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Assessment of Antibiotics Use in Respiratory Tract Infections in Accordance with WHO Core Indicators in a Tertiary Care Hospital in India



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**K.ASOK KUMAR^{*1}, SHREYA ROSE ABRAHAM¹,
SUBHASHINI P.A¹, SUJITH KURIAN¹, SUMAN
RAVI¹, MOHANKUMAR THEKKINKATTIL²**

**1Department of Pharmacology, Sri Ramakrishna
Institute of Paramedical Sciences - College of
Pharmacy, Coimbatore-641044, Tamil Nadu, India*

*1 Doctor of Pharmacy, Sri Ramakrishna Institute of
Paramedical Sciences - College of Pharmacy,
Coimbatore-641044, Tamil Nadu, India*

*2 Consultant Pulmonologist, Sri Ramakrishna Hospital,
Coimbatore-641044, Tamil Nadu, India*

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ABSTRACT

The Respiratory tract infection is the one of the most common public health problem dealt with in healthcare. Inappropriate use of antibiotics specifically broad-spectrum antibiotics results in antibiotic resistance. The objective of this study is to use WHO core indicators:- to assess antibiotics prescribing practice of prescribers, to evaluate the hospital service facilities, to determine compliance rates of physicians to generics and to estimate the level of adherence in prescribing from (NEML). A Prospective observational study conducted in the outpatient department of General Medicine and Pulmonology for a 6-month period. Out of 100 cases analyzed, most patients had LRTI+AEBA and Pharyngitis. Cefixime was the most commonly prescribed antibiotic. The average number of drugs prescribed (4.65), the percentage of generic prescribing (0%), the percentage of antibiotic prescribed (100%), and percentage of drugs from NEML (51.86%) deviated from standards. The average consultation time was 7.5 minutes and average dispensing time was 4.2 minutes. Percentage of drugs actually dispensed (99%), the percentage of patients having knowledge on correct dosage (27%), and only 33% of the patients were aware of antibiotics. The copy of EDL was available in the health facility and (90.47%) of key essential drugs were present. Only a few patients (33%) were aware of antibiotics. Selecting antibiotics without culture sensitivity testing in outpatients also pave the path for development of resistance. Illegible prescribing practice and improper labeling practice can lead to medication errors and thus previously addressed problems require interventions to improve patient care and rationality.



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INTRODUCTION

One of the most pressing problems faced by public health providers and administrators in many countries is the rational use of drugs. From various studies conducted across developing as well as in developed countries regarding the safe and effective use of drugs shown that irrational drug use has become a global phenomenon that should be dealt seriously. Development of microbial resistance to antibiotics is inevitable. Overuse, underuse and unnecessary use of antibiotics often result in the development of resistance towards antibiotics. The appropriate use of antibiotics delays the development of drug resistance by microorganisms¹.

The respiratory tract has an elaborate system of host defenses, including humoral immunity, cellular immunity, and anatomic mechanisms. When functioning properly, the host defenses of the respiratory tract are markedly effective in protecting against pathogen invasion and removing potentially infectious agents from the lungs².

Lower respiratory tract infections in children and adults most commonly result from either viral or bacterial invasion of lung parenchyma. They are bronchitis – acute and chronic bronchiolitis, pneumonia. Viruses commonly cause URIs, but distinguishing patients with primary viral infection from those with primary bacterial infection is difficult. Signs and symptoms of bacterial and viral URIs are, in fact, indistinguishable. Because routine, rapid testing is neither available nor practical for most syndromes, acute infections are diagnosed largely on clinical grounds. This situation makes the judicious use of antibiotics in this setting challenging. This includes common cold, sinusitis, pharyngitis, otitis media, laryngitis³.

The World Health Organization (WHO) suggests a set of drug use indicators that have proven useful in the investigation of drug prescribing patterns in healthcare facilities. The WHO defined rational antibiotic use as the rational use of antibiotics requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community. Drug use indicators were developed to be used as measures of performance in three general areas related to the rational use of drugs and the areas include:

1. Prescribing practices by health providers.
2. Patient care, covering both clinical consultation and pharmaceutical dispensing.

3. Facility specific factors, which support rational use⁴.

Antibiotics are a group of medicines used to treat infections caused by germs (bacteria and certain parasites). A parasite is a type of germ that needs to live on or in another living being (host). Antimicrobial cycling is a predetermined change in an antimicrobial recommendation for empirical therapy of a specific infection at a predetermined time. It also has been called rotation of antimicrobials. Antimicrobial cycling is employed as a mechanism to reduce or prevent antimicrobial resistance. In selecting a drug regimen for a given patient, consideration must be given to the necessity of using more than one drug. Combinations of antimicrobials generally are used to broaden the spectrum of coverage for empirical therapy, achieve synergistic activity against the infecting organism, and prevent the emergence of resistance².

The central government has amended rules in Indian medical council regulations 2002, directing to prescribe drugs with generic names in legible and capital letters. Fear of misinterpretation due to doctor's illegible handwriting may soon be a thing of past as government is set to make it a norm for the physician to prescribe the drugs generic and capital letters. The union health ministry came out with gazette notification under MCI regulation, which mandates doctors to prescribe the generic drugs in capital letter. Under this, the prescription should be legible and preferably written in capital letters along with the name of the generic drug prescribed. This will decrease prescription errors and patient able to know whether the drug is generic or not. In the month of June 2015, the rule has come out without disturbing the system of practice. Therefore, we planned to assess prospectively the practice of the use of the generic name and other WHO prescribing parameters and tried to find out reasons regarding the irrational trends drug utilization evaluation⁵. Therefore, the objective of this study is to assess the patterns of antibiotic use by WHO core indicators in respiratory tract infections in a tertiary care hospital in Tamilnadu prospectively.

The aim of present study was to assess antibiotic prescribing pattern, determine compliance rate of physicians to generics, to estimate the level of adherence in prescribing compared to national essential medicine list, to evaluate the hospital service facilities.

MATERIALS AND METHODS

A prospective observational study was carried out in Departments of General Medicine & Pulmonology of a 750 bedded multi-specialty tertiary care hospital in Tamilnadu for 6

months period from. The Institutional review board approved the study protocol. Patients with respiratory tract infections were identified based on laboratory data and clinical evaluation. Structured pro forma were used to collect various clinical and demographic details of the patient such as age, gender, allergic history, family history, primary diagnosis, antibiotic sensitivity test. Consent was obtained from each subject before initiating the study. The prescriptions were analyzed for the date, superscript, patient details such as age and name, legibility, prescribing in capital letters, prescribers name and sign. Treatment data including prescribed drugs, dosages, frequency and route of administration were recorded on indicator form and analyzed for adherence to prescribing indicators. The data for patient care indicators and facility indicators were collected from study departments and pharmacy and then the data were analyzed. The data obtained were compared with the WHO standards and the percentage of deviation was obtained. The calculation of various WHO indicators include:

TABLE 1: PRESCRIBING INDICATORS⁴

PRESCRIBING INDICATORS	PURPOSE	CALCULATION
Average number of drugs per encounter	To measure the degree of polypharmacy.	Dividing the total number of different drug products prescribed, by the number of encounters surveyed.
Percentage of drugs prescribed by generic name	To measure the tendency to prescribe by generic name.	Dividing the number of drugs prescribed by generic name by the total number of drugs prescribed, multiplied by 100.
Percentage of encounters with an antibiotic prescribed	To measure the overall level of use of two important, but commonly overused and costly forms of drug therapy	Dividing the number of patient encounters with an antibiotic prescribed by the total number of encounters surveyed, multiplied by 100.
Percentage of encounters with an injection prescribed	To measure the overall level of use of two important, but commonly overused and costly forms of drug therapy.	Dividing the number of patient encounters during which an injection are prescribed, by the total number of encounters surveyed, multiplied by 100.
Percentage of drugs prescribed from essential drugs list or formulary	To measure the degree to which practices conform to a national drug policy, as indicated by prescribing from the national essential drugs list or formulary for the type of facility surveyed.	Dividing the number of products prescribed which are listed on the essential drugs list or local formulary (or which are equivalent to drugs on the list) by the total number of products prescribed, multiplied by 100.

TABLE 2: PATIENT CARE INDICATORS⁴

PATIENT CARE INDICATORS	PURPOSE	CALCULATION
Average consultation time	To measure the time that medical personnel spend with patients in the process of consultation and prescribing.	Dividing the total time for a series of consultations, by the number of consultations
Average dispensing time	To measure the average time that personnel dispensing drugs spend with patients.	Dividing the total time for dispensing drugs to a series of patients, by the number of encounters.
Percentage of drugs actually dispensed	To measure the degree to which health facilities are able to provide the drugs which were prescribed.	Dividing the number of drugs actually dispensed at the health facility by the total number of drugs prescribed, multiplied by 100
Percentage of drugs adequately labeled	To measure the degree to which dispensers record essential information on the drug packages they dispense.	Dividing the number of drug packages containing at least patient name, drug name and when the total number of drug packages dispensed should take the drug multiplied by 100.
Patients' knowledge of correct dosage	To measure the effectiveness of the information given to patients on the dosage schedule of the drugs they receive.	Dividing the number of patients who can adequately report the dosage schedule for all drugs, by the total number of patients interviewed, multiplied by 100.

TABLE 3: FACILITY CARE INDICATORS⁴

FACILITY CARE INDICATORS	PURPOSE	CALCULATION
Availability of copy of essential drugs list or formulary	To indicate the extent to which copies of the national essential drugs list or local formulary are available at health facilities.	Yes or no, per facility.
Availability of key drugs	To measure the availability at health facilities of key drugs recommended for the treatment of some common health problems.	Percentage, calculated by dividing the number of specified products actually in stock by the total number of drugs on the checklist, multiplied by 100.

Data were analyzed and presented as percentage, mean and standard deviation. An analysis was done in Excel version 7.

RESULTS

In this study, 100 prescriptions, were included out of which 44% were females and 56% were males. Age categorization of the study population was done (Table 10). Most of the patients were in the age group of 36 to 50 years(43%) and followed by 51 to 65 years(31%) was plotted (Figure 1)

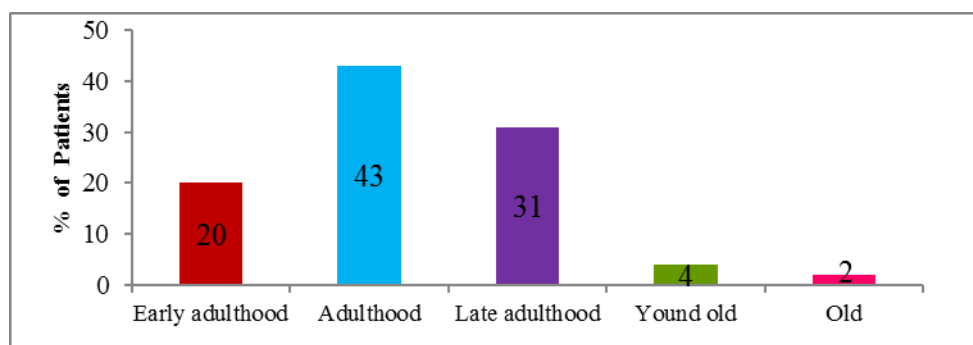


FIGURE 1: AGE DISTRIBUTION OF THE STUDY POPULATION

DISTRIBUTION OF PATIENTS WITH RTI

The study population visited study site during the study period for various reasons illustrated in Table 4.

TABLE 4: DISTRIBUTION OF PATIENTS WITH RTI

DIAGNOSIS	NUMBER OF PATIENTS (N=100)	PERCENTAGE (%)
Pharyngitis	15	15
Pneumonia	13	13
LRTI+AECOPD	10	10
LRTI+AEBA	17	17
LRTI+Gastritis	1	1
LRTI+BA	3	3
Sinusitis	5	5
Common Cold	4	4
Acute Bronchitis	8	8
LRTI+Chronic Bronchitis	10	10
LRTI+BE	13	13

The number of antibiotic prescribed for the study population was calculated (Table 5) and categorized. The categorizations were based on monotherapy, dual therapy, and triple

therapy. One antibiotic was prescribed to 86 patients, two antibiotics for 18 patients and three antibiotics for 2 patients shown in figure 2, 3& 4 respectively.

TABLE 5: PRESCRIBING PATTERN OF ANTIBIOTICS IN RTI

Sr. No.	ANTIBIOTICS	NUMBER	PERCENTAGE (%)
1	Azithromycin	7	6
2	Amoxicillin+ clavulanic acid	8	7.6
3	Cefixime	26	24.76
4	Clarithromycin	2	1.9
5	Clindamycin	2	1.9
6	Ciprofloxacin	1	0.9
7	Cefpodoxime	1	0.9
8	Cefixime+ azithromycin	1	0.9
9	Cepodoxime+azithromycin	8	7.6
10	Cefpodoxime+clavulanic acid	1	0.9
11	Doxycycline	17	16.19
12	Faropenem	25	23.80
13	Levofloxacin	1	0.9
14	Ofloxacin	5	4.7
	Total	105	???

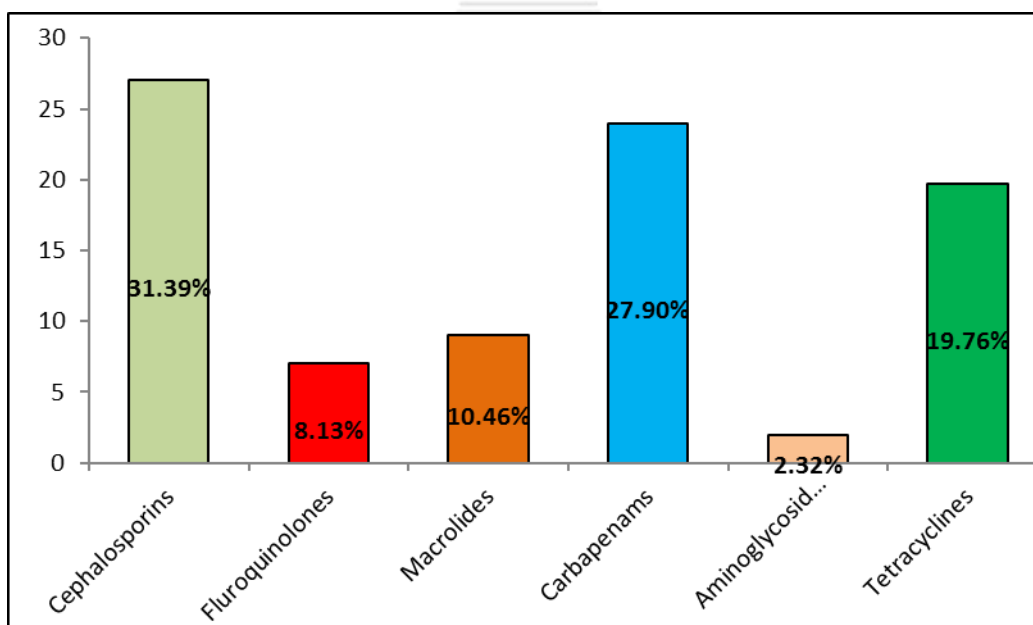


FIGURE 2: MONOTHERAPY OF ANTIBIOTICS

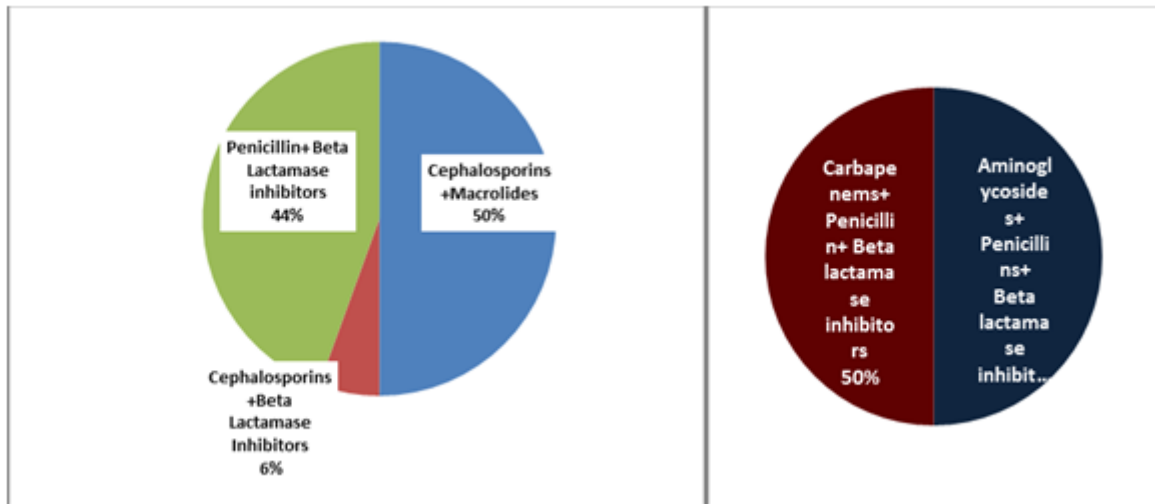


FIG 3: DUAL THERAPY OF ANTIBIOTICS

FIG 4: TRIPLE THERAPY OF ANTIBIOTICS

WHO CORE INDICATORS

Prescribing indicators

The WHO Prescribing indicators of drug use namely the average number of drugs per prescription, percentage generic prescribing, percentage prescribing based on NEML, percentage antibiotic prescribing and percentage injection prescribing. The Patient care indicators namely average consultation time, average dispensing time, the percentage of drugs actually dispensed, the percentage of drugs adequately labeled (various parameters to be considered as given in Table 7) and patient's knowledge on the correct dosage. The hospital service facilities can be assessed by checking the availability of key antimicrobials, antibiotic sensitivity test conducted and the existence of drug information resources [like Essential Drug List /Formulary].

TABLE 6: Deviation from WHO standards

Sr. No.	INDICATORS	OBSERVED	STANDARD	DEVIATION
A)	PRESCRIBING INDICATORS			
1	Average number of drugs per encounter	4.65 %	1.8 %	2.85 %
2	Percentage of drugs prescribed by generic name	0 %	100 %	Deviated
3	Percentage of encounters with an antibiotic prescribed	100	26.8 %	73.2%
4	Percentage of encounters with an injection prescribed	0	24.1 %	Nil
5	Percentage of drugs prescribed from essential drugs list	51.82 %	100 %	48.8 %
Sr. No.	INDICATORS	OBSERVED	STANDARD	DEVIATION
B)	PATIENT CARE INDICATORS			
6	Average consultation time	7.5 min	Greater than 10 min	2.5 min
7	Average dispensing time	4.2 min	Greater than 5 min	0.8 min
8	Percentage of drugs actually dispensed	99 %	100 %	1%
9	Percentage of drugs adequately labeled	*	100 %	Deviated
10	Patients' knowledge of correct dosage	27 %	100 %	63 %
C)	FACILITY INDICATORS			
11	Availability of copy of essential drugs list	Yes	Yes	Nil
12	Availability of key drugs	90.47 %	100 %	9.53%

***Based on various parameters (given in table 7)**

TABLE 7: VARIOUS PARAMETERS COVERED IN LABELLING

Sr. No.	PARAMETERS	PERCENTAGE (%) [n=100]
1.	Patient name	0%
2.	Medication name	18%
3.	Dose	18%
4.	Route of administration	8%
5.	Frequency	100%

PRESCRIPTION ANALYSIS

The prescriptions were audited and results were tabulated in table 8.

TABLE 8: PRESCRIPTION AUDIT RESULTS

PARAMETERS ANALYSED		NUMBER OF PRESCRIPTIONS	PERCENTAGE (%)
Date		100	100%
O.P./Account .no.		93	93%
Patient demographics		100	100%
1.	Name		
2.	Age		
3.	Gender		
Superscription(R _x)		28	28%
Prescribing in capital letter		28	28%
Dose, route, frequency		100	100%
Prescribers details		100	100%

DISCUSSION

Management of RTIs has been a challenge to the physician, mostly due to the emergence of multidrug resistance. The present study assesses prescribing pattern of antibiotics in an effective way of reflecting its use and appropriateness. In addition, it can also help in reducing the cost of therapy, minimizing the practice of polypharmacy and improving rational use of antibiotics.

The demographic profile of the study (involving 100 subjects) shows higher male (56%) to female (44%) incidence rate, which indicates that the males visiting the hospital were comparatively higher than that of females; the probable reasons relate to the social factors in the specific region of the country. From this study, the common diagnosis among the subjects

was found to be LRTI, which indicates the presence of infections in the pulmonary system and its prevalence rate among the local population in the region.

The number of patients found among the age group 41-50 years (33%) was higher and the lowest number was between age group 61-70 years (8%). Patients in adulthood (41-50 years) received more prescriptions containing antibiotics. Thus, patients with increased risk of co-morbid conditions added to the list of increased antibiotic use frequency. Maximum treatment forms prescribed in this study include empirical therapy as in some of the cases, the patients neither went for a complete diagnostic procedure due to the increased cost of diagnostic tools and procedures.

The average drug prescribed per prescription was 4.65, which was higher than the WHO standard and this indicates polypharmacy. In this study, every prescription contains at least one antibiotic (100%) and 22.5%, out of all the drugs prescribed. A similar study carried out in Cambodia⁶ reported the percentage of antibiotics prescribed to be 66.0% approximately. A study conducted in Nepal⁷ reported 43.95% of antibiotic use. The average percentage of antibiotics prescribed in Pakistan⁸, according to a study was very low (23%). This proves that India tops the list of many developing countries in the widespread use of antibiotics. About 96.48% of patients were treated with an antimicrobial agent as a monotherapy, which leads to the decreased chance of resistance to antibiotics and adverse events. The results of our study indicate that Cephalosporins, Carbapenems, and Tetracyclines were the choice of AMD's prescribed, which consist of Cephalosporins (31.39%), followed by Carbapenems (27.09%), Tetracyclines (19.76%). Cefixime was the most commonly prescribed antibiotic. Recently, combination therapy is gaining fame among the health care professions as it makes their job easier for treating an ailment with limited drug forms and increased patient compliance is observed, which in turn increases the therapeutic cost for the ailment. There was no incidence of a prescription containing antibiotics in parenteral form. Similarly, low incidence of injections prescribed was reported in Saudi Arabia⁹ (2%).

The antibiotics are widely available as over-the-counter (OTC) medications in many pharmacies, which leads to their widespread use, misuse, and overuse. The prescription pertaining to an appropriate dosage form for an appropriate patient for a recommended period of time with the 'dispense only on prescription' from a valid health care professional is considered to be the best method for tackling the irrational use of antibiotics and thereby controlling the widespread resistance of pathogens even to the higher degree antibiotics.

Though the government of India has taken statutory actions by generating schedule H1, still antibiotics can be obtained without any prescriptions in pharmacies. The extent of prescribing drugs from EDL was found to be 51.82%, which states that the physician's compliance towards EDL was poor and can be due to the availability of newer drugs with better efficacy and cost-effectiveness.

In this study, the average consultation and dispensing time in facilities was 7.5 minute and 4.2 minutes, which was more different from the study in Ethiopia¹⁰, which was 6.50 minutes and 1.25 minutes on average respectively. The probable reason for this variation may be due to differences in labor, setup of dispensary area and easy access for essential materials like drugs, medical equipment among health facilities. The study also showed that 65% of patients were able to repeat the correct dosage schedule of the drug they had received which is relatively low when compared with the Ethiopian¹¹ study, which stated 71.1%. The probable reason for this difference may be due to over- a load of the patient in dispensary areas, communication problem between dispensers and patients, even the dispensary area were not conducive to give full information to the patient. In the study facility, 99% of prescribed drugs were dispensed. The level of appropriate labeling needs to be improved.

The facilities namely essential drug list or formulary and the 90.47 % of the key drugs were available. Culture sensitivity testing was done for the majority of the subjects. In this study out of 100 patients, only 33% were aware of the antibiotics and its use, which strongly highlighted the need for patient education and counseling on the use of antimicrobial drugs (AMD).

A prescription is an outcome of a patient-doctor interaction that has an impact on a patient's health. The essential components of a prescription are the identity of the recipient and the drug, formulation, dose, route, timing, frequency and duration of administration¹². In most of the prescriptions, details about the patient demography, diagnosis were not mentioned clearly. Important pieces of information such as the date of consultation, patient's name and doctor's name and signature were there in most of the prescriptions. All the demographic details of the patient have clearly mentioned in 62% of the prescriptions collected. The patient's name was mentioned in 100% of the prescriptions, which is in accordance with the earlier findings (97%). The absence of the patient's address reflects a poor trend in prescription writing. The patient's address indicates the location to which the patient belongs and helps decision

making about follow-up¹³. The busy schedule and heavy workload of medical practitioners may be the reason for these missing details.

CONCLUSION

The study was aimed to assess the antibiotic use in respiratory tract infections in a tertiary care hospital in Tamil Nadu, South India, in accordance with the WHO core indicators. The antibiotic usage and its pattern were studied on 100 subjects. The present study has provided many useful findings which can be used as evidence for the prescribing pattern and the use of the antimicrobial drug at an outpatient department of tertiary care hospitals for this part of the country. The results of this study revealed that there is a need for awareness about the antibiotic use and guideline programme among the health care providers and the potential public.

The Hospitals Drugs and Therapeutics committee can play an important role in this regard and perform drug utilization studies and prescription reviews to improve drug use in general and its management. The study strongly highlighted the need for patient education and counseling on the use of AMD's and concomitant drugs with the help of a clinical pharmacist.

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