QUALITY AUDITING OF COMMUNITY PHARMACISTS IN KERALA: A CROSS SECTIONAL STUDY

DISSERTATION



The Tamilnadu Dr.M.G.R.Medical University Chennai-32 In partial fulfillment for the award of the degree of Master of Pharmacy DEPARTMENT OF PHARMACY PRACTICE

> UNDER THE GUIDANCE AND SUPERVISION OF K. USHA, M.Pharm SUBMITTED BY MOHAMMED MUHSIN U.P REGISTER NUMBER: 261540710



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This is to certify that this dissertation work entitled "QUALITY AUDITING OF COMMUNITY PHARMACISTS IN KERALA: A CROSS SECTIONAL STUDY" constitute the original work carried out by MOHAMMED MUHSIN.U.P Reg no: 261540710, under the guidance and supervision of ,K.USHA M.Pharm, department of pharmacy practice, Padmavathi college of pharmacy and Research institute, Periyanahalli, Dharmapuri, Tamilnadu-635205

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DECLARATION

Here by I declare that this thesis work "QUALITY AUDITING OF COMMUNITY PHARMACISTS IN KERALA: A CROSS SECTIONAL STUDY" has been originally carried out by myself under the supervision and guidance of K.USHA, M.Pharm, department of pharmacy practice, PadmavathI College of Pharmacy and Research Institute, Dharmapuri,Tamilnadu-635205. This work has not been submitted for any degree at any university

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DEDICATED TO ALMIGHTY Our BELOVED PARENTS, TEACHERS, & FRIENDS

LIST OF SYMBOLS AND ABBREVIATIONS

GPP	Good pharmacy practice	
FIP	International pharmaceutical federation	
PPAC	pharmacy practice activity classification	
CPD	Continuous professional development programmes	
отс	Over the counter	
ADR	Adverse drug reaction	
ANOVA	Analysis of variance	
SS	Sum of squares	
Df	Degrees of freedom	
F	Variance ratio	
P VALUE	Level of significance	
X ²	Chi square	

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ABSTRACT

BACKGROUND

Community Pharmacists are main supplies of medicines in developing countries. Pharmacy personnel are approached for medicines and advice on health problems. Quality standards are essential components of community pharmacists as they determine the extent of professionalism and quality of services provided by the pharmacists to patients.

AIM

To carry out quality auditing of community pharmacists across five districts of Kerala.

OBJECTIVES

To compare the quality of services provided by community pharmacists across 5 districts.

To compare job satisfaction among community pharmacists in these five districts.

To compare extend of awareness among community pharmacists these five districts.

To evaluate and compare patient satisfaction on services rendered by the pharmacists in these districts.

METHOD

A cross sectional study was carried out for six months, in 75 community pharmacies and 75 patients selected from five districts in Kerala, to assess the knowledge, attitude and behavior of pharmacists towards the various aspects of pharmaceutical care. A structured, self-administered and validated questionnaire was provided to the community pharmacists to determine their quality towards setting up and running of retail pharmacy.

RESULTS

By performing quality auditing study, 45 pharmacists were awarded with grade C which was satisfactory, 17 pharmacists with grade B which was good and 1 pharmacist with grade at which excellent. Total patient satisfaction was more for pharmacists from Ernakulam district than the other four. Job satisfaction was more for pharmacists from Alappuzha and least for pharmacists from Malappuram (χ^2 =13.083, df =4, p<0.05, for Malappuram). Total awareness score was significantly higher than patient satisfaction score (p<0.001). Total awareness score was higher for Ernakulam district and least for Wayanad. The overall services provided by pharmacists from Ernakulam were more than other four districts.

CONCLUSION

The study revealed that overall quality of services provided by the community pharmacists was found to be satisfactory, which necessitated the adoption of measures for improving the professionalism and proper enforcement of rules and regulations by the authority to maintain a professional standard among community pharmacists.

CHAPTER 1 INTRODUCTION

1. INTRODUCTION

Pharmacists have an important role in the healthcare system because of their expert knowledge and close relation with patients, such that they are sometimes the first respondents of the healthcare systems ⁽¹⁾. Pharmacy is the health profession which is committed to ensure safe and effective use of medicines. Community pharmacy is the pharmacy services given to the community to satisfy their needs regarding drug products, healthcare items, and related materials, along with pharmaceutical services ⁽²⁾. Uncontrolled dispensing and inappropriate distribution of medicines through community pharmacy are the major problems in developing countries. Dispensing practices in these in these can be described in a model of structure process and outcome where structure refers to a) premises of pharmacy which should comply with legal standards, materials and facilities to store and dispense drugs and b) dispenser, the person available and equipped with knowledge, qualification and skills ⁽³⁾. The pharmacists working in community pharmacies are the mostly accessible healthcare professionals to the public, who supplies medicines in accordance with/without prescription. Counselling is also given by community pharmacists for prescription and non prescription drugs. Pharmacist can educate the society about drugs related aspects. Community is an influential and image creating area of pharmacy profession. Community pharmacies are so focussed on business orientation and their interest in trade may be due to unawareness about their roles and responsibilities ⁽⁴⁾.

Based on the pharmacy practice activity classification (PPAC), initiated by American pharmacists association, community pharmacists covers wide range from a) ensure appropriate therapy and outcome b) Dispensing of medicines and devices c) Health promotion and disease prevention d) Giving contribution to health systems management.

Studies by several authors indicates the pharmacists double role as professional pharmacists to perform pharmaceutical care and businessman focusing profit gain, in which the pharmacists does works that are not related to the profession ⁽⁵⁾. Good dispensing practices require that the person who is responsible must ensure safe and effective drug dispensing. Any person who is trained or not, and who gives out medicines with sufficient knowledge and appropriate skills in known as dispensers ⁽⁶⁾. Good pharmacy practices are the essence of pharmacy profession. All pharmacists must ensure that the service provide by them is of appropriate quality ⁽⁷⁾. GPP is the

practice of pharmacy which responds to the needs of people who depend on pharmacies for getting evidence based care, and to support this practice, it is essential to have a national framework of quality standards and guidelines. Standards are the most parts for measuring quality of services provided by pharmacists and the International Pharmaceutical Federation (FIP) congress in Japan in 1993, the Tokyo declaration on GPP was first adopted ⁽⁸⁾. The role of FIP is to provide leadership for national pharmaceutical organizations and to set up standards. It is very essential to have commitment towards the profession ⁽⁷⁾. It is widely accepted and recognized that the conditions of pharmacy practice vary widely from country to country or may vary between different sectors/area within a country. The benefits that results from direct supervision of pharmacists in ensuring quality of products and services cannot be released in areas where there is shortage of pharmacists or persons with pharmaceutical training. The FIP has developed set of guidelines for developing countries which provides a stepwise approach for their implementation according to the available resources and focus on areas that are relevant to pharmacy practice in developing countries. The major four areas include are: personnel, training, standards, legislation and national drug policy (FIP 1998)⁽⁸⁾. National pharmacy associations should work together with their governing bodies and other healthcare professional associations to support pharmacists through continuing professional educational activities, including distance learning programs and establishing national standards of pharmacy services. All these guidelines describes how pharmacists can improve health care access, health promotion and use of medicines on behalf of patients they serve ⁽⁹⁾

The six major components of mission of pharmacy practice include a) ready availability to patients with or without an appointment. b) Identification and management of health related problems, c) promotion of health, d) to assure effectiveness of medicines, e) prevent harm from medicines, f) make responsible use of limited healthcare resources.

As health care products and services are obtained from pharmacist, some problems can be managed at this point of care, and the problems requiring additional diagnostic skill, which can't be available from pharmacies, can be referred to an appropriate health care professional or hospital. In order to improve the use of medicines; pharmacists have the responsibilities for many aspects of process of medicine use which is important to achieve good outcome from treatment. This begins with arising integrity of medicine supply chain, detection of spurious/falsely labeled/counter feet medicines ensuring proper storage of medicines and quality preparation of medicines when needed. It also includes assuring the proper prescribing of medicines so that dosage regimens and dosage forms are appropriate, instructions for use are clear, drug-drug, drug-food interactions are prevented; predictable and known adverse reactions, including allergies and other contraindication are evolved, minimization of unwanted treatments and considerations of cost of medicines,

Another major important component of pharmacy practice mission is to assist patients and those administering medicines to understand importance of taking medicines properly, which includes correct timing of doses, foods or other medicines to avoid while taking a dose and what to expect after taking a medicine. Monitoring of treatment to find out its effectiveness is another important part of process of use of medicines ⁽⁹⁾. The well-being of patients should be given priority, even though ethical and economic factors are important. A system should exists that enables pharmacist to report and obtain feedback about adverse events, medicines related problems, medication errors, misuse or medicine abuse, defects in product quality or detection of counterfeit products, and this may include information about medicines that are supplied by patients or health professionals to establish good pharmacy practice, a good relation with other healthcare professionals be established, and pharmacists should not consider each other as competitors, but should consider as colleagues seeking to improve pharmacy services. The pharmacists should be aware of the essential medical and pharmaceutical information like diagnosis, laboratory test results and medical history about each patient. Such kind of observation is obtained only if the patient always depend same pharmacy to get his prescription dispensed. It is the responsibility of pharmacist to have unbiased, comprehensive, evidence based current information about therapeutics, medicines and other healthcare products⁽⁹⁾.

The term community is used in the general sense, indicating a group of persons living in a locality, sharing the common interests and privilege. Community pharmacy aims to offer health care to a group of people with emphasis on prescriptions and related matters including the medications commonly used in homes. Community pharmacy is an important area in the operation of pharmacy practice which is sometimes more beneficial than hospital or clinical pharmacy. The community pharmacy in any country required to be designed to accommodate changes, modification and expansion in its functioning to meet expectations of the community. The pharmacists working in community pharmacies or those centres attached to them like drug information services, poison information services, and patient counselling are generally called community pharmacists. The duty of community pharmacist is to provide economic benefit to health care system and improved quality of life to the public.

Community pharmacy in India is commonly known as retail pharmacy where all registered formulations and health products are stocked, exhibited and dispensed to the patients and which utilizes the services of a professionally qualified person to get license from drug control department. The community pharmacists in a modern community pharmacy get ample opportunities to demonstrate that they are professionally qualified, trained, legally permitted and educated health professionals and their services can contribute to people's welfare. The pharmacists in community pharmacy have to be skilled enough to familiarize themselves with expectations of society.

1. FUNCTIONAL ACTIVITIES OF COMMUNITY PHARMACISTS.

The community pharmacies have to take care of both product centered and patient focused aspects of pharmacy. From product centered aspect they have to ensure that medicines of quality are procured, stored and dispensed from their pharmacies. Along with this they have to promote the rational and scientific use of medicines by patients. Pharmacists should know drug effects which includes understanding of kinetics and interactions, and patient factors which includes communication for compliance. In many countries, the community pharmacies manage the drug and poison information Centre for public as a part of their professional activity. The professional activities include:

1. Scientific storage and aesthetic display of medicines

It is the duty of pharmacist to ensure that drugs are stored properly and scientifically in the pharmacy. He has to ensure compliance with legal and statutory provisions regarding purchase, storage and sales of medicines. Scientific storage of medicines is very important in India as India is a country with considerable topographic variations where climate, prevailing temperature and humidity vary from region to region. The rules of Drugs and cosmetic Act prescribe the storage conditions and temperatures required for the medicines. The Indian Pharmacopoeia also specifies the conditions for proper storage of various categories of medicines. The pharmacist has a professional responsibility to make the pharmacy aesthetically appealing.

2. Processing of prescription

Prescription is a written medication order given by the doctor to patient for the purpose of achieving definite therapeutic goals. Pharmacists are duty bound to check the legality of prescription before dispensing.

3. Maintenance of patient medication records.

In many countries community pharmacy maintains patient medication records and for this purpose computers are used for this activity. It gives an advantage that pharmacist can review the past medication history of the patient and compare with current prescribed drugs. Any possible drug interactions found between the drugs taken by the patient can be minimized by spacing technique or referring to the doctor to make suitable changes in the prescription.

4. Professional dispensing

It includes the provision of giving advice, education and information along with medicines to patients or their representatives.

5. Patient counselling.

It is a pharmaceutical care activity taken by the practicing pharmacist to provide medication related or disease related information to the patient or patient's representative in oral, written or other forms. Information imparted during counselling ranges from complete details on disease, drugs and diet and lifestyle changes to basic information of drugs, like name, dose, duration and storage.

6. Health screening services

Health screening services of community pharmacists include blood glucose estimation, recording blood pressure, estimation of cholesterol, assessing lung functions etc...These services are popular in European countries and Australia. Patients are provided with blood glucose monitoring services, counselling on insulin dosage and proper usage of insulin pens, diabetic diet and life style changes and supply of diabetic footwear.

7. Responding to common ailments.

When possible and permitted, pharmacists can give basic treatment such as providing drugs for common cold, headaches and other mild ailments. They can also play an important role in family planning activities.

8. Home care services

Community pharmacists in many countries including UK, providing home care services to patients and old aged people. They also provide pharmaceutical care to patients in their home environment, and serve as clinicians, educators, product and equipment managers, and drug therapy consultants.

9. Advice on rational prescribing

Community pharmacists can influence the prescribers to promote rational drug use which involves prescribing right medication at the right time, to right patient in right dose for right period of time. With his knowledge in therapeutics, pharmacist can identify unnecessary drugs, high doses, potentially dangerous combinations and bring the same into the notice of prescriber for required corrections.

1.2 MODERN TRENDS IN COMMUNITY PHARMACY SERVICES

Prescription filling and filing, patient profiles recording, drug interaction surveillance, inventory control, counselling, patient education and similar activities are the routine activities of the community pharmacies. Computers are widely used to make their services more effective and less time consuming. The following include some of the latest trends in community pharmacy practice in India.

1 .Maintenance of patient medication records

In recent times this practice has been initiated in India like others countries, but in a limited manner. It provides the basis for monitoring drug therapy and identifying or preventing medication problems. The community pharmacists in many countries keep the original prescription given by the doctor in their file and dispense medicines along with information about drugs.

2. Providing medicines along with information and support

Along with dispensing, community pharmacists give information and support regarding the safe use of medicines to the patients.

3. Patient counselling

Community pharmacists counsel the patients to prevent misuse of drugs and increase their compliance with the prescribed medication. Patient counselling involves providing information and advice and ensuring that advice is properly understood by the patient. It involves sympathetically listening to the patient's doubts, problems or views and then responding in a professional or dignified manner. Pharmacists can also advice the patient regarding the financial aspects related to therapy like reimbursement, insurance and other schemes. Pharmacist should educate the patient regarding identification of medicines, use and expected action, route of administration, special precautions, contraindications, drug interactions, storage, life style modifications, refill information, storage, and dealing with missed doses etc...

4. Customer care activities

Pharmacists take an extra care in ensuring that patients get the relevant service safely, efficiently and conveniently in a professional manner.

5. Wearing uniform and identity cards

In many countries the practicing pharmacists wear uniform and identity cards during work hours without fail. They feel proud in wearing identity cards with the uniform .The Indian pharmacists were not encouraged to wear uniform during colonial period. Now the practice of wearing uniform and identity card is getting popular.

6. Modern facilities and utensils

Modern pharmacies are often provided with necessary facilities which include access to reference books, journals, and internet facilities. Some contemporary Indian community pharmacies have blood pressure monitoring, height, weight, body mass index checking and blood sugar checking facilities. Community pharmacies have provision for drinking water for patients which enables the patients to take their medicines in the community pharmacy itself.

7. Continuous professional developmental (CPD) programs

The practicing pharmacists regularly attend the reorientation courses, workshops and similar CPD programs, and there by update their knowledge base. Such programs are developed with objective of helping the pharmacists to be trained as therapeutic advisor cum dispenser of drugs.

8. Separate area for consultation and silent discussion

The role of consultant played by community pharmacists is a fast developing one. Many pharmacies have started establishing a special area for consultation in their pharmacies and they meet the patients in these premises. Pharmacist should tell the patient how to take the medicines, what should be expected from it and precautions to be taken while using it.

9. Pharmaceutical care

Pharmaceutical care encompasses the process through which pharmacists, in cooperation with patient and other professionals, design, implement and monitor a therapeutic plan for improving patient's quality of life.

10. Promotion of rational use of OTC medicines

The community pharmacists must be aware of information on drugs, which the public is receiving through advertisements in media. Patient counselling is important in case of OTC products⁽¹⁰⁾.

The world health organization defines an adverse drug reaction as "any response to a drug which is noxious and unintended and which occurs at doses normally used in the man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function". Pharmacovigilance is defined as the "Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problem". Most of the countries target physicians as the main source for reporting of ADR's. It is very important to motivate health care providers to understand their responsibility in detection, management, documentation and reporting of ADR's for optimizing patient safety. In India due to poor knowledge about the professional obligations, community pharmacists are confined to trade. Motivating the community pharmacists will strengthen the reporting system. Thus, there is a need for designing and implementing the ADR reporting system in community pharmacies ⁽¹¹⁾.

Providing drug information is a major responsibility of all pharmacists irrespective of practice settings. Drug information means providing clinically relevant information on any aspect of drug use relating to individual patients or general information on how best to use drugs. At the most basic level, a drug information service can consist of a small selection of text books, access to internet, and selection of most relevant journals ⁽¹²⁾. Certain studies have indicated that drug information provided by pharmacists lead to greater patient satisfaction with pharmaceutical services. Patients have a wide variety of questions about their medications and although internet is an important source of information, patients depend on pharmacists for information regarding their medications ⁽¹³⁾.

All pharmacists require a well-grounded knowledge of drug interactions to prevent harm to patients from medicine combinations. Pharmacists play a valuable role in screening for interactions and advising on management when interactions occur. Role of emerging importance is detection of interaction between medicines and other alternative therapies such as herbal and alternative remedies ⁽¹²⁾.

Patient satisfaction is a personal evaluation on product or service received. Data's obtained from patient satisfaction survey can be used for identification of potential areas needed for improvement. It can also be serving as an indicator of services quality and a predictor of health related behavior ⁽¹⁴⁾. According to Asadi - Lari et al. (2004) patients satisfaction is related to the extent to which general health care needs are met 'or'' evaluating to what extend patients are satisfied with health services is clinically as satisfied patients are more likely to comply with treatment, take an active role in their own care, to continue using medical care services and stay within a health provider and maintain with a specific system ⁽¹⁵⁾. Patient satisfaction is a key factor in quality assessment of health care system in developed countries, whereas in developing countries, the main quality concern has been the accessibility to health care services ⁽¹⁴⁾.

Job satisfaction is the degree of favorableness with which work is viewed by employees, is a very important contributing factor for person's motivation and productivity ⁽¹⁶⁾. In India, very few studies have been conducted about job satisfaction of pharmacists ⁽¹⁷⁾.Due to increase in the age of population and increased use of the drugs, services provided by pharmacists are increasing day by day.

Attitude towards work include role conflict role over load, work-home conflicts, job stress and job satisfaction ⁽²⁾. As per a study conducted in India, main reasons for poor job satisfaction involves salary status (21%) governmental policies (67%) less promotion opportunities (40%) working conditions, job security and affecting personal life. Pharmacy in India cannot be considered as number one compared to other countries ⁽¹⁶⁾. With reference to dissatisfaction, Schafheutle et al mentioned few domains which may influence job satisfaction such as working sector and other external pressure. If any dissatisfaction occurs in these domains, performance of pharmacists and quality of work is highly affected. Other major domain includes stress, depression, alcohol, cognitive impairment and other addictions. Pharmacists have expanded their role from solely dispensing to pharmaceutical care by maximizing the benefits of medication and safety and due to the increase in work load; it has directly or indirectly influenced job satisfaction and quality of work delivery ⁽¹⁶⁾.

There has been no systematic assessment of community pharmacists in Kerala, thus there is a little regarding the quality of services provided by them. Many of the pharmacists dedicate themselves in serving the profession and public about proper use of medicines. However many others are unaware about the professional role of pharmacists and how they should use their education and professional competence in the practice of pharmacy, as it has never been told to them. In order to make certain changes in current practice in community pharmacies , to promote the overall services provided by the pharmacist and to enhance the patient pharmacist relationship ,a quality auditing of community pharmacists have been conducted in five districts of Kerala.

CHAPTER 2 LITERATURE REVIEW

2. LITERATURE REVIEW

1. Akram Ahmed, et al (2016) conducted a cross sectional study to find out the level of job satisfaction among Indian Pharmacists .The study was carried out using a validated questionnaire for a period of two months, where the participants were contacted via e mail and social websites. Data were analyzed using SPPS version 20. From the study it was found that, satisfaction rate of pharmacists was 17.5%.it was concluded that pharmacists were not satisfied with their jobs. They also suggested the need for further studies to establish job satisfaction for pharmacists, to find out the intrinsic and extrinsic factors associated with dissatisfaction for developing suitable interventions for the same.

2. **Kiran Nagaraju, et al (2015)** carried a prospective study in hundred community pharmacists for a period of nine months in and around Bangalore city. The aim of this study was to create awareness in selected community pharmacists about the ADRs by presenting visual presentation, displaying awareness posters at each pharmacies and distribution of yellow cards. The study revealed that awareness showed a positive response in improving the knowledge about ADRs. Well trained pharmacists in the area of ADR detection, reporting and monitoring will prove to be an asset in providing better patient care. Several approaches like CME, training programmes, seminars and conferences adopted by the regulatory authorities would stimulate and become mandatory to the community pharmacists to be an integral part of reporting in ADR.

3. Levin Thomas, Jayakrishnan S. S (2015) carried out quality assurance auditing of community pharmacies across the state of Kerala. A descriptive cross sectional study was conducted in 112 community pharmacies for a period of 10 months. A scoring worksheet was prepared for quality auditing, based on GPP guidelines developed by Indian Pharmaceutical Association in march 2002. The study concluded that the adherence of community pharmacies to good pharmacy practice guidelines were quite poor. They also suggested for the need to bring immediate changes for the system of community pharmacy practice by the regulatory authorities and the attitude of pharmacist towards his ethics and professional duties.

4. Mao Yu Zhang et al (2014) carried out a study to analyze the community pharmacy perceptions and preferences of local residents and the tourists towards

community pharmacy and pharmacy products by a questionnaire survey to 135 community pharmacies in Macau. Among the sample 42 community pharmacies, 42 pharmacies were franchised pharmacies belonging to several business groups and the 25 community pharmacies were independently private. Data analysis was done by SPSS 18 software *p*-value of less than 0.05 was accepted as statistically significant. According to respondents, price level was the most important factor that influences local residents' choice of community pharmacy, with 49.25% of respondents choosing "great" and 37% choosing "much". Service quality was also emphasized, with 25.37% of respondents choosing "great" and 41.79% choosing "much". This study was limited in some aspects and could be advanced in the future. In this study they collected information from community pharmacies, which provided a way to understand a consumer preferences differences in a reflective way.

5. **Ibrahim K Rayes et al (2014)** conducted a study to find out perceptions and expectations of public on role of community pharmacists in Dubai. 25 individuals from different racial groups and socio economic background were interviewed and the same were audio video recorded and transcribed. Appropriate measures were taken to ensure study rigor and validity. The pharmacist as a health care professional in the public mind was the most prominent theme that was discussed in all 4 groups. Other themes identified were, in decreasing order of prevalence, psychological perceptions towards pharmacists, important determinants of a pharmacists, the pharmacy as a unique health care provider, and control over pharmacies by health authorities. This study provided insight into the way that the public looks at the role of community pharmacists in Dubai.

6. **Najam Ali Khan et al (2013)** conducted a prospective study on present status of pharmacy in outpatient and an in –patient department on prescribing and handling the prescription in hospital, rural and urban areas in Moradabad for a period of 3 months. The study assessed the behaviour, communication skill, qualification of the pharmacist, handling of prescriptions, frequency of dose, drug-food interaction, prescription records, changing of drugs and medication errors. The study concluded that rules and guidelines by FDA and IPA were not followed by the pharmacists.

7. Linu Mohan et al (2013) conducted a study to assess the patient satisfaction on the services provided by the pharmacists at Pulikkal panchayat, Kerala. A questionnaire was prepared to assess patient satisfaction level on services like availability of drugs,

time taken for billing and dispensing, approach of pharmacist, location and layout of pharmacy, refund system, counselling services on side effects etc...Patients expressed that they were satisfied with the availability of medicines and time taken for dispensing the medicines. The locations of pharmacies were convenient to the patients. Considering the factors overall rating of pharmacy was good.

8. Andi Hermansyah et al (2012) carried out a study to determine the type of professional and non-professional work of community pharmacists in Surabaya in Indonesia and to find out the difference between time spent for performing both works in current situation and expected situation. A cross sectional study was conducted by combining purposive sampling for selecting the community pharmacists. The data was analyzed using SPSS v16 to provide the descriptive results and completed with Wilcoxon signed rank test to find the difference between times spent in actual and ideal situation. The sample size was 100 respondents of 300 pharmacists who have been practicing in Surabaya. From 100 participants just 30 participants gave response to the questionnaire, 67% was female who 20-30 years old at most (53%) with working experience as pharmacist less than 3 years (60%) and working 30 hours per week (60%) in pharmacy. Significant difference between time spent in actual and ideal situation was found. The time spent for performing professional and non-professional work in ideal situation was significantly higher than in actual situation except for preparing medicines activity. This finding illustrated that the respondents did not have adequate time to provide ideal services in their daily practice. Therefore, they expected to improve their time and level of work in more professional manner and they were also willing to provide more time and higher level of work in some non-professional work. The Indonesian community pharmacists spent little time on both professional work and non-professional work in their daily activities which indicated that the pharmacists did not focus on delivering quality professional work.

9. Maher R Khdour, Hussien O Hallak (2012) designed a study to determine the perception of Palestinian consumers about the community pharmacists and the services they offer where they used survey methodology by administering structured interviews to consumers who attended 39 randomly selected community pharmacies in Palestine. The questionnaire had range of structured questions covering:

consumers' interaction with community pharmacists, consumers' views on how the pharmacists dealt with personal health issues, procedure with regard to handling private consultations. Proximity to home and presence of knowledgeable pharmacists were the main reasons for patients to visit the same pharmacy. Only 17% of respondents considered pharmacists as health professionals. The majority of respondents would be happy to receive different extended services in the community pharmacists like BP monitoring. Palestine consumers have positive overall perception of community pharmacists and the services they offer. Awareness should be created amongst the public about the role of pharmacists and the added value they can provide as health care professional. There is a need to consider privacy when giving patient counselling to increase user satisfaction.

10. Mr. Kiron S S et al (2012) conducted a cross sectional survey on job satisfaction in Kannur district. The methodology included administration of self-validated multiple choice questionnaire used to obtain the data. The questionnaire included: demographic status, qualification, job satisfaction parameters and stressful aspects of the work for community pharmacists. Of the 53 pharmacies, 78% of pharmacists working in those regions had D. Pharm qualification and 10% were B. Pharm graduates. 1.8% of the study population felt that their work activities were meaningless and very few thought that they did not receive a professional value from other people of the society. The pharmacists were satisfied with their inter personnel relations.

11. Mohamed N al- Arifi (2012) conducted a study about the population perception views and satisfaction with pharmacists' performance as healthcare provider in community pharmacy settings. A total of 125 community pharmacies in Riyadh city were randomly selected according to their geographical distribution. The questionnaire composed of about patients' views and satisfaction with pharmacists' role in the community pharmacy practice. The questionnaire was coded, checked for accuracy and analyzed using statistical package for social sciences version (SPSS) 17.0. the majority of respondents were young adults (82.8%), male(67.5%) and married (66.9%), 71% of respondents assured that the community pharmacies available in the working while only 37.3% perceived pharmacists as a mere vendor. 38% assured counselling by the pharmacists, 35% reported that pharmacists plays an active role in their compliance to treatment, 34% considered pharmacists as a health

awareness provider and 44.6% felt that pharmacist as an indispensable and an effective part of an effective system.

12. Azhar Hussain et al (2012) carried out a study which evaluated the compliance of community pharmacies with legal requirements as laid down by the regulatory frame work of Pakistan. A structured questionnaire with coded response and openended questions was used to get information on compliance of community pharmacies with legal requirements. The study concluded that none of the pharmacies completely compiled with the legal requirements in terms of licensing, premises, storage, documentation, narcotic section, drug labeling and prescription checking. The study would serve as a baseline for policy makers, managers, researchers and other stakeholders in developing designs for future interventions as well as for methods of accountability and control.

13. **Saira Azhar et al (2009)** published a work to highlight the role of pharmacists in developing countries, particularly in Pakistan. The paper highlighted the current scenario of Pakistan pharmacy profession. It concluded that although the pharmacy profession in Pakistan is continuously evolving the health care system of pharmacist's role. This lack of recognition was due to the limited interaction of pharmacists with the public. Pharmacists in Pakistan were concerned about their present professional role in the health care system. The main problem they were facing shortage of pharmacists in pharmacies. Moreover, their services were focused towards management more than towards customers. For these reasons, the pharmacists' role as a health care was not familiar to the public.

14. **Maria Luz Traverso et al (2007)** Conducted a study to develop and validate a questionnaire in Spanish for assessing patient satisfaction with pharmaceutical care received in 41 community pharmacies of the province of Santa Fe. Argentina. A self administered questionnaire with 27 items, 5 point likert response scale and demographic questions was designed considering multidimensional structure of patient satisfaction. Questionnaire evaluated cumulative experience of patients with comprehensive pharmaceutical care practice in community pharmacies.274 complete questions were obtained and the factor analysis resulted in 3 factors which included managing therapy, inter personnel relationship and general satisfaction. Mann Whitney U test for construct validity did not show significant differences between pharmacies that provide pharmaceutical care and those that do not. However, 23 items showed significant differences between 2 groups of pharmacies.

15. Zahid A Butt et al (2005) carried out a study to estimate the proportions of pharmacies meeting licensing requirements and to identify factors associated with these pharmacies in Rawalpindi Pakistan. A cross sectional survey was conducted in 311Pharmacies selected from a drug company list of 506. The pharmacies located on hospital premises or private dispensaries or those selling homeo or herbal medicines were excluded from the study. From each outlet pharmacists with a degree or diploma in pharmacy was identified. If a pharmacist was unavailable the most experienced drug seller was interviewed, a single respondent thereby being selected from each outlet. All the data were double entered in EPI INFO version 6.04 and analysis performed in SPSS version 10.0. The proportion of pharmacies meeting licensing requirements was 19.3% with few qualify persons. The practice of selling drugs without prescription was not found to have a significant association. Most drug sellers have fragmentary knowledge regarding drug dispensing and storage, and improper drug dispensing practices.

CHAPTER 3 AIM AND OBJECTIVES

3. AIM AND OBJECTIVES

3.1 AIM

To carry out quality auditing of community pharmacists across major districts of Kerala.

3.2 OBJECTIVES

- To compare the quality of services provided by community pharmacists across 5 districts.
- To compare job satisfaction among community pharmacists in these five districts.
- To compare the extend of awareness among community pharmacists these five districts.
- To evaluate and compare patient satisfaction on services rendered by the pharmacists in these districts.

CHAPTER 4 METHODOLOGY

4. METHODOLOGY

A cross sectional study was carried for six months in 75 randomly selected community pharmacies across five major districts of Kerala. The whole work was a two phased, six months study from December 2016 to May 2017.

4.1 STUDY SITE

The study was conducted in 75 community pharmacies in Malappuram, Calicut, Ernakulam, Wayanad and Alappuzha districts.

4.2 STUDY DESIGN

A cross sectional study was conducted to carry out the quality auditing of community pharmacists in Kerala.

4.3 STUDY PERIOD

The study was conducted over a period of six months.

4.4 STUDY POPULATION

Study population covered 75 accessible community pharmacies; that is 15 pharmacies each from Wayanad, Calicut, Malappuram, Ernakulam, and Alappuzha districts in Kerala which satisfied the inclusion and exclusion criteria. Stratified simple random sampling method was adopted by the investigators for the selection of pharmacies. For evaluating patient satisfaction, one patient from each pharmacy with a total of 75 patients, who met the inclusion and exclusion criteria were interviewed.

4.5 STUDY CRITERIA

4.5.1 INCLUSION CRITERIA

- All the accessible medical shops in those five districts of Kerala.
- Pharmacies which have at least one qualified pharmacist were included for the study.
- Patients who have got at least three prescriptions dispensed from the same pharmacy were included.
- Pharmacies dispensing an average of 100 prescriptions per day.

4.5.2 EXCLUSION CRITERIA

• Inaccessible retail shops were excluded.

- Newly established pharmacies (less than six months) were excluded from the study.
- Patients who possess any sort of relation with the pharmacy or pharmacist were excluded.

4.6STUDY PROCEDURE

4.6.1 DESIGNING OF DATA COLLETION FORM

A self designed, validated questionnaire for carrying out quality auditing was prepared, based on GPP guidelines. Scoring worksheet consisted of standards related to activities of pharmacist.

Questionnaire included three main annexure. Annexure 1 covered demographic details, Qualification, years of experience of the pharmacists. It dealt with general awareness of community pharmacists on various aspects like providing drug information, storage, patient counselling, drug interactions, recent updates and developments and adverse drug reactions. These were included to assess the pharmacist's extent of awareness regarding their professional roles and responsibilities.

Annexure II dealt with job satisfaction of community pharmacist's, personnel in the pharmacy, complaints and recall, procurement and inventory, training and educational programs, medicine recall, prescription handling, documentation system and storage.

Annexure III included patient satisfaction survey done in order to find out the perception and views of consumers regarding the services provided by the pharmacist and their opinion concerning possible future additional services to be provided by the pharmacists. It included various standards like facilities, patient counselling, personnel, dispensing, prescription filling and overall satisfaction of consumers.

Scores were given for each standard by the investigators and was validated by experts.

Pilot testing of data collection tool as well as data collection process was carried out in 15 community pharmacies; 3 pharmacies in each district of total sample size before the execution of study to revise and finalize the questionnaire.

4.6.2 DATA COLLECTION

The study was conducted in two phases, the first phase conducted during the first three months and the second phase during next three months.

Data collection was performed during the second phase of study during last three months. Personal visit was made by the investigator for the conduct of study and the objectives of study were explained to the pharmacist in charge and there by obtaining consent from the pharmacist. Interview method was adopted by the investigators to reduce bias. Each interview lasted for 15-20 minutes and was conducted during the working hours of pharmacy. All the interviews were conducted in local language. For assessing patient satisfaction, consumers were approached upon entering the pharmacies; the purpose of study and verbal assurance regarding the confidentiality of data were explained by the investigators.

4.7 DOCUMENTATION

All the relevant data collected were evaluated and documented in the corresponding data collection forms.

4.8STATISTICAL ANALYSIS

Data collected were compiled and statistically analyzed using

- i) Two factor ANOVA technique and
- ii) χ^2 for test of homogeneity of proportions for drawing inferences

The mathematical model used for framing the Two factor ANOVA is

$$x_{ij} = \mu + \alpha_i + \beta_j + E_{ij}$$
 where

 x_{ij} = the observation in the the ith row of the jth column

 $\mu = \text{overall effect}$ $\alpha_i = i^{\text{th}} \text{ row effect}$ $\beta_j = j^{\text{th}} \text{ column effect}$ $E_{ij} = \text{random error}$

 χ^2 statistic for testing the homogeneity of proportions was calculated using the formula

$$\chi^2 = \Sigma \left[(\text{O-E})^2 / \text{E} \right]$$

Where O is the observed frequency and E is the expected frequency

4.9 DETERMINATION OF SAMPLE SIZE

Sample size is determined using the formula

$$n > z^2 pq/d^2$$

Where n = sample size

p = prevalence rate

q = 1- p

z = confidence coefficient

d = error of estimate

By taking P as 50% with a confidence interval of 95% and an error of estimate 12%, minimum sample size was 67% expecting some non-cooperation. The minimum sample size was fixed as 75.

4.9.1 METHOD OF SAMPLING

Stratified simple random sampling was adopted for drawing shops for the study, where strata being each region.

4.9.2 TESTS FOR DRAWING CONCLUSION

- Chi square test for studying association of opinions
- ✤ ANOVA technique for analyzing the opinion of pharmacists

CHAPTER 5 RESULTS

5. RESULTS

Results of the statistical analysis of the data are presented below:

✤ GENDER WISE DISTRIBUTION

Except in Calicut, in all other 4 districts there is no significance between males and females (χ^2 for Calicut= 8.067, p<0.01)

	WAYANAD	CALICUT	MALAPPURAM	ERNAKULAM	ALAPPUZHA
MALE	11	2	9	10	5
FEMALE	4	13	6	5	10

Table 1: Gender wise distribution

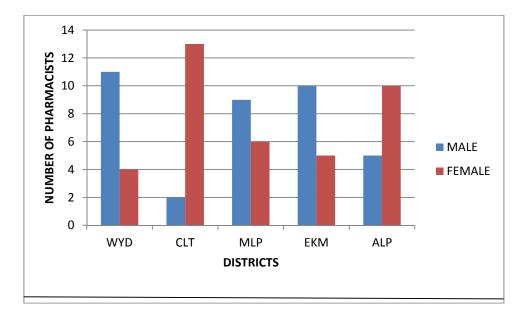


Figure 1: Column diagram showing gender wise distribution

✤ QUALIFICATION WISE DISTRIBUTION

In Wayanad and Calicut districts there is no significant difference in the number of D. Pharm and B. Pharm (p>0.05). But in Malappuram, Ernakulum and Alappuzha there is significant difference (p<0.05). In these 3 districts D. Pharm are significantly higher in numbers than B. Pharm.

	Wayana d	Calicut	Malappuram	Ernakulam	Alappuzha
D.PHARM	11	4	13	1	15
B.PHARM	4	4	2	2	0

Table 2: Qualification wise distribution

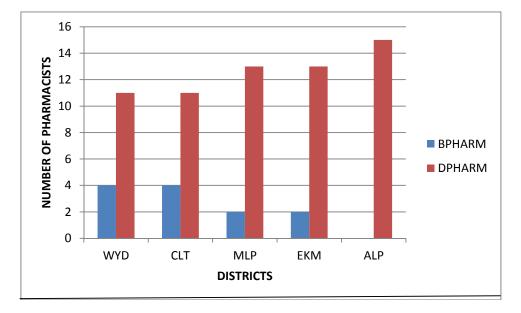


Figure 2: Column diagram showing qualification wise distribution

	Wayanad	Calicut	Malappuram	Ernakulam	Alappuzha
Less than 1 year	4	3	4	0	0
2-10 year	5	8	5	4	4
11-20 year	3	4	3	7	11
> 20 year	3	0	3	4	0

✤ EXPERIENCE WISE DISTRIBUTION

Table 3: Experience wise distribution

Source	Ss	Df	Ms	F	p-value
Total	140.2	19			
Experience	51.4	3	17.1333	2.347	p>0.05
Districts	1.2	4	0.3	0.041	p>0.05
Error	87.6	12	7.30		

Table 4: ANOVA table for experience wise distribution

There is no significant difference in the experience scores between districts (p>0.05)

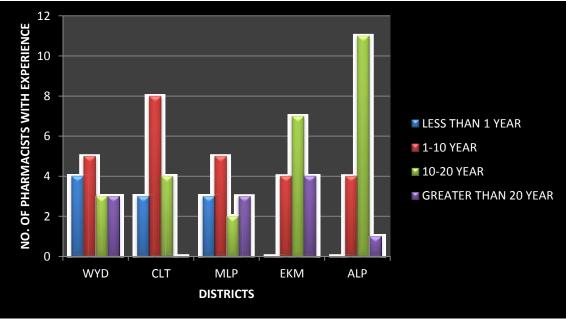


Figure 3: Experience wise distribution

ANNEXURE I: GENERAL AWARENESS OF COMMUNITY PHARMACISTS

1. DRUG INFORMATION

The scoring were same for all the districts.

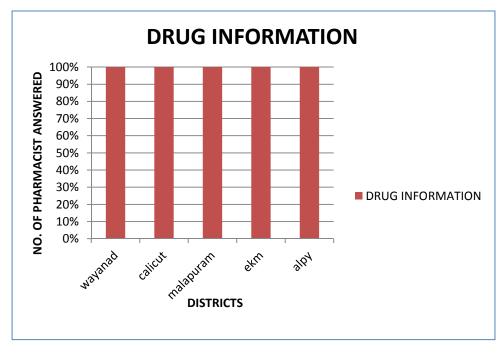


Figure 4: column diagram of drug information

2. STORAGE

Table 5: ANOVA table for storage

Source	Ss	Df	ms	F	p-value
Total	1664.4	19			
Districts	70.4	4	17.6	2.779	p>0.05
Storage	1518.00	3	506.00	79.895	P<0.001
Error	76.00	12			

Inference

- a) There is no significant differences between districts (p>0.05)
- b) But awareness about storage differ significantly (p<0.001).

Temperatures mean score is significantly higher than the rest.

QUALITY AUDITING OF COMMUNITY PHARMACISTS

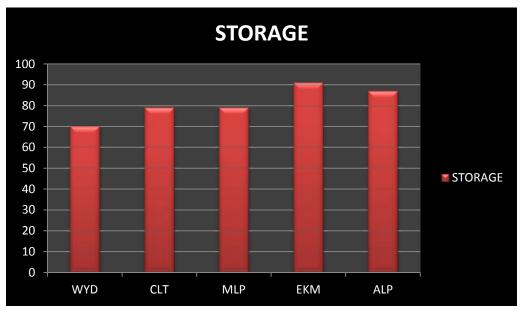


Figure 5: Scores obtained for storage

3. PATIENT COUNSELLING

Source	Ss	Df	Ms	F	p-value
Total	517.8	19			
Districts	37.3	4	9.325	2.670	p>0.05
Counselling	438.6	3	146.200	41.867	P<0.001
Error	41.9	12	3.492		

Table 6: ANOVA table for patient counselling

The mean score is significantly low after counselling and significantly higher in counselling without request (P<0.001)

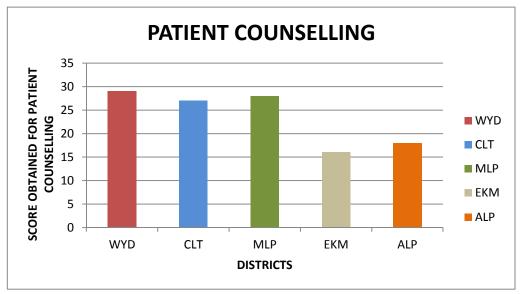


Figure 6: column diagram for patient counseling

4. DRUG INTERACTION CHECKER

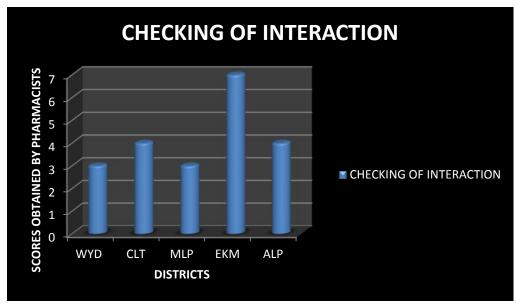


Figure 7: Cylindrical diagram showing scores for checking drug interaction No significant difference could be noted between districts. $(\chi^2 = 2.544, df = 4, p > 0.05)$

5. TYPES OF DRUG INTERACTIONS

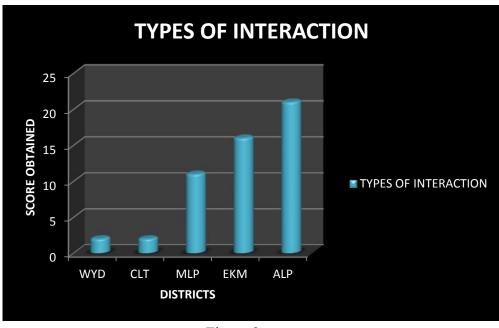
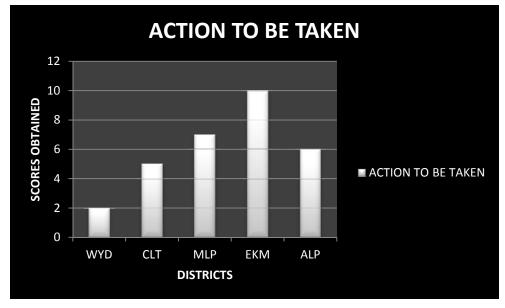


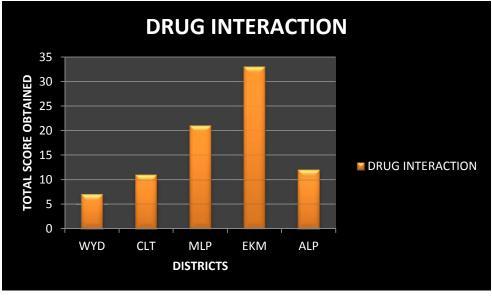
Figure 8 Drug interactions scores are significantly low in Wayanad and Calicut and significantly high in Alappuzha districts ($\chi^2=27.423$, df= 4, p<0.001).



6. MEASURES TO CHECK DRUG INTERACTIONS



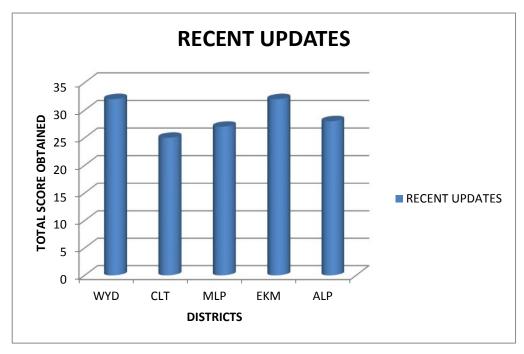
There is no significant differences in the scores between the districts (p<0.001)



7. TOTAL SCORE FOR DRUG INTERACTION

Figure 10

Total score for DI cases are significantly higher in Ernakulum districts and significantly low in Wayanad districts.($\chi^2=25.762$, df =4, p <0.05)



8. RECENT UPDATES AND DEVELOPMENT



No significant difference could be noted between the districts ,(p>0.05).

9. ADVERSE DRUG REACTION

Source	SS	Df	ms	F	p-value
Total	586.1710	34			
Districts	19.0281	4	4.7570	2.494	p>0.05
ADR	521.3710	6	86.8952	45.562	P<0.001
Error	45.7719	24	1.9072		

Table 7: ANOVA table for ADR

Score for 'Heard about ADR' is significantly higher than others (p<0.001). Between districts the difference is not significant (p>0.05) in the total ADR scores.

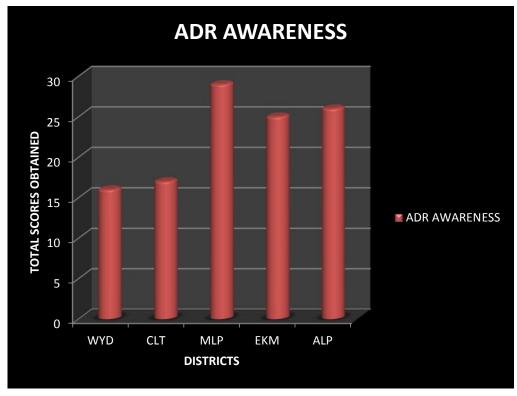


Figure 12

10. COMPARISON OF TOTAL AWARENESS

DISTRICTS	WAYANAD	CALICUT	MALAPURAM	EKM	ALEPPY
SCORES	169	174	199	212	186

Table 8: Comparison of total awareness of pharmacists.

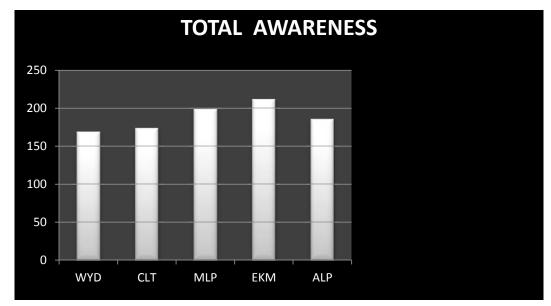


Fig: 13

ANNEXURE II

11. JOB SATISFACTION

Source	SS	Df	ms	F	p-value
Total	1548.7710	39			
Districts	164.8960	4	41.2240	3.080	p>0.05
satisfaction	1009.1710	7	144.1673	10.773	P<0.001
Error	374.7040	28	13.3823		

Table 9: ANOVA table for job satisfaction

The mean score of job satisfaction is significantly low in Malapuram district (p<0.05). Significantly lower mean score were obtained for "Income satisfaction and Rules and regulations" compared to others (p<0.001)

Based on the total scores, it could be seen that Malappuram district is having significantly lower job satisfaction scores than other districts.

(χ²=13.083, df=4, p<0.05)

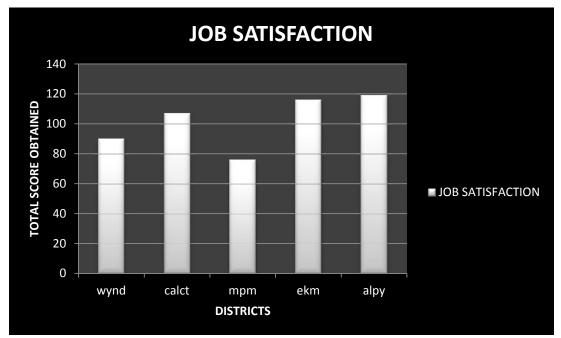


Figure 14

QUALITY AUDITING OF COMMUNITY PHARMACISTS

Source	Ss	Df	ms	F	p-value
Total	737.75	19			
Districts	1.50	4	0.3750	0.738	P>0.05
Personnel	730.15	3	243.3833	478.818	P<0.001
Error	6.10	12	0.5083		

12. PERSONNEL

Table 10: ANOVA table for personnel

Between districts the difference is not significant (p>0.05). But between personnel the difference is significant (p<0.001). The mean total score for the 'pharmacy managed by the supervisor' is significantly higher compared to wearing of neat white coat and badge (p<0.001)

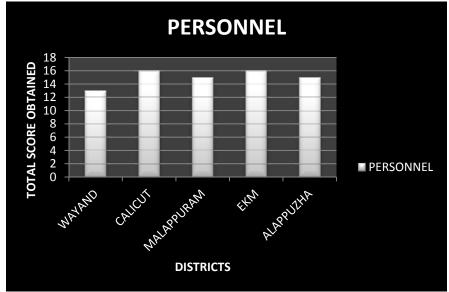


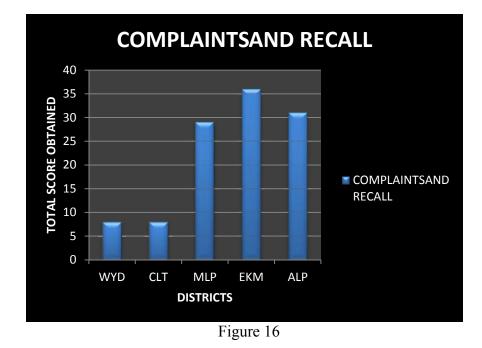
Figure 15

13. COMPLAINTS AND RECALL

Source	Ss	Df	Ms	F	p-value
Total	791.75	19			
Districts	169.00	4	42.25	3.305	p>0.05
Complaints	469.35	3	156.45	12.239	P<0.001
Error	153.40	12	12.78		

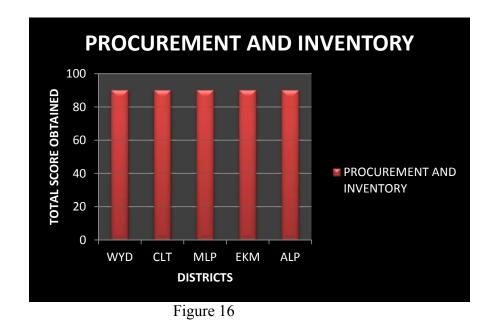
Table 11: ANOVA table for complaints and recall

Between districts there is significant difference in the complaint scores (p<0.05). Ernakulam and Alappuzha are having significantly high score with respect to complaints and recall (p<0.05). The scores for 'addressing of complaints by pharmacists and evaluation of causes' are significantly higher than the rest (p<0.05).



14. PROCUREMENT AND INVENTORY

All the 5 districts are having the same maximum score with respect to medicines checked, purchased from authorized sources, documents maintained, tallied against in voice, and purchased as per law.

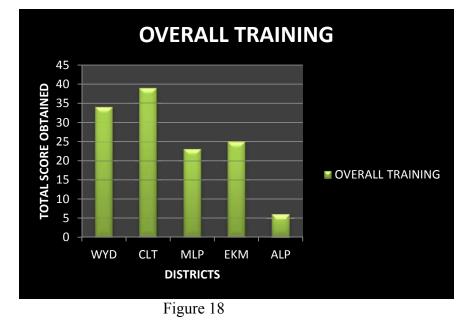


Source	Ss	Df	ms	F	p-value
Total	245.7333	14			
Districts	213.7333	4	53.4333	27.638	P<0.001
Training	16.53333	2	8.2667	4.276	P>0.05
Error	15.4667	8	1.9333		

15. TRAINING AND EDUCATIONAL PROGRAMMES

Table 12: ANOVA table for training and educational programmes

There is significant differences between districts (p<0.001).Calicut and wayanad are having significantly higher mean score and Ernakulum districts is having significantly lower score (p<0.001)



The same trend is observed in the total score also.

16. MEDICINE RECALL

Source	Ss	Df	ms	F	p-value
Total	569.3333	14			
Districts	27.3333	4	6.8333	2.929	P>0.05
Recall	523.3333	2	261.6665	112.144	P<0.001
Error	18.6667	8	2.3333		

 Table 13: ANOVA table for medicine recall

Between districts there is no significant differences (p>0.05) but Recall scores differ significantly (p<0.001). 'Scores for immediate stopping of sale of medicines in case of any suspicion and notifying the relevant parties ' is significantly higher than the other two (p<0.001)

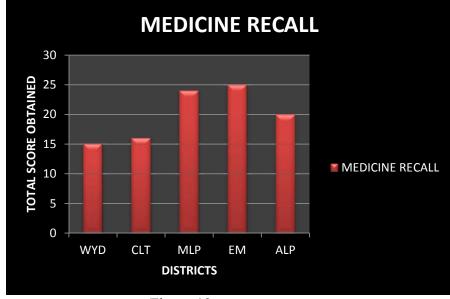


Figure 19

17. PRESCRIPTION HANDLING

Source	S S	Df	ms	F	p-value
Total	1686.4	9			
Districts	6.4	4	1.6	0.154	P>0.05
Handling	1638.4	1	1638.4	157.538	P<0.001
Error	41.6	4	10.4		

Table 14: ANOVA table for prescription handling

Mean score for 'prescription checking' is significantly higher than the other. (p < 0.001)

Between districts there is no difference is score (p>0.05)

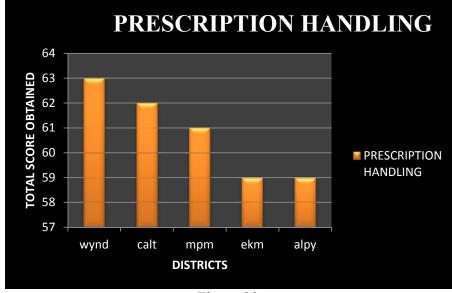
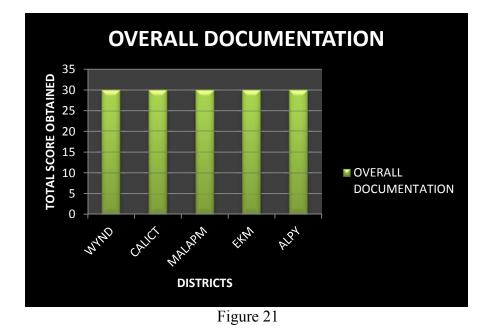


Figure 20

18. DOCUMENTATION

For all districts total scores are equal.



19. STORAGE

All the districts are equal as far as medicines checked, protected from temperature, light.

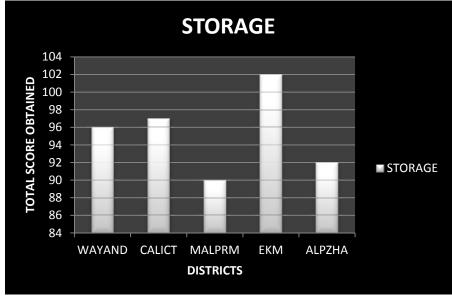


Figure 22

ANNEXURE III

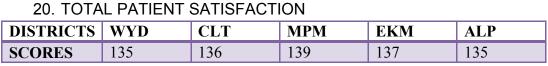
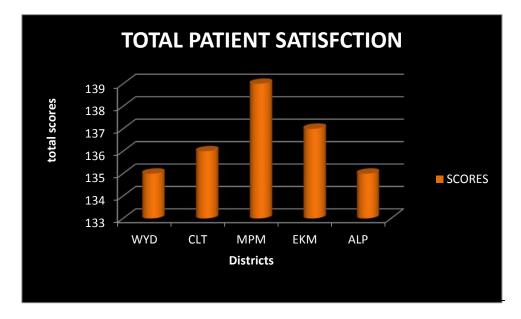


Table 15: comparison of total patient satisfaction





21. COMPARISON OF TOTAL AWARENESS, PATIENT SATISFACTION AND GENERAL AWARENESS

Source	Ss	Df	Ms	F	p-value
Total	21496.00	14			
Districts	988.67	4	247.17	1.860	P>0.05
satisfaction	19444.00	2	9722.00	73.142	P<0.001
Error	1063.33	8	132.92		

Table 16: comparison of total awareness, patient satisfaction and general awareness

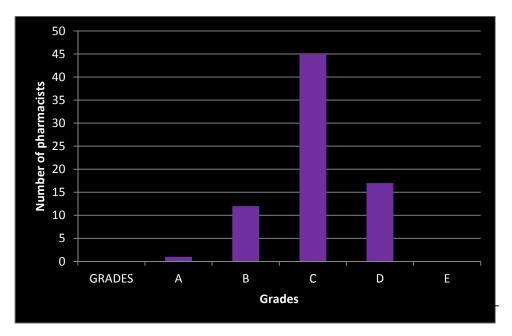
Total awareness score is significantly higher than patient satisfaction score and job satisfaction score (p<0.001)

Between districts the difference is not significant (p>0.05)

22. NUMBER OF PHARMACISTS WITH EACH GRADE

GRADE	NO OF PHARMACISTS
A (greater than 70 scores)	1
B (60-70)	12
C (50-60)	45
D(40-50)	17
E(less than 40)	0

Table 17: Number of pharmacists with each grade





GRADE A-Excellent GRADE B-Good GRADE C-Satisfactory GRADE E-Below satisfactory

23. TOTAL SCORES ACHIEVED BY EACH DISTRICT

DISTRICTS	WYD	CLT	MPM	EKM	ALP
SCORES	709	745	754	803	753

Table 18: comparison of total scores achieved by each district.

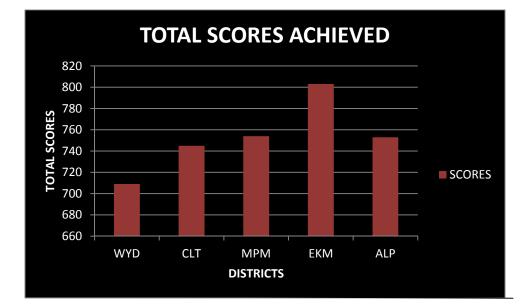


Fig 25

CHAPTER 6 DISCUSSION

6. DISCUSSION

This was the first quality auditing study of community pharmacists carried out in Wayanad, Calicut, Malappuram, Ernakulum and Alappuzha districts of Kerala. 75 community pharmacies were selected for the study using stratified random sampling technique, and the response rate was 100%. All the pharmacists were very cooperative and they actively participated in the survey. The survey questionnaires were designed and prepared by referring previous studies conducted in our country ⁽⁸⁾ as well as abroad ⁽³⁾.

Out of 75 study population, 50.66% were found to be females and the rest were males. 84% of pharmacists working in these regions had D. Pharm qualification and 16 % were B. Pharm graduates which was similar to findings reported by Kiron S.S et al in a cross sectional survey done in Kannur district of Kerala in 2012. From the study, it was surprising to know that no pharmacists in those regions had M. Pharm qualification. 13.33% pharmacists had more than 20 years of experience while 33.7% of the pharmacists had 11-20 years of experience.

Generally speaking there are 3 categories of drug information .Journals are the primary source of information which is most up to date and the best sources of information. Secondary sources such as bibliographic, indexing and abstracting services are quite useful for quick and selective screening of primary literature. The tertiary source of information such as books provides easy access to information's ⁽¹³⁾. In our study all the pharmacists scored the same for drug information awareness. During survey we found that majority of pharmacists were referring CIMS for acquiring drug information. They also depended on internet for clarifying their doubts regarding their medicines. No pharmacists in those regions had access to journals which provides the most accurate and up to date information.

Regarding temperatures used to store different medicines, majority of the pharmacists were aware about cool, cold and room temperatures and we couldn't find any pharmacists who know about controlled room and warm temperature. Regarding vaccine storage all the pharmacists except from Wayanad had a good score. All the pharmacists from each district scored high regarding suppository storage. 65% of pharmacists suggested placing drugs in safe dark areas to avoid drug deterioration from sunlight exposure.18.66% of pharmacists also answered usage of amber coloured bottles to prevent sunlight along with placing in dark areas. Only 2%

suggested usage of blister packing to prevent drug deterioration. From the study we found that pharmacists from Ernakulum districts had more knowledge on storage where as pharmacists from Wayanad scored least.

80% of the study population suggested importance of patient counselling without requisition from the patient. 20% of pharmacists considered it as unnecessary to provide counselling without request and the reason they explained was the busy schedule of the patients. Regarding the aspects discussed during patient counselling majority of the pharmacists explained to the patient only about how to take the medicine. Very few explained side effects, storage, drug food interactions to patients. None of the pharmacists assessed the knowledge of patients about medication after counselling. The reason stated by some pharmacists was the busy schedule of the patient and some found it unnecessary to assess the same. 98% of pharmacists suggested the need for patient counselling area in their pharmacy. Regarding patient counselling pharmacists from Wayanad scored higher whereas pharmacists from Ernakulum scored the least. The reason we could find from our study was the busy schedule of pharmacists in Ernakulam in dealing with a large number of prescriptions and the busy patients who have no time to spend for counseling by the pharmacist.

72% of pharmacists do not check for drug interaction. 38% of pharmacists depended on online drug interaction checkers for checking drug interaction. 56% of the study population had no idea about different types of drug interaction. 18.66% of study populations were aware of drug-food interactions. 25% of pharmacists were aware about both drug-drug and drug-food interaction. 40% of the study population informed the doctor when they detected any interactions within the prescription. 60% neglected if they found any interactions. Overall scoring by the pharmacists about drug interactions was higher in Ernakulum and the least in Wayanad.

72% pharmacists failed to mention any one recently approved drug for past one year. 65% of total population answered the number of fixed dose combinations banned recently from the market. Wayanad and Ernakulum districts scored same higher score whereas pharmacists from Malapuram districts scored low. Majority of pharmacists depended on news letters from 'AKCDA' and also govt.web site to get details about approved and banned drugs. They also used online social media for the regular updations like Whatsapp and face book.

81.3% pharmacists have heard about ADR. 26.6% population knew that ADR can be reported which is less compared with the study conducted by Kiran Nagaraju

et al ⁽¹¹⁾ where 31 % were aware of ADR reporting .Only 2% have reported ADR and 8% have heard about ADR reporting forms which is greater than that found by Nagaragu et al which was 1%. 8% suggested that ADR should be reported to doctor. Very few suggested reporting to CDSCO.20% of the study population suggested that adverse drug reactions should be compulsory and 4% of population was of opinion that the ADR reporting should be voluntary. It is very pathetic to know the situation of our Kerala pharmacists in ADR monitoring. Majority of pharmacists responded that they have heard about ADR during their academic years. Even though pharmacovigilance is gaining popularity in the present scenario and our state pharmacists being unaware about the fundamental aspects of ADR, it is a great responsibility to make them aware about ADR by taking classes so that more patient benefits can be achieved. The authorities should make necessary actions for this.

From our study, we concluded that the general awareness of pharmacists was not at all satisfactory. This may be due to the pharmacist's poor updation of knowledge, poor accessibility towards online data bases or other journals and lack of continuing education programmes regularly or periodically. It was found that the pharmacists from Wayanad scored low and the pharmacists from Ernakulum scored high. From the attitude of pharmacists, we found that they were not at all interested in making new interventions in profession.

14.66% pharmacists were highly satisfied with their profession where as 2% were unsatisfied. 70.6% were satisfied with the job security at work place. Only one pharmacist in Malapuram district showed neither satisfaction nor dissatisfaction. 69.3% satisfied with the balance between workload and personal life, 9.3% showed dissatisfaction. 73.3% were satisfied with the nature of work. 40% showed satisfaction , 40% showed dissatisfaction and 1.3% were highly unsatisfied with their income that is half of the population feels that they are poorly paid for the job which is similar to the study conducted by Kiron S S et al in 2012⁽²⁾. 64.8% were satisfied with rules regulating their profession whereas 33.3% were unsatisfied and 2.66% were highly unsatisfied. 77.33% were satisfied with their working hours inside the pharmacy. In the overall job satisfaction category Alappuzha scored high and Wayanad scored the least. The mean score of job satisfaction was significantly low in Malapuram district. The salary drawn by community pharmacist is very much less compared with others with an average of Rs. 8000. Significantly lower mean score were obtained for "Income satisfaction" and "Rules regulating profession" compared

to others. Based on the total scores, it has been seen that Malappuram district was having significantly lower job satisfaction scores than other districts.

94.6% pharmacist responded that the pharmacy was managed under their overall supervision, whereas 5.4% stated the interference of pharmacy owners. 5.3% pharmacists wore white coat and the rest were not wearing white coat which was similar to findings by Levin Thomas et al in a quality auditing study of community pharmacies in Kerala in 2015⁽⁸⁾. None of the pharmacists wore badge displaying their name and underwent periodic immunization. As per the guidelines for dispensing of medicines, prepared by Kerala State Pharmacy Council, "All the pharmacists must wear a neat, white overcoat and should additionally wear a badge prominently displaying their name and designation and register number of state pharmacy council." Many of the pharmacists responded that they wore white coat during inspection time only. Another major reason given by the pharmacists for not wearing white coat was the humid and hot climatic condition of Kerala. According to law, drug inspector is responsible for visiting pharmacies at least twice in a year. During the survey it was hard to believe that in certain districts there was no inspection taking place. This shows the irresponsible attitudes of corresponding authorities towards regulation of our profession.

None of the pharmacies interviewed had a written procedure /SOP to receive complaints. 76 % of pharmacists immediately addressed all the complaints received and 64% evaluated to find the underlying cause of complaint. 90.66 % of pharmacists didn't maintain a register for documentation of complaints. 6.6 % documented the complaints, 1.33% documented both complaint and action taken whereas other 1.33% documented all those three.

The whole study population scored equally for procurement and inventory. All the pharmacists checked medicines for their standard before they were accepted inside the pharmacy. Medicines were purchased only from authorized sources. All the details of suppliers including their addresses, contact numbers, names and address of their management persons, technical persons, and copies of licenses were properly maintained. All the errors made by the suppliers were informed to them and properly documented. All the medicines received from suppliers were tallied against their invoices and checked for the correctness of quantity price, batch number and expiry date. The whole 75 pharmacists maintained all the purchase records as per law.

62.66 % of pharmacists attended continuing educational programmes, 37.33 % didn't attend any such programmes. Some of them explained that they do not feel the need for attending any classes, some were not aware about those classes whereas some of them had no time to attend. It was surprising to know that some of the pharmacists attended the educational program conducted by Kerala state pharmacy council during registration time only. 46. 6 % pharmacists received educational programmes periodically. Pharmacists from Calicut scored higher for training and educational programmes whereas pharmacists in Alappuzha scored the least.

13.3 % of study population had a well-documented recall procedure. All the pharmacists took immediate steps to stop the sale of medicines in case of suspicion and notified the relevant parties. 20 % documented the initiation, progress and completion of the recall.

24 % pharmacists checked for identity of the patient, and whether the prescription is presented by the client himself or by someone's on client behalf. 1.33 % of the study population checked for name and address of the physician, his seal and registration number, name of the medicine, dose, dosage, and total amount, instructions to patients, refill information, prescriber's signature, any drug interactions, contraindications. It was found from the study that majority of prescription checking was limited to enquiring the dose of medication. Various parameters such as verifying the authenticity of prescription, drug interactions contraindications, refill information and patient counselling for safe and proper intake of drug was not properly carried out which is similar to other quality auditing work conducted in 2015. Various studies conducted elsewhere across the country have reported on the irrational prescribing and need for increased role of community pharmacists to avoid them ⁽⁸⁾. These studies highlighted the need for increased prescription verification and patient counselling by community pharmacists. Even though it is compulsory that medicines should be dispensed from the pharmacist only, during the study we found that medicines are dispensed by both pharmacist and the salesperson. One pharmacist may not be sufficient to manage all the customers. Appointing more than one pharmacist in a shop may help to solve this problem and enhances the professional role of pharmacists but as the pharmacists have to be paid more than salespersons, it becomes difficult for the pharmacy managers to appoint them. Hence, strict law must be come into existence and be enforced so that medicines will be dispensed only by the pharmacist.

All the pharmacists scored same .All the necessary statutory documents and the operational documents were maintained as per the law.

All the pharmacists checked for medicines quantity, batch number, and expiry before transferring into storage area and they also took measures for protecting the medicines from temperature and light. 21.33 % pharmacists kept drugs well protected from dusts by cleaning the racks regularly and locking the cupboards and the problem faced by the rest of pharmacists was the location of pharmacies near to main roads which results in dust accumulation inside the cupboard. Only 20 % of pharmacists took measures to protect drugs from humidity. Some kept silica gel inside cupboards to prevent humidity and very few pharmacies had centralized AC facilities. Most of the pharmacists had no idea about humidifier compulsory in the pharmacy or establishing AC pharmacies can contribute more to drug storage. Medicines to be kept in cold temperature were kept in refrigerator by all the pharmacists and all the records kept as per legal requirement. From our survey, we found that pharmacists in Ernakulum district scored high for storage and Malppuram scored least.

All the pharmacies were easy located by the people and had enough standing facilities for patients. During the survey, we could find only 4% of pharmacies with sitting facilities. Regarding patient counselling, all the 75 patients were getting counselling from their pharmacist. All the patients obtained counselling from the pharmacist regarding how to take their medicines only. Only 5% of people have seen their pharmacist wearing a white coat and all the patients expressed their views that they need their pharmacist to be seen in white coat so that they look more professional which is similar to study findings by Levin Thomas et al⁽⁸⁾ and also they were interested in getting services from a highly qualified pharmacist. The whole study population were satisfied in dispensing by the pharmacists and none of them ever obtained expired product which is an appreciable matter that pharmacists are very careful while drug dispensing. They were also satisfied with the time taken by pharmacist for prescription filling and all of them got their medicines straight away.

All the patients that we came across mentioned that they wanted to buy non medicated items from the pharmacy as they wanted to save their time which they spend in the other shops to buy these non-medicated health products. Majority of the patients were interested to depend on the same pharmacy for the purchasing of the medicines due to easy accessibility for patients and those pharmacies provided all the required medicinal products within the prescription. All the interviewed patients suggested that they need new services to be implemented in the pharmacy other than dispensing and counselling like checking of blood pressure, blood sugar levels, height, weight, temperature etc. They also included that the newly implemented services should be monitored by a well professionally qualified pharmacist and the pharmacy will be paid for the same.

By performing quality auditing study, 45 pharmacists were awarded with grade C which was satisfactory, 17 pharmacists with grade B which was good and 1 pharmacist with grade A which was excellent. Total patient satisfaction was more for pharmacists from Ernakulam district than the other four. Job satisfaction was more for pharmacists from Alappuzha and least for pharmacists from Malappuram (χ^2 =13.083, DF=4, p<0.05, for Malappuram). Total awareness score was significantly higher than patient satisfaction score and job satisfaction score (p<0.001). Total awareness score was higher for Ernakulam district and least for Wayanad. The overall services provided by pharmacists from Ernakulam were more than other four districts. From the study it was found that adherence of majority of community pharmacists to good pharmacy practice guidelines were poor which resulted in lack of professionalism, lack of awareness about importance of ADR monitoring, patient counselling , poor income which is below his qualifications.

It's the time to necessitate immediate changes to the system of community pharmacy practice by the concerned regulatory authorities and in the attitude of pharmacist with respect to his professional duties and ethics. One of the limitations of this study is the source of bias. Only 75 community pharmacists were interviewed for the study which represented only a small population. So the findings of the study cannot be extrapolated to represent the overall quality auditing of community pharmacists across the state of Kerala.

CHAPTER 7 CONCLUSION

7. CONCLUSION

Community pharmacy is a pharmacy service centre established in a community set-up catering to the needs of the society for their drug products, health care items and related materials. It provides the pharmaceutical services required for the health care of the people in general and the patients in particular. "Community pharmacists are the health professionals most accessible to the public. They are no more a "pill counter". In many countries, the pharmacists are in a unique position to be fully aware of the patients past and current drug history and consequently, can provide essential advice to the prescriber" [WHO]. A community pharmacist should perform a "patient oriented approach than a product oriented approach" as a health care professional. As our study is dealing with the quality auditing of the community pharmacists as a patient oriented health care professional.

This study reveals that many of the pharmacists are not well aware about the latest knowledge updating Media like journals, online databases and many other drug information resources. Many of them are not well aware about the different storage temperatures and the relevance of storing medicines in different temperature. Majority of the pharmacists want to provide the patient counselling without requisition of the patients but many of them are unaware about the aspects that to be discussed during a patient counselling. The pharmacists are not assessing the impact of counselling while they need a separate area for the effectiveness of patient counselling. This study also points out the importance of creating awareness about Drug interactions, recent updates and ADR.

The project also deals with the job satisfaction of the pharmacists. Majority of the pharmacists are satisfied for being pharmacists while majorities are unsatisfied about their income. From this study it is very clear that the rules and regulation of the pharmacy profession is not properly enforced in its all sense. The best example we found out that is majority of the pharmacists are not properly wearing the white coat and ID card as per the declaration of Kerala state pharmacy council. Pharmacists are not maintaining a register for complaints and recall. All the authorities are providing training programmes but not in a periodic manner. It is clear that many of the pharmacists are merely following the conventional way and not aware of making the profession as a patient oriented system. Every pharmacist should update their

knowledge as a student for the betterment of the smooth working of healthcare system.

As a pharmacist is considered to be the last man of healthcare providing system for the patient, pharmacists should provide a wide awareness about disease, drugs and life style modification. From the study it is clear that, few numbers of pharmacists are only strictly following the rules and regulations of the authority. It is very necessary to be adhered with the rules for the better service.

The quality auditing of community pharmacists in 5 districts of Kerala is a new kind of study and the study results highlights that the adherence of community pharmacists in these districts of Kerala to the service policy of good pharmacy practice guideline is poor.

FUTURE PLAN

- Formulate a guideline for practicing community pharmacists
- Develop a scale for carrying quality auditing of community pharmacists
- Provide awareness for community pharmacists about various aspects of pharmaceutical care.

CHAPTER 8 BIBILIOGRAPHY

8. **BIBILIOGRAPHY**

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CHAPTER 9 ANNEXURES

9. ANNEXURE

	QUALITY AUDITING OF COMMU	NITY PH	ARMACISTS IN KER	ALA: A
	CROSS SECTIONAL STUDY			
		ECE OF D	TADACA	
	PADMAVATHI COLL	EGE OF P		
	NAME:		AGE:	
	QUALIFICATION :		YEARS OF EXPE	ERIENCE:
	ADDRESS:		DATE:	
	ANNEXURE -I			
	1.GENERAL AWARENESS OF CO.	MMUNIT	Y PHARMACISTS	
	1. DRUG INFORMATION			
S1. No	Questions	Choice	Options	Scoring
07.	Name any available Drug		Text books	
	information sources?	<u> </u>	Journals	
			Online databases	
		<u> </u>	Newsletters	
			Others	
	2. STORAGE			
1.	Name the different temperatures		Cold	
	available?		Cool	
			Room temperature	
		<u> </u>	Controlled room Warm	
2.	Vaccines should be kept at which		warm	
.	temperature?			
4.	Suppositories can be stored in		Room temperature	
	which of this temperature?		Refrigerator	
			Warm temperature	
	Name some measures to avoid drug		Amber	
5.	deterioration from sunlight		colouredbottles	
5.			Aluminium blister	
5.	exposures?			1
5.			packing	
5.			packing Placing drugs in safe dark areas	

1.	3.PATIENT COUNSELLING Is it necessary to give patient	Yes
1.	counselling without requisition	No
	from patient?	
2.	Whether following aspects are	Name of the
	discussed during patient	medicines
	counselling?	How to take the
		medicine
		Expected actions of
		medicines
		Common risks
		effects of the
		medicines
		Proper storage of
		medicines
		Life style/dietary
		changes if any Contra indications Drug-drug/food interactions
2	Harring the level of the	
3.	How will you assess the knowledge	Name of the drug
	of patients about medication after counselling?	Indication of the
	counselling:	drug
		Dose of the drug
		Proper time of taking
		of the drug
		Duration to be taken
4.	Do you think that a patient	Yes
	counselling area is required in your	No
	pharmacy for effective patient	110
	counselling?	
	4.DRUG INTERACTIONS	
1.	How will you check for drug	Online drug
	interactions within a given	interaction checkers
	prescription	Reference books
		Do not check for interactions
2	Different trans of American strengt	
2.	Different types of drug interactions	Drug lab interactions
		Drug drug interactions
		Drug food interactions
3.	If you detect any interactions with	Inform the doctor
	in the prescription, what are the	
	measures you will take?	Neglect it
	measures you will take:	Substitute the drug

5.RECENT UPDATES AND DEVELOPMENTS

1.	Name any one recently approved drug for past one year?		
2.	How many fixed dose combinations are banned recently?		
3.	From where you get the details	Govt. site	
	about approved and banned drugs?	News papers	
		Journals	
		News letters	
		Books	

6.ADVERSE DRUG REACTIONS

1.	Have you heard about ADR?	Yes	
		No	
2.	Do you know that ADRs can be	Yes	
	reported?	No	
3.	Have you ever reported any ADR?	Yes	
		No	
4.	Do you know about ADR reporting	Yes	
	forms?	No	
5.	To where the ADRs should be reported		
6.	Do you think reporting ADR is	Yes	
	compulsory?	No	
7.	Do you think reporting ADR is	Yes	
	voluntary?	No	

	2. JOB SATISFACTION	
1	Are you satisfied with your	Highly satisfied
-	profession?	Satisfied
	-	Neither satisfied nor
		unsatisfied
		Unsatisfied
		Highly unsatisfied
2	Are you satisfied with job security	Highly satisfied
	at your work place?	Satisfied
		Neither satisfied nor
		unsatisfied
		Unsatisfied
		Highly unsatisfied
3	Are you satisfied with balance	Highly satisfied
	between work load and your	Satisfied
	personal life?	Neither satisfied nor
		unsatisfied
		Unsatisfied
		Highly unsatisfied
5	Are you satisfied with nature of	Highly satisfied
	your work?	Satisfied
		Neither satisfied nor unsatisfied
		Unsatisfied
		Highly unsatisfied
6	Are you satisfied with your	Highly satisfied
•	income?	Satisfied
		Neither satisfied nor
		unsatisfied
		Unsatisfied
		Highly unsatisfied
	Are you satisfied with rules	Highly satisfied
	regulating the profession of	
7	pharmacy?	Satisfied
	-	Neither satisfied nor
		unsatisfied
		Unsatisfied
		Highly unsatisfied
8	Are you satisfied with working	Highly satisfied
	hours inside the pharmacy?	Satisfied
		Neither satisfied nor
		unsatisfied
		Unsatisfied
		Highly unsatisfied

9	Are you satisfied being a		Highly satisfied	
	pharmacist?		Satisfied	
			Neither satisfied nor	
			unsatisfied	
			Unsatisfied	
			Highly unsatisfied	
	3.PERSONNEL			
1	Is the pharmacy managed under the		Yes	
	overall supervision of a			
	pharmacist?		No	
2	Do all personnel in the pharmacy		Yes	
	wear a neat white coat?		No	
3	Do all the pharmacist wear a badge		Yes	
	displaying their name and the word		No	
	pharmacist?		1.000	
4	Do all the personnel undergo		Yes	
	periodic immunization?		No	
	4.COMPLAINTS AND RECA	LL		
1	Does the pharmacy have a written		Yes	
	procedure /SOP to receive		No	
2	complaints? Are all the complaints immediately	2	Yes	-
4	addressed by the pharmacist?		No	-
3	Is the complaint evaluated to find		Yes	-+
2	the underlying causes?	2	No	-
4	Are the following documented in		Complaint	\rightarrow
	the complaint register?	<u> </u>	Erring person's name	_
	the complaint register:	-	Action taken	e
	5.PROCUREMENT AND INVENTOR	RY	Action taken	
1	Are the medicines checked for their	13	(es	1
	standard, laid down in the law,			_
	before they are accepted inside the	1	No	
2	pharmacy? Are the medicines purchased from	3	les	+
	authorised sources only?		No	-
3	Are the details of suppliers eg: their		les	+-
-	addresses, contact numbers,names			
	and addresses of their management	1	No.	
	persons,technical persons ,copies of various licences held by them maintained?			

QUALITY AUDITING OF COMMUNITY PHARMACISTS

4	Are all the errors made by the	Yes	
	suppliers ,nature of errors and repetition of same errors documented to avoid their recurrence?	No	
5	Are all the medicines received from suppliers tallied against their	Yes	
	invoices and checked for the correctness of quantity price, batch number and expiry date?	No	
6	Are all the purchase records	Yes	
	/invoices maintained as stipulated under the law?	No	

6. TRAINING AND EDUCATIONAL PROGRAMME

1.	Are you attending any continuing	Yes	
	educational programmes?	No	
2.	How many continuing educational programmes are attended in a year?		
3.	Is the training process received periodically?	Yes No	

7. MEDICINE RECALL

1	Does the pharmacy have well documented recall procedure?	Yes No	
2	In case of any suspicion, does the	Yes	
2.	pharmacist take immediate steps to stop the sale of medicine and notify the relevant parties?	No	
3	Are all the initiation, progress and	Yes	
	completion of the recall all documented?	No	

8.PRESCRIPTION HANDLING

1	Upon receiving a prescription does the pharmacist checked for	Identify of the client (name, address, age, sex)
		Whether the prescription is presented by the client himself/herself or by someone's on client behalf
2	Are the prescription checked for?	Name of the prescriber, his/her address and
		Seal and registration number

QUALITY AUDITING OF COMMUNITY PHARMACISTS

		Name of the medicine, dose, dosage and total amount
		Instructions to patients
		Refill information if any
		Prescribers signature
		Any drug interactions
		Contraindications; if any
3.	Does the pharmacist personally	Yes
	dispense medicines?	No
	9.DOCUMENTATION SYST	TEM
1.	Are all necessary	Yes
	statutarydocuments (liscenses, registration, permissions)for	No

	surety a pharmacy adequately maintained?		
2.	Are all operational documents eg : purchase invoices, sales invoices and other statutary documents maintained as per the law?	Yes No	

10.STORAGE

	10.STOKAGE		
1	Are all medicines coming into	Yes	
	pharmacy checked for correctness of quantity, Batch no, expiry before transferring in to storage location?	No	
2	Are all the medicines		
	 Stored under appropriate temperature 	Yes	
		No	
	Protected from light	Yes	
		No	
	Protected from dust	Yes	
		No	
	Protected from humidity	Yes	
		No	
3	Are all the medicines that are to be stored in a cold temperature kept in the refrigerator?	Yes	
		No	
4	Are the storage area enclosed and	Yes	
	locked whenever necessary?	No	
5	Are all the records and stock kept	Yes	
	as per legal requirement?	No	

	PATIENT SATISFACTION SURVI	Y FORM	[
	DEMOGRAPHIC DETAILS		107	
-	NAME:		AGE:	
1	ADDRESS:		SEX:	
	FACILITIES			
Sl No	QUESTIONS	CHOIC E	OPTIONS	SCOR
1.	Whether the pharmacy can be easily located and identified by the public? Whether there is sufficient place for patients to stand comfortably at		Remotely located	
			Accessible with difficulty	1
2			Easily accessible	
2.			yes	
	dispensing area?		No	
3.	Whether there is sitting facilities for the patients in the dispensing area?		Yes	
			No	
2	PATIENT COUNSELLING			
1	Whether you get counselling from pharmacist regarding your disease and drugs?		Yes	
			No	
2	Whether the following aspects are discussed during patient		Name of the medicine	
			how to take medicine	
	counselling?		expected action of	
		-	medicine common risk effects of	
			medicine	
			proper storage of	<u> </u>
			medicines	
			life style /dietary	
			changes	
			contraindications	
			drug -drug/food interactions	
3	PERSONNEL			
1	Is the pharmacist wearing white		Yes	
	coat and ID tag?		No	

QUALITY AUDITING OF COMMUNITY PHARMACISTS

2	Do you want your pharmacist to wear a white coat so that he/she looks more professional?	Yes
		No
3	Are you interested in getting	Yes
	services from a highly qualified pharmacist?	No
	4. DISPENSING	
1	Whether this pharmacy provide	Yes
	complete medicines in your prescription?	no
2	Have you ever purchased expired or spoiled products ?	Yes
		No
	5. PRESCRIPTION FILLING	
1	Are you satisfied with the time it	Yes
	takes to get your prescription filled?	No
2	When you come here to collect medicines, do you get it straight away?	Yes
		No
	6. OVERALL SATISFACTION	
1	Are you satisfied with services provided by the pharmacist?	Yes
		No
1	Do you like to collect other non	Yes
1	medicated items from pharmacy?	No
2	Do you always depend on the	Yes
	same pharmacy for getting medicines?	No
3	Do you want any new services to	Yes BP
-	be implemented in pharmacy?	Blood sugar
	oe implemented in pharmacy:	Height
		Weight
		Temperature
		Cholesterol
		No