

UPDATING OF CURRENT AH&RC HOSPITAL FORMULARY 2016 to 2019

Satish Kumar BP, Soumya A, Sarababu E, Moinuddin K

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To update Hospital Formulary for a Rural Tertiary Care teaching hospital in South India from 2016 to 2019 and compare it with the National List of Essential Medicine 2015 Delhi, India.

A Retro Prospective observational study was carried out in a tertiary care teaching hospital over a period of 8 months. A finalized drug list was obtained from the Pharmacy and Therapeutic(P&T) committee and monographs were prepared as per their recommendation. The drugs in the prepared formulary and National List of Essential Medicine (NLEM-2015) were compared. Microsoft Excel 2010 was used to prepare the bar graphs and pie charts for the percentage description of drug distribution

The updated Adichunchanagiri Hospital & Research Centre Hospital formulary (AH&RC-HF) comprised a total of 519 drugs. Out of these, 492

were single drugs and 27 FDCs. These 519 drugs were classified into 27 main categories and monographs were prepared for all 519 drugs. When AH&RC-HF drugs are compared to National List of Essential Medicine-2015, it showed that, out of 519 AH&RC-HF drugs, The NLEM 2015 consisted of 376 drugs of which 331 (88.03%) number of drugs were present in the updated AH&RC-HF 2018 and 45(11.97%) drugs of AH&RC-HF 2018 were non NLEM drugs. The effective implementation of a formulary system can improve the use of health care resources for improving patient outcome and can contribute to rationalized drug use. Pharmacists play an important role in the development and implementation of a formulary system.

Key Words: *Hospital Formulary, National List of Essential Medicine, Monographs, Pharmacy & Therapeutic(P&T) committee.*

INTRODUCTION

A formulary is a continually revised compilation of medications and related information, representing the current clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health [1]. 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. The implementation of the formulary will have a significant impact on clinical practice of health care professionals. It helps physicians to know about the available drugs in the hospital pharmacy and helps in better inventory control. 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 [2]. 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. A formulary can be used as a tool to rationalize the range of medicines used in standard practice.

The main reason for developing hospital formulary is to set standards for best practice, promoting high quality, evidence-based prescribing thus reduces the variation in the level of treatment provided to the patients and controlling drugs cost [3]. 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. 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 [4]. 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. 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. 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. In the updated 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. 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.

WHO model Formulary, British National Formulary and National formulary of India are some of the formularies used as standard references in many hospitals. The Pharmacy and Therapeutic (P & T) committee is

Department of pharmacy practice, Sri Adichunchanagiri College Of Pharmacy, Adichunchanagiri Hospital and Research centre, Adichunchanagiri University, Nagamangala, Karnataka 571448, India

Department of pharmacy practice, Sri Adichunchanagiri College Of Pharmacy, Adichunchanagiri Hospital and Research centre, Adichunchanagiri University, Nagamangala, Karnataka 571448, India

*Correspondence: Soumya A, Department of pharmacy practice, Sri Adichunchanagiri College Of Pharmacy, Adichunchanagiri Hospital and Research centre, Adichunchanagiri University, Nagamangala, Karnataka 571448, India, Tel: (256) 372- 4931; E-mail: soumyaforess@gmail.com

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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). The Pharmacy and Therapeutic (P & T) committee should be responsible for overseeing policies and procedures related to all aspects of medication use within an institution. 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.

MATERIALS AND METHOD

Study Design

This was a retrospective and prospective observational study.

Study Area

This study was conducted at Adichunchanagiri Hospital and Research Centre (AH & RC), B.G. Nagara, which is a 1050 bedded rural tertiary care teaching hospital with various departments like Anaesthesia, ENT, General Medicine, Obstetrics & Gynaecology, Ophthalmology, Orthopaedics, Paediatrics, Psychiatry, Radiology, Skin and STD and Surgery. The hospital has a 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. (Ethical Approval number: AIMS/IEC/1465).

Study Period

A period of 8 months from September 2018 to April 2019.

Source of Data

All the necessary data to update AHRC Hospital Formulary were taken from various online and offline sources. There are a total 9 references used to update monographs of the AHRC-HF drugs and are shown in Table 1.

TABLE 1 References used to prepare monographs of the drugs

S. No.	REFERENCE USED
1	National formulary of India, 2011.
2	Micromedex
3	CIMS India
4	Med India
5	Medscape
6	Drug Bank
7	Rxlist
8	Drugs.com
9	Medline

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

NLEM-2015, drugs included in the AHRC-HF (2016), NFI and drugs coming under the list of NLEM-2015 were considered.

Exclusion Criteria

The drugs and brands which are not selected or not approved by the P & T committee. By comparison study of AHRC-HF and NLEM-2015, the drugs which were excluded from the NLEM-2015 and NFI were excluded from the AH&RC hospital formulary 2016.

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

A complete list of medicines available in the pharmacy was provided along with the category by the retail pharmacist. All the members of the P & T committee were requested to select the drug 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 NLEM-2015 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, convener and chairman). A complete finalised hospital drug list was then prepared.

Preparation of monographs for the drugs

The drugs in the finalized list were classified by Pharmacologic-Therapeutic classification into 26 classes or categories. The monographs for those drugs were prepared as per the recommendation of the Pharmacy and Therapeutic (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 AH&RC-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 updated 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 finalized and printed in handy form.

Comparison of AHRC-HF (2016) with EML-2015

Drugs meeting inclusion criteria in the prepared AHRC-HF and NLEM-2015, India were compared. The comparison was made to check the difference between drugs in the prepared AHRC-HF (2016) and NLEM-2016 of national capital territory of Delhi, India. In the comparison study, the drugs meeting inclusion criteria were reclassified into 27 categories. The last category (27th) was made for those EML drugs which were not suitable to fit under the first 26 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 in total. The presence of NLEM and Non-NLEM drugs

in the prepared formulary were also identified and their percentage distribution was calculated.

Statistical Analysis

Microsoft 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 of drugs.

RESULTS

The updated AH&RC Hospital Formulary comprised of Total 519 drugs, out of these 519 drugs, there were totally 492 single drugs and 27 FDCs. Here only combinations whose monographs were described in AH&RC hospital Formulary were considered as FDCs and each FDC is counted as a single drug. When AH&RC-HF drugs are compared to National Essential Medicine List-2015(NEML-2015), it showed that, out of 519 AH&RC-HF drugs(one drug from Antimigraine medicines, three drugs from disinfectants ,were excluded from comparison. The NLEM 2015 consisted of 376 drugs of which 331(88.03%) number of drugs were present in the updated AH&RC-HF-2018.45(11.97%) drugs in AH&RC-HF 2018 were non NLEM drugs.

The updated AH&RC-HF (2018) consisted of a total 27 categories of drug classes, of which the 27th category was made for those drugs which were not suitable to fit under the first 26 categories. Starting from the first category, Analgesics, Antipyretics and NSAIDs, Antacids and, Antiulcer Drugs, Anti-allergic drugs and Drugs used in Anaphylaxis, Anti-Parkinsonism Drugs, Antiepileptic drugs, Antidiarrheal and Laxatives, Antidotes and substance used in poisoning, Antiemetic drugs, Anti-Infective drugs, Antineoplastic drugs Immunosuppressive drugs, Cardiovascular Drugs, Dermatological drugs, DMARDs & Drugs for Gout, Diuretics, Drugs for Anaesthesia, Drugs for Respiratory Diseases, Hormones, Contraceptives & Related drugs, Immunologicals, Muscle relaxants, Ophthalmological preparations, Psychotherapeutic drugs, Solutions Correcting Water, Electrolytes & drugs for acid Base Disturbances, Vitamins Minerals & Anti-anemia Drugs, Drugs related to child birth & pregnancy. Ulcer protective drugs ,Diagnostic aids and Miscellaneous drug classes, consisted of 19(3.66%), 12(2.31%),

14(2.70%), 4(0.77%), 13(2.50%), 10(1.93%), 10(1.93%), 12(2.31%), 78(15.03%), 9(1.73%), 56(10.79%), 39(7.51%), 12(2.31%), 9(1.72%), 15(2.89%), 20(3.85%), 34(6.55%), 19(3.66%), 19(3.66%), 35.(6.74%), 31(5.97%), 8(1.54%),19(3.66%),4(0.77%),2(0.39%), 4(0.77%)and 12(2.31%) drugs respectively.

Contents of the AHRC-Hospital Formulary

The whole content of the updated AHRC-HF was divided into 6 main parts. The preface part of the AHRC-HF contains information regarding the responsible role played by the P & Committee of AH & RC in updation of 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 (2018) and few tips to use AHRC-HF. Acknowledgements, in this part of AHRC-HF, all the members who contributed to development of AHRC-HF (2018) were acknowledged. Common abbreviations, in this part of AHRC-HF, commonly used abbreviations in AHRC-HF (2018) were expanded. Description of monographs of the drugs, which is the main part of the hospital formulary, contained monographs of 519 drugs of AHRC-HF, which were classified into 27 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 the Pharmaceutical product registration form was attached to the formulary.

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 conditions.

TABLE 2 Numbers and Percentage of each class of drug in the AHRC-HF

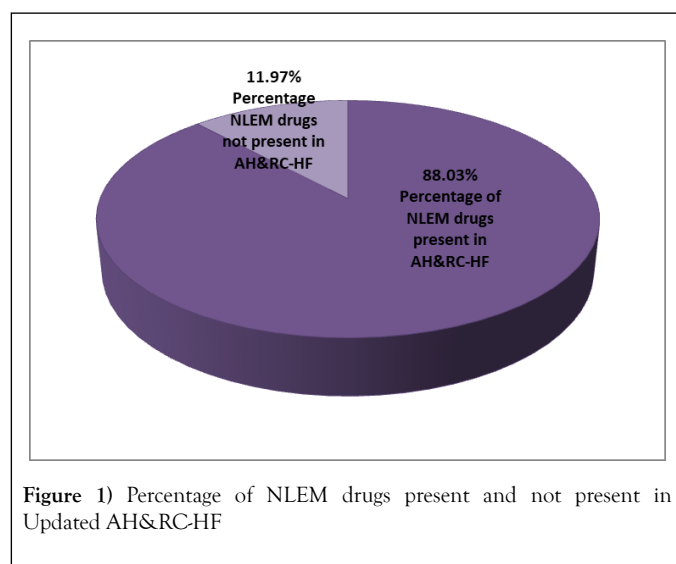
Drug class No.	Drug class	Number of drugs	Percentage of drugs n = 519
1	Analgesics, Antipyretics and NSAIDs	19	3.66%
2	Antacids and Antiulcer Drugs	12	2.31%
3	Antiallergic drugs and Drugs used in Anaphylaxis	14	2.70%
4	Anti-Parkinsonism Drugs	4	
5	Antiepileptic drugs	13	2.50%
6	Antidiarrhoeal drugs and Laxatives	10	1.93%
7	Antidotes and substance used in poisoning	10	1.93%
8	Antiemetic drugs	12	2.31%
9	Anti-Infective drugs	78	15.03%
10	Antineoplastic drugs and Immunosuppressive	9	1.73%
11	Cardiovascular Drugs	56	10.79%
12	Dermatological drugs	39	7.51%
13	DMARDs and Drugs for Gout	12	2.31%
14	Diuretics	9	1.73%

15	Drugs for Anaesthesia	15	2.89%
16	Drugs for Respiratory Diseases	20	3.85%
17	Hormones, Contraceptives and Related Drugs	34	6.55%
18	Immunological	19	3.66%
19	Muscle relaxants	19	3.66%
20	Ophthalmological preparations	35	6.74%
21	Psychotherapeutic drugs	31	5.97%
22	Solutions Correcting Water, Electrolyte and Acid Base Disturbances	8	1.54%
23	Vitamins, Minerals and Anti-anaemic Drugs	19	3.66%
24	Drugs related to childbirth and pregnancy.	4	0.77%
25	Ulcer protective drugs	2	0.39%
26	Miscellaneous drug classes	12	2.31%
27	Diagnostic aids	4	0.77%

The number of drugs in each class and the percentage they constituted to total AHRC-HF drugs are shown in table 2.

TABLE 3 Gross of the NLEM drugs in the prepared formulary (AHRC-HF)

Total number of drugs in NLEM 2015	Number of NLEM drugs present in AHRC-HF	Percentage (%) of NLEM drugs present in AHRC-HF n = 376	Number of NLEM drugs not present in AHRC-HF	Percentage (%) of NLEM drugs not present in AHRC-HF n = 376
376	331	88.03%	45	11.97%



The total number of drugs present in NLEM 2015 was 376, out of which 331(88.03%) drugs were present in AH&RC-HF and the number of NLEM drugs which were not present in the prepared AH&RC-HF was 45 (11.97%).The percentage and number of NLEM drugs which are present and not present in the updated AH&RC-HF is shown in table 3 and Figure 1.

TABLE 4 NLEM drugs and non NLEM Drugs in the updated AH&RC-HF 2018

Number of NLEM drugs in AHRC-HF	Percentage of NLEM drugs in AHRC-HF (n=519)	Number of non-NLEM drugs in AHRC-HF	Percentage Non-NLEM drugs in AHRC-HF
331	63.77%	188	36.22%

In the updated AH&RC-HF, out of the total 519 drugs 331 (63.78%) were NLEM drugs and 188(36.2%) were non- NLEM drugs. The percentage and number of NLEM and non NLEM drugs are shown in table 4 and Figure 2.

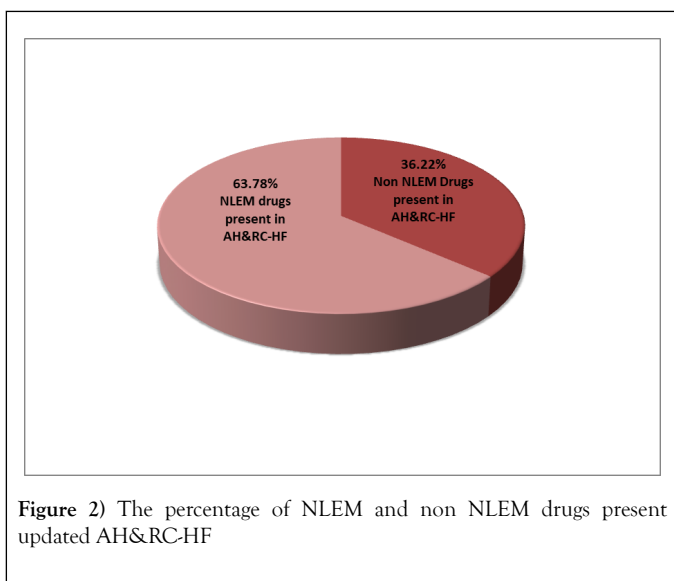


Figure 2) The percentage of NLEM and non NLEM drugs present updated AH&RC-HF

TABLE 5 Comparison of drugs present in the current AH&RC-HF (2016) with the updated AH&RC-HF (2018)

Number of drugs in Current AH&RC-HF (2016)	Percentage of drugs in current AH&RC-HF (2016) (n=519)	Number of Drugs in Updated AH&RC-HF (2018)	Percentage Drugs in Updated AH&RC-HF (2018)
357	40.75%	519	59.25%

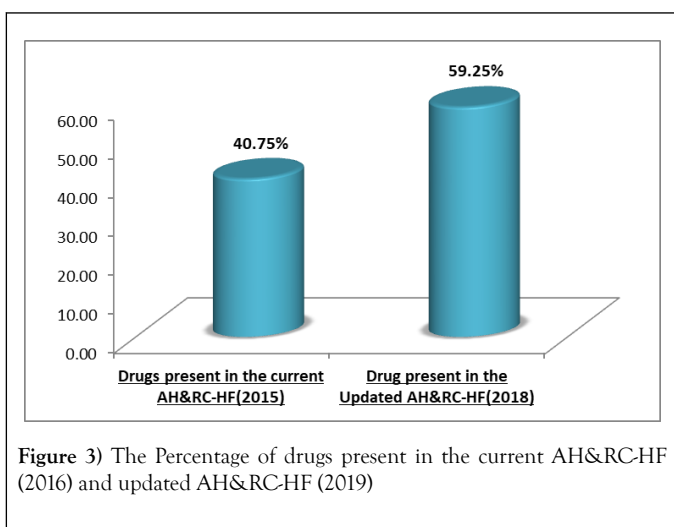


Figure 3) The Percentage of drugs present in the current AH&RC-HF (2016) and updated AH&RC-HF (2018)

The current AH&RC-HF consisted of 357 (40.75%) drugs and the updated AH&RC-HF consisted of 519(59.25%) drugs. The comparison is depicted in table 5 and figure 3.

Discussion

The main references used for the updating process were the current AH&RC Hospital Formulary 2016, National List of Essential Medicine 2015, List of drugs recommended by pharmacy and therapeutic committee of AH&RC 2018. Out of these references NLEM 2015 was used mainly for the selection process of drugs to include in the formulary. To prepare the monograph of selected drugs, 8 online databases were mainly used along with National Formulary of India. The main reason for using the NLEM 2015 is that it was a recent list of NLEM available according to the suggestion of P&T Committee AH&RC.

A suggested hospital drug list from the Pharmacy and Therapeutic (P & T) committee by considering health care requirements of the hospital was critically analyzed and compared with the current existing formulary for the

addition and deletion of drugs to update the formulary. The updated formulary consisted of 519 drug monographs which included information about Indications, Dose, Availability, Precautions, Contraindications, Adverse drug reactions and Storage, just as in NFI. Out of the total 519 drugs, 492 were single drugs and 27 were FDCs. The total 519 drugs were categorized into 27 main categories of classes .Additionally 4 categories were added along with the 23 categories which are , Drugs used childbirth and Pregnancy, Ulcer protective drugs, Diagnostic Aids and the last category of Miscellaneous drugs was used for the drugs which did not fit under any of the above mentioned 26 categories . Anti- Infective drugs comprised of 78 (15.03%) drugs which is the highest of all drug categories in AH & RC HF 2018.Second highest numbers of drugs were under cardiovascular drugs ,which comprised of 56 (10.79%) of drugs .The lowest numbers of drugs were under the class ulcer protectives (of 2 (0.39%) of drugs) since they have narrow therapeutic coverage of drugs . The information given in the monographs depended on recommendations of the Pharmacy and Therapeutic (P & T) committee and Schedule of drugs were mentioned for possible drugs. Brand names were not included in the updated formulary for the purpose of provoking and appreciating generic prescribing.

The prepared hospital formulary was compared to the NLEM 2015 and all the drug categories excluding Anti migraine, Disinfectants, Drugs for Dementia were present in both NLEM and AH&RC HF 2018. While evaluating the AH&RC with the NLEM 2015 that constituted of 376 drugs, it showed that 331 (88.03) drugs from NLEM 2015 were present in the AH & RC HF 2018 and 45 (11.97%) of NLEM drugs were not present in AH &RC- HF 2018. 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.

This missing 45 drugs were mainly in the categories of Antineoplastic drugs (28), Anti-infective drugs (9) and cardiovascular drugs (8). This is thought to be completely depended on epidemiological status, population, areas of specialized care, physicians choice and prescribing patterns. The missing 45 drugs were not added because of the recommendation from the Pharmacy and Therapeutic (P & T) committee regarding the necessity of these drugs in the particular hospital (AH & RC) health care set up.

When the drugs (519) of AH&RC HF-2018 were divided into NLEM and Non NLEM drugs it showed that 63.77% (331) drugs of the AH&RC -HF 2018 drugs are NLEM Drugs and 36.22%(188) drugs are Non NLEM drugs. The reasons behind the presence of 36.22% (188) drugs of Non NLEM drugs was because of the recommendations by Pharmacy and Therapeutic(P & T)Committee suggesting that the presence of these medicines in formulary can better serve the healthcare requirements of local populations, prescriber's choice and pharmaceutical promotional activities

The updated formulary of AH & RC 2018 and current Formulary AH & RC 2016 had a difference of 162 drugs in number. The current AH & RC-HF 2016 constituted 357 (40.75%) drugs and the updated AH & RC-HF (2018) constituted 519(59.25%).This considerable change explains about the changed requirements of population, varied prescriber's choice and diversified pharmaceutical promotional activities. This is also influenced by many factors like services provided by the organizations, market availability and decisions of the organizations P& T committee Kaur RJ, Misra A, Ambwani SR. Hospital Formulary Concept: Is India Ready and How it will Benefit from it? J Basic Clin Pharma 2017; 8:208-210, conducted a study that reflected that the use of numerous irrationals, unapproved and power quality medications are floating in Indian market leading to the health of millions at risk. This can be minimized by implementing a hospital formulary system that ensures safe ,efficacious and cost effective drugs .The implementation of hospital formulary system in India faces certain hindrances like lack of resources such as drug information, proper guidelines ,transparency in functioning of regulatory bodies and lack of interest among medical practitioners.

Ellena Anagnostis et al., conducted a national survey on hospital formulary management processes and showed that 85% of institutions conduct pharmaco-economic analysis to support their formulary decisions [8].

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 [7]. 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.

CONCLUSION

The whole study concludes that a hospital formulary should be implemented in the hospital which will contribute to rationalized drug use. It can also help to improve the use of health care resources for a pharmacy

and patient outcomes. The clinical Pharmacist can play an important role in the development and implementation of a formulary system.

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