

Journal of Pharmaceutical Advanced Research**(An International Multidisciplinary Peer Review Open Access monthly Journal)**Available online at: www.jpardonline.com**A prospective study of drug utilization pattern and evaluation using WHO guidelines and indicators in a selected rural Health care Hospital****M. Arumugavignesh**

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ABSTRACT: Background: In recent decades of drug explosion era, modern medicine has been blessed with much more powerful armamentarium, but yet rational use of drugs in various walks of medical field is still a dream. Promotion of a more stringent rational drug use practice in India is much warranted. **Aim:** The main objective of this study was to evaluate the patterns of drug prescribing using WHO core drug use and complementary indicators. **Methods:** About 282 inpatients were randomly and prospectively interviewed and their prescriptions were scrutinized for Pharmacoepidemiological variances in comparisons with the WHO guidelines. Case sheets were randomly evaluated from Government Headquarters Hospital, Virudhunagar, TamilNadu. A separate data collection form was used to evaluate the WHO core drug use and complimentary indicators. The result deliberate from our data is based on the pattern of drug utilization measured using the WHO's prescribing indicators. **Results:** The present study revealed that out of total drugs prescribed (1654), the mean number of drugs per encounter was 3.7. Use of antibiotics was 22 %, percentage of encounters with injection was 7.2 %, and the percentage of drugs prescribed from formulary was 99.8 %. **Conclusions:** In India, healthcare is dominated by private practitioners at the primary level. Prescription practices of the individual community-based clinician needs consistent monitoring with respect to generic name prescribing habits. The data collected by this study can be helpful to policymakers to monitor and improve the prescribing pattern and drug use in Southern India.

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INTRODUCTION:

Drug utilization study is described by the World Health Organization (WHO) as the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the medical, social and economic consequences^[1]. The main aim of drug utilization study in patients is to provide rational use of medicines among public populations^[2]. Drug Use evaluation is defined as the authorized structured, ongoing review of physician prescribing, pharmacist dispensing and patient use of medication. Drug Use evaluation is an ongoing,

systematic process designed to maintain the appropriate and effective use of drugs^[3]. Prescribing too much of drugs can result in polypharmacy issues, drug-drug interactions and adverse drug events^[4]. Hence our study aims to evaluate various issues using WHO prescribing indicators^[5]. These prescribing indicators are used to measure the performance of healthcare providers in several key dimensions related to appropriate use of drugs. Prescribing indicators are recommended by the WHO in order to enhance the quality of performance in prescribing medicines as appropriate to an individual's need^[6]. It has not been an empirical determination but with proposed significance in various clinical conditions in different settings. In particular, indicators such as drugs per prescription, drugs in generics, injectables and antibiotics usage might be influencing various other clinical parameters. Yet this study has to be expanded in different dimensions to enhance the rational use of medications

MATERIALS AND METHODS:

Study design:

This prospective longitudinal observational study was carried out in the Rural Health Care Hospital, Virudhunagar, Tamilnadu. The study was conducted between January 2018 and January 2019. Data collected from case sheets of patients from different departments of the Rural Health Care Hospital during the above mentioned period were documented properly.

Data collection:

The data collected from the case sheets includes age, gender and economic status of the patients, provisional diagnosis, final diagnosis, various laboratory parameters like, serum creatinine, urea, and hemoglobin levels, dose, dosage and frequency of prescribed drugs etc. The samples were collected by systematic random sampling method.

Ethical clearance:

The institutional human ethical committee was approved by the member secretary, Human ethical committee, Government headquarters hospital, Virudhunagar district, Tamilnadu, for permitting us to perform this study and the reference number for which the ethical certificate is given as R.No 110 / HS / GHQH - VNR / SEP 2019.

Prescribing indicators measurement:

The WHO prescribing indicators like average number of drugs per prescription, average number of antibiotics per

prescription, percentage of drugs prescribed in generic name, percentage of drugs prescribed as injections were pre tested. The tests were done using the formulas given by WHO in their prescription indicators manual^[7].

Patient care indicators measurement:

Patient care indicators include average consultation time, average dispensing time, percentage of drugs actually dispensed, patients' knowledge about correct dosage^[8]. Among these tests, average consultation time of physicians in the inpatient setting was measured. The consultation time was divided into three categories as follows; less than 5 min, 5 to 10 min and above 10 min. The longer consultation time has been linked to better healthcare outcomes.

Health facility indicators measurement:

It is the measurement of ability to prescribe drugs rationally^[9]. Compliance of (key) drugs prescribed were compared with that of essential drugs list of WHO or formulary and analyzed. The key drugs selected were oral rehydration salts, cotrimaxazole tablets, procaine penicillin injection, pediatric paracetamol tablets, chloroquine tablets, ferrous sulfate + folic acid tablets, mebendazole tablets, tetracycline eye ointment, iodine, gentian violet or local alternative, benzoic acid + salicylic acid ointment, paracetamol tablets for adults, retinol^[10]. These key drugs were selected according to the WHO's model list of key drugs for testing drug availability^[11].

Data analysis:

All the sources of data were collected from inpatient case sheets of health care hospitals and were segregated. Then the data were analyzed using Microsoft Excel 2007. The observed values of indicators were reported as means and proportions. About 282 prescriptions in 282 case sheets were analyzed.

RESULTS AND DISCUSSIONS:

Out of 282 patient encounters, 119 (42.2 %) were females and 163 (57.8 %) were males. This includes both male and female children. The average age of patients is 39.5 years. These socio-demographic features are represented in Table 1. As far as the prescription indicators are considered, the average number of drugs per prescription is 6. The total number of drugs in 282 prescriptions was found to be 1654. These calculations were carried out using MS Excel 2007. The average number of antibiotics per prescription is 1, whereas the percentage of patients encountered with at

least 1 antibiotic was found to be 75.53 %. The total number of antibiotics in 282 prescriptions was found to be 288. It was observed that 11 different antibiotics were prescribed randomly in a total of 282 prescriptions.

Table 1. Socio demographic details of study population.

Characteristics	Frequency (N)	%
Age (Years)		
Below 5	19	6.73
6 – 15	30	10.63
16 – 25	30	10.63
26- 35	35	12.41
36 – 45	45	15.95
46 – 55	50	17.73
56 – 65	40	14.18
66 – 75	28	9.92
Above 75	5	1.82
Gender		
Female	119	42.2
Male	163	57.8

Among them, cefotaxime was more frequently prescribed i.e. 118 times (40.972 %) followed by ampicillin, prescribed 47 times (16.319 %). Garamycin was the least prescribed. The antibiotics' prescription pattern is mentioned in Table 2.

Table 2. Different antibiotics' prescription pattern.

Name of Antibiotic	Frequency of Prescription	%
Cefotaxime	118	40.9
Ampicillin	47	16.3
Ceftriaxone	31	10.7
Ciprofloxacin	27	9.4
Gentamicin	23	7.9
Amoxicillin	14	4.8
Amikacin	13	4.5
Doxycycline	7	2.4
Cloxacillin	5	1.7
Cefixime	2	0.6
Garamycin	1	0.3
Total	288	--

The results were comparable with that of studies carried out at the pediatric wards of Bishoftu hospital, East Ethiopia, where Ceftriaxone accounted for 73 (43.50 %) followed by gentamicin 43 (25.60 %) out of 120 prescriptions^[12]. The percentage of patients encountered with at least one analgesic was found to be 23.4 %. Since the data was collected from government hospitals, almost all drugs were prescribed in generic names.

Among analgesics, tramadol (used in 15 patients, 18.75 %), diclofenac (used in 13 patients, 4.25 %), dexamethasone (used in 11 patients, 3.9 %), ibuprofen (used in 9 patients) and pentazocine (used in 7 patients) were used. The prescription indicators measured according to WHO guidelines are represented in Table 3. Analgesics' prescribing pattern is represented in Table 4 and 5.

Table 3. Analysis of Prescription using prescription indicators.

Prescribing indicators	Total number of prescriptions (N=282)	%
Number of drugs per prescription		
1	2	0.70
2	7	2.48
3	15	5.31
4	51	18.08
5	57	20.21
>5	150	53.19
Number of antibiotics/prescription		
Nil	70	24.82
1	151	53.54
2	48	17.02
3	10	3.54
>3	3	1.06

Table 4. Prescribing pattern of Analgesics with their frequency in prescriptions.

Name of analgesic	No. of times prescribed=X	%
Antispasmodic		
Dicyclomine	24	30
Opioids		
Tramadol	15	18.75
Pentazocine	7	8.75
NSAIDs		
Diclofenac	13	16.25
Ibuprofen	10	12.5
Corticosteroids		
Dexamethasone	11	13.75
	80	100

It is analogous to the study that was conducted at Federal Medical Centre, Lokoja; a tertiary health care and a major referral centre in Kogi State of Nigeria. In that study carried out in Nigeria, 624 prescriptions were analyzed out of which 784 analgesics were prescribed. The number of analgesics encountered per prescription was only one with a frequency of 479 (76.8 %) while 130 (20.8 %) prescriptions had two prescribed analgesics and only 15 (2.4 %) of the prescriptions had

three analgesics per prescription. A total of 16 different analgesics were prescribed throughout the period of their study.

Table 5. Prescription pattern of analgesics.

Prescription	Frequency	%
No. of prescriptions with 3 analgesics	1	0.355
No. of prescriptions with 2 analgesics	12	4.255
No. of prescriptions with only 1 analgesic	53	18.794
No. of prescriptions with at least 1 analgesic	66	23.4
No. of prescriptions with no analgesics	216	76.596

Close to half (46.6 %) of the prescribed analgesics was Paracetamol. One hundred and twenty nine i.e. (16.5 %) of the prescribed analgesics was Diclofenac and 95 (12.1 %) was Ibuprofen^[13]. Majority of prescriptions (73.40 %) were prescribed with five and more than five drugs indicating polypharmacy^[14]. In overall prescription antibiotics were not at all prescribed for 24.82 % of patients who were suffering from non infectious diseases and fever. This clearly indicates that antibiotics are only prescribed wherever required. Among patients prescribed with antibiotics, the majority (53.54 %) of prescriptions contain single antibiotic therapy, followed by dual therapy (17 %). For the measurement of health facility indicators, we selected availability of key drugs. Out of 12 key drugs; oral rehydration salts, pediatric paracetamol tablets, ferrous sulfate + folic acid tablets, iodine, benzoic acid + salicylic acid ointment, paracetamol tablets for adults were either mentioned in the prescription or seen during dispensing. Hence out of 12 key drugs, 6 (50 %) drugs were available with the hospital. The major complaints for admission include; fever 25 cases, (8.86 %), abdominal pain 20 cases (7 %) followed by 13 cases of cough (4.6 %) and 13 patients with inflammation (4.6 %). The other indications include diabetic foot cellulitis (3.9 %), pain (3.54 %), chronic kidney disease (2.83 %) etc. The prevalence of disease related data is furnished in Table 6. Patients show the general illness like cough, fever, and diarrhea are commonly occurring diseases, especially in pediatric patients below 12 years of age. Anemia has affected patients irrespective of age group^[15]. In our findings patients suffering from Chronic Kidney Diseases (CKD) increase with age and are found commonly among patients above 40 years of age. UTI cases were more

prevalent among adult females^[16]. COPD and breathlessness cases were found frequently (4.95 %).

Table 6. Prevalence of diseases among study population.

Indications	Frequency (N = 282)	Percentage (%)
Fever	25	8.86
Abdominal pain	20	7.09
Cough	13	4.60
Inflammation in various parts	13	4.60
Cellulitis	11	3.90
Pain	10	3.54
Chronic kidney disease	8	2.83
Chest pain	8	2.83
Breathlessness	8	2.83
Type 2 diabetes mellitus	8	2.83
Acute diarrhea	7	2.48
Giddiness for evaluation	7	2.48
Vomiting	6	2.12
Anemia	5	1.77
Poisoning	5	1.77
Gastritis	5	1.77
COPD	4	1.41
Febrile seizures	7	2.48
Schizophrenia	4	1.41
Sleeplessness	4	1.41
Hemi paralysis	3	1.06
Viral fever	2	0.70
Enteric fever	2	0.70
Hernia	4	1.41
Asthma	3	1.06
Ludwig Angina	2	0.70
Coronary Artery Disease	2	0.70
Bronchopneumonia	2	0.70
Dyspnoea	2	0.70
Breast cancer	2	0.70
Blurred vision	1	0.35
Other problems	79	28.0

Majority of the Cardiovascular patients were geriatric patients. Emergency cases like accident and poison patients in the casualty encountered with lesser consultation time when compared with other general illnesses. Prescribers spent more consultation time with patients suffering from chronic illness and for Pregnancy and Geriatric patients^[17]. These complementary indicators are listed in Table 7.

Table 7. Assessment of prescription pattern using complementary indicators.

Patient care indicators	Total number of prescriptions (N = 282)	%
Consultation time in minutes		
0 – 5	82	29.07
6 -10	124	43.97
11- 15	76	26.95

Poly pharmacy leads to decrease in medication adherence among patients. Medications should be assessed for benefit-risk ratio and the final combination of medications should be based on benefits outweighing the risks [18]. About 53.54 % of prescriptions contain at least one antibiotic. Rational use of antibiotics should be promoted because WHO warns frequently about the development of antibiotic resistance and about the formation of superbugs. Antibiotics should not be used empirically for more than three days. Physicians should use sensitivity testing to determine the appropriate antibiotic treatment for an infection and to monitor changes in bacterial resistance to antibiotics.

The most commonly used antibiotics were cefotaxime, ampicillin, amikacin, ciprofloxacin, gentamicin, amoxicillin, ceftriaxone. The least commonly used antibiotics were azithromycin, doxycycline, garamycin and cloxacilin. Except garamycin, all the other prescribed antibiotics are in WHO’s Essential Drug List. Amikacin and gentamicin are most frequently used in pediatric wards for infections like fever, bronchitis and bronchiolitis but these antibiotics are not the first line drug of choice. Ciprofloxacin is most commonly prescribed to treat urinary tract infections in adult females. Ceftriaxone and cefotaxime were most commonly used to treat diabetic foot ulcers in adults.

Cefotaxime is used for different illnesses like diabetic foot ulcer, urinary tract infections, alcoholic gastritis, simple febrile seizures etc whereas ciprofloxacin is most frequently used to treat urinary tract infections. Antibiotics with broad-spectrum activity were most frequently prescribed. However, patients admitted to hospital are often severely ill and need immediate antibiotic therapy. Thus antibiotic therapy to treat a broad spectrum of bacteria is usually commenced as empirical treatment [19]. Once the antibiogram is available, the treatment is focused to eliminate the specific bacteria identified for a specific patient. The pattern of antibiotics’ usage is enlisted in Table 8.

Table 8. Pattern of Antibiotics’ usage as per the category.

Category (Years)	NOP	NOD	NOPs	PP (%)	NOA
Pediatrics (0-12)	46	251	31	67.39	43
Adults (13-59)	194	1151	140	72.16	184
Geriatrics (>60)	42	244	34	80.95	45

NOPs – Number of prescription (5 or more), NOP – Number of patient, NOD – Number of drugs, NOA – Number of antibiotics and PP – Polypharmacy.

Polypharmacy among geriatric patients is 80.95 %. Moreover among adult patients, 72.16 % were having polypharmacy issues. Polypharmacy issues are more associated with patients suffering from multiple comorbid diseases, chronic illness and increases with incremental age, especially geriatric patients. The drug utilization pattern among geriatrics is mentioned in Table 9. The Polypharmacy among pediatrics is 31/46= 67.39 %. The drug utilization pattern among pediatrics is mentioned in Table 10.

Table 9. Drug Utilization pattern among Geriatric patients.

Age group	NOP	NOD	ANOD	NOA	ANOA
60-65	18	109	6.05	21	1.17
66-70	12	71	5.91	11	0.92
71-75	5	27	5.4	5	1
76-80	4	15	3.75	3	0.75
>80	2	15	7.5	5	2.5
60-87	42	237	--	40	--

NOP – Number of patient, NOD – Number of drugs, NOA – Number of antibiotics, ANOD - Average no. of drugs and ANOA – Average no. of Antibiotics.

Out of five analgesics used, two belong to NSAID class and two were from the opiates category. Prolonged use of NSAID in older patients increases the risk of Gastrointestinal (GI) bleeding and NSAIDs also increase the rate of mortality due to NSAIDs induced peptic ulcer as reported in the USA [20]. Nurses and pharmacists should closely monitor the drug utilization of opioid analgesics as opioids are prone to possess a serious threat for substance abuse [21]. Opioid analgesia is indicated for the management of pain in patients where an opioid analgesic is used with professional consent. Center for Disease Control and Prevention's 2016 guidelines for prescribing opioids especially in chronic

pain emphasize that clinicians should consider opioid therapy only if expected benefits for both pain and benefits are anticipated to outweigh risks to the patient.

Table 10. Drug Utilization pattern among Pediatric patients.

Age in years	Age (Months)	NOP	NOD	NOA
0 to 1	0 to 12	4	24	0
1 to 2	13m to 24	4	19	0
2 to 3	25m to 36	3	26	2
3 to 4	37m to 48	4	46	2
4 to 5	49m to 60	3	18	2
5 to 6	61m to 72	6	40	3
6 to 7	73m to 84	0	0	0
7 to 8	85m to 96	4	20	6
8 to 9	97 m to 108	2	10	8
9 to 10	109m to 120	7	24	6
10 to 11	121m to 132	4	11	7
11 to 12	133 m to 144	5	13	7
Total	--	46	251	43

NOP – Number of patient, NOD – Number of drugs and NOA – Number of antibiotics.

If opioids are used, they should be used scrupulously. The Center for Disease Control and Prevention's 2016 guidelines defines the indication of opioid use for acute pain, stating that when opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should not prescribe greater quantity than needed for more than expected duration of pain severe enough to require opioids. Opioids are often sufficient to be prescribed for three days or less and rarely prescribed for seven days or more.

CONCLUSION:

The current study demonstrates that prescribing indicators have shown slight deviation than that of expected norms as per WHO indicators. Slight deviation/variation from WHO indicators might be due to various other clinical reasons, co morbid diseases and depends on professional decisions taken by physicians. An established Standard therapeutic guideline should be followed for the treatment of every disease. This study indicates that polypharmacy issues cannot be addressed until or unless the therapeutic guidelines are strictly followed by the physicians. There is a mandatory need to improve prescribing patterns, utilization of dispensed drugs, judicious use of antibiotics and analgesics and

availability of essential guidelines and key drugs in the stock. Data gathered by this study can be used by researchers and policymakers to monitor and improve pharmaceutical prescribing patterns and consumption practices in the southern part of Tamilnadu. It would be also conducive for further Pharmacoepidemiological studies.

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