding number of drugs per prescription (Table 4) 28.7% prescriptions had three drugs, followed by 22.8% with four drugs and 20.9% with two drugs. There were 7-9 drugs per prescription in 5.6% prescription. In studies by Kusum and Prakash [7], number of drugs per prescription was three similar to the results of this study. In studies by Hemangini *et al.* [9], Debasis *et al.* [11], and Uday *et al.* [12], number of drugs per prescription were four, which show that polypharmacy is noted in majority of the studies.

The quality of the prescriptions was evaluated by assessing the prescription legibility. About 53% prescriptions were legible and 15% prescriptions were illegible. Signature of doctor was present in majority of prescriptions (92%) and review date was written in 81% prescriptions. The results were similar to study by Patil *et al.* [15] where 53.7% prescriptions were legible. In a study by Hemangini *et al.* [9] also 53.7% prescriptions were legible. Signature of doctor was missing in 75.7% and follow-up visit was not mentioned in 85.79%. In a study by Debasis *et al.* [11] follow-up advice was not mentioned in 97.87%. Bekele and Tadesse [19] reported that around 3% prescriptions were illegible and signature of doctor was present in 93.54% prescriptions.

Limitation

Radiotherapy department was a separate block; hence, audit was not conducted in the radiotherapy outpatient department in the study.

CONCLUSION

As per this study, it was evident that polypharmacy was present as indicated by the average number of medicines prescribed. Medicines prescribed by generic name and essential medicine list were low. Antibiotics and injections prescribed was in conformity with the WHO recommended values, which means that there was no irrational use of antibiotics and unwanted use of injectables in the outpatient department. Percentage of FDCs was 6.5%, and most commonly prescribed drug was Ranitidine as per our study. Hence, as per this study, prescribers did not follow prescribing core indicators of the WHO closely, except for two indicators. The quality of prescriptions with respect to legibility and clarity was found to be optimal.

The present study can be taken as a framework on which further studies can be launched to investigate the scope for educational intervention and improvement in prescribing pattern. The prevalence of morbidity and prescription data may help the health administration to take necessary interventions. Audit process should be a continual cycle.

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AUTHORS' CONTRIBUTION

Dr. Dhanya. T. H – Protocol preparation, data collection, data analysis, manuscript preparation, editing, review, and correspondence. Dr. Sanalkumar K. B – Protocol preparation, data collection, manuscript preparation, editing, and review. Dr. M.A Andrews – Protocol preparation, manuscript preparation, editing, and review.

CONFLICTS OF INTEREST

Nil by Authors.

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