Development of Hospital Formulary in Tertiary Care Referral Hospital

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ABSTRACT

Objective: An attempt was made to design and develop a hospital formulary in a multispecialty tertiary level for providing information on the available drugs in the hospital pharmacy to the physicians and other healthcare professionals and thus to ensure efficacy, safety and quality of the drugs to promote rational use, thereby ensuring the availability of drugs according to the needs of the population. To develop drug monograph for the enlisted medications and to compare the prepared hospital formulary with WHO Model Formulary 2004 and Essential Medicine list India, 2003 and WHO 2010. Methods: This study was conducted over a period of one year. A questionnaire with 10 questions was prepared and distributed to the healthcare professionals in the hospital to evaluate the need and desirable format for the required Hospital Formulary. The latest drug list was obtained from the chief pharmacist in the form of softcopy. All drugs present in the drug list were critically evaluated for its need, efficacy, safety, and cost. The selected drugs were classified according to the British National Formulary as the standard format for the formulary list. Monographs were prepared for all the selected 379 drugs in the hospital pharmacy with the following contents: Synonyms, Therapeutic category, Indication, Pregnancy risk factor, Contraindications, Precautions/ Warnings, Adverse reactions, Dosage, Drug interactions, Patient information, Brands available/ strength/ formulation/ cost. Copies of the prepared hospital formulary were given to medical superintendent, chief medical officer, and chief pharmacist and to Pharmacy and Therapeutic Committee. Results: The prepared hospital formulary contains 379 drugs generic drugs excluding FDCs where the WHO model list consists of 358 drugs and National drug list consists of 354 drugs including FDCs. The drugs included in the CNS, CVS, Obstetrics Gynaecology and UTI, Respiratory System, Endocrine System, and Musculo skeletal and joint disease were more in Al Shifa hospital formulary. The number of brands included in the prepared formulary is less. In the prepared list 86 drugs were safe to use in pregnancy, drugs used with caution during pregnancy are more of 225 drugs (category C, D, B/D, A/C, and C/D), 20 drugs are contraindicated (category X). Information on generic name, use, contraindication, drug interactions, precautions, ADR, dose, drug price, pregnancy category, lactation, US FDA approval information, synonym and patient information were present in prepared hospital formulary. Conclusion: The prepared hospital formulary was made into handbook and electronic format, the latest version of formulary which can be considered as the first edition. Continuous updation of the drug information is must for the every six months. The transformation of handbook into electronic format made the drug information available at the fingertip of the healthcare professionals.

Key words: Hospital formulary, WHO Model List, NEDL, Monographs

INTRODUCTION

“The hospital formulary is a continually revised compilation of pharmaceuticals, which reflects the current clinical judgment of the medical staff including physicians, pharmacist and nurses and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health.”[1] Medicines are primarily initiated to prevent, cure or control various diseases and alleviate sufferings in humans. Hospital formulary is intended to assist physicians in selecting appropriate medicines, enhance rational drug use, and also help the inventory control to utilize the budget allotted in the best suited way. By designing a formulary, unsafe and ineffective drugs can be eliminated which can subsequently decrease morbidity and mortality. Studies have shown that formularies help the health care practitioners in implementing cost effective evidence based prescribing practice without negatively influencing the quality care. [2] Hospital formularies originally started life in hospitals as collection of commonly prescribed pharmaceutical preparations, produced mainly for reference purpose. As time went on, the hospital formulary was adapted to the detailed information on the increasing number and diversity of medicines. [3] However, these new and expensive preparations required ever increasing funds, and the formulary rapidly turned into a list of restricted medicines. When a hospital 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 the drug cost. [4] It promotes high quality, evidence based prescribing and reduces variation in the levels of treatment provided to patients and can be used as a tool to rationalize the medicines used in standard practice. The healthcare professionals make use of the system hence it is important that it should be complete, concise, updated and easy to use. [6] The World Health Organization (WHO) released the first edition of the WHO model list of essential drugs in 2002. The heart of the Formulary System is the Pharmacy & Therapeutics Committee (PTC). Membership will be comprised of representatives of the professional departments/services, pharmacy, house staff, nursing, administration and other interested parties. The PTC reviews the formulary one or more times in a year, for the addition and deletion of drugs. [7] 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. A formulary system is the ongoing 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. [8] 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. This document focuses on the use of formulary systems in hospitals and health systems [9,10]. At present many of the pharmaceuticals on the world market represent duplicate, “me-too,” or nonessential products. Many are minor variations of a prototype drug and offer no therapeutic advantage over other drugs that are already available. Other drugs show high toxicity relative to their therapeutic benefit. In some cases drugs are newly released with insufficient information on efficacy or toxicity. Finally, many new products are for therapeutic indications not relevant to the basic needs of the population. [11] They are nearly always more expensive than existing drugs. The formulary system is a mechanism by which professional staff can solve these. A number of other problems known to exist in most pharmaceutical system are limited drug budgets, increasing numbers of therapeutically alternatives, improper prescribing and use of medications, presence of unsafe and non-eficacious drugs, lack of unbiased drug information, high costs of handling large numbers of drugs, drugs of questionable quality on the market. [12,13] Although National formulary exists in India, use is limited because of unawareness of the health care professionals about national formulary and nonavailability of updated information. Hospital formulary system can be an asset for our health care system, as in our country national pharmacovigilance programs and drug safety reporting is evolving. [14]

METHODOLOGY

(1%) drugs, Eye disorder 10 (3%) drugs and Endocrine system 25 (7%) drugs.
This study was conducted over a period of one year from May 2010 to February 2011. Al Shifa hospital is 450 bedded multispeciality tertiary level referral and teaching hospital situated in Perinthalmanna, Malappuram district. This hospital has not yet developed an effective hospital formulary system. There are over 1003 medicines and ancillary products with different brand names available in the hospital pharmacy. To promote safe, cost-effective, high quality and rational use of medicines and prescribing, there is a need to develop a hospital formulary for the hospital. The study was approved by the ethical committee at the meeting held on July 9, 2010 and also got permission from the medical superintendent and from the management trustee for doing the project on hospital formulary at Al Shifa hospital. This was a prospective study to design and develop hospital drug formulary for a tertiary care referral hospital with an aim to provide drug information to healthcare professionals in the hospital in order to set standards of best practice for safe and effective drug therapy and for the better patient care. The study was conducted with PTC and other healthcare professionals to give the awareness about the need and importance of Hospital Formulary in the hospital and to announce the starting of the study. Before developing the hospital formulary a questionnaire with 10 questions was prepared and distributed to the healthcare professionals in the hospital which includes 40 physicians from different departments, pharmacist and nurses. The healthcare professionals consisted of doctors, nurses and pharmacists. The survey emphasized a need for a hospital formulary. With reference to the questionnaire a sample monograph was prepared and distributed to the medical superintendent, chief medical officer, and chief pharmacist and to Pharmacy and Therapeutic Committee in loose leaflets to get the feedback about the contents. Views and suggestions of the medical staff were obtained for the same. The latest drug list was obtained from the chief pharmacist in the form of softcopy. The drug list has 1003 formulations which include single and combination formulations. All drugs present in the drug list were critically evaluated for its need, efficacy, safety, and cost. The doctors of each head of department were asked to select the preferable brand of drugs or they can write drugs that have proven efficacy on their practice which are available but not available in hospital pharmacy. All their suggestions were considered. The doctors clearly informed that from their chosen drugs only cost effective, safe and quality drugs of at least 3 or 4 brands will be selected. At the same time prescription that comes to the hospital pharmacy had been analysed for few weeks to know which all drugs are not available in the hospital pharmacy that are prescribed by the doctors. Drugs which met with the goal of these criteria were selected and included in the formulary list and approval was obtained for the same from the pharmacy and therapeutics committee. The selected drugs were classified according to the British National Formulary as the standard format for the formulary list. Monographs in the formulary were organized within chapter, each of which represents an organ system or broad therapeutic drug class. Classification provides a readily accessible, concise, up to date source of drug information for effective, rational, safe and economic prescribing and dispensing and also guide as an educational tool for practitioners and students. Monographs were prepared for all the selected drugs in the hospital pharmacy with the following contents: Synonyms, Therapeutic category, Indication, Pregnancy risk factor, Contraindications, Precautions/ Warnings, Adverse reactions, Dosage, Drug interactions, Patient information, Brands available/strength/ formulation/ cost .Copies of the prepared hospital formulary were given to all the health-care professionals who participated in the first survey, medical superintendent, chief medical officer, and chief pharmacist and to Pharmacy and Therapeutic Committee. The prepared hospital formulary was compared with WHO model formulary 2010, National essential drug list 2003, WHO 2005 on the following parameters:

- Number of drugs present
- Class wise distribution of drugs
- Number of brands available for generic drugs in Al Shifa hospital formulary.
- Pregnancy category of drugs
- Monograph content.
- Fixed drug combinations

RESULTS:

I. Class Wise Comparison of Prepared Al Shifa Drug Formulary with National and WHO List of Essential Medicine

WHO Essential Medicines list 2010:

In WHO Essential Medicines List, out of 358 drugs Cardiovascular, Anaesthetics and Anti-infective had 40 (11%), 12 (3%), 104 (29%) drugs respectively. The Gastro intestinal drugs and Antidotes comprised same number of 14 (4%) drugs in each. Seven (2%) drugs were present in the categories of Diagnostic agents, Nutrition and blood products respectively. Respiratory system consisted of 5

Vaccines and Central nervous System had the same number of 26 (7%) drugs. Eleven (3%) drugs were present under each categories of Obstetrics and gynecology, Musculoskeletal system 19 (5%), and 27 (8%) drugs were present in the Skin disorders and Malignant diseases respectively.

National Essential Medicines list 2003:

Out of 354 drugs in the National Essential Drug List, drugs under cardiovascular, gastro intestinal, respiratory, and central nervous system, were 17 (5%), 30 (8%), 7 (2%) and 22 (6%), respectively. 72 (20%) drugs were present in anti-infective, 16 (5%) medicines were from endocrine system and 12 (3%) under obstetrics and gynecology. Malignancy and immunosuppression, nutrition and blood category consists of 23 (6%), 38 (11%), drugs respectively. Musculoskeletal system, immunological products and vaccines, antigens and diagnostic agents comprised of 13 (4%) of drugs respectively. Twenty (6%) were used for ENT &eye disorders and 30 (8%) drugs used for skin disorders. Fifteen (4%) of drugs were used as anaesthetics.

II. Comparison between Monograph Content of Al Shifa Hospital Formulary and WHO Essential Drug List 2010.

The monographs of prepared hospital formulary were compared with the WHO essential drug list 2010. Information on generic name, indication, con-

Figure: II. Total Number Of Drugs Present In Who, Nedl And Al-Shifa Hospital Formulary
traindication, drug interactions, precautions, adverse effects, dose, drug price, pregnancy category, lactation, US FDA approval information, synonym of drug and patient information were present in prepared hospital formulary. But information on drug price, pregnancy category, lactation, US FDA approval information, synonym of drug was not present in the WHO model formulary 2010. The Al Shifa hospital formulary does not contain information on pharmacology and pharmacokinetics of the drugs which was present in the WHO list. (Table: II)

Table: II comparison between monograph content of Al- Shifa hospital formulary and WHO essential drug list 2010

<table>
<thead>
<tr>
<th>Content</th>
<th>WHO essential list 2010</th>
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<td>Present</td>
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<tr>
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<td>Present</td>
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III. Pregnancy Category of Drugs Present in the Hospital Formulary
Out of 379 drugs, 1 (0.2%) drug was present in category A, 85 (22.52%) drugs in category B, 183 (47.76%) drugs in category C, 34 (8.97%) drugs in category D and category X consisted of 20 (5.27%) drugs, while category C/D had 18 drugs (4.75%). The category B/D and B/C consisted of 4 (1.05%) drugs and category A/C had 2 (0.52%) drugs. There were 30 (7.91%) drugs in the prepared formulary whose pregnancy category was unknown. (Table & Figure: III)

IV. Comparison of Available Fixed Drug Combination (FDCs) Products in Al Shifa Hospital Formulary, National And WHO Essential Drug List
WHO essential drug list 2010 and 12 FDCs in National Essential List, while the prepared hospital formulary consists of 379 generic drugs excluding Fixed Drug Combinations (FDCs) [fig: 2]. The prepared formulary comprised 379 generic drugs excluding Fixed Drug Combinations where the WHO model list consists of 358 drugs and National drug list consists of 354 drugs including Fixed Drug Combinations (FDCs) [fig: 2]. The prepared formulary consisted of 379 drugs i.e. 21 drugs more than WHO list and 25 drugs more than national list. The reason for inclusion of more drugs in hospital formulary was because, the PTC emphasised the need of these drugs in the hospital. Al Shifa hospital is a multispecialty tertiary care hospital and is situated in Malappuram District and has 19 medical specialities and 15 surgical specialities. Every day there is a use of large number of medicines in the hospital. During the prescription analysis of the hospital pharmacy prior to hospital formulary work, it was found out that some drugs were not available in the hospital which was repeatedly prescribed by the doctors. Some of these drugs were noted down and evaluated for its need in the hospital. Such drugs were included in the hospital formulary by the PTC. The study revealed that the drugs included in the cardiovascular system, central nervous system, obstetrics, gynaecology and UTI, respiratory system, endocrine system, and Musculo skeletal and joint disease were more in Al Shifa hospital formulary when compared with WHO and national list. The reason for this was that PTC considered these drugs as a must to this hospital. This shows the maximum
utilization of the above mentioned category drugs in the various departments of the hospital. The drugs included in the anaesthetic, anti-infective, malignant disease and immunosuppressant, antitoxins and vaccines were less in number when compared to the WHO and national drug list. The gastro intestinal system and eye disorder had same number of drugs as in WHO essential list and lesser number than NEDL. Nutrition and blood and Diagnostic Agents were not included in the prepared formulary. The number of brands used in the prepared formulary was less. The Al Shifa hospital pharmacy prescribed generic drug based on the sales and availability of the drug. This utilizes the budget in proper inventory and to avoid zero stock level. Before selecting the drugs and brands, the doctors of each head of department were asked to select the preferable brand of drugs or they were asked to suggest drugs that have proven efficacy on their practice which are available/not available in hospital pharmacy. All their suggestions were considered. During the prescription analysis it was found out that in some departments more than ten brands for the same drug were prescribed by the doctors every day. The doctors were clearly informed that from their own experience to restrict the number of brands of generic drug to maximum three. In the prepared formulary about 78% of drugs were available in one or two brands. Three brands were available for 17% of drugs and 3-5% of drugs were available for 2% of drugs. The information was not given in the WHO and NEDL but it was included in the Al Shifa hospital formulary. The information on lactation is also not given in the WHO and NEDL and this may due to the influence of pharmaceutical companies promoting these combinations. There were 168 FDCs present in Al Shifa Hospital formulary with 25 FDCs present in WHO EDL and 12 FDCs present in NEDL. The increased number of FDCs in Al Shifa Hospital may be due to these facts: the physicians were mostly used to prescribe combination drugs and pressure PTC for each drug. Some drugs of at least 3 or 4 brands will be selected by the PTC. Al Shifa hospital has the policy to restrict the number of brands of generic drug to maximum three.

All drugs present in the prepared list were evaluated for the pregnancy category with the approved definition by the US FDA. Out of 379 drugs only 86 drugs were safe to use in pregnancy. The drugs used in caution during pregnancy included 225 drugs which were in the pregnancy category C, D, X. Twenty drugs were absolutely contraindicated during the distribution of questionnaire it was found out that most of the doctors were unaware about the drugs in hospital pharmacy. Hospital formulary thus ensures the availability of drugs needed for the patients coming to the hospital. As Al Shifa hospital is multispecialty tertiary care hospital situated in a populated area, large number of medicines were used daily by the hospital departments. So the drugs and fixed drug combinations were more in the prepared list. All the drugs in the prepared list were analysed with FDA approved drug list. In our hospital formulary, 146 drugs were present which were approved by FDA. The combination drugs and the brands present in the prepared formulary which were approved by FDA were very few in number. It was found out that more medication error was reported from the side of the pharmacists. The pharmacists were restricted to prescribe one brand for each generic drug. During the prescription error monitoring and then started work on developing the Hospital Formulary through PTC in the hospital. Drug monograph were arranged in a format which can guides the medical, pharmacy and nursing trainee students for promoting the concept of rational drug therapy and it even act as teaching tool for them. The monographs of the hospital formulary were prepared from standard references for providing unbiased information to the healthcare professionals because the information provided by the medical representative to the physicians result in the irrational prescription. More effective hospital formulary system can be established here by continuously updating the prepared formulary and conducting the Drug Utilization Evaluation (DUE) programs.

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