Explication and Standardization of Ongoing Hospital Formulary in a Tertiary Care Referral Hospital, Perinthalmanna, Kerala

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ABSTRACT

Background: The important motive for creating a formulary is to set standards for great practice, merchandising high quality evidence-based prescribing, consequently, reduce the variant in degree of treatment furnished to the patients and controlling drug cost. Addition of drug to formulary is based on measures like safety, efficacy, quality and including drugs that are economically available for all types of patients. Routine therapeutic class review is necessary to standardize the formulary. Reviewing and evaluating all the therapeutic class of drugs and a new drug having an advantage over the current medicine is analyzed and included in the formulary. On the whole, the formulary helps to improve therapeutic outcome in a standardized manner and guides health care professionals in the rational prescription of drugs. Materials and Methods: This study is a prospective study. The 4th edition was prepared by formulating a drug list that was standardized according to the WHO guidelines. Then the prepared formulary was compared with WHO 2019 and NLEM 2015. Preparation of a new edition was notified prior, and a well-prepared questionnaire was distributed among the physicians and other health care providers for their opinion and feedbacks. Results: While comparing the prepared formulary with NLEM and WHO, we found that a greater number of drugs were included in the prepared hospital formulary which reflects the advanced clinical set up of the hospital. Conclusion: The study thus proves that timely standardization of formulary is essential for providing evidence-based medicine. A copy of the newly prepared formulary was circulated among different departments.

Keywords: Hospital formulary, Drugs, Rationality, Standardization, Therapeutic outcome.

INTRODUCTION

Formulary is a continuously revised compilation of pharmaceuticals and important ancillary information that reflects the current clinical judgement of the medical staff.¹

Hospital formulary initially started of life in hospital as a series of frequently purchased pharmaceutical preparations, produced for reference purpose only. As time passed by, formulary was adopted to include certain records on the increasing varieties of medicines. The main purpose of the hospital formulary is to provide a standard prescribing guideline for medical practitioners, which helps in improving the evidence-based use of medicine and reduce the variation in the prescribing patterns of the medical practitioner within an institution. The essential medicine concept states that a limited number of carefully selected medicines with proven efficacy, safety, and quality leads to a better health



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care, better management of medicines and lower health care costs for most of the population with common disease.² We need extra recognition of clinical pharmacist, as they are the most expert clinicians in this filed. Supporting this role through organizational policies and by law, delivering more safe culture to our patients can be attained. The clinical pharmacist representing the Pharmacy and Therapeutic Committee can oversee all the safe monitoring and rational use of prescription drugs through health care facility. The need for clinical pharmacist as leaders in the pharmacy career will streamline these functions and make certain Pharmacovigilance principles and safe drug use each in place. Formulary is employed by health organization to select and use medication that offer best therapeutic outcomes while minimizing potential risks and costs. The need of a formulary will reduce the inventory cost to utilize the budget allotted in the best way. The developed formulary will be useful for reducing the brands in the hospital which further aids in the rational use of medicines and will also help physicians, pharmacist and other healthcare professionals working under hospital to update their information about the use of medicines. It also helps physician in the appropriate choice of treatment and to make prescribers

follow uniform choice of treatment. This will enhance indirectly the quality of life in patients and reduce bias, therefore making formulary a tool for rationalizing the use of medicines.³ The medicines should be selected according to the need of the population and for particular disease of the patient. Guidelines are tools that helps to opt a better decision for improving the quality and efficiency of health care. It evaluates clinical and cost effectiveness of treatments and ways of managing a particular condition. Guidelines are based on research evidence although it is used as a reference in managing a medical condition. One approach of selecting medicines is by referring National List of Essential Medicines or WHO list of medicines. Main criteria for including drugs into formulary is based on safety, efficacy, quality, and cost of drugs. By critical evaluation of the medicine list, condensed drug list is prepared, and PTC committee analyzes these individual drugs for their safeguard and choose those drugs as first line agent for a particular disease. The pharmacy and therapeutic committee (PTC) is responsible for approbating the principles and procedures to promote quality enhancing medicine use. The formulary list should always ensure the availability of drugs. PTC should provide approval only for those drugs with need of clinical monitoring setup which is available at hospital. The prepared formulary consists of introductory section, drug and therapeutic information and addendums To execute formulary in presence, chief step is to publicize the formulary to health care providers including physician, nurses and pharmacist via supplying the copies of formulary to each department of hospital. Reviewing hospital formulary in a systematic approach of each therapeutic class intervention with every year can also promote the use of formulary.⁴ Reviewing and evaluating all the therapeutic class of drugs and new drugs having advantages over the current medicine list is analyzed and included in the formulary. While deleting a most widely used drug from the formulary an alternative efficacious medicine should be substituted to formulary. The formulary will be always updated and annually revised depending on the current requirements.

MATERIALS AND METHODS

The study was conducted in KIMS Al-shifa Hospital, situated in Perinthalmanna, Malappuram district of Kerala. It was carried out over a period of 6 months from January 2021-July 2021. This was a prospective study on explication and standardization of ongoing formulary in a tertiary care referral hospital to promote the rational prescribing patterns through best practice of prescribing. The medicines that are approved/registered in India, those approved for use in KIMS Al-shifa Hospital by P&TC, and the drugs of which safety, efficacy and quality are available from clinical trials are considered for inclusion in the hospital formulary. Medicines which are banned in India for sale and manufacture, medicines that are not approved by Pharmacy and Therapeutic Committee, medicines with the report of concerns on the safety profile issues are not taken into regard. The first step

was to collect gualified material based on the topic. Around 35 articles were reviewed, and all have been collected from relevant sources to ensure the authenticity of the information shared. The literatures were selected based on relevant criteria to meet the quality of the study. Peer-reviewed medical literatures including Pharmaco-economic studies were also carefully chosen. An objective type of questionnaire with queries regarding the basics of formulary was prepared and disseminated to each department of the hospital. The primary intention of the questionnaire was to determine how well the concept of hospital formulary was familiar within the medical community and to notify the ongoing revision process of the formulary. It was a paper questionnaire with both open ended and close ended questions. The questionnaire evaluated everyone's understanding about the formulary concept and knowledge of the previous editions of formularies published. Standardization of formulary was an immense process that began with prioritizing a list of diseases of relevance in the hospital and determining the respective first choice of treatment. Once a draft is prepared, it is circulated for appropriate clinical comments and further finalization. This was followed by educating all the healthcare staff about the importance of developing and implementing a hospital formulary. Finally, policies and guidelines for implementing the formulary were developed. Changes in principles and procedures and formulary maintenance were carried out by complete evaluation of individual drug classes. The benefit, risk, usage statistics and the potential outcomes were thoroughly evaluated and was brought under the notice of the advisory committee (PTC) for further discussion and conclusion. Decisions made on formulary changes were completely based on clinical evidence, ethical aspects, and safety measures. Single drug class review was completed via addition/deletion request. Drugs that no longer displayed a therapeutic value, drugs that were toxic, expensive, or used less were excluded from the formulary. The prepared formulary was compared with 21st WHO Essential Medicine List (2019) and NLEM (National List of Essential Medicines) 2015. The parameters compared are Therapeutic drug category of drugs, Number of brands available, Monograph content of drugs, Number of Fixed dose combinations, Number of vaccines, Pregnancy category, Number of drugs added and deleted from the formulary, Total number of drugs in the formularies, Number of drugs categorized as AWaRe classification, Drugs in WHO model formulary 2019 and NLEM 2015 but not included in the prepared formulary. Data analysis was prepared using descriptive statistical approaches SPSS statistical software version 20 was used for the data analysis. Chi square test with 95% confidence interval is used to present the results and a p value <0.05 was considered statistically significant.

Table 1: Number of drugs added and deleted in the prepared formulary.

Parameter	No. of drugs
Drugs added in the prepared formulary.	323
Drugs deleted in the prepared formulary.	197

Table 2: Number of vaccines available.

Formulary	No. of vaccines	Percentage
Hospital formulary	26	44%
WHO 2019	24	41%
NLEM 2015	9	15%

RESULTS

The prepared formulary consists of 546 drugs belonging to 16 different therapeutic classes which were then compared with WHO model formulary 2019 and NLEM 2015. 405 drugs out of the total drugs in WHO model formulary and 278 drugs of the total drugs in NLEM 2015 were found in the newly developed hospital formulary (Figure 6). Two parameters when calculated gave the *p* value <0.05, which shows that the result is statistically significant and the p value for number of antibiotics categorized as AWaRe classification was > .05 and shows that the parameter is not statistically significant. The hospital formulary consists of 546 drugs and WHO model formulary 2019 consists of 517 drugs and NLEM 2015 consists of 355 drugs. There are total of 40 fixed dose combinations in WHO model formulary 2019 and 22 FDCs are present in NLEM 2015 whereas 228 FDCs are there in prepared formulary (Figure 5). Out of 546 drugs, 230 (42%) drugs were present in category C, 124 (23%) drugs were present in category B, 74 (14%) drugs were included in the category D, 61 (11%) drugs category were unknown, 32(6%) drugs were present in category X, 11(2%) drugs were included in category A and 7 (1%) were involved in category B/C and C/D drugs (Figure 1). In the 4th edition of KIMS Al Shifa hospital formulary, 323 drugs were added to prepared formulary and 197 drugs were deleted from the formulary (Table 1). Out of 323 drugs, 72 (22%) drugs were added to malignant and immunosuppression, 36(11%) drugs were included into central nervous system and anti-infective. Cardiovascular system consisted of 34(11%) drugs. Nutrition and blood comprised of 28(9%) drugs. Obstetrics, gynecology and urinary tract disorder and musculoskeletal disease and joint disorder consisted of 19(6%) drugs. 14 (4%) drugs were comprised of endocrine system, gastrointestinal drugs involved 11(3%) drugs and 10 (3%) drugs included in respiratory system, eyes and immunological products and vaccines. Antidotes consisted of 6 (2%) drugs and 5 (2%) drugs were included in anesthetics and 2 (1%) drugs comprised of diagnostic agents (Figure 2). Hospital formulary involved 44% (n=26) vaccines and 41% (n=24) vaccines were found in the WHO model formulary 2019. 15% (n=9) vaccines are available in NLEM 2015 (Table 2,



Figure 1: Pregnancy category of drugs.



Figure 2: Therapeutic class wise distribution of drugs.



Figure 3: Patterns of brands available for generic drugs.



Figure 4: Therapeutic class wise distribution of drugs deleted from formulary.



Figure 5: Comparison number of fixed dose combinations.

Figure 7). Out of 37 antibiotics present in WHO model formulary, 19 drugs were categorized as ACCESS group of drugs, 11 drugs were consisted of WATCH group and 7 drugs were included in RESERVE group of antibiotics. Out of 26 antibiotic drugs in NLEM, 11 (25%) drugs were categorized as ACCESS group, 14 (27.5%) drugs were included in WATCH group and only 1(7.1%) drug were present in the RESERVE group of drugs. In prepared formulary, out of 46 antibiotic drugs 14 (31.8%) drugs included in ACCESS group, 26 (51.0%) drugs comprised of WATCH group and 6 (42.9%) drugs were included in the RESERVE group of drugs (Figure 3). In the prepared formulary, 240 (44%) drugs were available in single brand, 173(32%) drugs were available in 2 brands, 107(20%) as in 3 brands, 19 (3%) drugs as in 4 brands, 2 drugs as in 5 brands and 5(1%) drugs were available in 6 brands. 197 drugs were deleted from the third edition of hospital formulary, from that 34(17%) drugs deleted from anti-infectives, 31(16%) drugs from central nervous system, 25(13%) drugs from malignant disease and immunosuppression, 23(12%) drugs from cardiovascular system, 18(9%) drugs from gastro intestinal system, 15(8%) drugs from obstetrics, Gynecology and urinary



Figure 6: Total number of drugs present.





tract disorder, 12(6%) drugs from endocrine system, 9(5%) drugs from musculoskeletal disease and joint disease, 8 (4%) drugs from nutrition and blood, 7(4%) drugs from skin, 5 (3%) drugs from respiratory and immunological products and vaccines, 3(2%) drugs from anesthetics, 1(1%) drugs from eyes and diagnostic agent and no drugs were deleted from antidotes (Figure 4).

DISCUSSION

To promote the rational use of medicines, the World Health Organization (WHO) released the first edition of WHO model list of essential drugs in 2002. This was the first global publication which includes 325 Generic drugs. The first edition of Al Shifa formulary was released in the year 2010 which contains 378 drugs and after revision, the second edition was released in the year 2013 which contains 417 drugs. The third edition was released in the year 2015 which involves around 421 drugs. The fourth edition of hospital formulary has been prepared in the year 2021. After revision and consequent addition and deletion from the third edition, the latest edition of the formulary contains

Contents	Hospital formulary	WHO 2019	NLEM 2015
Generic name	Present	Present	Present
Indication	Present	Present	Absent
Dosage and strength	Present	Present	Present
Contraindication	Present	Present	Absent
Pharmacology and pharmacokinetics	Absent	Absent	Absent
Lactation	Present	Absent	Absent
Pregnancy category	Present	Absent	Absent
Adverse effects	Present	Present	Absent
Warning/instructions	Present	Absent	Absent
Patient information	Present	Absent	Absent
Precautions	Present	Present	Absent
Price	Present	Absent	Absent
Synonyms	Present	Absent	Absent
Storage condition	Absent	Absent	Absent
Proportion of presence	0.86	0.43	0.14

Table 3: Comparison of monograph content.

Table 4: Patterns of brands available in the prepared formulary.

No. of brands	No. of drugs	Percentage
1 brand	240	44%
2 brands	173	32%
3 brands	107	20%
4 brands	19	3%
5 brands	2	0%
6 brands	5	1%
Total	546	100%

546 drugs which reflects the sustainability of Kims Al-Shifa Hospital formulary. This edition involves changes in the use of certain medications. Certain drugs have been withdrawn and some drugs have been added. There have been rewrites to the monographs for some drugs along with significant updates on others (Table 3). The prepared hospital formulary was compared with National List of Essential Medicines (NLEM) 2015 and WHO essential medicines list 2019. WHO model list consist of 36% (n=517) drugs, NLEM consists of 25% (n=355) drugs and the newly prepared formulary comprises 39% (n=546) generic drugs, which is 29 drugs more than WHO and 191 drugs more than NLEM. Total number of drugs available in WHO 2019 is 423 which are greater than those in NFI which has 342 drugs, and the finding was in accordance with study conducted by Sridhar et al.⁹ The reason behind the inclusion of more drugs in hospital formulary is that the PTC emphasized the need of certain drugs in the hospital. The study revealed that the drugs involved under the cardiovascular system, central nervous system, gastrointestinal system, respiratory system, endocrine system, musculoskeletal and joint disease, anesthetics, eye, nutrition and

blood, immunological products and vaccines were more in KIMS Al Shifa formulary when compared with WHO 2019 and NLEM 2015 whereas the drugs included in anti-infectives, OBG and urinary tract disorder, malignant and immunosuppression, skin, antidotes, diagnostic agents were less compared to WHO 2019 and NLEM 2015. The study results show a p value of .000 which reflects that the parameter is more significant.

For a better inventory, it is always recommended to limit the number of brands for each generic drug based on availability and sales of the drug. Out of 546 drugs, single brand of 44% (n=240) drugs were available and the examples involve Metolazone, Timolol, Rizatriptan, Tirofiban. Only 1% (n=5) drugs have 6 brands (Table 4, Figure 3). The survey by Raveenchauhan et al.⁵ disclosed that 225 medications are having single brands, whereas 88, followed by 56 and 21 medications bear two brands, three-four brands and quite or adequate 5 brands, teneligliptin being an example. The reason attributed for the availability of more than four brands for a single generic drug was the promotion from pharmaceutical companies, physician's choice of prescribing and difference in cost between brands. The WHO model list of essential medicine 2019 includes 14% (n=40) FDCs and NLEM includes 8% (n=22) FDCs. The prepared hospital formulary includes 79% (n=228) FDCs. The previous edition of KIMS Al Shifa formulary contains 152 FDCs. The reason for the inclusion of more FDC in this edition is for achieving a better approach for achieving optimal therapeutic benefits. PTC restricted the use of some irrational FDCs, and those combinations were deleted during the preparation of fourth edition. According to the study conducted by Sridhar Srimath et al.,6 Fixed dose combinations accounts for highest percentage of drugs in VHF i.e., 22.22% (*n*=94) whereas it is only 8.19% (*n*=28) in NFI.

The drugs present in the formulary were also evaluated for the pregnancy risk categorization approved by US FDA. There were 6% (n=32) drugs contra indicated in pregnancy like Danazol, Exemestane, Desogestral. In the study conducted by Lakshmi Prasana *et al.*¹ Manipal hospital formulary (221) the percentage of drugs present in Pregnancy Category X, A, B, C, D, are 5.88%, followed by 2.71%, 39.81%, 35.29%, 14.02% respectively,¹ Out of 546 drugs, there were only 142 drugs that were considered safe during pregnancy. Most of the anticancer drugs were grouped in category D. The drugs used with caution were 318 which came under category C, D, B/C, C/D. Pregnancy category of 11% (n=61) drugs were unknown.

The monograph content of the prepared hospital formulary was compared with WHO essential medicine list and NLEM. The prepared formulary contains all the information but lacks in pharmacology, pharmacokinetics, and storage condition of the drug. The KIMS Al-Shifa hospital formulary does not contain information onpharmacology and pharmacokinetics of the drugs which was present in the WHO list.7 All this information will help to support the healthcare providers and update their knowledge about drugs. The study results show a p value of .001 which implies that, this parameter is more significant. There are some drugs which are not available in KIMS Al-Shifa formulary though it is in WHO and NLEM. There were 59.3% (n=112) drugs found in WHO and 40.7% (n=77) drugs in NLEM of class anti-infectives, OBG and urinary tract disorder, malignant disease, and immunosuppression, endocrine, eye, nutrition and blood, skin, antidote, immunological product, vaccines, diagnostic agents, anesthetics, respiratory system, gastro-intestinal system, central nervous system, cardiovascular system. The study conducted by R. J. D'Almeida, et al. states that, there are a total of 75 drugs, which were not included in the prepared hospital formulary with reference to WHO/National list of essential medicine.8 The study results show a p value of 0.043, which evidently demonstrates the study is significant. During the development of 4th edition, 197 drugs were deleted from the third edition of formulary and 323 drugs were newly added. Most of the drugs were added to central nervous system, anti-infectives, followed by cardiovascular system and nutrition and blood. And most of the drugs were deleted from anti-infectives and central nervous system category. This shows the advancement of clinical setup and promotes physicians' choice of prescribing. These 357 drugs were classified into 23 main categories or classes. While preparing the fourth edition of the formulary the number of vaccines included in this edition with respect to NLEM and WHO list were found to be more; The prepared formulary consists of 44% (26) vaccines and the WHO list and NLEM involves 41% (24) and 15% (n=99) vaccines respectively. KIMS Al Shifa promotes immunization for the public to safeguard the health of each individual. In this edition various antibiotic drugs were categorized under AWaRe classification. The number of ACCESS group in the prepared

formulary is 31.8% (n= 14) and in WHO list is 43.2% (n=19) and in NLEM it was found to be 25.0% (*n*=11). Number of WATCH group drugs in prepared formulary is 51.0% (*n*=26), WHO list is 21.6% (n=11) and in NLEM is 27.5% (n=14). Vinodkumar's⁹ study points out that 4 antibiotics from the access category and 5 from Watch category were prescribed in the study. The Watch category of antibiotic were consumed in a high number. Number of RESERVE groups in prepared formulary is 52.0% (n=6), WHO list is 50.0% (n=7) and NLEM is 7%(n=1). Here the p value is 0.076 which shows this parameter is not significant. Comparison of class wise distribution of drugs where the prepared formulary consist of great number of drugs represents cardiovascular system 76(55.1%) whereas WHO formulary 2019 and NLEM 2015 consist of great number of drugs represents anti-infectives with 148(55.4%) and 61(22.8%). This current effort is undertaken to promote rational drug therapy in the hospital. This edition provides unbiased and more efficacious information to the health care professionals. A more efficient hospital formulary can be established by continuously updating the hospital formulary. The limitation of this study describes during the beginning process of 4th edition hospital formulary, certain groups of Drugs were included but under some cases discontinuation of a particular department lead to the discontinuation of drugs corresponding to that department e.g.: department of oncology and cytotoxic drugs.

CONCLUSION

This study provided an updated hospital formulary which revealed the expertise in prescribing process and ultimately offered better patient outcome. This updated edition exhibits chiefly drugs which were present in WHO model formulary 2019 and NLEM 2015 and contribute better inventory of drugs within the hospital.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

WHO: World Health Organization; **NLEM:** National List of Essential Medicines; **PTC:** Pharmacy and Therapeutic Committee; **FDC:** Fixed Dose Combinations; **NFI:** National Formulary of India; **VHF:** Varma Hospital Formulary.

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