

DEVELOPMENT OF HOSPITAL FORMULARY FOR A RURAL TERTIARY CARE TEACHING HOSPITAL IN SOUTH INDIA

By

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*Dissertation Submitted to the
Rajiv Gandhi University of Health Sciences, Karnataka, Bengaluru*



*In partial fulfillment
Of the requirements for the degree of*

**MASTER OF PHARMACY
In
PHARMACY PRACTICE**

Under the Guidance of

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APRIL 2015



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*Dedicated
To
My Parents*



ACKNOWLEDGEMENT

This thesis is the end of my journey in obtaining my M.pharm degree. I have not travelled in a vacuum in this journey. This thesis has been kept on track and been seen through to completion with the support and encouragement of numerous people.

*At this moment of accomplishment, first of all I pay homage to the **GOD ALMIGHTY**. I wouldn't have made it this far without him being the head of my life.*

*“Nothing in this universe is comparable to the love of parents” life without them is not imaginable. I truly owe my life to my dear dad **Mr. Maltheshappa Majjigere** and mom **mrs. Dhaksahayani Maltheshappa**. I thank my mom and dad for their immortal love and blessings. Their love and support made me to achieve this far.*

*I also thank my only loving brother **Chandrakanth Majjigere (Chandu)**, my cousin brothers **Shivu, Raju, Kumar, Santosh, Mohan kumar, Manu, Jayanth, Mallikarjun, Avi** and my cousin sisters **Archana, Kanchana, Chethana, Swetha, Vijaya, Saroja, Kavitha, Nagu, Ranjitha and Mangala**. for their love and support.*

*I express my deep sense of gratitude to my guide **Satish Kumar B.P Associate professor, department of Pharmacy practice, S.A.C. College of pharmacy**. This work would not have been possible without his guidance, support and encouragement from the inception to its completion. I am extremely thankful for his guidance and support rendered.*

*My sincere and deep felt thanks to **Dr. B. Ramesh principal S.A.C. College of pharmacy** for providing necessary infrastructure and resources to accomplish my research work and also to great support and suggestions.*

*I express my gratitude to **DR. T.R Manohar chairman of the P & T committee and medical superintendent** for his great support and suggestions.*

I extend my thanks to all the P & T committee members of AH & RC for their valuable support and suggestions.

I hearty thank to Mr. Ramnath K.V Associate professor and head, department of pharmacy practice, S.A.C. College of pharmacy.

I take this opportunity to say heartfelt thanks to Mr. Kumaraswamy Associate professor, Dr. Rajveer Singh Chopra, Dr. Meenu Pandey, Dr. Sree Charan Chama, department of pharmacy practice, S.A.C. College of pharmacy.

I also extend my thanks to all the Pharm D friends for your generous help, support and suggestions during my thesis work.

A journey is easier when you travel together. Interdependence is certainly more valuable than independence. I take this opportunity to acknowledge my M.pharm classmates and college mates Sachin, Guru, Bipin Kafle, Thakur, Surendra, Saroj, Suman, Manjula, Nayana, Jamuna, Narendra, Amrit, kharel, Dakal, Nirajan, Ravi, Suvesh, Braj, Harika, Ashwini, Akshata, Chetana, Pavitra, Shilpa, Sarala and others for their valuable advice and helping hand when needed.

“I would rather walk with a friend in the dark, than alone in the light.” I express my heartfelt thanks to my dearest child hood friends Vijay Durgesh, Sunil, Chetan, Naga, Raja, Malli, Prassana, Adithya, Ujwal, Nitesh and many others.

I also express my heartfelt thanks to my B.Pharm friends Siddu, Raju (Guddi), Vishwas, Rathore Kethen Singh, Srikanth, Anvesh and seniors Kuldeep, Keyur, Vidya (Singh) and all others.

I thank my juniors Girish, Abhi, Pramodh, Sashi, Naga, Simha (Ravi), Avinash, Amogh, Niranjan, Nagesh (Tiger), Pavan, Nishanth, Shivananda and others for their affection love, care and concern.

A very special thanks to my M.Pharm seniors Vinay (Crazy) and Madhu for their help, support and suggestions.

*Last but not least, i express my deep felt thanks to my **GURUYRUNDA**, the unforgettable teachers of my life – my primary school teachers Sheela madam, Sashikala madam, Savitri madam, Uma madam, Sunitha madam, my high school teachers Rudrappa sir, Basavaraj sir, Siddalingiah sir, my B.pharm teachers Girish sir, Somu sir, Murthy sir, BRS Gouda sir, Sharma sir, Natraj sir, Manjjanna sir, Shafi sir and Kirana madam. I am greatly indebted for them, they made me strong in all ways to achieve this far.*

I thank each and everyone who have helped me

Your's

Kiran Majjigeri

LIST OF ABBREVIATIONS

SL No.	ABBREVIATIONS	EXPANSION
1	AH & RC	Adichunchanagiri Hospital & Research Centre
2	AHRC-HF	Adichunchanagiri Hospital & Research Centre Hospital formulary
3	DMARDs	Disease Modifying Anti-Rheumatic Drugs
4	EDL	Essential Drug List
5	EML	Essential Medicine List
6	FDC	Fixed Dose Combination
7	Ig	Immunoglobulin
8	IPC	Indian Pharmacopeia Commission
9	NFI	National Formulary of India
10	NSAIDs	Non-Steroidal Anti-inflammatory Drugs
11	PTC	Pharmacy and Therapeutic committee
12	P & T	Pharmacy and Therapeutic
13	WHO	World Health Organization

Abstract

ABSTRACT

Back Ground: A formulary is a continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health. A formulary system is the on-going process through which a health care organization establishes policies regarding the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

Objective: To develop hospital formulary for a rural tertiary care teaching hospital in south India and compare it with Essential Medicine List (EML) 2013 Delhi, India.

Methodology: A prospective study was carried out in a tertiary care teaching hospital over a period of 9 months. A finalised drug list was obtained from the P & T committee and monographs were prepared as per the recommendations of the P & T committee. The drugs in the prepared formulary and EML-2013, meeting inclusion criteria were compared.

Results: The prepared Adichunchanagiri Hospital & Research Centre Hospital formulary (AHRC-HF) was comprised of total 357 drugs. Out of these 357 drugs, there were totally 306 single drugs, 21 FDCs, 18 immunologicals and 12 vitamins. These 357 drugs were classified into 23 main categories and monographs were prepared. Pharmaceutical product list was prepared, which comprised of total 948 brands selected for the drugs listed in AHRC-HF. When AHRC-HF drugs are compared to EML, it showed that, out of 351 AHRC-HF drugs 255 (72.64 %) drugs were present in EML. These 255 EML drugs of AHRC-HF covered 67.81 % of 376 EML drugs. When the drugs (351) of AHRC-HF are divided into EML and non-EML drugs, it showed that 72.64 % (255) of the AHRC-HF drugs are EML drugs. Where, 27.35 % (96) of the AHRC-HF drugs are non-EML drugs.

Abstract

Conclusion: The prepared Hospital formulary is unique in its features, as recommended by the hospital's P & T committee to suit its patient's health care requirements. The prepared hospital formulary should be implemented in the hospital with effective formulary system, which will support and contribute to rationalize drug use in the hospital. Clinicians of the AH & RC hospital were satisfied with the prepared formulary and commented that, it is informative and will be useful for the health care professionals working in the hospital. Where, the prepared pharmaceutical product list can be referred for brand names and other details of the brands approved to use in the hospital. Pharmacist play important role in developing formulary and formulary system to a hospital.

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Chapter 1

INTRODUCTION



A formulary is a continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medications and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. A formulary system is the on-going process through which a health care organization establishes policies regarding the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population. Formulary systems are used in many different settings, including hospitals, acute care facilities, home care settings, and long-term-care facilities, as well as by payers such as Medicare, Medicaid, insurance companies, and managed care organizations. Many organizations have policy statements on the use of formularies.¹

With increased prevalence and incidence of diseases and with increased number and diversity medicines worldwide, every hospital should maintain a formulary of its own so as to reduce the variations in the level of treatment provided to the patients. Formulary is a continually revised compilation of pharmaceuticals and some important ancillary information that reflects the current clinical judgment of medical staff. The main reason for developing hospital formulary is to set standard for best practice, promoting high quality, evidence based prescribing thus reduces the variation in the level of treatment provided to the patients and controlling drug cost. Hospital formulary is the vehicle by which the medical, pharmacy & nursing staff make use of the system; hence it is important that it should be complete, concise, updated and easy to use. The implementation of the formulary will have significant impact on clinical practice of health care professionals. It helps physicians to know about the available drugs in the hospital pharmacy and also helps in better inventory control.²

Drug formularies are a ubiquitous, heterogeneous yet often contentious feature of both US and international drug policy. Formularies represent the fundamental approach embodied in the World Health Organization (WHO) Model Formulary 2004 and various countries' essential medicines lists. In addition, WHO encourages each hospital to establish a drug and therapeutics committee to oversee selection of drugs and to set policies for that institution's local formulary. Formularies and committees that oversee them are present in some form in virtually every US hospital and outpatient drug plan and are highly visible components of public drug benefits in many countries. Thus decisions made by these committees directly or indirectly impact every prescriber, pharmacist, and patient.³

A formulary can be used as a tool to rationalize the range of medicines used in standard practice. When a formulary is used effectively, it becomes the cornerstone of a formulary system, which can be one of the most effective methods of ensuring rational drug therapy and controlling drug cost. Implementation of hospital formulary systems helps to optimize treatment, make essential drugs available, and control costs of therapy.⁴ The main reason for developing hospital formulary is to set standards for best practice. This should promote high quality; evidence based prescribing and reduces variation in the level of treatment provided to patients.⁵ Many people use the term formulary and drug list interchangeably, which is wrong in view of the fact that there exists a vast difference in scope and preparation of formulary over a drug list. A formulary usually consists of listing of therapeutic agents by their generic names followed by information on strength, form, dosage, toxicology and use whereas drug list usually consists of listing of therapeutic agents by their generic names followed by data on strength and dosage form.⁶ Developing hospital formulary will be helpful to provide information for the hospital staff about the drug products approved for use by the Pharmacy and Therapeutic committee. It also highlights basic therapeutic information about each

approved item, information on hospital policies, procedures governing the introduction of drugs in hospital formulary and special information about drugs and drug use.⁷

Hospital formularies are heterogeneous in nature, the drugs to be included in a formulary, information to be presented for individual drugs, other policies and procedures related to drug use in the hospital depends on decisions taken by P & T Committee of the hospital.

The drug formulary contains a list of the drugs; monographs with information on each drug, such as uses, dosages and warnings; and a general reference section with information that might be helpful in treating patients. Some formularies may have more drugs than others depending on level of expertise; some are detailed, while some may only be limited to a mere list. A formulary should be reviewed regularly to remain relevant to the prescribers due to changing medication therapies. Additions and deletions from the formularies are indicated by accessing clinical merits, gathering relevant drug information from literature as well as own research so that additional benefits are weighed against existing molecules. A physician can request the addition of a drug to the formulary. The drug is compared with similar agents present on the formulary in terms of effectiveness, side effects and cost. New drugs of appropriate quality may be rejected if products on the formulary already cover the medical needs, qualitatively and quantitatively.⁸

Generic name, dosage form and strength, main indication, pharmacology/pharmacokinetics, contraindications, dosage schedule, adverse effects, drug and food interactions, instructions, and warnings are considered as the basic information to include in the monographs of individual drugs. While supplementary information may include brand names, price, level of use or distribution code, prescription category, patient information precautions, labelling information, storage instructions, stability, essential drug list number, main supplier catalogue number and procurement priority code.⁹

In the developed hospital formulary of AH & RC, each individual monograph of the drugs contains information about its indication, availability, dose, contraindications, precautions, adverse reactions, pregnancy category and storage. Availability category of the drugs in the developed hospital formulary of AH & RC does not contain brand names, instead the information regarding availability of the drugs is mentioned in terms of what dosage form and strength the drug is available in the hospital pharmacy. Pharmaceutical product list of AH & RC was prepared, which consists information regarding the brands/pharmaceutical products approved by the P & T committee to use in the hospital.

Awareness for effective use of drug formulary and prescribing practices for medical practitioners and students is essential to maintain an affordable and sustainable health care system for a country.¹⁰

Pharmacy and Therapeutic committee in relation with the formulary system:

Irrational and appropriate drug use of medicines leads to hospital admission and can prolong the stay of admitted patients thus eventually increase the cost of health care. Therefore, rationalization of pharmacotherapy is needed. Effective, safe, and economic drugs have to be selected, used and monitored to ensure high quality therapy at an acceptable price for as many as people as possible. In hospital settings, a drug and therapeutic committee (DTC) provides a tool for promoting and managing rational pharmacotherapy and appropriate use of medicines, develops policies for managing pharmaceutical use and administration, and manages the formulary system. In many developing countries, a well-functioning DTC has been shown to one of the most effective structures in hospitals able to address drug problems. However, in many developing countries, DTCs do not exist and in others, they do not function effectively.⁴ The most important function of DTC is to prepare and implement a formulary for the hospital.¹¹ The formulary system must have its own policies, or adhere to

other organizational policies, that address conflicts of interest and disclosure by P & T committee members.⁷

The P&T committee is responsible for managing the formulary system. It is composed of actively practicing physicians, other prescribers, pharmacists, nurses, administrators, quality improvement managers, and other health care professionals and staff who participate in the medication-use process. Customarily, P&T committee member appointments are based on guidance from the medical staff. The P&T committee should serve in an evaluative, educational, and advisory capacity to the medical staff and organizational administration in all matters pertaining to the use of medications (including investigational medications). The P&T committee should be responsible for overseeing policies and procedures related to all aspects of medication use within an institution. The P&T committee is responsible to the medical staff as a whole, and its recommendations are subject to approval by the organized medical staff as well as the administrative approval process. The P&T committee's organization and authority should be outlined in the organization's medical staff bylaws, medical staff rules and regulations, and other organizational policies as appropriate. Other responsibilities of the P&T committee include medication- use evaluation (MUE), adverse-drug-event monitoring and reporting, medication-error prevention, and development of clinical care plans and guidelines.¹

A well-structured P & T committee was formed in AH & RC, which includes physicians, pharmacists, a nurse and hospital administrator. One person from each department of the hospital was included as member of the committee, except from radiology, dental and microbiology department. The hospital formulary of AH & RC is prepared under the guidance and suggestion of this P & T committee.

Health systems should develop, maintain, and implement a formulary management process. Decisions on the management of a formulary system should be founded on the evidence-

based clinical, ethical, legal, social, philosophical, quality-of-life, safety, and economic factors that result in optimal patient care. The process must include the active and direct involvement of physicians, pharmacists, and other appropriate health care professionals. This evidence-based process should not be based solely on economic factors. The formulary system should be standardized among components of integrated health systems when standardization leads to improved patient outcomes and safety.¹ Pharmacist play a key role in developing policies and procedures governing the hospital formulary. Pharmacist should ensure that the quality of drugs is not compromised by economic considerations.¹¹

Selection of medicines for inclusion in hospital formulary is a crucial, sensible and the most important phase in developing hospital formulary for any hospital. The P & T committee members of AH & RC actively involved in selecting the medicines for inclusion in the hospital formulary. Essential medicines list 2013, eighth edition of national capital territory of Delhi, India, was used as reference by the P & T committee members to the select medicines for inclusion in the hospital formulary of AH & RC.

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety and comparative cost effectiveness. Essential medicines are intended to be available at all times in adequate amounts, in appropriate dosage forms with assured quality and adequate information and at a price the individual and community can afford.¹²

Who model Formulary, British National Formulary and National formulary of India are some of the formularies used as standard references in many hospitals. Some of the hospitals in India have developed their own hospital formularies like Kasturba Hospital at Manipal, Christian Medical college Hospital at Vellore and KLE Hospital at Belgaum and more.¹¹

Adichunchanagiri Hospital & Research Centre (AH & RC) is a 1050 bedded rural tertiary care teaching hospital. The AH & RC hospital was not having a hospital formulary. Although

a hospital formulary for paediatric department does exist in the hospital, it is limited to the drugs used in paediatric department. The hospital drug list was not regularly updated; hence most of the medical practitioners were unaware of all the drug products available in the hospital pharmacy. So, it was necessary to develop a hospital formulary to promote and manage rational use of drugs and obviously, to contribute for a better health care system.

Chapter 2

Objectives



OBJECTIVES OF THE STUDY:

Primary objective:

To develop Hospital Formulary for a rural tertiary care teaching hospital in south India.

Secondary objectives:

1. To develop Hospital formulary that is simple, precise, and handy to use.
2. To compare the prepared hospital formulary with Essential Medicine List (EML) 2013 of Delhi, India.

Chapter 3

Literature Review



REVIEW OF LITERATURE:**Formulary and the formulary system:****What is a formulary?**

A formulary is a manual containing clinically oriented summaries of pharmacological information about selected drugs. The manual may also include administrative and regulatory information pertaining to the prescribing and dispensing of drugs.

A national formulary generally concentrates on available and affordable medicines that are relevant to the treatment of diseases in a particular country. Formularies are also frequently created for different levels of health care, different sectors and for individual hospitals.

The need for formularies

Medicines play a crucial role in the prevention and treatment of diseases. When used correctly, they can offer simple and cost-effective solutions to many health problems. Today many people have little or no access to safe and effective drug therapies and may be at risk of serious health problems due to treatment with ineffective, poor quality products, or incorrect and irrational use of medicines.

Formularies can be useful tools in solving some of these problems of drug therapy as they can:

- provide impartial drug information to counteract biased promotional activities or fill the gap where access to accurate and up-to-date information is limited;
- promote the appropriate use of safe, effective and good quality medicines;
- help in the elimination of unsafe, ineffective or poor quality medicinal products by identifying effective and safe medications; and
- support cost-effective utilization of drug budgets and improve access to essential medicines.⁹

What is a formulary system?

A formulary system is the on-going process through which a health care organization establishes policies regarding the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

Formulary systems have evolved over time. Modern formularies began as rudimentary drug lists developed by the military in the 1940s and came into more widespread use during the 1950s. Pharmacists, in conjunction with their organizations, developed policies to dispense generic equivalent drugs when a specific brand-name drug was prescribed. During the 1960s, the concept of a hospital formulary continued to grow. Hospitals developed policies that authorized pharmacists to make generic interchanges in an institutional formulary system based on prior consent from physicians. By the 1980s, literature describing the clinical and economic value of well-designed formularies had emerged. Today, formulary systems are considered an essential tool for health care organizations. Formularies have grown from simple drug lists to comprehensive systems of medication use policies intended to ensure safe, appropriate, and cost-effective use of pharmaceuticals in patient care.¹

The formulary system

- Provides drug product selection and formulary maintenance.
- Provides drug use evaluation (also called utilization review) to enhance quality of care for the patients by assuring appropriate drug therapy.
- Provides for the periodic evaluation and analysis of treatment protocols and procedures to ensure that they are up-to-date and are consistent with optimum therapeutics.

- Provides for monitoring, reporting and analysis of adverse results of drug therapy (Examples: adverse of drug reactions, medication errors) to continuously improve the quality of care.

Formulary system policies should

- Require P & T committee members to reveal, by signing a conflict of interest of statement, economic and other relationships with pharmaceutical entities that could influence committee decisions.
- Exclude product sponsor representatives from P & T committee membership and from attending P & T committee meetings.
- Require P & T committee members to adhere to the formulary system policy on disclosure and participation in discussion as it relates to conflict of interest.
- The formulary system should include educational programs for prayers, practitioners, and patients concerning their roles and responsibilities.

The formulary system should

Inform physicians, pharmacists, other health care professionals, patients, and payers about the factors that effects formulary system decisions, including cost-containment measures, the procedures for obtaining non-formulary drugs, and the importance of formulary compliance to improving quality of care and restraining healthcare costs.

- Proactively inform practitioners about changes to the formulary or to the pharmaceutical management procedures.
- Provide patient education programs that explain how formulary decisions are made and the roles and responsibilities of the patient, especially the importance of patient compliance with drug therapy to assure the success of that therapy. Disclose the existence of formularies and have copies of the formulary readily available and accessible.

- Provide rationale for specific formulary decisions when requested.
- The formulary system should include a well-defined process for the physician or other prescriber to use a non-formulary drug when medically indicated.
- Enable individual patient needs to be met with on-formulary drug products when demonstrated to be clinically justified by the physician or other prescriber.
- Institute an efficient process for the timely procurement of non-formulary drug products and impose minimal administrative burdens.
- Provide access to a formal appeal process if a request for a non-formulary drug is denied.

Include policies that state that practitioners should not be penalized for prescribing non-formulary drug products that are medically necessary.

The pharmacy and therapeutic (P&T) committee:

The pharmacy and therapeutic (P&T) committee, or equivalent body, comprised of actively practicing physicians, pharmacists and other healthcare professionals, is the mechanism for administering the formulary system, which includes developing and maintain the formulary and establishing and implementing policies on the use of drug products. Objectively appraises, evaluates, and selects drugs for the formulary. Meets as frequently as is necessary to review and update the appropriateness of the formulary system in light of new drugs and new indications, uses, or warnings affecting existing drugs.

Establishes policies and procedures to educate and inform healthcare providers about drug products, usage, and committee decisions.

- Oversees quality improvement programs that employ drug use evaluation.
- Implements generic substitution and therapeutic interchange programs that authorize exchange of therapeutic alternatives based upon written guidelines or protocols within a formulary system (Note: Therapeutic substitution, the dispensing

of therapeutic alternates without the prescribers approval, is illegal and should not be allowed).

- Develops protocols and procedures for the use of and access to non-formulary drug products.
- Physicians, pharmacists and other healthcare professionals provide oversight of the formulary system.
- Healthcare organization policies should ensure appropriate oversight of the P & T committee and its decisions by the medical staff or equivalent body.
- The formulary system must have its own policies, or adhere to other organizational policies, that address conflicts of interest and disclosure by P & T committee members.⁷

Managing the Formulary System

Health systems should develop, maintain, and implement a formulary management process. Decisions on the management of a formulary system should be founded on the evidence-based clinical, ethical, legal, social, philosophical, quality-of-life, safety, and economic factors that result in optimal patient care. The process must include the active and direct involvement of physicians, pharmacists, and other appropriate health care professionals. This evidence-based process should not be based solely on economic factors. The formulary system should be standardized among components of integrated health systems when standardization leads to improved patient outcomes and safety.

The formulary system should include review and approval of all policies related to the medication-use process. Specific medication-use policies should address

- How medications are requested for addition to or deletion from the formulary,

- How medications are reviewed for addition to or deletion from the formulary, including who performs the reviews,
- The process for developing, implementing, and monitoring medication-use guidelines,
- Methods for ensuring the safe prescribing, distribution, administration, and monitoring of medications,
- Methods for selection of suitable manufacturers for specific medications (a pharmacist shall be responsible for specifications for the quality, quantity, and source of supply of all medications, chemicals, biologicals, and pharmaceutical preparations used in the diagnosis and treatment of patients),
- The process for using non-formulary agents within the institution,
- The process for managing drug product shortages,
- The process for developing an organization-specific MUE plan,
- Policies regarding specific medication-use processes (e.g., procurement, prescribing, distribution, administration, monitoring), and
- The process for disseminating medication-use policies and how users will be educated regarding the process.

Evaluating Medications for Inclusion in the Formulary

The P&T committee should use a structured, evidence-based process in the evaluation of medications for formulary consideration. The P&T committee should be provided with information that reflects a thorough, accurate, and unbiased review and analysis of the evidence available in the scientific literature. The evaluation process should encourage objective consideration of clinical and care delivery information, facilitate communication, foster positive patient outcomes, and support safe and effective medication ordering,

dispensing, administration, and monitoring. Decisions made by the P&T committee should support improved patient care outcomes across the continuum of care.

Evidence-Based Evaluation. Inclusion of a medication on a health system's formulary should reflect that an evidence based evaluation of the relative merits and risks of the medication has been performed and that the institution's P&T committee, with input from appropriate experts, has determined that the medication is appropriate for routine use in the management of the patient population at that institution.

Types of Drug Reviews. There are four major types of drug reviews: new drug monographs, reevaluations of previous formulary decisions, therapeutic class reviews, and expedited reviews of newly approved medications. Because of the expertise and training of pharmacists (drug information specialists in particular), pharmacists should play an integral part in the preparation and presentation of the drug review document to the P&T committee.

Elements of a Drug-Evaluation Document. The drug evaluation document should present the evidence in a manner that is thorough, is consistent from medication to medication, and provides all necessary facts and analysis to the P&T committee to allow for an informed formulary decision. Document structure may vary, depending on the needs of the specific health system and P&T committee, but the following elements are essential to all such documents:

- Brand and generic names and synonyms,
- FDA approval information, including date and FDA rating,
- Pharmacology and mechanism of action,
- FDA-approved indications,
- Potential non-FDA-approved (off-label) uses,
- Dosage forms and storage,

- Recommended dosage regimens,
- Pharmacokinetic considerations,
- Use in special populations (e.g., children, elderly, patients with renal or liver failure),
- Pregnancy category and use during breast-feeding,
- Comparisons of the drug's efficacy, safety, convenience, and costs with those of therapeutic alternatives (with evidence tables when feasible),
- If information on comparative efficacy is minimal or lacking, data on absolute efficacy (i.e., efficacy versus placebo),
- Clinical trial analysis and critique,
- Medication safety assessment and recommendations (adverse drug reactions; drug–drug and drug–food interactions; specific therapy monitoring requirements; unusual administration, storage, or stability issues; and potential for medication errors, such as look-alike or sound-alike issues), and
- Financial analysis, including pharmacoeconomic assessments.

Formulary Exceptions. Regardless of health-system setting, the formulary system should include an exception process that provides prescribers and patients with timely access to medications that are not on the formulary but are medically necessary for the care of the patient. Criteria for approval of nonformulary medications should be developed (e.g., allergy to or therapeutic failure of formulary alternative, condition not treatable by formulary medications).¹

Previous studies:

R. J. D'ALMEIDA et al., conducted a study on development of hospital formulary for a tertiary care teaching hospital in South India. The study involved development of a formulary for the hospital and comparing it with WHO Model Formulary. Monographs of the drugs were prepared as per the recommendation of Pharmacy and Therapeutic Committee of the

hospital. Prepared hospital formulary consisted of 476 generic drugs of various categories and 95 fixed dose combinations. Availability of brands varied from single to many. About 75 medicines recommended by the essential medicine list (National list of essential medicine, 2003) were not present in the prepared hospital formulary. The drugs to be avoided or used with caution in renal failure, hepatic failure and in pregnancy were categorized and included in the formulary as additional information. The prepared hospital formulary was recommended for implementation in the hospital, which could thereby help as a tool to promote rational drug use.⁵

Mahendra Kumar B J et al., conducted a prospective survey based study on evaluation of development and implementation of hospital formulary for paediatric department in a rural tertiary care teaching hospital of South India. The study was carried out to develop a hospital formulary for paediatric department of a rural tertiary care teaching hospital. Well-designed suitable questionnaires were piloted and given to the staff of paediatric department. Drug list was prepared and monographs were prepared accordingly. The developed paediatric formulary was implemented in the department of paediatrics and later evaluated by using suitably designed feedback questionnaire. Prepared paediatric hospital formulary consisted of 102 drugs various categories. Availability of brands was from single to many and 49 brands of drug combinations were present. The prepared paediatric hospital formulary was implemented in the hospital. The authors mentioned that the staff and postgraduate students of department of paediatrics were very satisfied with the implemented formulary and appreciated that the work was carried out at a great level. Authors conclude that the developed paediatric hospital formulary provides them unbiased information about the drugs and available brands with cost in the hospital pharmacy. This formulary promotes the safe and effective use of medicines thereby reducing the cost of treatment of the patient.¹¹

Sabah B. Abdelrahim et al., conducted a cross-sectional descriptive study on assessment of structure, implementation and activities, hospital formulary system in Khartoum state hospitals. The aim of the study was to define the structure and activities of hospital formulary system and to investigate the presence of antibiotic subcommittees and policies in Khartoum state hospitals. The senior pharmacists in Khartoum state hospitals were interviewed by asking questionnaire of 30 items in between December 2010 to September 2011. The survey questions consists of two parts, the first part addressed the presence and functions of drug and therapeutic committee and availability of drug formulary. The second part addressed the hospitals presence of antibiotic subcommittee and antibiotic policy and antibiotic monitoring and audit. Eight hospitals (27 %) of the surveyed hospitals had a drug and therapeutic committee (DTC) and implement formulary system. The formulary system was located in 5 (62 %) non-teaching hospitals and 3 (38 %) teaching hospitals. 50 % hospitals regarded their formulary system as restricted or closed formularies. The average size of the committee was (11) members with physicians comprising the majority (mean = 7.63) individuals, pharmacist and nurses had approximately equal representation. No hospital had antibiotic subcommittees and only two hospitals had guidelines for antibiotic prophylaxis in surgery, and seven hospitals had a local standard prescription protocols for the first-line antibiotic treatment for main infections. Authors mentioned that the results of the study show that DTCs and drug formularies clearly under presented in Sudan hospitals and at the same time there is no presence of antibiotic subcommittees and policies. The authors also mentioned that pharmacists were prevalent as a member in all DTCs and this may be due to the need for him as a technical adviser. The authors conclude that hospitals should put considerable efforts in formulating drug and therapeutic committees and active it's role.⁴

Dr Gongera Enock George conducted a study, Critical analysis in the management of hospital drug formularies: case of health facilities in Nairobi, Kenya. This study critically

analysed the management of drug formularies by both private and public health facilities in Nairobi. A cross-sectional descriptive study was employed where the researcher used stratified random sampling as well as convenient sampling to draw a sample of 189 health facilities from the population. The result showed that there is 94% awareness of drug formularies, only 41.8% have participated in development of a Standard Treatment Guideline or a drug formulary. 71.4% of respondents considered drug formularies very important. 73.5% of registered health facilities in Nairobi have adopted the Kenya Essential drug List (KEDL). Out of the 73.5% above, 49.2% of the facilities have developed facility own drug formularies while 26.5% confirmed to not have used the national essential drug list at all. Majority, 93.6% considered their formularies open while only 6.4% considered their formularies closed. Drug promotion poses the greatest influence to drug formulary non-compliance while insurance was considered the least external factor in Nairobi health facilities. Under internal factors, lack of pharmacy and therapeutic committees or its equivalent topped the most challenging internal factor affecting the drug formulary availability and compliance. The author concludes that drug formulary management in Nairobi health facilities is not fully developed and is also facing a lot of challenges. The author recommends that there is need to base all facilities-own formularies on set standards while exploration of higher levels of formulary management will ensure more benefits to patients. Individual facilities must be more proactive in ensuring they operate within the national medicine policies which is possible through self-regulation.⁸

Wajiha Gul conducted a survey based study on PTC is important for the betterment of the hospital pharmacy, including 43 hospitals (large, medium-sized and small) of the city. A questionnaire was sent to all the hospitals, only 53.5% (23) of the hospitals responded. After analyzing the received data the results showed that 15 hospitals in Karachi have P & T committee out of which only few are working in a well-defined manner while others are

merely meant for approving the drugs for the pharmacy and any other functions are not performed, while in the remaining hospitals either there is no such committee as P&T but if there is such committee, then its major task is not fulfilled. Hence it can be concluded that the hospitals in Karachi lacks the pharmacy and therapeutic committee and therefore the development and designing of the formulary is affected. Most of the large and few medium sized hospitals have such recommending body and therefore it helps the institution in selecting cost-effective and safe medicines and also in improving the implementation and evaluation strategies concerned with the use of medicine.¹³

Jonathan Penm et al., carried out a study on the use of formulary systems and pharmacy and therapeutics (P&T) committees in the Western Pacific Region (WPR) and explored the factors associated with their use. Minor additions were made to a previously validated survey and reviewed by a WPR advisory committee. The Basel Statements 26 and 27 survey was made available in eight languages and sent electronically to 1989 hospital pharmacy directors through respective hospital pharmacy associations in the WPR. The results showed that A total of 797 responses (40%) from 34 nations were received. Of these responses, 87% of hospitals (691 of 797) used a formulary. Also, 93% of respondents (619 of 664) indicated that their hospital had a P&T committee. However, only 44% of respondents (274 of 626) reported that more than half of their formulary medicines were linked to standard treatment guidelines. Furthermore, only 41% of hospitals (247 of 601) had a policy for off-label medication use. The pharmacy directors' perceived benefits of formularies were correlated with having more formulary medicines linked to standard treatment guidelines, basing their use on the best available evidence, and having a policy for the use of off-label medicines. The authors conclude that a large proportion of hospitals in the WPR have implemented formularies and P&T committees. Although formularies are commonly used, their

effectiveness may be limited, as formularies are often not linked to standard treatment guidelines or the best available evidence.¹⁴

Seetharama G. Rao et al., conducted a study on Comparison of essential drug list in a rural secondary care hospital in South India with Indian & World Health Organization list 2011. Objective of the study was, fixed drug combinations (FDCs) are a major marketing strategy in India but it can compromise the rational use of medicines. In this study they have compared the FDCs and dosage forms in the hospital pharmacy before and after introducing the essential drug list. They also compared the Hospital Essential Drug List (HEDL) 2011 with the World Health Organization (WHO) Essential Drug List (EDL) 2011 and the National Essential Drug List of India (NEDL) 2011. Results showed that the number of medicines used in the hospital before and after the introduction of the HEDL was 1627 and 424 respectively. On comparison, WHOEDL 2011 have 350 and NEDL of India have 348 medicines. While preparing the HEDL, 46 double drug combinations decreased to 15 and 9 triple drug combinations decreased to 1. In the case of injections, 20 double drug combinations decreased to 6 and 1 triple drug combination increased to 2. The authors concluded that there was drastic reduction in the number of medicines and dosage forms when the HEDL was implemented. Many of the fixed drug combinations were also removed for improving the rational use of medicines. The WHOEDL 2011, NEDL of India 2011 and the HEDL 2011 were comparable with few exceptions.¹⁵

Ellena Anagnostis et al., conducted a national survey on hospital formulary management processes. The purpose of the study was to determine member institutions' standard of practice in formulary management, In light of formulary management guidelines from the American Society of Health System Pharmacists (ASHP), and discussion of pharmacies' noncompliance with recent Joint Commission accreditation requirements. The results showed that 52 institutions across the United States provided responses. Most institutions maintain

written policies for how medications are requested (94%) and reviewed (88%) for formulary addition; 92% of institutions have a non-formulary medication process. Non-formulary medication use is tracked at 88% of institutions, and 85% of institutions conduct pharmacoeconomic analyses. Regarding The Joint Commission's requirement to approve drugs for specific indications, 40% of institutions approve drugs for all FDA approved indications; 35% of institutions have not formally addressed this requirement. Approximately 31% of the institutions have a policy for approving a medication for an off-label indication. The authors concluded that portions of the ASHP guidelines have been implemented by most institutions.¹⁶

Sangeeta Sharma et al., conducted a prospective survey on Attitude and opinion towards essential medicine formulary. Objective of the survey was, the Delhi State Essential Medicines Formulary was brought out in 1997. A need was felt to revise the formulary to match with the EML as the EML is renewed every 2 years. A survey was undertaken to elicit the opinions of the doctors practicing in the state on the usefulness of the formulary before revising and printing the updated version. Of the 200 doctors approached, only 90 doctors completed the questionnaire. Sixty nine respondents (76.6%) had received the copy of the formulary. Most practitioners welcomed the formulary and were satisfied with the coverage and selection of the medicines. Most respondents (76.9%) agreed that a well-developed formulary would improve the quality of the public health care system, although they had reservations about the authority, relevance and effect on professional autonomy. The authors concluded that about 74% of the respondents used the formulary in clinical practice as a source of medicine information, which makes its regular revision necessary.¹⁷

Dipika Bansal and Vilok K. Purohit conducted a review on Accessibility and use of essential medicines in health care: Current progress and challenges in India. Authors mentioned in their article that the selection process has evolved from expert evaluation to

evidence-based selection. Health expenditure is less in India as compared to developed countries. India faces a major challenge in providing access to medicines for its 1.2 billion people by focusing on providing essential medicines. In the future, countries will face challenges in selecting high-cost medicines for oncology, orphan diseases and other conditions. Authors concluded that the essential drugs concept introduced since 1975 is now widely accepted as a highly pragmatic approach to provide the best of modern, evidence-based and cost-effective health care. The challenge is to regularly update drug selections in the light of new therapeutic options, changing therapeutic needs, the need to ensure drug quality and continued development of better drugs, drugs for emerging diseases and drugs for coping with changing resistance patterns. There is also a need to fill gaps in availability, accessibility and affordability of medicines to the poor.¹⁸

Thamizhanban Pillay et al., conducted a review on the role of pharmacoeconomics in formulary decision-making. The authors mentioned that in both settings, cost was important, although the elements of cost considered varied. Acquisition cost was mentioned more frequently than pharmacoeconomic or cost-effectiveness information. Other factors, including drug characteristics, quality of life, supply related issues, and physician demand, also influenced decisions. Despite the relatively low reported usage of pharmacoeconomic data in decision making, most respondents considered the information to be "somewhat" or "very" important. Barriers to the use of pharmacoeconomic information included institutional factors and lack of training. Further research on the use of pharmacoeconomic information is required.¹⁹

FT Odedina et al., conducted a study on the use of pharmacoeconomic data in making hospital formulary decisions. Data were collected from pharmacist members of pharmacy and therapeutics (P&T) committees in 204 Florida hospitals. Participants were asked, via a cross-sectional telephone survey. Data were analyzed using descriptive statistics and correlation

analysis. Eighty-six percent (86 %) of the participants indicated that pharmacoeconomic data were used all the time or very often when formulary decisions were made, with only 6% stating that these data were rarely or never used. Pharmacoeconomic data were rated by 63% of participants to be very important in formulary decisions. The usual sources of pharmacoeconomic data listed by participants are inhouse data (75%), published literature (57%), and pharmaceutical industry studies (13%). Participants rated drug efficacy, toxicity, and side effects as the most important and avoiding use of home infusions as the least important factors in making hospital formulary decisions. About 70% of the hospitals had someone with pharmacoeconomic skills on staff, while 4% reported consulting with an external pharmacoeconomics expert. Most P&T committees in Florida hospitals relied on pharmacoeconomic data to assist them in making formulary decisions.²⁰

Akram Ahmad et al., conducted review on the role of pharmacoeconomics in current Indian healthcare system. Focusing on the formulary system the authors mentioned two advantages of the effective formulary system; 1. Availability of cost contained quality drugs: When medications are purchased in bulk, there is more price competition and “economies of scale” for procuring, storing, and distributing the quality drugs. This makes it possible to provide drugs at subsidized rates to people who require them the most. 2. Provision of quality care: Healthcare personnel can be better trained to provide cost effective medications. Where, the practitioners prescribe fewer drugs whose drug interactions and adverse reactions they are aware of. This in turn will improve the provision of quality care as the selection of medication is evidence based. The authors also mentioned that pharmacoeconomic evidences can be utilized to support decisions on licensing, pricing, reimbursement, and maintenance of formulary procedure of pharmaceuticals. For the insurance companies to give better facility at minimum cost, India must develop the platform for pharmacoeconomics with a validating methodology and appropriate training. Authors concluded that development of

pharmacoeconomics is at an infancy stage in India at the moment, despite the rapid growth of clinical research. The role of clinical pharmacists including PharmD graduates are expected to be more beneficial than the conventional pharmacists, as they will be able to apply the principles of economics in daily basis practice in community and hospital pharmacy.²¹

Bochner F et al., conducted a study on approaches to rationing drugs in hospitals, an Australian perspective. The authors mentioned that there are several measures that a hospital must have in place before the concept of drug rationing can be contemplated. The approach essentially involves ensuring rational drug approval processes based on critical review of the available data, coupled with ongoing education and audit. Thus, accurate information and clinical budgeting systems, processes which encourage and ensure structural and technical efficiencies within the drug use sequence and an effective Drug and Therapeutics committee are required to facilitate this approach. To assist with its overriding goals of the quality use of medicines and optimal patient care, the Drug and Therapeutics committee needs to implement an effective formulary system, obtain detailed guidelines governing drug use within the institution, conduct an ongoing drug utilisation review programme, and provide education and training.²²

R. Fijn et al., conducted a nation-wide survey on Dutch Hospital Drug Formularies: pharmacotherapeutic variation and conservatism, but concurrence with national pharmacotherapeutic guidelines. The research was aimed to examine current hospital drug formularies (HDFs) of all Dutch general hospitals, with this approach the assessment was focused on the extent to which they recommend the same drugs, therapeutic areas, drug groups incorporated and individuals drugs included, and their extent of conservatism. Furthermore, it considered the extent of Dutch HDFs concurrence with national pharmacotherapeutic guidelines and the WHO Essential Drugs List (EDL). The results showed that the total number of indications addressed and drug groups incorporated within

HDFs varied from 28 to 72 (median 56) and from 30 to 123 (median 97), respectively. The total number of individual drug entities included ranged from 239 to 658 (median 430) and the total number of drug products, from 412 to 1121 (median 655). Depending on the drug group, HDFs' concurrence and compliance with national guidelines and the WHO EDL ranged from 35% to 100%. The authors concluded that Dutch HDFs are rather uniform in the indications addressed and the drug groups incorporated. However, the number of individual drug entities and drug products included within groups varies considerably. Furthermore, Dutch HDFs are considered rather conservative, as older drugs are favoured over more recent drugs. Generally, with some drug exceptions, Dutch HDFs concur and comply with recommendations in national pharmacotherapeutic guidelines and with the WHO EDL over 90%.²³

Chapter 4

Methodology



METHODOLOGY:**STUDY SITE**

This study was conducted at Adichunchanagiri Hospital and Research Centre (AH & RC), B.G. Nagara. AH & RC is a 1050 bedded rural tertiary care teaching hospital. This hospital provides primary and specialized health care facilities to people in and around Nagamangala taluk. The hospital has various departments like Anaesthesia, ENT, General Medicine, Obstetrics and Gynaecology, Ophthalmology, Orthopaedics, Paediatrics, Psychiatry, Radiology, Skin and STD and Surgery. The hospital has Pharmacy and Therapeutic committee which holds the responsibility of the hospital formulary system.

STUDY APPROVAL

The study was approved by the ethical committee of AIMS (Adichunchanagiri Institute of Medical Sciences), B.G Nagara. A photocopy of ethical committee approval certificate has been attached in Annexures.

STUDY DESIGN

This was a prospective study.

STUDY PERIOD

The study was carried out for over a period of nine months from July-2014 to march-2015.

SOURCE OF DATA

All the necessary data to prepare AHRC Hospital Formulary were taken from various online and offline sources.

Table 1: **References used to prepare monographs of the drugs**

SL No.	REFERENCE USED
1	National formulary of India, 2011.
2	Micromedex
3	CIMS India

4	Med India
5	Healthplus24.com
6	www.icm.tn.gov.in
7	patient.co.uk
8	Drugs.com
9	News Medical

There are total 9 references used to prepare monographs of the AHRC-HF drugs and are shown in the table 1. Out of 9 references used, 1 was off line source, i.e. National formulary of India, 2011 (NFI) and other 8 were online databases, they are as follows Micromedex (micromedexsolution.com), CIMS India (current index on medical science), Med India (www.medindia.net), Healthplus24.com, www.icm.tn.gov.in (formulary drugs acting on respiratory system), patient.co.uk, Drugs.com (www.drugs.com), News Medical (www.news-medical.net). The references used to prepare appendices part of the AHRC-HF are NFI-2011 and results of a research “Assessment of drug interactions in a tertiary care teaching hospital” conducted by Uma Maheswari R, in the year 2013 at the medicine units of AH & RC.

STUDY CRITERIA

INCLUSION CRITERIA:

All the drugs and brands selected/approved by the P & T committee to include in the AHRC-HF. For comparison study of AHRC-HF and NEML-2013, drugs included in the AHRC-HF and drugs coming under the list of essential medicines for hospitals 2013 in NEML-2013 were considered.

EXCLUSION CRITERIA:

The drugs and brands which are not selected/ not approved by the P & T committee. For comparison study of AHRC-HF and NEML-2013, the drugs coming under Peritoneal dialysis solutions class, Solutions correcting water, electrolyte and acid base disturbances class, Solutions for enteral & parenteral nutrition class, Disinfectants & antiseptics class and diagnostic agents class of EML-2013 were excluded. The drugs coming under the drug class 22: Solutions correcting water, electrolyte and acid base disturbances of the AHRC-HF were also excluded from the comparison study AHRC-HF and EML-2013.

STUDY PROCEDURE**Hospital Formulary design:**

A discussion was made in the P & T committee regarding the design of the Hospital formulary. By taking suggestions from the committee members, contents to be added, monographs design, appendices design and overall design of the formulary was made. And also it was decided to design the formulary in concise, precise and handy form.

Selection of drugs to be included in the AHRC-HF:

All the members of the P & T committee were requested to select the drugs and brands to include in the formulary as per the requirements of health care needs of the local population. Where, each member of the P & T committee was representing each department of the hospital. A copy EML-2013 was distributed to all the members of the P & T committee to use it as reference. Committee members selected the drugs and brands coming under the drug classes relevant to their department, for example: drugs coming under the anaesthetics class were selected from the member representing anaesthesia department and psychotherapeutic drugs were selected from the member representing Psychiatric department. The selected drug

lists were collected from all the members and were verified and finalised by the office bearers of the P & T committee (secretary, convenor and chairman). A complete finalised hospital drug list was then prepared.

Preparation of monographs for the drugs:

The drugs in the finalised list were classified by Pharmacologic-Therapeutic classification into 23 classes or categories. The monographs for those drugs were prepared as per the recommendation of the P & T committee members. As suggested by committee member's information regarding indication, availability, dose, contraindications, precautions, adverse effects, pregnancy risk category and storage in each monograph of the drugs was included.

Preparation of appendices:

The appendices part of the AHRC-HF was made into 7 sub-parts, relevant information was derived from the above (source of data) mentioned sources and added to the formulary as recommended by the P & T committee.

Hospital Formulary was prepared by using Microsoft Office 2010 in computer; few sample copies were printed in A-4 size and distributed to the committee members for review and editing. Suggestions and comments were collected. Corrections were made as per the suggestions and comments and the formulary was finalised and printed in handy form.

Pharmaceutical product list:

A pharmaceutical product list of AH & RC was prepared, which consists information regarding the brands/ pharmaceutical products approved by the P & T committee to use in the hospital.

Comparison of AHRC-HF with EML-2013:

Drugs meeting inclusion criteria in the prepared AHRC-HF and EML-2013, eighth edition of national capital territory of Delhi, India were compared. The comparison was made to check the difference between drugs in the prepared AHRC-HF and EML-2013 of national capital territory of Delhi, India. In the comparison study, the drugs meeting inclusion criteria were reclassified in to 23 categories. The last category (23rd) was made for those EML drugs which were not suitable to fit under the first 22 categories.

The EML drugs present and not present in each class of the AHRC-HF were identified, and their percentage distribution was calculated within each drug class and also in total. The presence of EML and Non-EML drugs in the prepared formulary were also identified and their percentage distribution was calculated in total.

STUDY ANALYSIS:

Micro soft Excel 2010 was used to prepare the bar graphs and pie charts for the percentage description of the prepared hospital formulary and essential medicines list drugs.

Chapter 5

Results



RESULTS:

The prepared Adichunchanagiri Hospital & Research Centre Hospital formulary (AHRC-HF) comprised of total 357 drugs. Out of these 357 drugs, there were totally 306 single drugs, 21 FDCs, 18 immunologicals and 12 vitamins. Here, only combinations whose monographs were described in the AHRC Hospital Formulary are considered as FDCs and each FDC is counted as a single drug. The prepared pharmaceutical product list comprised of total 948 brands selected for the drugs listed in AHRC-HF, out of these 948 brands, 184 brands were in different combinations. The number of brands per generic drug varied from single to eight. When AHRC-HF drugs are compared to Essential medicines list-2013 (EML-2013), it showed that, out of 351 AHRC-HF drugs (6 drugs from the class- Solutions Correcting Water, Electrolyte and Acid Base Disturbances, were excluded from comparison) 255 (72.64 %) drugs were present in EML-2013. These 255 drugs of AHRC-HF covered 67.81 % of total 376 EML-2013 drugs.

Contents of the AHRC-Hospital Formulary:**Table 2.1: AHRC-HF contents**

SL No.	Content Title
1	Preface
2	Introduction to AHRC-HF
3	Acknowledgements
4	Common Abbreviations
5	Description of monographs of the 357 drugs
6	Appendices

The whole content of the prepared AHRC-HF was divided into 6 main parts, which are shown in the table 2.1. The preface part of the AHRC-HF contains information regarding the responsible role played by the P & Committee of AH & RC in developing AHRC-Hospital Formulary. Membership structure of the P & T committee of AH & RC, process to add new drugs/drug products and formulary revision process were also included in the preface part. Introduction part of the AHRC-HF contained information regarding the formulary and its objectives, number of drugs present in AHRC-HF and few tips to use AHRC-HF. Acknowledgements, in this part of AHRC-HF, all the members who contributed to development of AHRC-HF were acknowledged. Common abbreviations, in this part of AHRC-HF, commonly used abbreviations in AHRC-HF were expanded. Description of monographs of the drugs, which is the main part of the hospital formulary contained monographs of 351 drugs of AHRC-HF, which were classified into 23 main classes. The Appendices part of AHRC-HF was divided into 7 sub-appendices. In these appendices, information regarding antimicrobial resistance and steps to prevent it, drug interactions and

list of some potential drug-drug interactions observed during a research conducted in medicine department of the AH & RC, drug use in special conditions (pregnancy, lactation, hepatic and renal impairment), pharmacogenetics, pharmacovigilance (PVPI programme), dose calculation in special conditions (Paediatric and geriatric) were included. And at last a sample copy of Pharmaceutical product registration form was attached to the formulary.

Table 2.2: A sample drug monograph of AHRC-HF

Paracetamol:

Pregnancy Category: B

Indication	Mild to moderate pain including dysmenorrhoeal pain, headache; pain relief in osteoarthritis and soft tissue lesions; pyrexia including post-immunisation pyrexia; acute migraine attack.
Availability	Tab 500 mg, 650 mg, Syp 250mg/5ml, Suppositories 250mg, Inj 150mg/ml, 10 ml IV, and 100 ml IV and also in combination with other drugs.
Dose	Oral: Adult- 0.5 to 1g every 4 to 6 h (max. 4g, max 2g in alcoholics per day). Child- for post-immunisation pyrexia, up to 2 months: 60 mg. 3 month to 1 year: 60 to 120 mg every 4 to 6 h. 1 to 5 years: 120 to 250 mg every 4 to 6 h. 6 to 12 years: 250 to 500 mg every 4 to 6 h. Intramuscular injection: Adult- 250 mg every 4 to 6 h or as required. Intravenous infusion: Adult- 1g every 6 hours, maximum daily dose 4 g. Child- 15 mg/kg upto 4 times a day, maximum daily dose 60 mg/kg.
Contraindications	Active and severe hepatic disease, hypersensitivity to acetaminophen or any other components of the product, severe hepatic impairment.
Precautions	Hepatic impairment; renal impairment; alcohol dependence; lactation; pregnancy; overdose; G-6-PD deficiency.
Adverse effects	Rare but rashes and blood disorders reported; important: liver damage (and less frequently renal damage) following overdose; dyspepsia.
Storage	Store protected from light and moisture.

The drug monographs of AHRC-Hospital Formulary contained information regarding pregnancy risk category, indication, availability (mentioned in strength and formulation type), dose, contraindications, precautions, adverse effects and storage condition. A sample monograph of a drug as in prepared AHRC-HF is shown in the table 2.2.

Table 2.3: Sample view of the Pharmaceutical product list

Generic Name	Brand name	Quantity	Price (INR)	Manufacturer
Acetazolamide	Diamox Tab 250mg	10	32.00	Weyth
Amiloride + Furosemide	Frusenex Tab	10	4.75	Geno

Pharmaceutical product list, AH & RC: The pharmaceutical product list of AH & RC, a part of AHRC-HF or Formulary system of AH & RC comprised of total 948 brands. Out of which 766 brands were with single drug and 182 brands were with various drug combinations. The prepared pharmaceutical product list of AH & RC contained the information regarding brand names, their strength, quantity, price and manufacturer name of all the drug products approved by the P& T committee of the AH & RC, for use in the hospital. A sample view of the pharmaceutical product list of AH & RC is shown in the table 2.3

Drugs in the prepared hospital formulary (AHRC-HF):**Table 3.1: First three drug classes of AHRC-HF**

SL No.	1		2	3
Drug Class	Class 1: Analgesics, Antipyretics and NSAIDs		Class 2: Antacids and Antiulcer Drugs	Class 3: Antiallergics and Drugs used in Anaphylaxis
Drugs in Generic Names	Aceclofenac	Mefenamic-acid	Aluminium-hydroxide	Adrenaline
	Aspirin	Naproxen	Esomeprazole	Chlorpheniramine
	Diclofenac	Paracetamol	Magnesium-hydroxide	Dexamethasone
	Etodolac	Piroxicam	Omeprazole	Hydrocortisone
	Etoricoxib	Codeine	Pantoprazole	Levocetirizine
	Ibuprofen	Tramadol	Rabeprazole	Mometasone
	Indomethacin	Morphine	Ranitidine	Noradrenaline
	Ketorolac		Misoprostol	Pheniramine
				Prednisalone

Class1: Analgesics, antipyretics and NSAIDs, class 2: Antacids and antiulcer Drugs and class 3: Antiallergics and drugs used in anaphylaxis constituted 15, 8, and 9 drugs of the AHRC-HF respectively. The drugs belonged to these classes of the AHRC-HF is listed in table 3.1.

Table 3.2: class 4, 5 and 6 of AHRC-HF

SL No.	1	2		3
Drug Class	Class 4: Anti-Parkinsonism Drugs	Class 5: Antiepileptic's		Class 6: Anti-diarrhoeals and Laxatives
Drugs in Generic Names	Levodopa + carbidopa Pramipexole Ropinirol Trihexyphenidyl	Carbamazepine Clobazam Clonazepam Diazepam Divalporex-sodium Gabapentin Levetriacetam	Lorazepam Magnesium-sulphate Oxcarbazepine Phenobarbitone Phenytoin Pregabalin Sodium-Valporate	Loperamide Bisacodyl Isaphaghula Liquid paraffin ORS

Class 4: Anti-Parkinsonism drugs, class 5: Anticonvulsant/Antiepileptic drugs and class 6: Anti-diarrhoeal and Laxative drugs constituted 4, 14 and 5 drugs of the AHRC-HF respectively. The drugs belonged to these classes are listed in table 3.2.

Table 3.3: class 7 and 8 of AHRC-HF

SL No.	1	2
Drug Class	Class 7: Antidotes and substance used in poisoning	Class 8: Antiemetics
Drugs in Generic Names	Acetylceysteine Atropine Deferiprone Deferoxamine Mesylate D-Penicillamine Methylene blue Naloxone Pralidoxime Snake Venom Antiserum	Dicyclomine Domperidone Doxylamine + pyridoxine Granisetron Simethicone Hyocine Metoclopramide Ondansetron Prochlorperazine Promethazine

Class 7: Antidotes and substance used in poisoning and class 8: Antiemetic's constituted 9 and 10 drugs of the AHRC-HF. The drugs belonged to these classes are listed in table 3.3

Table 3.4: Class 9 and 10 of AHRC-HF

SL No.	1			2
Drug Class	Class 9: Anti-Infectives			Class 8: Antineoplastics and Immunosuppressives
Drugs in Generic Names	Diloxanide	Erythromycin	Mefloquine	Bleomycin
	Metronidazole	Gentamycin	Primaquine	Cyclophosphamide
	Ornidazole	Imipenem + cilastin	Artesunate	Daunorubicin
	Tinidazole	Levofloxacin	Sulphadoxine	Doxorubicin
	Amikacin	Meropenam	+	5-Fluorouracil
	Amoxycillin	Nitrofurantoin	Pyrimethamine	Filgrastim
	Amoxycillin + clavulanic acid	Norfloxacin	Clofazimine	Imatinib
	Ampicillin	Procaine Penicillin	Dapsone	L-Asparaginase
	Azithromycin	G	Ethambutol	Methotrexate
	Benzathine-benzylpenicillin	Piperacillin + Tazobactam	Isoniazide	
	Cefixime	Teicoplanin	Pyrazinamide	
	Cefoperazone + Sulbactam	Vancomycin	Rifampicin	
	Cefotaxime + Sulbactam	Diethylcarbamazine	Rifampicin + Isoniazid	
	Cefpodoxime	Ivermectin	Rifampicin + Isoniazid + Ethambutol	
	Ceftazidime	Amphotericin B	Rifampicin + Isoniazid + Pyrazinamide	
	Ceftriaxone	Clotrimazole	Rifampicin + Isoniazid + Pyrazinamide	
	Cephalexin	Fluconazole	Rifampicin + Isoniazid + Pyrazinamide	
	Chloramphenicol	Griseofulvin	Rifampicin + Isoniazid + Pyrazinamide	
	Ciprofloxacin	Terbinafine	Rifampicin + Isoniazid + Pyrazinamide	
	Cloxacillin	Albendazole	Rifampicin + Isoniazid + Pyrazinamide	
	Co-Trimoxazole	Levamisole	Rifampicin + Isoniazid + Pyrazinamide	
	Doxycycline	Mebendazole	Rifampicin + Isoniazid + Pyrazinamide	
		Sodium-Sitboglucanate	Rifampicin + Isoniazid + Pyrazinamide	
		Chloroquine	Rifampicin + Isoniazid + Pyrazinamide	
			Streptomycin	
			Acyclovir	
			Valacyclovir	

Class 9: Anti-Infective drugs and class: 10 Antineoplastic and Immunosuppressive drugs constituted 62 and 9 drugs of the AHRC-HF respectively. The drugs belonged to these classes are listed in table 3.4

Table 3.5: class 11 and 12 of AHRC-HF

SL No.	1		2	
Drug Class	Class 11: Cardiovascular Drugs		Class 12: Dermatological drugs	
Drugs in Generic Names	Glyceryl-	Ramipril	Clindamycin	Dianthrol
	Trinitrate	Telmisartan	Mupirocin	Salicylic acid
	Isosorbide-	Alteplase	Povidone Iodine	Podophyllin
	Dinitrite	Clopidogrel	Silver sulphadizine	Trioxsalen
	Isosorbide-5-	Heparin	Whitefield	Adapalene
	Mononitrate	Reteplase	Miconazole	Benzoyl peroxide
	Metoprolol	Streptokinase	Betamethasone	Tertinoiin
	Verapamil	Urokinase	Calamine	Benzoyl benzoate
	Amiodarone	Albumin	Clobetasol	Gama benzene
	Disopyramide	Tranexamic acid	Desonide	hexachloride
	Lidocaine	Acenocoumarol	Flucinolone	Permethrin
	Mexilitine	Bivalirudin	Mometasone	Hydroquinone
	Procainamide	Dalteparin	Hydrocortisone	Zinc oxide
	Quinidine	Enoxaparin	Coal Tar	
	Amlodipine	Heparin		
	Atenolol	Reviparin		
	Clonidine	Warfarin		
	Enalapril	Digoxin		
	Labetolol	Dobutamine		
	Losartan	Dopamine		
	Methyldopa	Atorvastatin		
	Nifedipine	Fenofibrate		
	Prazosin	Nicotinic acid		

Class 11: Cardiovascular drugs and class 12: Dermatological drugs constituted 43 and 25 drugs of the AHRC-HF respectively. The drugs belonged to these classes are listed in table 3.5

Table 3.6: Class 13, 14 and 15 of AHRC-HF

SL No.	1	2	3
Drug Class	Class 13: DMARDs and Drugs for Gout	Class 14: Diuretics	Class 15: Drugs for Anaesthesia
Drugs in Generic Names	Sulfasalazine Allopurinol	Acetazolamide Amiloride Furosemide Hydrochlorthazide Mannitol Metolazone Spironolactone Torasemide	Halothane Midazolam Oxygen Propofol Thiopental Bupivacaine Lidocaine Fentanyl Glycopyrrolate

Class 13: DMARDs and drugs for Gout, class 14: Diuretics and class 15: Drugs for anaesthesia constituted 2, 8 and 9 drugs of the AHRC-HF respectively. The drugs belonged to these classes are listed in table 3.6

Table 3.7: class 16 and 17 of AHRC-HF

SL No.	1		2	
Drug Class	Class 16: Drugs for Respiratory Diseases		Class17: Hormones, Contraceptives and Related Drugs	
Drugs in Generic Names	Budenoside	Cromoglicic acid	Ethinylestradiol +	Methyl-
	Budenoside +	Terbutaline	Levnorgestrel and	prednisolone
	Ipratropium	Theophylline	Ethinylestradiol +	Glibenclamide
	Montelukast	Theophylline +	Norethisterone	Glicazide
	Salbutamol	Etophylline	Levnorgestrel	Gilmepride
	Salmeterol +	Bromohexine	Clomifene	Glipizide
	Fluticasone-	Dextromrthorphan	Conjugated-	Insulin human
	propionate	Guaiphenisin	estrogen	Insulin aspart
	Formeterol		Ethinyl estradiol	Insulin Glulisine
			Hydroxy-	Insulin lispro
			progesterone	Insulin Glargine
			Medroxy-	Metformin
			progesterone	Mifepristone
			Progesterone	Carbimazole
			Danazol	Levothyroxine
				Alendronate

Class 16: Drugs for respiratory diseases and class 17: Hormones, contraceptives and related drugs constituted 13 and 24 drugs of the AHRC-HF respectively. The drugs belonged to these classes are listed in table 3.7

Table 3.8: Class 18 and 19 of AHRC-HF

SL No.	1		2
Drug Class	Class 18: Immunologicals		Class19: Muscle relaxants
Drugs in Generic Names	Anti-D Ig	Hib Vaccine	Atracurium besylate
	Diphtheria Antitoxin	Hepatitis A vaccine	Baclofen
	Hepatitis B Ig	Measles Vaccines	Methocarbamol
	Human normal Ig	MMR vaccine	Neostigmine
	Rabies Ig	Polio vaccine	Pancuronium
	Tetanus Ig	Pneumococcal vaccine	Vecuronium
	Varicella-Zoster Ig	Rabies Vaccine	
	BCG Vaccine	Typhoid Vaccine	
	DPT Vaccine	Varicella vaccine	

Class 18: Immunologicals (18) and class 19: Muscle relaxants constituted 18 and 6 drugs of the AHRC-HF respectively. The drugs belonged to these classes are listed in table 3.8

Table 3.9: Class 20 and 21 of AHRC-HF

SL No.	1		2	
Drug Class	Class 20: Ophthalmological preparations		Class 21: Psychotherapeutic drugs	
Drugs in Generic Names	Naphazoline	Dorzolamide	Amitriptyline	Chlorpromazine
	Olapatadine	Pilocarpine	Duloxetine	Haloperidol
	Adenine-arabinoside	Timolol	Escitalopram	Olanzapine
	Gatifloxacin	Homatropine	Etizolam	Quetiapine
	Moxifloxacin	Phenylephrine	Fluoxetine	Risperidone
	Natamycin	Tropicamide	Mirtazapine	Lithium
	Ofloxacin	Cellulose/hypromellose	Sertraline	Clomipramine
	Sulphacetamide	Fluorescein	Venlafaxine	Clozapine
	Tobramycin	Hyaluronidase	Amisulpride	Fluvoxamine
	Flurbiprofen	Propacaine	Arpiprazole	
	Brimonidine	Trypan Blue		
		Xylometazoline		

Class 20: Ophthalmological preparations and class 21: Psychotherapeutic drugs constituted 23 and 19 drugs of the AHRC-HF respectively. The drugs belonged to these classes are listed in table 3.9

Table 3.10: class 22 and 23 of AHRC-HF

SL No.	1	2	
Drug Class	Class 22: Solutions Correcting Water, Electrolyte and Acid Base Disturbances	Class 23: Vitamins, Minerals and Anti-anaemic Drugs	
Drugs in Generic Names	Glucose Glucose + Sodium chloride Potassium chloride Sodium carbonate Sodium chloride Water for injection	Ascorbic acid Calcium Carbonate + Vitamin D3 Ergocalciferol Methylcobalamin Nicotinamide Pyridoxine Riboflavin Thiamine	Vitamin A Vitamin D ₃ Vitamin K Cyanocobalamin Erythropoietin Iron Salts Folic acid Iron Dextran

Class 22: Solutions correcting water, electrolyte and acid base disturbances and class 23: Vitamins, minerals and anti-anaemic drugs 6 and 16 drugs of the AHRC-HF respectively. The drugs belonged to these classes are listed in table 3.10

Table 3.11: Numbers and Percentage of each class of drug in the AHRC-HF

Drug class No.	Drug class	Number of drugs	Percentage of drugs n = 357
1	Analgesics, Antipyretics and NSAIDs	15	4.20 %
2	Antacids and Antiulcer Drugs	8	2.24 %
3	Antiallergics and Drugs used in Anaphylaxis	9	2.52 %
4	Anti-Parkinsonism Drugs	4	1.2 %
5	Antiepileptics	14	3.92 %
6	Anti-diarrhoeals and Laxatives	5	1.40 %
7	Antidotes and substance used in poisoning	9	2.52 %
8	Antiemetics	10	2.80 %
9	Anti-Infectives	62	17.36 %
10	Antineoplastics and Immunosuppressive	9	2.52 %
11	Cardiovascular Drugs	43	12.04 %
12	Dermatological drugs	25	7.00 %
13	DMARDs and Drugs for Gout	2	0.56 %
14	Diuretics	8	2.24 %
15	Drugs for Anaesthesia	9	2.52 %
16	Drugs for Respiratory Diseases	13	3.64 %
17	Hormones, Contraceptives and Related Drugs	24	6.72 %

18	Immunologicals	18	5.04 %
19	Muscle relaxants	6	1.68 %
20	Ophthalmological preparations	23	6.44 %
21	Psychotherapeutic drugs	19	5.32 %
22	Solutions Correcting Water, Electrolyte and Acid Base Disturbances	6	1.68 %
23	Vitamins, Minerals and Anti-anaemic Drugs	16	4.48 %

The number of drugs in each class and the percentage they constituted to total AHRC-HF drugs is shown in table 3.11

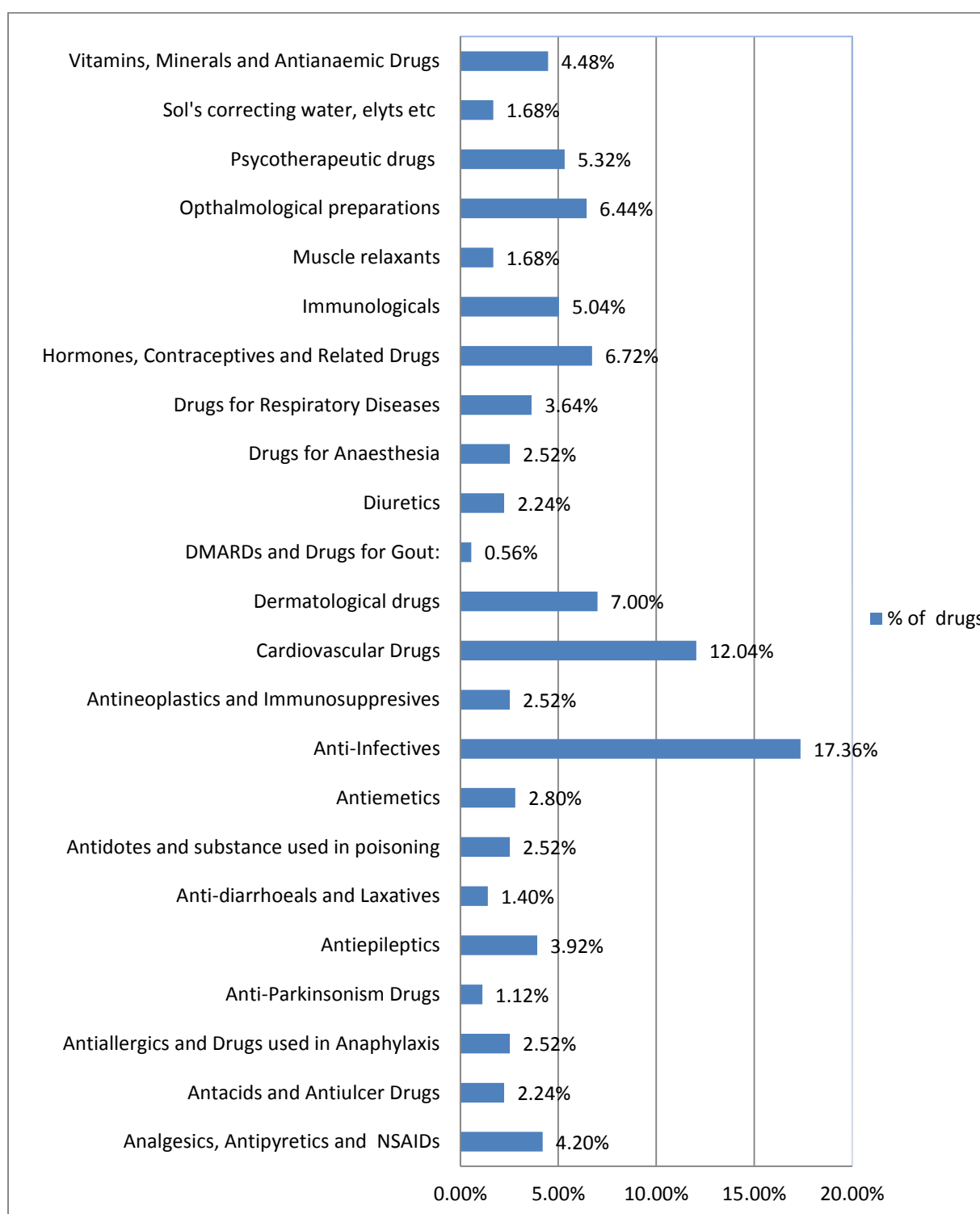


Figure 1

The percentage of each drug class which constituted the AHRC-HF is shown in Figure 1.

Comparison of EML drugs with AHRC-HF drugs:
Table 4: EML drugs in AHRC-HF

Class No.	Drug class	No. of drugs present in NEML	No. of NEML drugs present in AHRC-HF	Percentage (%) of NEML drugs present in AHRC-HF n = 376	No. of NEML drugs not present in AHRC HF
1	Analgesics, Antipyretics & NSAIDS	09	07	77.77 %	2
2	Antacids and Antiulcer Drugs	05	05	100 %	0
3	Antiallergics and Drugs used in Anaphylaxis	09	08	88.88 %	1
4	Anti-Parkinsonism Drugs	03	02	66.66 %	1
5	Anticonvulsants/Antiepileptics	08	07	87.5 %	1
6	Antidiarrhoeals and Laxatives	06	04	66.66 %	2
7	Antidotes and substance used in poisoning	09	08	88.88 %	1
8	Antiemetics	07	07	100 %	0

9	Anti-Infectives	65	51	78.46 %	14
10	Antineoplastics and Immunosuppr- sives	32	09	28.12 %	23
11	Cardiovascular Drugs	38	28	73.68 %	10
12	Dermatological drugs	15	13	86.66 %	2
13	DMARDs and Drugs for Gout	03	02	66.66 %	1
14	Diuretics	06	05	83.33 %	1
15	Drugs for Anaesthesia	18	10	55.55 %	8
16	Drugs for Respiratory Diseases	10	06	60.00 %	4
17	Hormones, Contraceptives and Related Drugs	36	21	58.33 %	15
18	Immunologica- s	22	13	59.09 %	9
19	Muscle relaxants	06	04	66.66 %	2
20	Ophthalmologic- al preparations	23	23	100 %	0

21	Psychotherapeutic drugs	15	08	53.33 %	7
22	Vitamins, Minerals and Antianaemic Drugs	18	14	77.77 %	4
23	Others	13	0	00 %	13

The number of EML drugs present in each class of the AHRC-HF, with their percentage of EML drugs covered with in the respective class, when compared to the drugs in EML-2013 and number of EML drugs not present in each drug class of the AHRC-HF are shown in table 4.

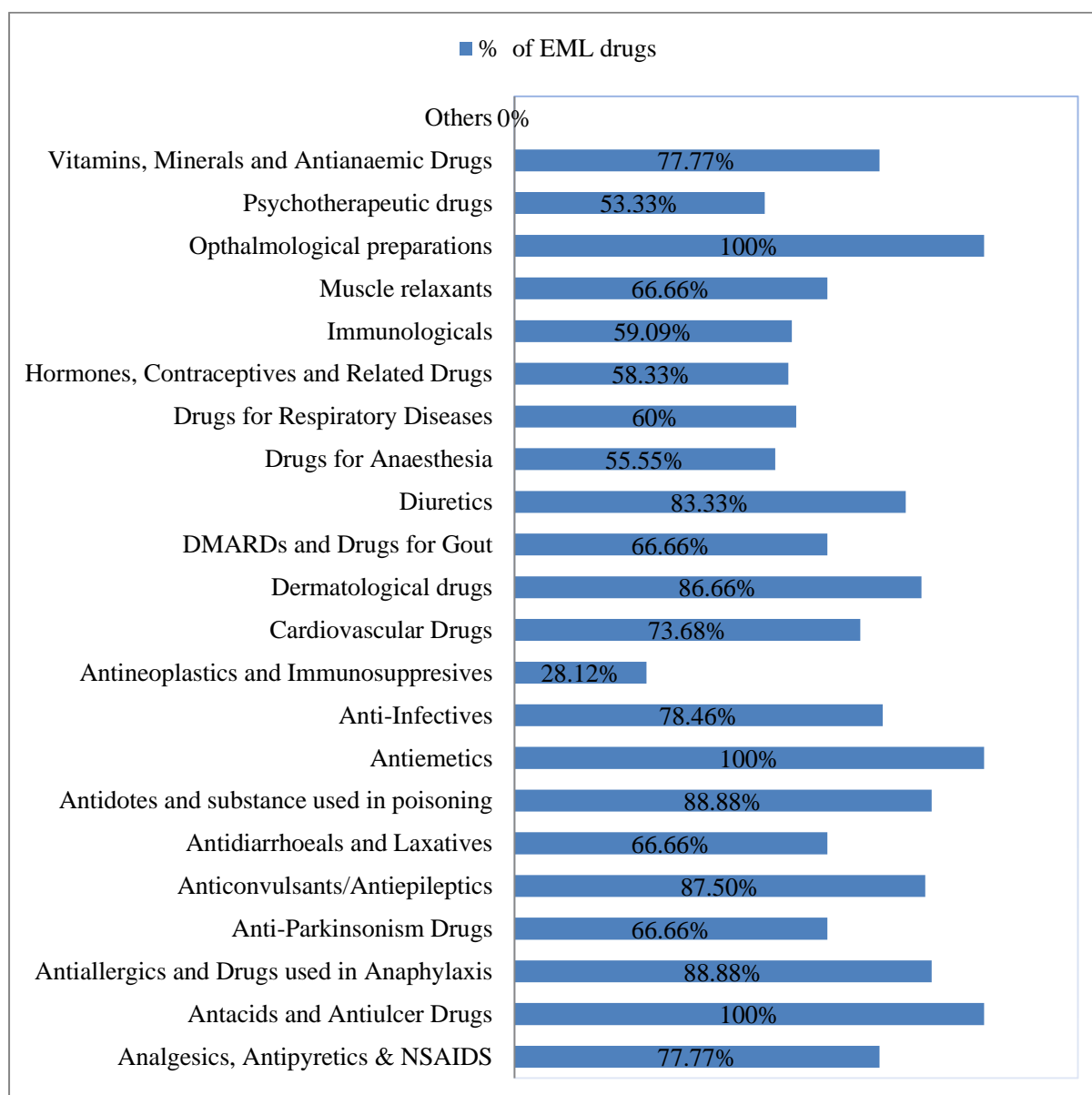
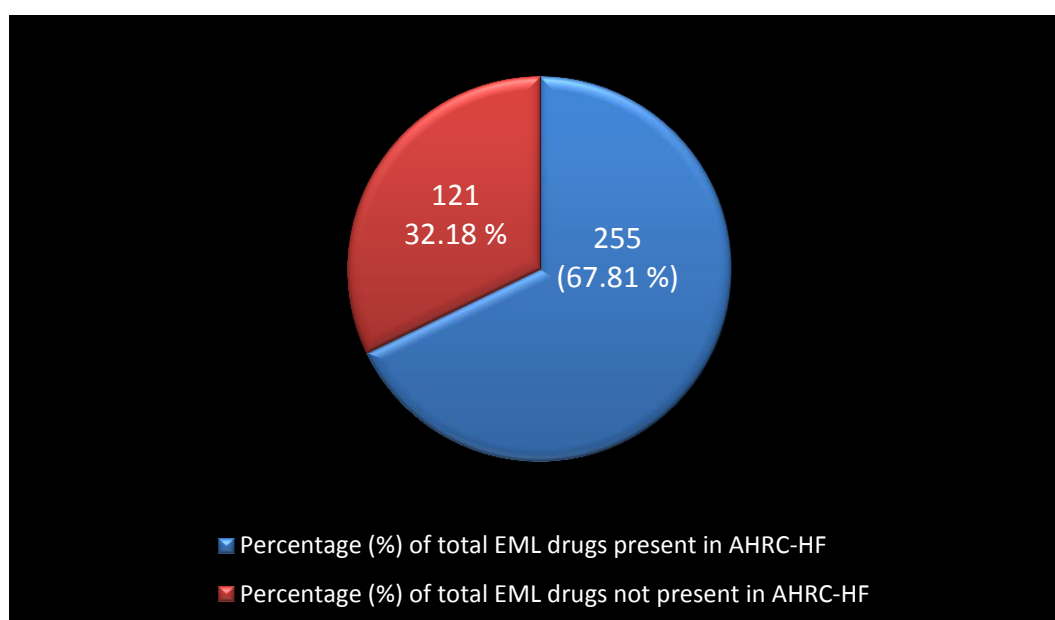


Figure 2

The percentage of EML drugs present in each drug class is shown in figure 2.

Table 5: Gross of the EML drugs in the prepared formulary (AHRC-HF)

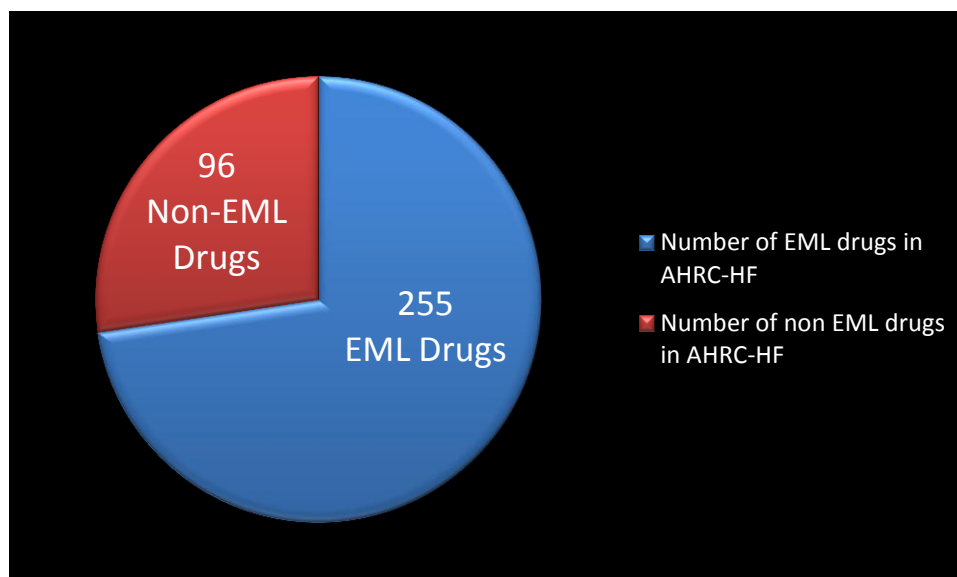
Total number of drugs in EML 2013	Number of EML drugs present in AHRC-HF	Percentage (%) of EML drugs present in AHRC-HF n = 376	Number EML drugs not present in AHRC-HF	Percentage (%) of EML drugs not present in AHRC-HF n = 376
376	255	67.81 %	121	32.18 %

**Figure 3**

The total number of drugs which were present in EML-2013 was 376, out of which 255 drugs were present in the prepared AHRC-HF and the number of EML drugs which were not present in the prepared AHRC-HF was 121. The percentage and number of EML drugs which are present and not present in the prepared AHRC-HF is shown in table 5 and figure 3.

Table 6: EML drugs and Non-EML drugs in the prepared AHRC-HF

Number of EML drugs in AHRC-HF	Percentage of EML drugs in AHRC-HF (n=351)	Number of non-EML drugs in AHRC-HF	Percentage Non-EML drugs in AHRC-HF
255	72.64 %	96	27.35 %

**Figure 4**

The number of EML and non-EML drugs out of 351 AHRC-HF drugs were respectively 255 (72.64 %) and 96 (27.35 %), which is shown in table 6 and figure 4.

Chapter 6

Discussion



DISCUSSION:

National Formulary of India (NFI) which consist monographs of 431 drugs including FDCs, immunologicals and vitamins was published in 2011 by the IPC on behalf of the Govt. of India, Ministry of Health and Family Welfare. The national formulary was adopted from the WHO model formulary and thoroughly updated for its content, especially keeping in view the end user in India. Since NFI-2011 was prepared in keeping the end user in India, i.e. local population, it was adopted as a model to develop AHRC Hospital Formulary. Many other references were used during the preparation of the formulary. Where, EML-2013 of Delhi was used in selection process of drugs to include in the formulary. To prepare monographs of AHRC-HF drugs, including NFI-2011 other 8 references were used.

The reason behind using the EML-2013 of Delhi is that, it was a recent list of EML available, which is relevant to the local population as Delhi is capital of India. But, it is known that there will be a difference in the health care requirements of the local population of Delhi and the local population the AH & RC. So, members of the P & T committee of AH & RC made the hospital's drug list by considering health care requirements of hospital's local population. The prepared formulary is comprised of total 357 drugs, out of these there were 21 FDCs, 18 immunologicals and 12 vitamins. These 357 drugs were classified into 23 main categories or classes. Antiinfectives class comprise 62 (17.36 %) drugs, which is highest in any of the AHRC-HF drug class. Second highest numbers of drugs were under the cardiovascular drugs class, which comprise 43 (12.04 %) drugs. Second lowest numbers of drugs were under anti-parkinsonism drugs class, which comprise 4 (1.12 %) drugs. While, lowest numbers of drugs were under the class DMARDs and drugs for gout, which comprise 2 (0.56 %) drugs. The reason behind highest number of drugs under antiinfectives and cardiovascular classes is because of broad therapeutic coverage of drugs under these categories which are more frequently used in the hospital. Since the anti-parkinsonism drugs class and DMARDs and

drugs for gout class have narrow therapeutic coverage of drugs under these categories, they remained as the drug classes having lowest number of drugs in the AHRC-HF.

The information to be present in monographs of the drugs depends up on recommendations of the P & T committee. Monographs of the AHRC-HF drugs were prepared according to recommendations of members of the P & T committee and information present in monographs of the AHRC-HF drugs is indication, dose, availability (in terms of strength and formulation type), contraindications, precautions, adverse effects, pregnancy risk category and storage conditions of the drugs. Schedule of the drug was mentioned for possible drugs. The reason behind not including brand names in the prepared formulary is to provoke generic prescribing. Since the availability of drugs in detail with their strength, formulation type and other required information was given clearly in the prepared formulary, clinicians can prescribe the drugs without using the brand names. This type of monograph design is quite similar to the monographs in NFI-2011. The difference between monographs of AHRC-HF and NFI-2011 is, specific information regarding the drug interactions was not mentioned in monographs of the prepared formulary, where it is present in the monographs of NFI-2011.

The prepared hospital formulary was compared with EML-2013 of national capital territory of Delhi, India, which was used as reference during selecting the medicines for the formulary. The reason behind this comparison is to check the difference between the drugs in the prepared formulary and EML-2013.

When the prepared hospital formulary was compared to the EML-2013, all the EML drugs coming under the categories Antacids and antiulcer drugs, Antiemetics and Ophthalmological preparations were present in the prepared hospital formulary. So, these 3 categories showed 100 % presence of EML medicines. The presence of EML drugs was 80 % to 90 % in the following 5 categories, Antiallergics and drugs used in anaphylaxis, Anticonvulsants/Antiepileptics, Antidotes and substance used in poisoning, Dermatological drugs and the

Diuretics. The presence of EML drugs was 70 % to 80 % in the following 4 categories Analgesics, antipyretics & NSAIDS, Anti-Infectives, Cardiovascular drugs, and the Vitamins, minerals and antianaemic drugs. The presence of EML drugs was 60 % to 70 % in the following 5 categories Anti-Parkinsonism drugs, Antidiarrhoeals and laxatives, DMARDs and drugs for gout, Drugs for respiratory diseases, Muscle relaxants. The presence of EML drugs was 50 % to 60 % in the following 4 categories Drugs for anaesthesia, Hormones, contraceptives and related drugs, Immunologicals, Psychotherapeutic drugs. In Antineoplastics and immunosuppressives drug class there were only 28.12 % EML drugs present. There were 13 other EML drugs like Mosapride citrate dehydrate, Uredoxy cholic acid, turpentine oil etc., which are not present in any class of the prepared formulary and were also not suitable to include any drug class of the AHRC-HF for comparison.

While evaluating for the EML drugs missing from each class of the AHRC-HF drugs, there were 23 EML drugs missing from the class Antineoplastics and immunosuppressives, which was the class missing highest number of EML drugs. This is because, the hospital (AH & RC) is not providing specialized care in oncology or because of the health care issues of local population may not demand these drugs. The class Hormones, contraceptives and related drugs was missing second highest number of EML drugs, under which 15 EML drugs were missing, like Octreotide, Insulin NPH, Insulin premixed, Sitagliptin, Propyl thio uracil, Lugol's Iodine, Methylethergometrine Maleate etc. This is because members of the P & T committee recommend that these drugs are not necessary for this health care setup (AH & RC). Anti-Infectives and Cardiovascular drugs under these categories 14 and 10 EML drugs were missing respectively. In remaining categories (except others category), the EML drugs missing were less than 10 in each category. The EML drugs missing from Anti-Infectives class of the prepared were almost nucleoside and non-nucleoside reverse transcriptase inhibitors such as zidovudine, lamivudine, stavudine, nevirapine, efavirenz etc. antivirals like

adeofovir, ribavirin etc. were also missing, except these almost all other anti-Infective EML drugs were present.

There were totally 255 EML drugs present in the prepared formulary, which covers 67.81 % of the total drugs (376) in EML-2013. This shows that there is considerable difference between the drugs in the prepared AHRC-HF and EML-2013. The remaining essential drugs which were not present in the prepared formulary were 121, covering 32.18 % of the total drugs in EML-2013. R. J. D'ALMEIDA et al., conducted a study which showed the result that, about 75 medicines recommended by the essential medicine list (National list of essential medicine, 2003) were not present in their prepared hospital formulary. Authors mentioned that the reason for this is the poor response and recommendations from the clinicians regarding the use of these drugs, and availability of newer drugs with better efficacy.⁵ The reason for 121 essential drugs missing from the prepared formulary is recommendations of the P & T committee, where clinicians think that the health care requirements of the local population does not demand these drugs or other medicines can fulfil those health care requirements with better efficacy.

When the drugs (351) of AHRC-HF are divided into EML and non-EML drugs, it showed that 72.64 % (255) of the AHRC-HF drugs are EML drugs. Where, 27.35 % (96) of the AHRC-HF drugs are non-EML drugs. The reasons behind the presence of 27.35 % (96) of non-EML drugs in the prepared formulary are recommendations by P & T committee that the presence of these medicines in the formulary can better serve the health care requirements of the local population, prescriber's choice and pharmaceutical promotional activities.

The prepared formulary is positively similar to EML-2013 of national capital territory of Delhi, India. But, there is also considerable difference between the drugs in the prepared formulary and the EML-2013. Because, many factors like health care requirements of the

organization's local population, speciality services provided by the organization, pharmaceutical promotional activities, market availability, prescriber's choice and also the decisions of the organization's P & T committee varies with different organizations.

The prepared Pharmaceutical product list is also considered as a part of the hospital formulary system. Where, prescribers if necessary can refer the prepared Pharmaceutical product list for the detailed information regarding the brands available in the hospital pharmacy. There are total 948 brands available in the prepared Pharmaceutical product list of AH & RC, out of which 184 brands were having different type of combinations. These combinations vary from simple to complex combinations. The number of brands per drug varied from single to eight, decisions taken by the P & T committee is responsible for this. Factors which reflected the decisions of the P & T committee in this regards are prescriber's choice and pharmacist recommendations, cost variations between the brands and pharmaceutical promotional activities.

Seetharama G. Rao et al., conducted a study which showed decrease in number of medicines from 1627 to 424 after introduction of the Hospital Essential Drug List (HEDL) 2011 and On comparison, WHO-EDL 2011 have 350 and NEDL of India have 348 medicines. While preparing the HEDL, 46 double drug combinations decreased to 15 and 9 triple drug combinations decreased to 1.¹⁵ Similarly, the number of brands in the hospital pharmacy of AH & RC before the development of hospital formulary was more than 1700, which was decreased to 948 after the development of Hospital formulary.

Ellena Anagnostis et al., conducted a national survey on hospital formulary management processes, the results showed that 85% of institutions conduct pharmacoeconomic analysis to support their formulary decisions.¹⁶ Pharmacoeconomic analysis was not conducted by the P & T committee of AH & RC to support its formulary decisions, the reason behind this is lack

of skills in applying pharmacoeconomic analysis, members of the committee think that pharmacoeconomic analysis may not help their formulary decisions or it is time consuming.

The appendices part of the formulary was prepared as per the recommendations of the P & T committee, which contains clinically useful information on topics like antimicrobial resistance, drug interactions, drug use in special conditions, pharmacogenetics, pharmacovigilance and dose calculations in special conditions.

Chapter 7

Conclusion



Adopting National Formulary of India, 2011 as a model was greatly helpful in preparing this hospital formulary. It will be wise to say that, hospitals in India can successfully adopt NFI-2011 as a model to develop their own formularies. The health care organizations should put prompt efforts to have their formularies adhered to essential medicines concept, as this will help in achieving rational drug use. Using EML-2013 of Delhi, national capital of India, as reference was helpful to select the required medicines for the hospital. Medicines selected for the prepared hospital formulary satisfy the health care needs of the hospital's local population.

Hospital formularies are heterogeneous in nature. The prepared Hospital formulary is unique in its features, as recommended by the hospital's P & T committee to suit its patient's health care requirements.

Not all the hospitals in India have their own formularies. In this world of advanced health care system, hospitals in India should develop their own formulary with effective formulary system and P & T committee to achieve rationality in drug use. P & T committees of the hospitals must implement pharmacoeconomic analysis to select drugs and their products for inclusion into formulary. Pharmaceutical promotion is a delicate area, where it is the responsibility of hospital's P & T committee to solve if any conflicts in drug products selection and look after that, drug products are selected for the hospital by considering cost, safety and efficacy.

The prepared hospital formulary should be implemented in the hospital with effective formulary system, which will support and contribute to rationalize drug use in the hospital. Clinicians of the AH & RC hospital were satisfied with the prepared formulary and commented that, it is informative and will be useful for the health care professionals working in the hospital. By referring the prepared hospital formulary, prescribers of the hospital can

know about the drugs available in the hospital Pharmacy. Where, the prepared pharmaceutical product list can be referred for brand names and other details of the brands approved to use in the hospital.

Pharmacy and therapeutic committee of any hospital must be well balanced with active health care professionals like physicians, pharmacists and nurse. Pharmacist play important role in developing formulary and formulary system to a hospital. Pharmacist participation in structuring guidelines, policies and procedures for drug use in the hospital is essential.

A well-developed hospital formulary, well-structured policies and procedures for additions and deletions of the drugs from the formulary and to address other drug related issues in the hospital are essential to run an effective formulary system. Where, this in turn gives rise to rational drug use.

Chapter 8

Summary



A hospital based prospective study was carried out with the main objective to develop hospital formulary for a rural tertiary care teaching hospital in South India. The prepared hospital formulary was compared with EML-2013 of Delhi, India, to check the difference between the drugs in the prepared formulary and EML-2013. The study was carried out for over a period of nine months from July-2014 to march-2015 at Adichunchanagiri Hospital and Research Centre (AH & RC), B.G. Nagara.

NFI-2011 was adopted as a model to develop AHRC Hospital Formulary. Many other references were used during the preparation of the formulary. Where, EML-2013 of Delhi was used as reference in selection process of drugs to include in the formulary. To prepare monographs of AHRC-HF drugs, including NFI-2011 other 8 references were used.

The whole content of the prepared AHRC-HF was divided into 6 main parts. They are Preface, Introduction to AHRC-HF, Common Abbreviations, and Monographs of the 357 drugs and the Appendices.

The prepared Adichunchanagiri Hospital & Research Centre Hospital formulary (AHRC-HF) was comprised of total 357 drugs. Out of these 357 drugs, there were totally 306 single drugs, 21 FDCs, 18 immunologicals and 12 vitamins. The 357 drugs finalised by the P & committee were classified by Pharmacologic-Therapeutic classification into 23 classes or categories. The monographs for those drugs were prepared as per the recommendation of the P & T committee members. As suggested by committee member's information regarding indication, availability, dose, contraindications, precautions, adverse effects, pregnancy risk category and storage in each monograph of the drugs was included.

Pharmaceutical product list was prepared, which consists information like brand names, strength, cost and manufacturer name of the brands or drug products selected for use in the hospital. The prepared pharmaceutical product list is considered as a part of prepared hospital formulary or formulary system of the hospital and it was comprised of total 948

brands selected for the drugs listed in AHRC-HF, out of these 948 brands, 184 brands were in different combinations. The number of brands per generic drug varied from single to eight.

When AHRC-HF drugs are compared to essential medicines list-2013 (EML-2013), it showed that, out of 351 AHRC-HF drugs (6 drugs from the class- Solutions Correcting Water, Electrolyte and Acid Base Disturbances, were excluded from comparison) 255 (72.64 %) drugs were present in EML-2013. These 255 drugs of AHRC-HF covered 67.81 % of 376 EML-2013 drugs.

When the drugs (351) of AHRC-HF are divided into EML and non-EML drugs, it showed that 72.64 % (255) of the AHRC-HF drugs are EML drugs. Where, 27.35 % (96) of the AHRC-HF drugs are non-EML drugs. There is considerable difference between the drugs in the prepared AHRC-HF and EML-2013. Because, many factors like health care requirements of the organization's local population, speciality services provided by the organization, pharmaceutical promotional activities, market availability, prescriber's choice and also the decisions of the organization's P & T committee varies with different organizations.

Hospital formularies are heterogeneous in nature. The prepared Hospital formulary is unique in its features, as recommended by the hospital's P & T committee to suit its patient's health care requirements.

The prepared formulary should be implemented in the hospital with effective formulary system, which will support and contribute to rationalize drug use in the hospital. Pharmacist play important role in developing formulary and formulary system to a hospital. Pharmacist participation in structuring guidelines, policies and procedures for drug use in the hospital is essential.

Chapter 9

Limitations



LIMITATIONS:

- The study does not involved assessment of impact on implementation of the prepared hospital formulary.

Chapter 10

Future Directions

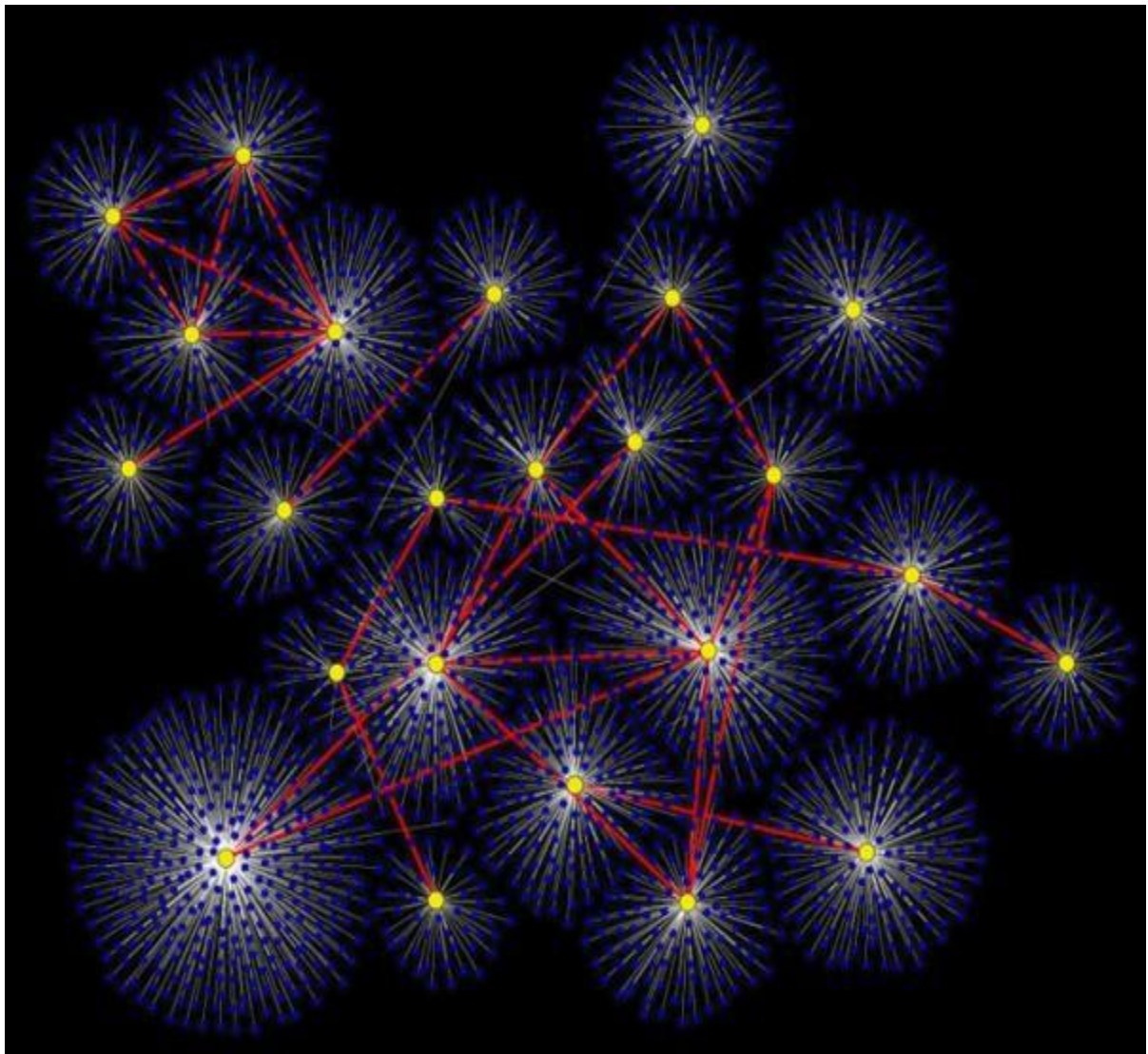


FUTURE DIRECTIONS:

- Hospitals in India must develop their own formularies and more studies must be conducted on hospital formularies and formulary systems.
- More studies must also be conducted on comparison of hospital formularies with national and other relevant essential medicines lists.

Chapter 11

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ANNEXURES

Annexures


ETHICAL COMMITTEE APPROVAL CERTIFICATE

|| Jai Sri Gurudev ||


Sri Adichunchanagiri Shikshana Trust (R)

Adichunchanagiri Institute of Medical Sciences

(Recognised by Medical Council of India, New Delhi, General Medical Council,
London (U.K.) & Affiliated to Rajiv Gandhi University of Health Sciences, Karnataka)




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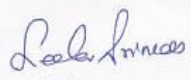
Date: 16-07-2014

CERTIFICATE

This is to certify that the M. Pharm. research project titled
**“Development of hospital formulary for a rural tertiary care teaching hospital
in South India”** to be submitted to the Rajiv Gandhi University of Health Sciences,
Bengaluru, and to be conducted by the research scholar Mr. Kiran Majjigeri, under
the guidance of Mr. Satish Kumar B P, Associate Professor, Department of
Pharmacy practice, SAC College of Pharmacy, BG Nagara, Mandya, Karnataka -
571448 has been discussed and approved by the Institutional Ethical Committee,
Adichunchanagiri Institute of Medical Sciences, BG Nagara, Mandya, Karnataka-
571448 on 14th July 2014.



Member Secretary
IEC, AIMS, BG Nagara
PRINCIPAL
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Annexures

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Dated: 7th August, 2014

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