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Development of Hospital Formulary for a Tertiary Care Teaching Hospital in South India

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D'Almeida, *et al.*: Development of a Hospital Formulary

Formulary is a continually revised compilation of pharmaceuticals (plus important ancillary information) that reflects the current clinical judgment of medical staff. Kasturba Hospital is a 1400 bedded tertiary care teaching hospital with different specialties, having more than 3000 brands and ancillary products in use. The hospital does not have a formulary of any kind. Present 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 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.

Key words: Formulary, WHO essential drug list, national essential drug list, pharmacy and therapeutic committee, rational drug use

Hospital formularies originally started life in hospitals as a collection of commonly prescribed pharmaceutical preparations, produced mainly for reference purposes. As time went on, the hospital formulary was adapted to incorporate the detailed information on the increasing number and diversity of medicines. However, these new and expensive preparations required ever increasing funds, and the formulary rapidly turned into a list of restricted medicines.

Presently the formulary is a continually revised compilation of pharmaceuticals (plus important ancillary information) that reflects the current clinical judgment of medical staff^{1,2}. 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. 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 patients³. A

formulary can be used as a tool to rationalize the range of medicines used in standard practice. Hospital formulary is the vehicle by which the medical and nursing staffs make use of the system, hence it is important that it should be complete, concise, updated and easy to use.

In its efforts to promote safe and cost-effective use of medicines, World Health Organization (WHO) released the first edition of the WHO Model Formulary in 2002. This Formulary is the first global publication to give comprehensive information on all 325 generic drugs contained in the WHO Model List of Essential Medicine⁴. It presents information on the recommended use, dosage, adverse effects, contraindications and warnings on these drugs. Correct use of this tool will improve patient safety and limit excess medical spending. Therefore, the WHO Model Formulary is primarily intended as a model, for national governments and institutions, as a basis for creating their own formularies³.

It has been stated that the main reason for developing a formulary is to promote rational prescribing⁵. WHO also recommends in their policy perspectives

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on medicine that development of formulary system through Drugs and Therapeutic Committee in the hospitals will promote rational use of medicines⁶.

Developing a hospital formulary will be helpful to provide information for the hospital staff about drug products approved for use by the Pharmacy and Therapeutic Committee^{7,8}. 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.

Kasturba Hospital, Manipal is a 1400 bedded tertiary care teaching hospital in south India with various specialties. Over 3000 medicines and ancillary products with different proprietary names are available in the hospital pharmacy. More than 1300 prescriptions are dispensed per day. Although the hospital has its drug list it is not updated regularly and the hospital has not prepared formulary of any kind, hence most of the physicians and other healthcare team are unaware of the drugs available in the hospital pharmacy. To provide brief description of these available drugs in a concise manner and to ensure the rationality and economic use of these drugs, a hospital formulary is needed. The study was carried out with the following objectives, to prepare a hospital formulary and to compare the prepared hospital formulary with WHO Model Formulary 2002, WHO and National list of Essential medicines 2003.

MATERIALS AND METHODS

Kasturba Hospital is a multidisciplinary hospital with no hospital formulary of its own. Hence, department of pharmacy practice initiated the concept of preparing hospital formulary. The existing drug list was obtained from the chief pharmacist of the hospital pharmacy. A sample monograph was prepared and distributed to

all the Pharmacy and Therapeutic Committee (PTC) members including the Medical Superintendent/Chief Operating Officer to obtain the feedback about the contents. The information for the preparation of individual monographs was collected from various references which are listed in Table 1. The contents of each monograph were also compiled under several aspects and these were also given in Table 1.

There was no one single format or arrangements, which all hospital formularies must follow. But the contents were arranged as recommended by the American Society of Health-System Pharmacist (ASHP). The prepared hospital formulary was submitted to the Medical Superintendent in loose-leaf form, for implementing in the hospital.

The prepared formulary was evaluated based on the following categories and compared with WHO model formulary 2002, WHO and National list of Essential Medicines 2003. The parameters evaluated were number of drugs, fixed dose combinations (FDCs), class wise distribution of drugs, number of brands, monograph content, drugs to be avoided or used with caution in pregnancy and drugs present in the WHO/National list of essential medicines but not included in the prepared hospital formulary. Products of Pharmacy Manufacturing wing (PMW) of Kasturba Hospital, Manipal were also categorized.

RESULTS

Since there were a large number of drugs included in the hospital formulary, considerable amount of variation was present with the drugs included in the Essential list of medicines to that of the formulary.

Number of drugs, fixed dose combinations (FDCs) and class-wise distribution:

WHO model formulary is the global publication,

TABLE 1: REFERENCES USED FOR PREPARING MONOGRAPHS AND THE CONTENTS OF EACH MONOGRAPH

References used for monographs	Contents of each monographs
WHO Model Formulary 2002	Synonyms
WHO list of Essential Medicines 2003	Therapeutic category
National List of Essential and Emergency Medicines 2003	Use
American Hospital Formulary Service (AHFS) Drug Information 2003	Pregnancy risk factor
Lexi-Comp's Drug Information Handbook, 11 th Ed	Precautions/Warnings
Australian Medicines Handbook-2000	Contraindications
Martindale - The complete Drug References 33 rd Edition.	Adverse reactions,
Micromedex® Healthcare Services, Vol. 119 and 120-Drugdex System	Dosage,
Stockley's Drug interactions 6 th Ed	Drug Interactions
Drugs in Pregnancy and Lactation A reference guide to fetal and neonatal risk 6 th Ed,	Brands available/formulation/ strength/cost.
Meyler's Side Effects of Drugs 14 th Ed.	

which gives the comprehensive information on all the 325 generic drugs contained in the WHO model list of essential medicines 2002. The National list of Essential Medicines 2003 consists of 354 formulations, including FDCs and vaccines. The prepared Hospital Formulary comprised of total 476 generic drugs excluding the combination products and vaccines. There were totally 18 FDCs in WHO Essential Medicine list and 13 in National list of Essential Medicines while the prepared hospital formulary consisted of 95 FDCs. The number of drugs in each category of the prepared hospital formulary was compared with the WHO and National list of essential Medicines 2003, shown in Table 2.

WHO model list of essential medicines 2003:

In the WHO model list the drugs under the gastrointestinal, cardiovascular, respiratory and central nervous systems were 12 (4%), 21 (7%), 6 (2%) and 24 (8%), respectively. Ninety two (29%) drugs were from antiinfective class. Drugs falling under endocrine system and obstetrics and gynecology were 10 (3%) each. Malignancy and immunosuppression, nutrition and blood category and musculoskeletal system, comprised of 22 (7%), 22 (7%) and 12 (4%) drugs, respectively. Eleven (3%), 22 (7%) and 19 (6%) preparations were used for eye disorders, skin, immunologicals and vaccines category respectively. Fourteen (4%) were under the anaesthetic, 12 (4%)

TABLE 2: CLASS-WISE DISTRIBUTION OF THE DRUGS IN THE PREPARED HOSPITAL FORMULARY WITH WHO AND NATIONAL LIST OF ESSENTIAL MEDICINES

Drug category	WHO	National EDL	Hospital Formulary
Gastrointestinal system	12	17	26
Cardiovascular system	21	30	56
Respiratory system	6	7	30
Central nervous system	24	22	70
Antiinfectives	92	72	86
Endocrine system	10	16	30
Obstetrics, gynaecology, and urinary tract disorders	10	12	12
Malignant disease and immunosuppression	22	23	44
Nutrition and blood	22	38	33
Musculoskeletal and joint diseases	12	13	32
Eye	9	20	12
Skin	22	30	27
Immunological products and vaccines	19	13	1
Anaesthetics	14	15	9
Antidotes	12	13	5
Diagnostic agents	8	13	3
Total Number	315	354	476

Numbers mentioned indicates the drugs of particular therapeutic category present in WHO, National drug list and prepared hospital formulary

were under the category of antidotes and 8 (3%) were diagnostic agents.

National list of essential medicines 2003:

In the national list of essential medicines, the drugs under the gastrointestinal, cardiovascular, respiratory and central nervous systems were 17 (5%), 30 (8%), 7(2%) and 22 (6%), respectively. Seventy two (20%) drugs were antiinfectives, 16 (5%) medicines were falling under endocrine system and 12 (3%) under obstetrics and gynecology. Malignancy and immunosuppression, nutrition and blood category consisted of 23 (6%) and 38 (11%) drugs, respectively. Musculoskeletal system, skin disorders, antidotes and diagnostic agents each comprised of 13 (4%) drugs respectively. Twenty (6%) were used for eye disorders and 30 (8%) were immunologicals, vaccines and anesthetics, respectively.

Prepared hospital formulary:

In the prepared Hospital Formulary, drugs under the gastrointestinal, cardiovascular, respiratory and central nervous systems were 26 (5%), 56 (12%), 30 (2%) and 70 (15%), respectively, while 80 (18%) were antiinfectives. Endocrine system, obstetrics and gynecology, malignancy and immunosuppression comprised of 30 (6%), 12 (3%) and 44 (9%) drugs, respectively. Nutrition and blood category, musculoskeletal system, eye disorders and skin disorders consisted of 33 (7%), 32 (7%), 12 (3%) and 27 (6%) medicines, respectively. Nine (2%), 5 (1%) and 3 drugs each were anesthetics, antidotes and diagnosis agents, respectively. Immunologicals and vaccines were not included.

Number of brands:

Out of the 476 generic drugs, 216 (45%) drugs were available as single brand, 124 (26%) drugs as two brands, 60 (13%) drugs in three brands, 43 (9%) drugs in four brands, while five brands for 16 (3%) drugs, six brands for 9 (2%) drugs and seven brands were available for 5 (1%) drugs.

Monograph content:

The differences in the monograph content of the two formularies are shown in Table 3. The WHO Model formulary does not contain synonyms, pregnancy risk factor, drug interactions, available brands and cost, whereas the prepared Hospital Formulary does not contain information on reconstitution and administration.

TABLE 3: COMPARISON OF MONOGRAPH CONTENT OF THE PREPARED HOSPITAL FORMULARY WITH WHO MODEL FORMULARY

Contents	WHO model formulary 2002	Hospital formulary
Synonyms	×	√
Therapeutic category	√	√
Use	√	√
Pregnancy risk factor	×	√
Contraindications	√	√
Precautions/Warnings	√	√
Adverse reaction	√	√
Dosage (Adult/Paediatric)	√	√
Drug interactions	×	√
Reconstitution and administration	√	×
Patient information	√	√
Brands available	×	√
Formulation	√	√
Strength	√	√
Cost	×	√

Table represents presence or absence of particular category of information in WHO and prepared hospital formulary. √ = Present, × = Not present

Drugs to be avoided or used with caution in pregnancy:

Drugs should be prescribed in pregnancy only if the expected benefits to the mother are thought to be greater than the risk to the fetus. The WHO model formulary consists of 199 drugs and hospital formulary consists of 145 drugs, which should be avoided or used with caution in pregnancy. The number of drugs available in prepared hospital formulary which falls under each pregnancy category according to US FDA (USFDA categories are described in Table 4) is shown in Table 5.

Drugs present in the WHO/National list of Essential Medicines but not included in the hospital formulary:

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. The number of drugs not included in each category with respect to WHO and National list of essential medicines are given in Table 6.

Pharmacy manufacturing wing (PMW) products:

The PMW of Kasturba Hospital is mainly involved in the manufacturing of the un-parallel products, which are not readily available in the pharmaceutical market and are prepared specially for the hospital patients, even though it is not economical always. Quality of the products prepared in the PMW is ensured by the in-house quality control department. There were a total of 140 such preparations, manufactured here and the formulation-wise distribution as follows; out of the 140 preparations, the maximum were external preparations 45 (32%). Oral liquids were 32 (23%), eye/ear/nasal drops were 22 (16%), tablets/capsules were 16 (11%), antiseptic/disinfectant category was 13 (9%), injectables were 9 (6%), and Ayurvedic extracts were 3 (2%).

DISCUSSION

To promote safe and cost-effective use of medicines, the WHO has released the first edition of the WHO Model Formulary in 2002. This formulary was the publication to give comprehensive information on all 325 drugs contained in the WHO Model List of Essential Medicines 2002. This formulary was primarily taken as a model for developing our own hospital formulary⁴. Along with this WHO Model List, National list of Essential Medicines 2003 was also included for reference. The prepared hospital formulary consists of 476 generic drugs. WHO Model Formulary consists of all 325 essential drugs including

TABLE 4: US FDA PREGNANCY CATEGORY DEFINITIONS

Pregnancy category	Definitions
Category A	Adequate, well-controlled studies in pregnant women fail to demonstrate a risk to the fetus in the first trimester with no evidence of risk in later trimesters. The possibility of fetal harm appears remote
Category B	Animal studies do not indicate a risk to the fetus: however, there are no adequate, well-controlled studies in pregnant women OR Animal studies have shown an adverse effect on the fetus but adequate, well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus. Despite the animal findings, the possibility of fetal harm appears remote, if used during pregnancy.
Category C	Animal studies have shown that the drug exerts teratogenic or embryocidal effects, and there are no adequate, well- controlled studies in pregnant women, OR No studies are available in either animals or pregnant women
Category D	Positive evidence of human fetal risk exists, but benefits in certain situations(e.g. life-threatening situations or serious diseases for which safer drugs cannot be used or are ineffective) may make use of the drug acceptable despite its risks
Category X	Studies in animals or humans have demonstrated fetal abnormalities or there is positive evidence of fetal risk based on human experience, or both , and the risk clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.

TABLE 5: PREGNANCY CATEGORIES OF THE DRUGS PRESENT IN THE HOSPITAL FORMULARY

US FDA pregnancy category	Number of drugs
*A	11
B	101
C	204
C / D	29
D	66
X	19
Not reported	46
Total	476

US FDA = United States Food and Drug Administration

TABLE 6: DRUGS NOT INCLUDED IN THE PREPARED HOSPITAL FORMULARY WITH RESPECT TO WHO AND NATIONAL LIST OF ESSENTIAL MEDICINES

Therapeutic category	WHO	National
Gastrointestinal system	2	-
Cardiovascular system	1	6
Respiratory system	1	1
Central nervous system	2	3
Anti-infectives	10	12
Endocrine system	-	1
Obstetrics, gynaecology, and urinary tract disorders	1	1
Malignant disease and immunosuppression	1	1
Nutrition and blood	1	2
Musculoskeletal and joint diseases	2	1
Eye	2	3
Skin	5	3
Anaesthetics	1	2
Antidotes	2	5
Diagnostic agents	1	2
Total	32	43

Table represents the number of drugs of particular category present in WHO and National essential drug list but not included in prepared hospital formulary

FDCs and vaccines. The reason for inclusion of more number of drugs in the hospital formulary is, the drugs are added or deleted by the PTC, and the committee considers that these many drugs are required for the hospital. In view of the fact that Kasturba Hospital is a multidisciplinary hospital, the different departments in large number will utilize many drugs.

Although the WHO Model Formulary includes only 18 FDCs and National List contains only 13, the prepared hospital formulary has 95 FDCs. The prepared hospital formulary consists of only 9 FDCs that are found to be essential considering the above two references. Many of the combinations are not standard and this may be due to the fact that, pharmaceutical companies are promoting these combinations, and prescriber's choice for better patient compliance, lesser side effects, increased efficacy and reduced cost. A study (Kastury *et al.*) was carried out on prescriptions giving FDCs, to find out the rationality of the different FDCs prescribed by the doctor⁹. It was observed that 80% of the fixed dose combinations prescribed

is not recommended by the WHO list of essential medicines^{9,10}. The most widely prescribed fixed dose combinations were analgesics, antimicrobials, multivitamins, and cold/cough mixtures.

While comparing the prepared hospital formulary with WHO model formulary and National list of essential medicines it is observed that the prepared formulary contains higher number of drugs in the following categories; Central nervous system, respiratory system, cardiovascular system, endocrine, malignancy and immunosuppression, and musculoskeletal and joint diseases. This correlates with the maximum utilization of the above-mentioned category drugs in the different departments of the hospital. The following categories of drugs in the prepared formulary are less in number compared to WHO model Formulary and National list of Essential Medicines, i.e. eye, skin, anaesthesia and antidotes.

For better inventory control and to avoid zero stock level, it is recommended to limit the number of brands for each generic drug based on the availability and sales of the drug¹¹. While verifying available brands to 476 generic drugs, it is observed that there is single brand available for 216 (45%) drugs, e.g. acarbose, bambuterol, nebivolol and sulfasalazine. But there are even six or seven brands available for 2-5% of drugs and cefixime, fluoxetine and methotrexate are some for which six brands are available. Seven brands were available for amoxicillin, carbamazepine, cefuroxime, and fluconazole. There are even eight brands in our hospital for sodium valproate and nine for ciprofloxacin. The reason attributed for the availability of more than four brands for a single generic drug was promotion from the pharmaceutical companies, physician's choice and difference in the cost between brands. Also some of the drugs are most widely used e.g. acetaminophen, carbamazepine, and ciprofloxacin. The sales of these drugs are higher and there is cost variation within the brands of the same generic drug.

The content of the monographs of the prepared formulary was compared with that of the WHO Model Formulary. Most of the information was similar, except that WHO Model Formulary does not include synonyms of the drug, pregnancy risk factor, drug interactions, formulation and cost. The prepared formulary does not include the information on reconstitution and administration. The main reason

for not including this in depth information is that the number of contents to be included in the monograph is recommended by the Pharmacy and Therapeutic Committee of the hospital. The information on reconstitution and administration is not included because it is provided by the manufacturer in package insert for specific products.

The number of drugs to be avoided or used with caution in pregnancy is less in prepared hospital formulary compared to the WHO Model formulary. The number is less because only category C/D, D and X of the US FDA pregnancy category list and drugs whose pregnancy risk factor is not known have been included, whereas, WHO Model Formulary has given only the list of drugs and has not specified the pregnancy category. In the prepared hospital formulary there are a total of 19 drugs which are absolutely contraindicated and 126 drugs to be used with caution in pregnancy. HMG CoA reductase inhibitors, estradiol, leflunomide are absolutely contraindicated in pregnancy and these drugs fall under the category X. Similarly most of the antineoplastic agents, benzodiazepines, tetracyclines fall under category D. Drugs like carvedilol, enalapril, and fentanyl fall under C/D category and for drugs like drotaverine, flunarizine, and nicorandil the pregnancy category are not reported.

There are also some drugs, which are not available in the hospital pharmacy though recommended in the list of essential medicines. There are total 75 such medicines, and out of these, 22 drugs fall under anti-infective category for e.g. nitrofurantoin, sulfadiazine, praziquantel, pentamidine, trimethoprim. Antitrypanosomal medicines like suramin, eflornithine, and nifurtimox were not included in the national list of essential medicines as well as in the hospital formulary. Drugs like didanosine, stavudine and pyrimethamine are available in combinations. Skin preparations like aluminium diacetate, permethrin and cardiovascular drugs like chlorthalidone, procainamide, bretylium are not available. 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.

Out of 140 preparations of the pharmacy manufacturing wing (PMW) the external preparations comprised of 45(32%) and oral liquids are 32(23%). This is because dermatology and paediatric department

recommend most of the unparallel products that are not available in the market, for better patient compliance and the other department clinicians are also utilizing these facilities, whenever required. The majority of the vaccines and the drugs falling under obstetrics and gynecology (contraceptives) are available in the paediatric and family planning departments respectively; therefore these preparations were not included in the hospital formulary.

The study was conducted with the main objective of providing information on the available drugs in the hospital pharmacy to the physicians and the healthcare professionals by developing hospital's own formulary and comparing it with the WHO Model Formulary 2002, WHO and National list of Essential medicines 2003.

While evaluating, it was found that the more number of drugs and drug combinations were present in the prepared formulary. The PTC was responsible for the inclusion of more number of drugs because it is a multidisciplinary tertiary care hospital. The prepared hospital formulary did not have few drugs which were recommended in the Essential Medicine lists. The number of brands available for individual drug was higher than recommended. Implementation of hospital formulary will help in better inventory control. Therefore, the prepared hospital formulary can be used as a vehicle to provide information to the physicians and healthcare professionals about the available drugs in the hospital pharmacy and can be used as a tool to rationalize the medicines used in the hospital.

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