

**RATIONALITY PATTERN AND DETERMINANTS
OF PRESCRIBING BEHAVIOUR
AMONG
MODERN MEDICINE PRACTITIONERS
OF THIRUVANANTHAPURAM DISTRICT, KERALA**

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*Dissertation submitted in partial fulfilment of the requirements
for the award of the degree of
Master of Public Health*



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May 2001.

DECLARATION

I hereby Certify that the work embodied in this dissertation entitled "Rationality pattern and determinants of prescribing behaviour among, modern medicine practitioners of Thiruvananthapuram district, Kerala" is the result of original research and has not been submitted for any degree in any other University or Institution.

Thiruvananthapuram

May 2001

A handwritten signature in black ink, consisting of a series of loops and strokes, positioned above the name Saiju Hameed.

Saiju Hameed

CERTIFICATE

This is to certify that the dissertation titled "Rationality pattern and determinants of prescribing behaviour among modern medicine Practitioners of Thiruvananthapuram district Kerala" is an authentic record of the work carried out by Saiju Hameed in partial fulfillment of the requirements for the Degree of Masters Of Public Health, under our supervision and guidance.

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ABBREVIATIONS

ARI	Acute Respiratory Infections
ADD	Acute Diarrhoeal Diseases
CME	Continuing Medical Education
DDD	Defined Daily Dosage
EDL	Essential Drug List
GP	General Practitioners
IFDC	Irrational Fixed Dose Combinations
IMA	Indian Medical Association
JIMA	Journal of Indian Medical Association
KSSP	Kerala Sastra Sahithya Parishad
MBBS	Bachelor of Medicine and Surgery
NSAID	Non-Steroidal Anti Inflammatory Drugs
OP	Out Patient
OPD	Out Patient Department
O&G	Obstetrics and Gynecology
OTC	Over The Counter
ORS	Oral Rehydration Solution
PVT	Private
RMP	Registered Medical Practitioner
USA	United States of America
WHO	World Health Organization

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ABSTRACT

Back ground:

Escalation of treatment expenditure was several folds in Kerala during the past few decades. Undesirable drug use can be a major reason contributing to this. There was no previous published study in Kerala analyzing the overall undesirable drug use, factors influencing the undesirable or irrational drug use. In this context, this study attempts to document the prescribing behavior, its pattern and determinants from the physician side

Methodology:

The study was conducted in the Thiruvananthapuram district of Kerala, where almost all levels of healthcare facilities are present. The study sample was collected during the period commencing from 3rd week of December 2000 to 3rd week of February 2001. 960 prescriptions collected from 32 doctors constituted the sample. The sample was collected prospectively by exit –interviews of the patients immediately after consultations. Representative samples from the following categories of doctors were collected.viz, Government, private, male, female, urban, rural, specialists and general practitioners. WHO prescribing indicators and few supplementary indicators developed for this study enabled the analysis of the overall undesirable drug use. An analysis guideline developed for the study gave scores for the obvious irrationalities seen in the prescriptions, like inappropriate dose, durations, unnecessary drugs, irrational fixed dose combinations, presence of hazardous drug etc.

Results:

The overall distribution of results shows a shift towards rationality. i.e. all the prescriptions have a score above 9 which is above the median score. No doctor of the sample prescribed banned drugs. Prescriptions with irrationalities amounts to 66.7 % of the sample, but majority have minimal irrationalities. The percentage of rational was 33.3%. Prescriptions were significantly better in the public sector when compared to private.($p<.001$) Also female doctors(p value-- $.01$) and specialists($p<.001$) were found to be better than their counterparts. Use of essential drugs was fairly good in all categories. As the number of drugs per prescription increased, the overall undesirable drug use also was found to increase. The average number of drugs per prescription for this study was found to be 3.4, which is relatively high.

Conclusions:

The overall quality of prescriptions is low in the private sector and among general practitioners. Though majority of the irrationalities belongs to the minimally irrational group, the overall undesirable use of irrational fixed dose combinations and unnecessary drugs and the inappropriate duration of treatment, emphasize the need for an in depth analysis based on a standard prescription guideline. Specific educational interventions focusing on the more irrational group of doctors is the need of the hour. Development of national or regional treatment protocols with reasonable flexibility, regulation of brand drugs and irrational combinations, promotion of generic drugs and periodic prescription audit in each institutions are suggested for, rational drug use in future.

CHAPTER-1

INTRODUCTION

Modern society considers drugs or medicines as the main stay for overcoming ill health. Per capita drug consumption is also considered as an indicator of development in the modern world. Worldwide in the past decade, drug consumption increased dramatically from US \$ 43 to 94.1 million¹. In India, starting from a mere 10 crores at the time of independence, the drug production has reached Rs 7000 crores². Drug consumption in developing countries including India hiked from 24 % to 75%, between 1976 and 1985². Majority of the drugs produced or available in the Indian market are by and large irrational². Most of them are fixed dose combinations. The sale of leading 22 irrational brands accounted for about Rs 2,870 million in 1992². These are costly and available mostly in the private pharmacies. All these drugs are just "me too" drugs causing unnecessary wastage of resources, of the citizens of a poor country like India. With the cut in public sector health expenditure, following the structural adjustment reforms initiated by the new economic policy in 1991, public health facilities the asylum of the poor are getting deprived of even the essential drugs.

People's money is wasted not only due to irrational drug formulations, but also due to irrational use of even rational drugs e.g.: unnecessary use of antibiotics [leads to financial wastage and antibiotic resistance.] Worldwide data showed that 50 million of the 150 million OP prescriptions for antibiotics a year were unnecessary³

Though the drug industry is the main accused for the irrational and exploitative nature of drug marketing and production, the doctors both qualified and unqualified have been party to the promotion of irrationality owing to their, apathy,

ignorance and in some cases their indulgence in outright corruption. There are several factors interacting between the doctor and the patient⁴ in deciding the rational therapy.

- The lack of training for doctors in clinical pharmacology and the basic principles, underlying rational drug use.
- Lack of Continuing Medical Education, supervision and prescription audit.
- Biased promotional activity by the drug companies.
- Patient load and the unrealistic demand for relief
- Uncertain diagnosis and poor diagnostic facilities
- Reliance of physicians on their limited experience with a drug regarding its scientific merit.

Essential Drug Policy

International efforts to ensure rational drug use were initiated by the WHO in the mid seventy's. In 1975 the world health assembly requested the director general to advise member states on the selection, and procurement of essential drugs corresponding to their national health needs⁵. Essential drugs were defined as those drugs that satisfy the health care requirements of the majority of the population. A model essential drug list, first issued by WHO expert committee in 1977 has since been updated biennially. In the case of rational antibiotic use, the factor affecting treatment cost and also drug resistance, the WHO committee endorsed the concept of reserve antibiotics, so that costlier antibiotics should be kept as reserve for non-response cases. The committee points out that timely provision of information on antibiotic susceptibility and emergence of resistance will help to use common and cheaper antibiotics in most cases and selectively use newer and costlier ones. For this the committee suggests setting up of reference laboratories where ever needed⁶.

Since the launching of the essential drug list, efforts initiated to assess the drug needs, drug prescribing pattern, distribution, drug promotion activity, etc. The essential drugs policy was adopted by many of the developing countries. Zimbabwe is an example. Because of political will and the power of the drug control council they could achieve rational drug use by regulating entry of non-essential drugs to the market⁷.

What is a Rational prescription?

The first international summit for rational drug use⁸ Nairobi (1985) participated by experts from various spheres of policy reforms in health. Defines, "**rational prescription**" as the appropriate drug prescribed, available at the right time, at a price people can afford and that is dispensed correctly, and taken in the right dose at the right interval and for the right length of time. The drug should be effective, and of acceptable quality and safety. The conference outlined the following responsibility to the prescribers"⁹

- They should prescribe rationally in conformity with health as well as social and economic criteria.
- Provide appropriate information and insist on entirely truthful information.

Rational drug use can be achieved only when, it is widely appreciated that the use of drugs in medical practice is under the control of a number of forces, viz., the pharmaceutical production sector, the governmental regulatory and policy making machinery, the physician prescribers who chooses what medicines should be consumed, the medical teaching institutions and professional organizations who gives guidelines to the prescribers, the mass media which provide information to the consumers and finally the patients or consumers. Extensive studies and specific interventions are required, on the role played by all these actors on rational drug use. Based on this theme, the drug utilization studies were initiated.

Drug utilization studies are defined as studies on, the marketing, distribution, prescription and use of drugs in a society with special emphasis on the resulting medical, social and economic consequences. These studies will enable to assess 1) the prescription pattern and the determining factors, 2) improvements after any intervention programs 3) Overall misuse of drugs 4) Changes or newer trends in the choice of drugs, 5) Effects of the information on drugs and community education, 6) Influence of drug promoters, 7) Influence of media 8) Prevalence of adverse reactions, 9) the average costs of prescribing, 10) Drug use and drug needs, 11) Policy impact or Legislation, 12) National formulary and essential drug lists¹¹

Research Questions and Objectives

The major research Questions of this study are

- 1, what is the pattern of prescription behavior among the modern medicine practitioners of Trivandrum district. ?
- 2, what is the magnitude of over all undesirable drug prescriptions?
- 3 what are the, differences in prescription pattern according to variations in educational qualifications of the doctor, region of practice [rural/ urban], sex of doctors [male Vs female], sectors [i.e. private/ public]?
- 4.what are the factors affecting the prescribing behavior of doctors?

Objective: The main objective of this study is to analyze the rationality, pattern and determinants of allopathic drug prescriptions among modern medical practitioners of Kerala. The Specific Objectives of this study are

1. To document the prescription behavior of medical practitioners in Kerala.
2. To estimate the overall undesirable drug use.
3. To compare the pattern of prescription between various categories of doctors, based on their qualification, area of service, gender and sector of service.

4. To list the factors leading to the over all undesirable drug prescriptions.

Though Kerala is famous for its model of health at low cost, the medical treatment expenditure eats away a good chunk of the earnings of an average Keralite. The aggressive promotion of drugs indiscriminately by both drug companies & doctors and the patient demands can lead to adverse health effects. Studies done by KSSP, shows that the escalation of medical expenditure in Kerala over the past decade is more than 500% ¹⁰. One of the reasons contributing to this can be the undesirable drug use. The drug market comprises of elements such as pharmaceutical companies and distributors, the government, physicians and consumers. Any intervention strategy should include these actors in order to be more effective.

Justification

There was no previous broad based published study in Kerala analyzing the overall undesirable drug use, factors influencing the undesirable or irrational drug use, variations in the drug prescribing pattern among different category doctors etc. In this context, this study attempts to document the prescription behavior, its pattern and determinants from the physician side.

CHAPTER -2

REVIEW OF LITERATURE

Studies on rational drug use were conducted in various societies, world over in the last four decades. These studies analyze irrational or undesirable drug use in the various sectors, namely pharmacies, physicians, hospitals, indirect consultations, drug distributors etc. No relevant, published studies highlighting the Kerala scenario of the pattern of prescription behavior among doctors were available.

In this context this chapter reviews the literature under the following pattern. First we would discuss the studies analyzing the extent of undesirable distribution and sale of drugs in the informal sector as a background. Then we will discuss relevant studies in India and abroad on the rationality and pattern of prescription behavior among the medical practitioners. Few studies on the factors affecting the prescription behavior of doctors will be discussed; lastly the pioneer international drug utilization studies included basic data collection on almost all the above-mentioned categories and were carried out in 1966-67 by Dr A. Engel of Sweden and Dr.P. Siderius of Netherlands¹¹

Studies on rational drug use in the informal sector

A study conducted by Vikram Dua et al in Nagpur¹² examined the client and pharmacist behavior, which lead to irrational drug use. Conducted in 34 pharmacies, the study observed, that the sale of antimicrobials accounted for 23.3 % of the total. Most often they were prescribed for non- specific complaints, by pharmacists and doctors and were taken for periods less than 5 days. Tonics or irrational supplements were co prescribed. Most were brand drugs. Sales increased with increased demand by patients and prescribing by doctors¹²

A study in Brazil, conducted in 70 randomly selected pharmacies showed that it is easy to buy drugs from these pharmacies without a doctors prescription even

in cases of drugs with untoward effects. In only 12.8 % cases the seller asked to consult the physician. Clients could secure 67.7% Non-Steroidal Anti Inflammatory Drugs [NSAID's] 65% of Corticosteroids, and 20 % of sedatives from the drug list, without producing a prescription¹³. The magnitude of irrational drug production, distribution, prescription and use is explained in a survey of prescription, supply and consumption of drugs, in Mali¹⁴, the study revealed that unqualified people were being allowed to prescribe. Widespread self-medication was present. There was no true control on drug prices. Too many products in the market lead to loss and wastage. Lack of competition in the supply system favored very high prices.

A study in Wollo region, Ethiopia¹⁴ shows. Drug management; require careful evaluation of quantities delivered, of the types of medicaments provided and the appropriateness to local needs. The study showed substantial variation between districts in the over or under utilization of drugs. Drug requirement is shown to vary with the local situation. There can be several factors, which affect the prescribing behavior of drugs. The following few studies tell us about few of such factors.

Studies on rational drug use [formal sector]

Systematic studies, examining the extent of undesirable prescribing, patient care, and the quality of care provided by health facilities, based on a set of internationally acceptable indicators were initiated following the Nairobi conference for rational drug use. The results of field testing of these indicators by H.V. Hogerziel et al¹⁵, in twelve developing countries, show that a high average number of drugs per encounter was seen in Indonesia (3.3), Nigeria (3.8), high percentage of antibiotics in Uganda and Sudan (56% and 63% respectively) injections in Uganda, Sudan, Nigeria (36% to 48%) and low availability of essential drugs in Ecuador (38%). These studies and their findings were used to increase the awareness among prescribers in Malawi and

Bangladesh, to identify priorities for action (e.g. Poly pharmacy in Indonesia and Nigeria, overuse of injections in Uganda, Sudan and Nigeria, low percentage of patients knowledge on the dosage schedule in Malawi. The studies were highly useful to quantify the impact of interventions in Yemen, Uganda, Sudan and Zimbabwe¹⁵.

A study conducted at a tertiary teaching hospital in northeastern New York, picked out all the prescribing errors in around 2.9 lakh medication orders written during the one-year study. Errors made by each category of doctors, departments etc were separately noted. Nine hundred and five errors were detected of which 57.7% were rated as having potential adverse effects. More errors were committed by doctors between the time 12 pm and 3.59 pm in the error rate was 3.13 per 1000 prescriptions overall. First year postgraduate medical students had the highest error rate. The error rate was high in the Obstetrics & Gynecology, the departments of surgery and anesthesia. The results alarm about the significant risk and the need for effective intervention¹⁶.

An audit of prescriptions containing anti-microbial in office based medical practice at the Loiret France, showed that respiratory tract infections with a presumed viral etiology accounted for 36% of antimicrobial prescriptions. That is, there was unnecessary and indiscriminate use of antibiotics. In children a high percentage of antibiotic prescriptions were under dosed. The variability of the daily dose was very high. Whatever be the clinical hypothesis, the duration of treatment was close to 8 days.¹⁷

Another study from South America deals with the irrational pattern of antibiotic use. To describe the pattern of antibiotic use in a peri urban community of Mexico, a household and drug store survey was conducted. Twenty-nine percentages of drug sales was for antibiotics. The majority of antibiotics were prescribed by a

physician. In about two third of individuals, antibiotics were used only for a period less than 5 days. The physicians prescribed antimicrobials for less than 5 days in 33% of cases, 5-10 days in 64 % cases and more than 10 days in 3% cases. Course of treatment was less than 5days in 91% cases of self-medication and 54 % case of doctor's prescriptions. Drug purchases for 72 % were for insufficient quantity of drugs¹⁸.

Studies on prescription pattern and undesirable drug use in the Indian subcontinent

Indiscriminate use of antibiotics, prescribing of costly brand drugs in the place of rational generic ones (especially irrational fixed dose combinations), inappropriate duration, and dose, unnecessary use of vitamins and tonics, unnecessary injections, prescribing hazardous drugs etc and similar irrational or undesirable drug use is prevalent among Indian practitioners this may vary according to the type of doctor, qualification, area of practice etc. this fact is evidenced by the following studies.

An exploratory survey¹⁹ on drug prescription and Self medication in India by Trisha Green Halgh in 1984 reports on the prescribing and dispensing of drugs in India. The drugs supplied to 2400 patients by the public and private physicians (n=600) and by private pharmacies were recorded and analyzed with respect to there presenting complaints and diagnosis. Trisha Green Halgh herself did data collection by traveling through out India. There was no over all sample frame for the study. She visited PHC's, GP's, large towns in different parts of India, OPD's of large teaching hospitals (Delhi, Calcutta, Bangalore, Vellore, Trivandrum) and copied prescriptions and also recorded the sale of OTC drugs. The survey revealed that, doctors in the private sector prescribe large numbers of drugs. Combination preparations containing 'hidden'

classes of drugs are often given. Anti-infectives are widely and often inappropriately used. Potentially dangerous drugs are sold over the counter and prescribed for trivial or bizarre indications. Drugs that have been withdrawn as dangerous in west remain as popular first line drugs in India. Food supplements and tonics of dubious nutritional and pharmacological value made up a high proportion of the total drugs bill.

An urban-based study conducted in 1995 at the Metropolis of Delhi & Calcutta²⁰ was peculiar as it was based on 8901 prescriptions of doctors, collected from 209, randomly selected pharmacies of the two cities. The average cost per prescription was Rs.58 compared to the rational average cost of Rs.37. The findings revealed the extent of irrational prescription. In this sample, antibiotics were prescribed in one-third of the cases. Two-thirds of the antibiotics were irrational. Only 8% contained generic names, most irrational prescriptions were for Acute Diarrhea diseases (rationality was only 11%). One-third of the prescriptions contained more than one dangerous drug. Average number of drugs prescribed was more in the case of specialist doctors compared to that of general practitioners. 35% of the specialist prescriptions contained one superfluous drug. Irrational treatment was common in the case of tuberculosis²⁰.

Antimicrobial prescribing patterns was surveyed in the in-patient setting of an 800-bedded tertiary hospital. The prescriptions were assessed on the basis of type of use, specialty, site of infection, route of administration and the antimicrobial agent used. The study sample included 556 in patients at the St. John's medical College Hospital, Bangalore. The study showed that 56% of in patients were prescribed antimicrobial agents and 44% of them received a combination of antimicrobials. A total of, 36 different antimicrobial agents were prescribed. Lower respiratory tract infection was

the most common. The type of use was empirical in 34%, directed in 27% and prophylactic in 32% of the prescriptions.²¹

Oral dehydration therapy being the most essential and rational mode of treatment the antimicrobials should be used with caution in diarrhoeal diseases. In this context a study was done on the prescribing pattern of drugs for diarrhoeal diseases of children in a Pediatric Gastroenterology Unit Calcutta for a period of 6 months. Study shows that an average number of 4.4 ± 0.4 drugs were used in the ward. A total of 78% of cases were treated with different drugs, while 22% cases of diarrhea were treated with non-drug treatment, e.g. Oral electrolyte solution (ORS), diet, advice and vitamins. For the ward patients, 50% of the drugs were prescribed by generic names. In the clinic 73% were prescribed by trade names and 20% by generic name. Seven percentages were a combination of both which indicates prescribing of costly drugs with trade name. Drug choice and dosage form was appropriate to the tune of 98-99%. However, dose choice showed 13% inappropriateness in clinic prescribing, and sometimes dose was not specified. Multiple vitamins are prescribed for some patients. Duration of drug intake, choice of drugs and inter dose interval was appropriate in some prescriptions. In few cases, the dose was either not mentioned or it was overdose or under dose²².

Perhaps the first broad based comprehensive study in India which analyses the rationality of prescriptions was done by Dr. Anant Phadke et al in Satara - a district of Maharashtra. A stratified purposive sample of 3582 prescriptions was collected from 49 doctors during the year 1993. This was the first study in India which compares the difference in prescription behavior of doctors on the basis of the socio- economic zone they are catering to, the educational qualifications they have, the sector in which they are working (private/ public) etc. The study shows that the average rationality

score per prescription was only 14.2 out of 30 (the max: score). The score increased significantly with educational qualification. The drug use was irrational in 19% of prescriptions, unnecessary in 47% prescriptions, and hazardous in 11%. Unnecessary injections were given in 24% of cases. Prescriptions of doctors working in the public sector were significantly better than those of the private sector in all respects, except in the use of unnecessary injections²³

In another study, which is from Pakistan²⁴, doctors were randomly selected from a list compiled by a local doctors organization. Details of 996 encounters (of 28 pediatricians and 62 GP's) belonging to Karachi city were recorded. The study on childhood diarrhea, found that ORS was prescribed in 52 and 51%, antibacterial in 41 and 36 %, anti diarrheals in 48 and 29%, and anti amoebics in 26% and 22 % of encounters by GP's and pediatricians respectively. Anti diarrhoeals and self-made 'mixtures' were more often prescribed by GP's. Mean duration of encounters between GP's and patients was 3 ± 2 minutes and 9 ± 4 minutes for pediatricians. Excessive prescription of anti bacterials, antiamoebics, and anti diarrhoeals and inadequate prescription of ORS was observed in the study.

Dr. M. J Kshirsagar et al conducted a study among GP's, Consultants and Dentists in the city of Pune, to quantify any correlation between the prescribing behavior of medical practitioners and the concept of essential drugs and to identify the prescribing errors using WHO indicators. The study found that the average number of drugs per prescription as 2.81 ± 1.22 (i. e polypharmacy). As the number of drugs per prescription increased, the proportion of patient encounters, which led to the prescribing of antibiotics, injections, vitamins and irrational fixed dose formulations increased. The proportion of cases prescribed essential drugs was in the range of 25%-66%.

The overall errors and irrationality (though not a clear trend) was observed to increase with increase in number of drugs. In this study, comparison between various categories of doctors, based on qualification, area, sector etc are not done²⁵. A major impact of irrational prescribing is the financial wastage caused by it to the individual and the community.

Financial wastage due to undesirable prescriptions

In Mali, a survey analyzed the potential financial wastage found in an average prescription containing 10 drugs. It contained duplication in the form of same antibiotic under different brand names. This prescription actually represents a potential financial wastage of around 80-90%. A realistic or rational prescription saves 75 % of the wastage¹⁴.

A study in Ghana in 1980 shows increase in irrational drug use. Prescriptions at several health centers were found to have an average of 3.9 drugs prescribed. If the prescriptions were rational, the cost per prescription would have fallen by about 70%¹⁸. In Nigeria a study of prescriptions for 299 cases of diarrhea, poor prescription and overuse of antibiotics has resulted in wastage of 97% of amount spent for treating the cases¹⁴.

Similarly prescription of brand antibiotic instead of a generic by the 11 doctors, of which 7 knew that the brand was very expensive of a hospital resulted in an over expenditure of 78%. In 82 % of cases the drug was used unnecessary. Compliance is lower in developing countries, owing to the poor prescribing and dispensing practices. The paper concludes that implementation of rational prescription would save as much as 50-70% of the drugs bill¹⁴.

Factors determining undesirable prescription and use of drugs

There can be several factors that cause variations in the prescribing behavior of doctors. As discussed in the study by Phadke et al, educational qualifications, sector (private or public), area of practice (urban/rural) etc can influence the prescribing behavior. Private sector was found to be more irrational. Also educational qualifications affected the prescribing behavior. There are yet other factors influencing the prescribing behavior of doctors. Some of these factors are analyzed in the following studies.

Patient demands leads to a great deal of irrational prescriptions: eighty percentages of doctors attending seminar opined that they prescribed antibiotics against the judgment of their conscience, because of pressure from the patient or relatives²⁶.

A free health day experience from Kenya showed that. 54% to 84% cases received either an antibiotic or an anti microbial. Only 0.09% was managed without drugs. The patients were seen queuing up for doctors prescribing more drugs especially unnecessary drugs, and the queues were found to thin up for the doctors who prescribed less or no drugs²⁷.

Another study conducted in Netherlands, doctors were asked to write the drugs of choice for two clinical conditions. Results proved that it's not the patient demands that determines the prescribing behavior but the professional environment, norms and personal experiences that have the decisive role [74 %to 78 %] in determining the drug of first choice for a doctor. Unless values and norms are changed or modified, technical and cost information cannot change the prescribing behavior²⁸.

Practice of defensive medicine by doctors encourages the choice for expensive and often dangerous symptomatic therapy in self-medication. Prescription practices by

doctors have many harmful characteristics in common with self-medication. The study by Anita.P.Hardon²⁹ in a Philippine village on the use of pharmaceuticals is an example. In majority cases they prescribe three or more medicines. For moderate cough antibiotics are commonly prescribed almost many of the cough syrups and anti diarrheals are irrational fixed dose combinations.

Another factor affecting irrational drug use is the indirect consultation which leads to over prescribing. Indirect consultations through telephone or with the receptionist in general practice result in more prescribing than during direct (face-to-face) consultations. Analysis of prescribing data for 14,660 disorders, presented in one week at 52 general practices, shows a significant, increase in prescribing during indirect consultations. The effect varies strongly, relevant for repeat-prescriptions for the chronic pain and other disorders.³⁰

Pharmaceuticals companies and their marketing tactics, significantly affect prescribing behavior. This is evidenced by the following study. A study to identify the extent of and attitudes toward the relationship between physicians and the pharmaceutical industry and its representatives and its impact on Knowledge, attitude and practice of physicians, based on articles obtained by Medline search, revealed that the extent of physician -industry interactions appears to affect prescribing and professional behavior. Frequent contact with the pharmaceutical representatives leads to higher prescribing cost, and rapid prescription of a new drug. After sponsored CME programs (5.5 –18.5 %) there occurs increase in the rate of prescription of the sponsor's drug. Sponsorship for attending conferences lead to 4.5 to 10 fold increase in post conference prescribing of the sponsor's drug. Free samples resulted in awareness, preference and rapid prescription of the new drug. Research grants by drug companies also show proven impact on the prescribing behavior of the doctor³¹.

A case study on antibiotic use and abuse in Trivandrum city, India examines, the causes of antibiotic use and abuse, finds that almost all prescription for an antibiotic is from a doctor itself. Non adherence to treatment usually occurs due to lack of money, side effects, fast subsiding of illness. In public health facilities, lack of facilities for lab diagnosis, limited stock, and empirical treatment lead to irrational prescription of the antibiotics. In larger public health facilities over crowding leads to improper treatment³²

CHAPTER-3

METHODOLOGY

This study on rationality, pattern and determinants of prescription behavior, specifically aims to

- Document the prescribing behavior of medical practitioners in Thiruvananthapuram district of Kerala
- Estimate the overall undesirable drug use
- Compare the pattern of prescriptions between various categories of doctors, based on their qualification, area of service, gender and sector of service
- List the factors leading to the over all undesirable drug prescriptions

Study Design: A comparative cross- sectional study was conducted among a stratified purposive sample of male and female doctors, belonging to urban, and rural Trivandrum, classified with respect to their educational qualifications, and sector of service [private public]. The data for the study was obtained prospectively, from the patients attending the consultations of various categories of doctors. The WHO manual gives two options for sample collection. 1) Retrospective and 2) prospective. Though retrospective was easy, we didn't go for that, because, many details about the drug dispensed by the doctor may not be present in the prescription document. Above all these reasons most of the health facilities have no system of systematic storage of clinical records of patients.

Measures like Defined daily dosage and unit cost were used for comparison of drug use¹¹ in the studies conducted in seventies. Later more precise and sensitive drug use indicators easily adaptable to all nations was proposed and field-tested in twelve developing countries by a WHO team. These indicators are published later as a

guiding manual namely'' How to investigate drug use in health facilities?''³³ This manual still remains as the most widely acceptable manual for international drug utilization studies. Other studies conducted previously in India and abroad adopted methodological guideline from this manual. Our study also used this manual, for selecting the sample, basic prescribing indicators, method of data collection, etc. We also tried to incorporate the acceptable and useful methods of previous Indian studies except by M.V Shrishyla et al²¹ in an urban tertiary hospital and Nahar et al²² at a pediatric gastro enterology ward to develop our analysis guideline. They focused mainly on indoor patients, admitted at hospitals. As the cases attending the OPD's of medical college are mostly referred cases and majority requiring admission and series of investigations, prescriptions from medical colleges were avoided in the present study. Our study was conducted from the last week of December 2000 to 21st February 2001, the winter season in Kerala.

Study Area: Trivandrum, the capital district of Kerala, have almost all levels of health care facilities ranging from tertiary/ teaching hospitals to rural health centers. We have GPs rubbing shoulders with super-specialists and their likes from the tertiary care centres within the district. The area was familiar to the investigator.

Predictor variables: The factors supposed to be predicting the out come (rationality of prescribing,) are,

- 1) Sector of service,
- 2) Educational qualifications of the doctor
- 3) Socio economic zone of service
- 4) Attendance in Continuing Medical Education programs (CME),
- 5) Average out patient number,
- 6) Frequency of visits by medical representatives.

7) Gender of the doctor

8) Years of experience of the doctor.

Sector of service: This means, the public and private sectors. In Kerala, both the public and private sector health institutions and doctors cater the health needs of the people. There exist varying views on the quality of services provided by the two sectors. Many think that the services in the private sector are better as they are paid services. Evidences to the contrary are provided by certain Indian studies by Phadke et al²³ and Trisha Green Halgh et al¹⁹. Hence in our study we decided to document the sectoral differences in rationality. The government sector prescriptions were defined as those prescriptions of doctors working in the government health institutions. And the private sector prescriptions belong to doctors working in the private sector (i.e. hospitals or private clinics.). Those prescriptions during practices other than their official services were not taken in to account.

Socio economic zone: Classified as urban and rural. This factor is assumed to be important in the current study. Drug companies may less frequently influence the rural doctors; chances of CME are also less for rural doctors compared to their urban counter parts. Study by Phadke et al²³ shows that there is significant difference in rationality between the two categories. In our study urban and rural facilities were selected according to the classification seen in the list of Government allopathic institutions, published by Directorate of health services⁴⁷. The urban belongs to cities or municipalities and the rural belong to the villages or Panchayat,

Gender: Differences in rationality can occur due to gender differences also. Though there are no studies to substantiate this, it is expected that there can be differences in rationality between two sexes of doctors as they can differ, in CME attendance,

average Out patients, private practice, etc. so a representative sample of 31.3% of prescriptions of females were collected.

Educational Qualification: As evidenced by earlier studies, Phadke et al²³, and Ghosh²⁰ et al, S.Q Nizami²⁴ et al in Pakistan, showed that there exist significant differences in the prescribing behavior according to difference in qualification. In our study a general practitioner is one who has MBBS degree only, while specialist is one who has a postgraduate degree or diploma in the concerned specialty. Care was taken to take same types of specialist to compare different sectors in our study we didn't collect prescriptions of super specialist and dentists.

C.M.E program attendance: After passing out of the medical school many of the doctors are not continuing their education. To update the medical knowledge, of doctors, CME 'are conducted. So this may have a direct impact on the rationality of the doctors. In our study we collected information on the number of CME programs attended in the last 6 months. Relation of rationality with increase or decrease in CME attendance is noted.

Years of experience: Though we may not find studies examining rationality relating to years of service or experience. It is thought to have an impact on the prescribing behavior. As the years increase, if not updated, doctors tend to become less knowledgeable, than the fresh graduates who have the latest knowledge do. In the present study the total years of experience after passing the basic medical degree was asked.

Average out patient number: This also has an impact on the rationality of prescriptions. Interviews with members of medical fraternity, reveals that there is an impact of over crowding on the prescribing behavior of doctors. Our study measures

the average out patient number for the doctor in the particular institution. from the records or by direct assessment.

Average number of representative visits.

Studies abroad³¹ have shown that frequency of contacts and the gifts offered from pharmaceutical industry has a definite impact on doctor's prescribing behavior. Hence the frequency of representative visits if measured may show relationship with the prescription behavior. Here the study measures the frequency of representative visits in terms of average number of representative visits per week, as revealed by the doctor. The variations in rationality with increase in frequency of representatives visits, is calculated.

Selection of sample:

As there was no available data on the probable magnitude of irrational prescriptions, it was difficult to assess how large the sample should be. So I followed the WHO guide line³³ (How to investigate drug use in health facilities? For comparing between two health facilities, at least 30 prescriptions from each were required. The required sample size was calculated, by allocating 30 prescriptions for each doctor. Number of prescriptions collected was thus 960, i.e. 30 each from 32 doctors. According to the WHO manual, the sample selected for a prescribing indicator study should be, a minimum of 10 health facilities (preferably 20). Thus the minimum sample size should be 600. If more prescriptions are collected, the more valid the study will become. As there were no available list of doctors, classified or otherwise, systematic random sampling was not possible. So as Phadke et al did²³, we also went for a stratified purposive sample. A minimum of 30 prescriptions was collected, from each doctor. Facilities were also selected based on the average number of patients per day, to ensure completion of sample collection in one facility

in the same day itself. To obtain a representative sample, the doctors from the Govt: sectors were selected from the four major geo political units [Thaluks] of the district. The Thaluks selected were Trivandrum, Chirayinkil, Nedumangad and Neyyatinkara. Specialist doctors in the government sector were selected from the thaluk head quarters hospital or a secondary referral hospital in the same thaluk. The doctors were selected after assessing the willingness of the doctor to co-operate and the average out patient number. Care was exercised to include both the GPs and the specialists in equal number. One general practitioner each from two primary health centers from each of the four Thaluks with more than average 30 out patients was selected. Equal number of Private specialists and GP's were selected from the same zones according to logistic convenience. Private and government doctors were selected from each of the four zones, according to the permission obtained. Care was taken to include a representative percentage of female doctors (31.3%), urban (53.1%) and rural (46.9%) doctors in the sample. In our study we attempt to analyze the variations in prescription behavior between the different categories. Other than the studies by Phadke et al and Trisha Greenhalgh et al, no other study tries to compare urban /rural, and private public differences.

Data Collection

Prescriptions were collected from the patients as soon as they came out of the OPD or the doctor's consultation room, or near the hospital pharmacy. The samples were collected from the patients as soon as they leave the doctor's consultation room. This is done because many of the poor patients may not come to the private pharmacies.. Most of the prescriptions reaching the private pharmacies, many a times contain only few of the medicines actually advised for the patient. Some may be dispensed from

the clinic itself. As two other Indian studies did (Kshirsagar et al²⁵ and Ghosh et al²⁰), we didn't attempt a sample collection from pharmacies

Prescriptions were collected after getting permission from the concerned doctor. Since we had plans to analyze the prescriptions based on diagnosis also, those Op tickets with diagnosis / chief symptoms / signs recorded only were collected. Moreover prescriptions sent outside, mostly from private doctors may not contain any detail about diagnosis or chief symptoms. In the study by Phadke et al²³ the investigators sat along with the doctors. While protesting the questionnaire, we found that this will cause more cautious writing by doctors than normal. So we caught the patient only when the consultation was over. In case of government facilities the doctors wrote the diagnosis or main symptoms in the op ticket itself. But in the case of private institutions, prescriptions many times contained only the drugs prescribed. So the diagnosis were collected from the case sheets which are kept as the hospitals records, with the permission of the hospital authorities. Prior permission was obtained from the doctor, telling him that the confidentiality will be ensured, and the information collected will be used to compare the prescription pattern among the various categories of doctors [not individual doctors] of Trivandrum. An introduction letter by the District Medical Officer and the Assistant Registrar Sri Chitra Tirunal Institute for Medical Science and Technology helped the investigator to overcome the hurdles in getting permission of the doctors for co-operating with the study.

The investigator collected the data with a pharmacist as a copying assistant. A short Data collection form used for this purpose recorded the following information.

Name of the doctor, sex, address, qualifications, Pvt./ public, common constraints in prescribing, Average No of out patients/ day, number of CME's attended in the last 6months, Other modes of up dating medical knowledge, average Number of medical

representatives visiting per week etc. Diagnosis / chief symptoms of the patient, no: of drugs, main drug & dosage, complementary drugs and dosage schedule, details of the patient (age, sex, address, presenting complaints, any chronic illness diagnosed and taking treatment, if female, whether pregnant or not, is the patient a proxy or not), quantity of drug, brand name.

After making an initial rapport, those doctors, who were willing to talk about the factors affecting their prescription behavior were selected for focused discussions on, the journals they subscribe, the other ways of continuing medical education, their attitude towards drug companies and their gifts, their impression about the patient behavior and demands etc. Only 21 doctors cooperated with such type of a detailed discussion. For the rest the basic data was obtained.

What is an Irrational Prescription?

WHO defines irrational drug, as a drug employed when there is little likelihood that it will have a beneficial effect, or the anticipated benefit is not worth, the potential harm or cost of the drug. It can occur when the medicine prescribed is incorrect, inappropriate, excessive, unnecessary or inadequate, multiple (polypharmacy), and more expensive when equally good cheaper alternative was present⁴.

The prescribing indicators for irrational drug use for this study were developed based on this concept. As basic indicators we used the prescribing indicators of WHO developed and field tested under the leadership of H.V Hogerzeil. Three type indicators were developed, 1) prescribing indicators 2) patient care indicators 3) health facility indicators. But we used only the prescribing indicators.

Prescribing Indicators

- 1 Average number of drugs per encounter
- 2 Percentage of drugs prescribed by generic name

- 3 Percentage of encounters with an antibiotic prescribed.
- 4 Percentage of encounters with an injection prescribed
- 5 Percentages of drugs prescribed from essential drugs list or formulary³³

In addition to the WHO indicators we included certain supplementary indicators of undesirable drug use. The WHO indicators will only give a rough idea about the pattern of drug use in a particular area; hence we used additional indicators, which are calculated using the same pattern of the basic WHO indicators. Previous Indian studies were helpful in developing these indicators.

- 1) The percentage of prescriptions having more than three drugs and [four drugs in the case of a chronic case], 2) percentage of cases where antibiotic is prescribed,
- 3) percentage of cases where injection was given, 4) percentage of prescriptions containing banned drugs, 5) percentage of prescriptions containing unnecessary drugs/ injections [eg: vitamins, minerals, antacids etc.], 6) percentage of drugs prescribed with generic name, 7) inappropriate dosage, 8) inappropriate duration,
- 9) percentage of vitamins prescribed, 10) percentage of cases with tonics prescribed, 11) percentage of cases with wrong route of administration, 12) percentage of drugs prescribed from essential drug list, 13) percentage of prescriptions with harmful drug interactions, 14) percentage of prescriptions with irrational fixed dose combinations, 15) percentage of prescriptions containing banned drug, 16) average no: of drugs per encounter.

Indices, 2, 3, 6, 10 and 16 were the basic prescribing indicators of WHO.

Grading of Rationality: This was one of the major tasks. Initially, with the help of standard textbooks available in India, obvious errors/irrationalities, observed in the collected prescriptions, viz.; inadequate duration, inappropriate dosage, presence of

banned drugs, undesirable drug interactions, unnecessary drug or injections, irrational fixed dose combinations, wrong route of administration, more number of drugs, etc were detected. Each of these errors were assigned negative points, based on a set of criteria or guideline prepared for this study, with the help of pharmacological and clinical experts. A prescription will be getting reduced scores based on their degree of irrationality. Negative scores will be deducted from a total score 15 for the rational prescription, based on the following criteria.

Unnecessary Drug: A category of drug or formulation, not necessary to cure the illness i.e., cases with vitamin tablets or injections/ minerals, tonics or antacids as the fourth or fifth drug *-score- [-1]*

Unnecessary Injection: an injection drug prescribed which has no relevance to the diagnosis or symptom written. [Unnecessary, vitamin and steroid injections were included in this category] *-score-[-2]*

Irrational Fixed Dose Combination. ; A drug combination not included in the list of rational fixed dose combinations, listed in the national drug formulary/ WHO list of fixed dose combinations. *- score (-2)*

Banned Drug: Drugs listed as banned by the national government of India a score of (+2) will be given if no banned drugs are present. But if present the prescription is graded as grossly irrational irrespective of the scores.

Inappropriate Duration: A drug not prescribed for the required duration of time recommended for the cure of the illness is classified as inappropriate duration this can be over or under. *-score (-1)*

Inappropriate Dose not the recommended dosage by standard textbooks. This can be over or under dosage. *-score- (-2)*

More Drugs prescriptions containing drugs more than 3 in acute cases and more than 4 when one or more chronic illness is present. Assigned a negative *-score-(-1)*, as there is every risk of interactions as drug number increases.

Wrong Route – not prescribed in the recommended route *-score -(-2)*

Undesirable Interactions- drugs causing harmful interactions when prescribed together. *-score- (-2)*

If a prescription does not contain irrationality, (example: inappropriate dosage,) the prescription will get a positive score for having the correct dosage. Likewise, a score of + 15 will be obtained by adding all the positive scores if the prescription does not contain any irrationality or error. This is obtained by adding the scores after changing the sign. For banned drugs if present it is considered grossly irrational, while if not present a positive score of +2 is given. According to this guideline the worst prescription can get a score of zero and the best will get a score of 15. Based on the following criteria, prescriptions were classified as those having irrationalities and those not having irrationalities.

Data Storage and Analysis Plans

The data was saved in Microsoft Excel version 4 and the statistical calculations were done using the SPSS package. Chi-square test was used for testing the significance

Instruments: Questionnaire, prescription analysis guide line

CHAPTER -4

RESULTS

As discussed earlier, our study aimed at quantifying the extent of undesirable drug use, the overall irrationality in prescriptions, the differences in prescribing behavior between various categories of doctors and their determinants. The study sample was total 960 prescriptions. Representative samples of Private (50%), Public (50%), GPs (50%), Specialists (50%), Urban- (53.13 %) Rural (46.87%), and Females (31.3%), were collected.

The sample characteristics were as follows. The variations in rationality with respect to the various factors are shown in the tables.

Sample Characteristics

Total number of prescriptions	960	Total number of doctors	32
Total Urban „	510	Urban doctors	17
Total Rural „	450	Rural doctors	15
Total Government „	480	Govt: doctors	16
Total Private „	480	Pvt: doctors	16
Total GP „	480	General practitioners	16
Total specialist „	480	Specialists	16
Total male doctor „	660	Male doctors	22
Total female doctor „	300	Female doctors	10

Table-1 Frequency Distribution of Prescriptions According to Rationality Score

Rationality score	Frequency	Percentage
0-8	0	0
9	8	0.8
10	19	2.0
11	71	7.4
12	119	12.4
13	253	26.4
14	170	17.7
15	320	33.3
total	960	100

Table shows that all of the prescriptions have a score above 9, which is above the median score. 7.5. The distribution shows positive shift towards rationality. Even the irrational ones have an above median level of rationality score

Table 2 Distribution of Prescriptions in various Ranges of Rationality scores

Rationality Score =15	Rationality Score ≤ 10	Rationality Score 11-12	Rationality Score 13-14	Total prescriptions
320(33.3%)	27(2.8%)	190(19.8%)	423(44.1%)	960(100%)

The preliminary interpretation of the total figures shows that 44.1% of the total prescriptions show minor degree of errors or irrationalities [scores 13-14]. The scores of 22.6 % of the total prescriptions fall between 9 and 12. Major irrationalities or more errors belong to this group

Table-3 Influence of Socio Economic zone on Rationality

Area	R-score ≤10	R-score 11-12	R-score 13-14	R-score 15	Total(%)
Urban	11 (2.2%)	98 (19.2%)	233 (45.7%)	168 (32.9%)	510 (100%)
Rural	16 (3.6%)	92 (20.4%)	190 (42.2%)	152 (33.8 %)	450 (100%)
Total (%)	27 (2.8 %)	190 (19.8%)	423 (44.1%)	320 (33.3 %)	960 (100 %)

R-score = rationality score

The table shows that 2.2% of the urban doctor prescriptions are having a higher degree of irrationality while a comparatively more (3.6%) of the rural prescriptions have the same type of irrationalities. Difference in rational prescriptions between the urban and rural doctors is only 0.9%. But among the rural doctors, rational prescriptions are slightly more than urban. The urban – rural differences seems to be not significant. Chi square p value 0.46695, not significant.

Table-4 Influence of Sector of Service on Rationality

Sector	R-score ≤10	R-score 11-12	R-score 13-14	R-score 15	Total
Government	8(1.7%)	76(15.8%)	219(45.6 %)	177(36.8%)	480(100%)
Private	19(3.9 %)	114(23.7%)	204 (42.5%)	143(29.8%)	480(100%)
Total	27(2.8 %)	190 (19.8%)	423(44.1 %)	320(33.3%)	960(100%)

Among the private sector prescriptions, 3.9 % belongs to a comparatively higher grade of irrationality than that of the government sector prescriptions (1.7 %). Of the total government doctor prescriptions, 63.1 % is having some degree of irrationalities; while in private sector it is more than 70%. These differences are statistically significant. (Chi- square p value 0.001)

Table 5 Relation of Sex difference of the Doctors with Rationality

Sex of Doctor	R-score ≤10	R-score 11-12	R-score 13-14	R-score 15	Total
Male	23 (3.5%)	143(21.7%)	290(43.9%)	204(30.9%)	660(100%)
Female	4(1.33%)	47(15.7%)	133(44.3%)	116(38.7%)	300(100%)
Total	27 (2.8%)	190(19.8%)	423(44.1%)	320(33.3%)	960(100%)

Of the prescriptions coming from the male doctors 3.5 % had comparatively higher degrees of irrationality. Among the male doctor prescriptions, 69.1% is having irrationalities. But in the case of females it is 61.3%. Rational prescriptions constitute 38.7% of female prescriptions and 30.9% of male prescriptions. There exists significant difference between male and female doctor prescriptions (Chi square p-value = 0.01).

Table- 6 Relation of Educational Qualification with Rationality

Qualification	R-score ≤10	R-score 11-12	R-score 13-14	R-score 15	Total
MBBS	21 (4.4%)	107 (22.3%)	203 (42.3 %)	149 (31.1%)	480 (100%)
Specialist	6 (1.3%)	83 (17.3%)	220 (45.8%)	171 (35.6%)	480 (100%)
Total	27 (2.8 %)	190 (19.8%)	423 (44.1%)	320 (33.3%)	960 (100%)

Prescriptions with higher amount of irrationalities constitute 4.4% of the GP (MBBS) prescriptions and only 1.3% of the specialist prescriptions. Among the specialist prescriptions, 35.6% and between the GP's 31.1% are rational. Table shows a significantly better rationality among specialists (Chi square p value 0.003) and is statistically significant.

When comparing the total irrationality, of the two categories, 68.9 % of the GP prescriptions and 64.4 % of specialist prescriptions show varying amounts of irrational behavior.

Table-7 Relationship of Average no: of OP's per day with Rationality

OP number Group	R-score ≤10	R-score 11-12	R-score 13-14	R-score 15	Total
< 30	3(3.3)	16(17.8)	47(52.2%)	24(26.7%)	90(100%)
30-50	15(4.5%)	83(25.2%)	130(39.4%)	102(30.9%)	330(100%)
51-100	3(1.7%)	45(25%)	72(40%)	60(33.3%)	180(100%)
>100	6(1.7%)	46(12.8%)	174(41.1%)	134(37.3%)	360(100%)
Total	27(2.8%)	190(19.8%)	423(44.1%)	320(33.3%)	960(100%)

As the OP number increases, the percentage of rational prescriptions show a steady increase from 26.3% (for groups less than 30 out patients per day) to 37.3 % (for the group more than 100). Prescriptions of doctors with lesser number of OP's are belonging mostly to the private sector, found to be less rational earlier.

Table- 8 Relation of Years of Experience with Rationality

Exp: Years Group	R-score ≤10	R-score 11-12	R-score 13-14	R-score 15	Total
<10	13(4.3%)	69(23%)	130(43.3%)	88(29.4%)	300(100%)
10---20	8(2.1%)	82(21.02%)	165(42.3%)	135(34.6%)	390(100%)
>20	6(2.22%)	39(14.5%)	128(47.4%)	97(35.9%)	270(100%)
Total	27(2.8%)	190(19.8%)	423(44.15%)	320(33.3%)	960(100%)

4.3% of prescriptions have relatively higher grades of irrationalities and these prescriptions are of doctors with experience less than 10 years. The irrationality decreases with increase in years of experience as the table shows.

Table 9 Influence of C M E attendance on Degree of Rationality

NO: OF CME'S IN 6MONTHS	R-score ≤10	R-score 11-12	R-score 13-14	R-score 15	TOTAL
0	2(6.7%)	9(30%)	15(50%)	4(13.3%)	30(100%)
1-2	15(2.3%)	125(18.9%)	282(42.7%)	238(36.1%)	660(100%)
3-5	9(4.3%)	50(23.8%)	98(46.7%)	53(25.3%)	210(100%)
>5	1(1.7%)	6(10%)	28(46.7%)	25(41.7%)	60(100%)
Total	27(2.8%)	190(19.8%)	423(44.1%)	320(33.3%)	960(100%)

Majority of the prescriptions (63.9 %) of doctors who attended 1-2 CME in last 6 months have irrationalities. These doctors constitute 69 % of the total sample. Except for the group attending 3-5 CME s, the others show an increasing trend in rationality as the attendance in CME increases.

Table-10 Average no: of Representative visits and Rationality

Rep: Visits Per Week	R-score ≤10	R-score 11-12	R-score 13-14	R-score 15	Total
<6	12 (3.33%)	70 (19.4%)	162 (45%)	116 (32.3%)	360 (100%)
6-12	10 (4.2%)	51 (21.25%)	109 (45.4%)	70 (29.2%)	240 (100%)
13-20	5 (1.7%)	57 (19%)	130 (43.3%)	108 (36%)	300 (100%)
>20	0 (0%)	12 (20%)	22 (36.7%)	26 (43.3%)	60 (100%)
Total	27 (2.8%)	190 (19.8%)	423 (44.1%)	320 (33.3%)	960 (100%)

The percentage of prescriptions with irrationalities show a decreasing trend and the percentage of prescriptions which are rational show an increasing trend, with increased number of representative visits, except for the group of doctors visited by 6-12 representatives a month.

Table—11a Relation of Drug number with Degree of Rationality

Number Of Drugs	R-score ≤10	R-score 11-12	R-score 13-14	R-score 15	%	Total
0-2	0(0%)	5(1.98%)	73(28.9%)	174	(69.1)	252(100%)
3-4	5(.009%)	99(18.6%)	284(53.5%)	143	(26.9)	531(100%)
5-6	20(12.7)	68(43.3%)	66(42.1%)	3	(1.9)	157(100%)
>6	2	18(90%)	0(0%)	0	(0)	20(100%)
Total	27(2.8%)	190(19.8%)	423(44.1%)	320	(33.3%)	960(100%)

The table shows a sharp increase in irrationality as the drug number increases.

Table -11b Relation of Drug number with various Indicators of Rationality

Drug Number	% Antibiotics	% Vitamines	% IFDC's	%Having Essential Drugs	%Having Generics	Irrational %
0-2	25.4%	18.3%	78.9%	86%	52.4%	30.9%
3-4	47.4%	34.8%	68.5%	95.29%	74.4%	73.1%
5-6	62.4%	49.04%	61.1%	98.7%	86.6%	98.1%
>6	85%	30%	45%	100%	100%	100%

As the drug number increases, we find a definite increase in the percentage of antibiotics prescribed, and vitamins prescribed. Irrational fixed dose combinations are more seen in the 0-2 drug number group. Presence of one or other types of irrationality reaches 100% as the drug number exceeds six. This is also because of the inclusion of drugs more than as a minor irrationality

Table 12 a- WHO indicators of Drug use

Prescription Category	Antibiotics	Injections	Generics	Essential drugs	Average No: of drugs
Total 960	44.3	18.2	49.6	74.7	3.4
MBBS 480	44.8	21.9	59.4	86.7	3.4
Specialist 480	43.7	14.6	37.6	77.1	3.3
Public 480	45.6	17.3	62.7	85.5	3.4
Private 480	43.3	19.2	30.7	71.8	3.3
Urban 510	47.3	17.3	49.5	76.2	3.4
Rural 450	40.9	19.3	45.4	72.7	3.4
Female 300	42	13.3	63.2	82.3	3.4
Male (660)	45.3	20.5	39.9	73.9	3.2

Table 12 b- Some Supplementary Indicators of Drug use

Prescription Category	IFDCs	Un Nec'y Drugs	Inapp. Duration.	Inapp. Dosage.	Vitamins
TOTAL 960	30.4	19.6	27.4	1.9	32.7
MBBS 480	24.4	24.8	36.7	2.5	37.5
Specialist 480	36.5	14.4	18	1.2	27.9
Public 480	13.7	20.2	33.8	1.9	34.4
Private 480	47.1	19	21	1.9	31
Urban 510	30.2	20.8	25.9	2.2	34.9
Rural 450	30.7	18.2	29.1	1.6	30.2
Female 300	17	19	33.7	1.3	37.7
Male 660	36.5	19.8	24.5	2.1	30.5

All values given above are in percentages

The WHO indicators are given in table 12a and the supplementary indicators in table 12b. The figures are expressed as the percentage of pooled up prescriptions of the particular category of doctors. Percentage of prescriptions containing, antibiotics, and injections appear to be, desirable. Percentage of drugs prescribed generic is less than 50% for the total sample, and the private and specialist doctor prescriptions are found the more undesirable, in this respect. The overall prescription of essential drugs is nearly 75 percent, and it is a good desirable, percentage. Average no. of drugs for the sample appears high, i.e. 3.4. Prescriptions containing most undesirable percentage of irrational fixed dose combinations belong to private doctors. In the prescription of unnecessary drugs, and inappropriate duration of prescribing the public sector GP's show the more undesirable nature.

CHAPTER - 5

DISCUSSION

The main objectives of the study were a) to assess the overall undesirable drug use, b) to describe the prescribing pattern prevailing among different categories of doctors, and c) to identify the different factors affecting the prescribing behavior of doctors. Among the total sample of 960, only 33.3% was found without errors or irrationalities defined in the methodology. In other words 66.7% of prescriptions contained varying degrees of irrationalities. As the tables show, majority of the prescriptions are belonging to a group with rationality score 13-14, which means we have minimum level of irrationality in these prescriptions. When the criteria were designed, we expected scores ranging from 0 to 15. But the results showed that all the scores fall between a score of 9 and 15. This indicates that on a whole majority of the prescriptions, even those with irrationalities have a level of rationality above the median. This indicates that majority of the modern medicine practitioners of Trivandrum shows a desirable inclination towards rational prescribing.

Over all Undesirable Drug use - Comparison of Categories

The comparison is based on the set of WHO indicators and few supplementary indicators in the guideline of this study. The average number of drugs for the total sample is 3.4. When comparing the average number of drugs government sector has a slightly higher average 3.4 compared with the average (3.31) in the private sector. Among them highest average is for the urban government doctors (3.55) and the lowest is for the rural government doctors. This may possibly be due to the fact that, the urban government doctors mainly belong to the secondary referral hospitals where, more complicated cases are dealt with. The average drug number seen in female doctor prescriptions is 3.2, which is the lowest in the sample. This is an

interesting finding in the gender perspective. Of the total 32 doctors 20 had an average drug count above 3, which is a high average. In this study three was taken as the rational limit of drugs for an OP case. More than this limit there is every chance of drug interactions. The same standard is adopted by an earlier Indian study²³].

In the case of the percentage of cases prescribed generic drugs, there exists marked difference between government sector and private sector prescriptions. While the percentage of generics is 62.7% for the government doctors, it is very low, i.e. 30.7 % for the private sector. This may be due to the fact that generic drugs constitute, majority of the drugs, available for the government doctors, and they tend to prescribe more generic drugs. Percentage of prescriptions containing generic drugs, in the total sample is 49.6%. This is a less desirable percentage. But, when accepting the Indian fact that most of the available drugs in the market are brand drugs, this percentage is satisfactory. Another peculiarity is that the specialist doctors and private doctors seem very reluctant to prescribe generic drugs. Some client beliefs like costlier drugs are better also may be influencing their decisions. The percentage here is less than half of public sector doctors.

Percentage of prescriptions containing, injections is highest for MBBS doctors. The lowest in this case is among the female doctor prescriptions i.e. 13.3% .The total sample percentage is 18.2%. As revealed from the discussions the GP'S are the ones who frequently yield to the patient demand for the 'fast cure wonder drug' (injection). Even then the overall use of injections among them is not so high.

Regarding the percentage of prescriptions containing drugs prescribed from essential drug list, the public sector doctors have the highest percentage i.e. (85.5%). The private sector prescribes about 72% of drugs from EDL. In the case of antibiotic prescriptions, in the public and private sectors percentages come closer i.e., 45.6%

and 43.3 % respectively. The prescriptions of female doctors have comparatively less (42%) percentage antibiotics. Regarding the prescribing of Irrational fixed combination drugs, an over all percentage of 47.1% prescriptions contain this category of drugs among the Private doctor prescriptions. The public sector the percentage is only 13.7%, which is a noted advantage. Those fixed dose combinations not recommended by the national formulary or the WHO, majority of them are not of extra advantage and are more expensive.

In the case of prescribing drugs for an inadequate duration, public sector doctors especially MBBS doctors (36.7%) are the most irrational. 33.8% of public sector prescriptions are for a period inadequate to cure the illness. Comparing with this, the percentage in private sector is 21% only. Prescription of unnecessary drugs is slightly more by the MBBS doctors; higher percentages are seen among urban and public sector doctors. The overall sample shows 19.6% prescriptions with irrational unnecessary drugs prescribed. This will lead to unnecessary hike in treatment cost and increased drug number may lead to reduce compliance. Specialist doctors are found to be the most rational in this aspect. Their sample of prescriptions containing only 14.4% unnecessary drugs i.e. the least among other categories. When compared, prescriptions of almost all categories of doctors show above 30% vitamins. The highest is by female doctors (37.7%) followed by GP's (37.5%). vitamins mostly are prescribed as extra or unnecessary drug leading to financial wastage.

Over all percentage of inappropriate dosage is 1.9% and most of the categories lie in a range of 1.3% to 2.5%. While many other Indian studies reported the prescription of banned or hazardous drugs, and wrong route of administration, none of the prescriptions in the sample contained any banned drug or wrong route of administration. The percentage of unnecessary injections(1.8%) and harmful drug

interactions(1.4%), appears to be negligibly less. This is an interesting and very positive finding.

Overall Comparison of Rationality and Influence of Various Factors

Percentage of prescriptions in each category according to the increasing score in rationality will be 2.8%, 19.8%, 44.1%, and 33.3% respectively in the range 9-10, 11-12, 13-14 and 15. The figures show that majority of the irrationalities, belongs to minimal irrational category. It should be noted that this is in spite of a liberal analysis guideline. The problems like incompleteness in prescription writing, diagnostic and treatment accuracy etc were not tested in this study owing to time-resource constraints. Also most of the doctors were aware that their prescriptions were audited. Very obvious irrationalities only were noted. In such a circumstance even the minimally irrational ones also should not be neglected. But any way the scores show a distribution, which tells that even the lowest score is much above the median, i.e. even the worst case is much rational or otherwise the distribution shows an increasing trend i.e. a positive shift towards the rational side. In spite of the highest literacy, and other achievements in the field of health, absence of private medical colleges etc presence of irrationalities in majority of prescriptions is a matter of concern.

Differences in Rationality between Different Categories of Doctors

When comparing the rationality scores of the government sector doctors with that of the private, we found that, among the private sector prescriptions, more than 70% contain irrationalities, i.e. having scores 10 to 14. While among government doctors, those with irrationalities were 63.1%. The prescriptions, with lesser scores and belonging to the private sector, is double that of government sector prescriptions. This shows a marked difference in irrationalities between the two sectors and is statistically significant. The difference between the two sectors can be due to several reasons, a)

because of the competition prevailing in the private sector .b) the drug promotional activities of pharmaceutical representatives observed to be more concentrated on the private sector .The limitations of the government doctor, who has to prescribe from an available stock of rational and essential drugs, automatically make the government doctor prescriptions more rational. Still the rationality grades of government sector prescriptions are only slightly better. To confirm this difference, a study on comparison of private prescriptions of government doctors is essential.

Urban Rural Differences in Prescription Pattern

When comparing the prescriptions of urban and rural doctors, we find there is not a significant difference in the rationality between them. The percentage of prescriptions, with the lowest scores is relatively more in the case of rural .The percentage rational is also more in the urban. But as we have seen earlier, we find some factors, which contribute to the overall irrationality score varying among the urban and rural doctors. It seems other factors nullify this differences.

Gender Difference in Rationality of Prescriptions

Out of the total prescriptions only 31.3 % was by female doctors. But the share of female doctors in the prescriptions, with irrationalities is only 14.8%. When the rationality percentage of the prescriptions belonging to the two sexes of doctors were calculated separately, we see that, while 30.9% of male doctor prescriptions are rational the rational fraction of female doctor prescriptions is 38.7%. This is statistically significant. The possible explanation for this may be the majority of female doctor prescriptions come from the public sector, mostly rural areas and are not indulged in competitive practices.

Educational Qualifications and Prescription behavior

When we discussed the over all undesirable drug use, we found the differences in qualification affecting the prescription behavior considerably. Here the more irrational prescriptions, among GP's are 3 fold the percentage in specialists. Comparing the comprehensive indicator, the rationality score we see that qualification significantly affects the rational prescribing. While 69 % of GP prescriptions contained irrationalities, among Specialist prescriptions it was 64.4%. This shows that specialist prescriptions, though comparatively less irrational, are more than 60% irrational. This presents a less impressive picture on the impact of specialization on rationality.

Impact of Outpatient Number

The findings seen here is interesting i.e. as the number of outpatients per day increases rationality score increases. Though this may be observed as a paradoxical finding, this figure throws light to the fact that most of the prescriptions coming from doctors with less OP's are from the private sector who are found to be less rational. And as the poor goes more to the public sector doctors, the larger queues of patients will be for the government sector doctors and none of them had an average op less than 50. From the discussions with the government sector doctors we could find that their out patient number is unbearable and this is leading to mechanical prescribing. Because of the time resource constraints of the study we could not study the patient care indicators, which may be less desirable in the public sector.

Years of Experience and Rationality

This is a significant factor affecting rational prescribing. Prescriptions with lower scores are very high among doctors having experience less than 10 years and the

irrationality is seen decreasing with increase in years of experience. The fraction of rational prescriptions shows a gradual increase with increase in years of experience.

Influence of CME Attendance and Representative Visits on Rationality Score

In this study we don't find any significant relation between CME attendance and rationality. The majority prescriptions 68.8% come from the group of doctors attending 1-2 CME 's in last six months, so also the majority of prescriptions with irrationalities. Except for the group attending 3-5 CME the other groups show a decrease in percentage of irrationality as number of CME attended increases. The trend is that rationality increase gradually as the number of representative visits increase. This trend is difficult to explain. Probably well-reputed and qualified consultants are visited by more number of representatives and the quality seems to be less affected by representative visits. Most of them, as they revealed, are not actively listening to this marketing literature. They and claim that they prescribe well established brands.

Drug Number and Extent of Undesirable Drug Use

The study shows marked increase in irrationality of prescriptions as the drug number increases. The prescriptions with very less irrationalities are more seen in the 3 to 4 drug number group. This may be by virtue of the high drug numbers alone or other minor irrationalities. Also the more irrational prescriptions, majority is from the 5-6 drug number group. As the drug number increases from one to 6 there is definite increase in the percentage of prescriptions containing vitamins (range 18.3 t% to 49.04%) .We find a sharp increase (ranging from 25.4% to 85%) in the presence of antibiotics in the prescriptions, as the drugs per prescription increase from 1to 6 and above. A similar increase in undesirable drug use is seen with increase in number of drugs, in a study conducted in 1996 in the Pune city ²⁵

Doctor's Views

The qualitative data collected, during this study tells about some important factors affecting the prescription behavior of doctors. Of the 32 doctors involved in the quantitative study, a set of basic data was collected, which include, demographic characteristics, the number of CME seminars attended by the doctors whether subscribing any journals, average number of medical representatives visiting a week or a day, the major constraints in prescribing, etc. Based on this basic data the investigator initiated, focused discussions with the cooperative doctors. Twenty-one out of 32 doctors cooperated. Of this 13 were from the government sector and the rest from the private sector. The discussion focused on the following themes.

- a) The various routes available to the doctors for updating their medical knowledge
- b) The influence of drug promotional activities and representative visits on the prescribing behavior.
- c) Any additional training or quality improvement programs attended.
- d) Impacts of the government drug policy on the prescribing behavior.
- e) Patient demands that mounts pressure on the prescriber etc.

Except one all others in the total sample attended at least one or two CME's in the last six months. Majority (22 of 32) of the doctors belong to the category attending at least one to two CME in the last six months. Of these, 60% of the government doctors have attended mostly training sessions on the national health programs. Majority of the private doctors attend CME's conducted by rural branches of IMA, which many a times are unattractive. There are some leading specialist doctors in the private and government sectors who attend the annual special summits of specialist doctors. Also

doctors in the rural / peripheral institutions, complain that they are not getting any information about the frequent CME's taking place at the teaching/ tertiary hospitals. Only 30% of these doctors subscribe to one or other type of a journal. Majority of the IMA members subscribe the JIMA. The representative visits and the Sponsored CME'S play an important role in modifying the prescribing behavior. Some young doctors admitted that many of the uses of brand drugs are taught to them by the drug companies. Though majority of the doctors were unwilling to admit the influence of representative visits and CME's, on them, they agree that the frequent visits of representatives, enable them to remember some brands of drugs. Studies conducted in USA revealed that there was sharp increase~~x~~ in prescription of the sponsor's drug following a sponsored CME.³¹ The public sector doctors, by virtue of the fact that they are bound to prescribe from an available stock of essential drugs appear more rational. Actually, these doctors are unhappy that they are unable to prescribe the right choice drug, considering the pocket of the patient. They are worried about the less or meager time they get to examine patients because of the very high out patient number. Many of the new generation doctors are of the opinion that they have to practice defensive medicine even if the medical expenditure of the patient may escalate, in view of the threat posed by the consumer protection act.

Public sector doctors cite the lack of timely supply of the necessary drugs, as a reason for prescribing drugs to private pharmacies. Interestingly two PHC doctors confessed that there is no shortage of drugs in the central drug stores at present. Only problem is that doctors are not giving timely and responsible intents, according to the well-assessed needs of the institution. The doctors refuse to agree on any peer pressure on prescribing drugs. Almost majority of the doctors are worried about the lack of a

clinical pharmacology orientation, especially during the initial days of practice [internship]

Conclusions and Policy Implications of the Study

Our study reveals that, in spite of the good health care indicators, in Thiruvananthapuram district many of our prescriptions contain some amount of irrationalities (67%). The fact that majority of the prescriptions belongs to minimally irrational type and even the worst score is much above the median score is a good trend. The study indicates a very high average of drugs per prescription (poly pharmacy) that leads to undesirable interactions. As the drug number increases, the rationality decreases steadily. Meanwhile, the percentage of vitamins, unnecessary drugs and antibiotics also increases steadily to an undesirable level. The study also confirms that private prescribers are more irrational in drug prescription. The general practitioners are comparatively less rational than the specialist. The provision and prescribing of drugs for an inadequate duration in the government health facilities and lack of proper advice regarding duration of treatment is leading to inadequate treatment. Interestingly female doctors appear to have less error on prescribing. In the case of irrational fixed dose combinations³⁴, they are widely prescribed and the private sector doctors and specialists are the major promoters. However the fact that none of the prescription contained a banned drug³⁵ is a very positive finding inclining towards the rational side.

Factors that significantly affect the rational prescribing, found by this study are, sector of service, educational qualifications, gender, etc. There is an increasing trend in rationality with increase of years of experience and CME attendance, but not statistically significant. There are no significant urban rural differences in rationality. According to the view of the medical fraternity, the lacunae in medical curriculum

should be the first accused. At present there are no systematic ways to familiarize young doctors on rational therapy and updating of older doctors on newer drugs. The public sector doctors working in rural areas are often not invited for CME's at the teaching institutions. The doctors are falling prey to the aggressive promotional activities of drug companies by way of gifts, research grants, CME sponsorships etc. Lack of interest of doctors, to update medical knowledge, is also making them vulnerable to the tactics of drug promoters.

Financial constraints of the patient, lack of availability of medical supplies in time, patient demands, etc leads to undesirable drug use and irrational prescribing.

A three pronged approach consisting of a well designed educational intervention for the doctors and clients, supported by implementation of a rational drug policy, strengthening of the drug supply system and also regulation of the pharmaceutical industry is essential. Private institutions should be enforced to prescribe generic drugs and avoid irrational fixed dose combinations. The educational programs should intensely focus on the more irrational doctors. However the large volume of minimally irrational prescriptions demands analysis of prescriptions based on standard prescriptions for each disease. Efforts should be made as the continuation of this study to estimate the financial wastages due to irrational prescribing. There should be patient counseling at pharmacies. The effects of educational interventions should be periodically monitored and revised strategies if necessary should be formulated.

Well-designed educational interventions were proved to be success full in modifying the prescribing behavior towards the rational side as evidenced by the results in the past on regulatory and educational interventions. In the treatment of Rhinopharyngitis in Mexico, there was 40% improvement, following the, educational intervention.³⁵

Campaign against anti motility drugs in the child hood Diarrhoea cases in Pakistan, lead to banning of antimotility drugs³⁶. Another example from Indonesia, shows significant reduction in overuse of injections, following interactional group discussions with physicians.³⁷ These examples gives positive hope regarding educational interventions, particularly in a highly literate state like Kerala.

Limitations of the Study:

Though we could take care to avoid many biases, the following are limitations of the study.

1. Strict randomization in the selection of the sample was not possible as there was no comprehensive list of doctors available in the district. Compiling this would have been a tedious job, which was beyond the scope of this dissertation. However care was taken to avoid bias for places with better transportation facility.
2. As the study took place during the winter season, there is a seasonal bias in the sickness profile [consisting more of ARI] as revealed by the data.
3. Modification of prescribing behavior might have happened at least in some cases, because of the consciousness that the prescriptions are audited. In spite of all the se consciousness, the doctors fail to modify their behavior to a greater extent.
4. Comparison of the drugs prescribed with that of the standard prescriptions didn't take place in this study. If the analysis was made based on scores assigned for sticking to the rational treatment guideline that would have been more meaningful. But it was not possible within the time constraints
5. In patients and patients from teaching hospitals were not included in the study. If included they would stand apart in many of the sample characteristics

Strengths of the Study

Though the pioneer attempt to study prescription behavior in Kerala, the study touches almost all aspects of the determinants of prescription behavior.

It attempts to classify the prescriptions based on the obvious errors in prescription.

Tries to compare the prescription behavior based on educational qualifications, area, sector, gender etc.

The data is collected prospectively and directly from the source.

The investigator was directly present in all phases of data collection, hence no observer bias. The study also attempts to collect qualitative data on the perceptions of the doctors on the factors affecting the prescription behavior. The study used the much-approved guideline by WHO for basic prescription audit.

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Appendix

DATA COLLECTION FORM

Pattern of prescription behavior

Thaluk

PLACE & DATE OF INTERVIEW:

PRIVATE/ PUBLIC

AVERAGE OP/ DAY

Details of the Doctor :

Name

Qualifications

Age

Sex

Address

Years of Experience

No: of Medical Representatives Visiting You /Week

Journals Subscribed

Any Special Training Programs Attended.

No: of CMEs Attended in the Last 6 Months

& Other Modes of CME

Common Cases Encountered in Your Practice?

Major Constraints in Prescribing & Patient Demands

Details of the Patient:

Name

Age

Address/Place

Presenting Complaints

For What Symptoms You Asked Treatment ?

Did You Tell the Truth ?[proxy?]

Any Diagnosed Chronic Illness/ Pregnancy [hypertension, diabetes, arthritis etc.....] for which You are Taking Treatment Regularly

Prescription details

Diagnosis/ chief symptoms:

No: of drugs

B) MAIN DRUG	
Brand name	Dosage &Route

C) INJECTIONS	brand name	dosage
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D) <u>COMPLIMENTARY DRUGS</u>	
Brand name	Dosage & Route

TRIVANDRUM DISTRICT



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