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Development and Implementation of Hospital Formulary

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ABSTRACT

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Medicine plays a crucial role in the prevention and treatment of diseases. World Health Organization (WHO) model formulary defines a formulary is a manual containing clinically oriented summaries of pharmacological information about selected drugs. 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. Till now in India only few hospitals viz. Kasturba Medical College Hospital, Manipal, Karnataka and Christian Medical College Hospital, Vellore, Tamilnadu had developed and implemented formularies which had been effectively utilized in these hospitals. Hence, developed formulary will be useful for reducing the brands available in the hospital which helps in rational drug use. The formulary aims to provide physicians, pharmacists and other healthcare professionals working under hospital to update information about the use of medicines and hence the central goals of the formulary are to help prescribers in the appropriate choice of treatment and to make prescribers follow uniform choice of treatment. The implementation of the formulary will have significant impact on health care professionals' clinical practice to upgrade indirectly the quality of life in the patients, by promoting rational use of prescriptions and proper utilization of drugs. It provides impartial drug information to counteract biased promotional activities. It can be used as a tool to rationalize the range of medicines.

Keywords: Hospital Formulary, Rational Drug Use, Prescription

INTRODUCTION

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. This is particularly important during pregnancy where the risk to both mother and fetus must be considered.

WHO model formulary defines a formulary as a manual containing clinically oriented summaries of pharmacological information about selected drugs. The manual may also include administrative and regulatory information pertaining to the prescribing and dispensing of drugs. Formularies can be useful tools in solving some of these problems of drug therapy as they can:

- Provide impartial drug information to counteract biased promotional activities or fill the gap where access to accurate and up-to-date information is limited.
- Promote the appropriate use of safe, effective and good quality medicines.
- Help in the elimination of unsafe, ineffective or poor quality medicinal products by identifying effective and safe medications and support cost-effective utilization of drug budgets and improve access to essential medicines.[1]

Hospital formularies originally started life in hospitals as a collection of commonly prescribed pharmaceutical preparations, produced mainly for reference purposes. Later 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.[2]

The formulary is a continually revised compilation of pharmaceuticals (plus important ancillary information) that reflects the current clinical judgment of medical staff.[3,4] 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 patients.[5] 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 staff makes use of the system. Hence, it is important that it should be complete, concise, updated and easy to use.

In efforts to promote safe and cost-effective use of medicines,

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WHO released the first edition of 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 Medicine.[6] 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 formularies.[3] It has been stated that the main reason for developing a formulary is to promote rational prescribing.[7] WHO also recommends in their policy perspectives on medicine that development of formulary system through Drugs and Therapeutic Committee in the hospitals will promote rational use of medicines.[8]

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.[9,10] 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.

Till now in India only few hospitals viz. Kasturba Medical College Hospital, Manipal, Karnataka and Christian Medical College Hospital, Vellore, Tamilnadu had developed and implemented formularies which have been effectively utilized in these hospitals. Hence, developed formulary will be useful for reducing the brands available in the hospital which helps in rational drug use. The formulary aims to provide physicians, pharmacists and other healthcare professionals working under hospital to update information about the use of medicines and hence, the central goals of the formulary are to help prescribers in the appropriate choice of treatment and to make prescribers follow uniform choice of treatment. The drug formulary is an extended version of drug list, which offers information on the drug when required.

Designing of formulary:

The formulary should be designed on Pharmacologic–Therapeutic Classification of drugs so as to help in relating the pharmacological action of specific drugs. The formulary contains general notes for each pharmacologic class of drugs and specific information for each drug including indication, caution, drug interaction, side effect, contraindication, dose and administration and information on storage condition. The formulary also contains general notes on prescribing practices, and supplementary information under appendixes. The formulary is designed as a digest for rapid reference and it may not always include all the information necessary for prescribing and dispensing. And by no means does it substitute manuals for treatment guidelines.

Hospital formulary is divided in to four general aspects

1) Introduction

2) Therapeutic Index

3) Drug Monographs and d) General Information.[11]

Guiding Principles for Development of Formulary:

- Formulary system decisions are based on scientific and economic considerations that achieve appropriate, safe and cost-effective drug therapy. Clinical decisions are based on the strength of scientific evidence and standards of practice that include the following: Assessing peer-reviewed medical literature, including randomized clinical trials (especially drug comparison studies), Pharmacoeconomics studies, and outcomes research data.
- Employing published practice guidelines, developed by an acceptable evidence-based process.
- Comparing the efficacy as well as the type and frequency of side effects and potential drug interactions among alternative drug products.
- Assessing the likely impact of a drug product on patient compliance when compared to alternative products.
- Based on the formulary system decisions on a thorough evaluation of the benefits, risks and potential outcomes for patients; risks encompass adverse drug events (adverse drug reactions and medication errors, such as those caused by confusing product names or labels).
- Economic considerations include to the following: Based on the formulary system decisions on cost factors only after the safety, efficacy and therapeutic need have been established. Permitting financial incentives only when they promote cost management as part of the delivery of quality medical care. Financial incentives or pressures on practitioners that may interfere with the delivery of medically necessary care are unacceptable.
- The formulary system encompasses drug selection, drug utilization review, and other tools to foster best practices in prescribing, dispensing, administration, and monitoring of outcomes[12].
- Each Section of the formulary lists, within a particular therapeutic group, the drugs that are considered most appropriate for use on grounds of efficacy, safety and cost. If a physician feels that a particular drug should be included in the formulary, the matter should be discussed: with his Consultant; and with the Director of Pharmacy or Principal Pharmacist, who will arrange for the case to be put to the Drugs and Therapeutics committee. The formulary will be continually updated,

and revisions of the formulary will be made annually. If changes that may influence prescribing are made between issues, a no will be sent to all holders of the formulary.[13]

Developing locally relevant introductory information

The intended purpose, audience and ease of use should be kept in focus when compiling information for the preliminary section of the formulary. The preliminary section of a formulary usually contains the following sections and can include additional information, as listed below:

1. Acknowledgements

The acknowledgements should include the names of those who contributed to the development of the formulary, i.e. the editorial group, members of the advisory group, any technical support personnel and other institutions, professional organizations and donor agencies who provided either technical or financial support.

2. Introduction or preface

This section is usually a brief description of the purpose of the formulary, the intended audience, and the "ownership" of the formulary or the official publisher. The range and types of medicines included and the methodology of development. It is commonly contains a correspondence address to which comments can be sent by post, fax or email.

3. Table of contents

Together with the index at the back, the table of contents is often the most frequently consulted section in a formulary, so care must be taken to design the structure and layout to achieve the greatest clarity and ease of use. The table of contents at the front of the formulary can be very brief, giving only the titles and page numbers of the main sections.

4. Abbreviations

Internationally accepted units and symbols should be used wherever possible. The use of abbreviations in the formulary should be kept to a minimum to avoid any potential misinterpretation or confusion. qd = quoque die = once a day, or qid = quarter in die = four times a day.

5. Units of measurement:

Including a short table of the acceptable units of measure at the front of the formulary can encourage safe prescription-writing practices. Also remember to maintain the same safe practices when adding text to the formulary, e.g. write microgram in full instead of µg or mcg, which may be misinterpreted as mg. In those countries where imperial measures are still widely used, it can be useful to include a conversion table for SI units.

6. Instructions on how to use the formulary

This section can give a very brief description of what to expect in the different parts of the book (e.g. monographs) and provide explanations on use of local symbols and codes for distribution and prescription categories; information on origin and interpretation of prices can also be included.

7. Glossary

A list of some of the medical terms commonly used in the formulary, together with short definitions in one or two pages, can be useful if the users' educational backgrounds are likely to differ, but the compilers should avoid writing a whole medical dictionary.[14]

8. Introductory text of therapeutic sections

General statements about national clinical guidelines, policies and warnings can be added to the introductory text using the uniform text style mentioned above. (Example, a summary of the national tuberculosis treatment schedules can be given a prominent place, with a clear title at the beginning of Section "Antituberculosis drugs", whereas contact details for treatment centers for multi-drug resistant tuberculosis in the country can be inserted).

The Producing drug and therapeutic information - the Malawi approach to developing standard treatment guidelines manual gives useful information and practical tips for those who may be simultaneously developing or revising national standard treatment guidelines while working on the formulary.[15]

9. Monographs:

If there is any need to alter the basic information about individual drugs (e.g. dosage schedule) this should be done using the same uniform text style to show that this is a national recommendation or national information. The locally specific, supplementary information for individual drugs can be inserted at the end of each monograph.

Information to be presented for individual drugs in a formulary

Basic information	Supplementary information
Generic name	Common brand name(s)
Dosage form and strength	Price
Main indication	Level of use or distribution code
Pharmacology/pharmacokinetics	Prescription category
Contraindications	Patient information Precautions Labeling information
Dosage schedule	Storage instructions and stability
Adverse effects	Essential drug list number
Drug and food interactions	Main supplier catalogue number
Instructions, warnings	Procurement priority code (VEN)

10. Brand name(s):

Brand names of locally marketed original products (produced by the innovator) and/or brand names of multi-source products (branded generics) can be included under this heading. Listing the names of nationally registered, quality products (with established bioequivalence in the case of generics) can help to decrease the use of substandard or counterfeit products.

Writing new material for the national formulary: Once information has been collected and summarized for the purpose of insertion into the formulary it is crucial that development of the draft text follows a rigorous process including:

Writing the draft text in a clear, accurate style that is tailored to the purpose of the with formulary sufficient detail in both introductory texts and in the monographs.

Structuring the draft text to make the information easily accessible subheadings should follow existing structures. If the additional medicine will be used for different conditions, the relevant cross-references should be carefully included and monographs should reflect all recommended indications, dosage schedules, warnings etc. for the different uses.

Reviewing the draft text at several levels

Peer-review by members of the editorial team and content review by members of the advisory group to check readability and relevance to the intended audience and technical copy-editing and proof reading to check accuracy and validity, as already described.

Technical copy-editing

Copy-editing is the process whereby editors check the draft text to ensure correct spelling, grammar and conformity with the pre-agreed style requirements and to correct any inconsistencies or inaccuracies.

Inserted text should be checked for. The consistent use of drug names (recommended International Non-proprietary Names and disease names.

- Conformity of all units of measurement with the SI units.
- Accuracy of local units of measure and provision of explicit and accurate conversions to SI units.
- Definitions of any local abbreviations added.
- Compatibility between new local text in the introduction and in the newly added monographs.
- Accurate cross-references and potential connections to existing cross-references.

Special attention must also be paid to the careful validation of the new text using current references i.e. Martindale drug reference guide and other drug information textbooks, selected clinical guidelines, drug reviews and manufacturer's literature.[16]

Additional sources of information

A vast amount of information is available about medicines and can be accessed in a number of ways, i.e. through journals, books, electronic sources and the Internet. Often, it is difficult to separate the "wheat from the chaff", i.e. to find relevant and useful information. All efforts should be made to locate high-quality local evidence, if it exists, as this will reduce any uncertainty about transferring recommendations to local patient populations.

Types of sources

Published information can be divided into primary, secondary and tertiary sources manufacturer's literature can fall into any of these three categories. For examples of selected sources that are useful in the development of formulary information.

Developing specific information sections

The appendices usually contain additional therapeutic, safety, pharmaceutical and administrative information to supplement the monographs and general introductory texts. The information in this part of the formulary is frequently presented in a tabulated or summarized form and can also be illustrated with specific examples of local requirements.

Each appendix has a general introductory text and a detailed medicine-specific information section.

There are two important steps to be taken during the adoption of appendices.

Additions: When a new monograph is developed for the formulary, where the specific information is to be included in the appendices, this material should also be written at the time of development. In the case of interactions, the new entry would be inserted under the medicine being characterized in the new monograph as well as under the interacting medicines. In the other appendices, additional information would be inserted into the existing alphabetical lists as appropriate.

Deletions: If a decision is made not to include certain monographs in the NF, then all associated information from the appendices should also be removed. In the interaction appendix, a careful search should be made for the name of the active ingredient and this should be followed by careful deletion of all interactions and reversals for the deleted medicine.[20]

Drug Formulary System: An ongoing process whereby a healthcare organization, through its physicians, pharmacists, and other healthcare professionals, establishes policies on the

use of drug products and therapies, and identity drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population.

The formulary system

- Provides drug product selection and formulary maintenance.
- Provides drug use evaluation (also called drug utilization review) to enhance quality of care for patients by assuring appropriate drug therapy.
- Provides for the periodic evaluation and analysis of treatment protocols and procedures to ensure that they are up-to-date and are consistent with optimum therapeutics.
- Provides for the monitoring, reporting, and analysis of adverse results of drug therapy (Example: adverse drug reactions, medication errors) to continuously improve the quality of care.

Formulary system policies should

- Require P&T committee members to reveal, by signing a conflict of interest statement, economic and other relationships with pharmaceutical entities that could influence Committee decisions.
- Exclude product sponsor representatives from P&T committee membership and from attending P&T committee meetings.
- Require P&T committee members to adhere to the formulary system policy on disclosure and participation in discussion as it relates to conflict of interest.
- The formulary system should include educational programs for payers, practitioners, and patients concerning their roles and responsibilities.[21]

The formulary system should:

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

- Proactively inform practitioners about changes to the formulary or to other pharmaceutical management procedures.
- Provide patient education programs that explain how formulary decisions are made and the roles and responsibilities of the patient, especially the importance of patient compliance with drug therapy to assure the success of that therapy. Disclose the existence of formularies and have copies of the formulary readily available and accessible.
- Provide rationale for specific formulary decisions when requested.
- The formulary system should include a well-defined process for the physician or other prescriber to use a non-formulary drug when medically indicated.
- Enable individual patient needs to be met with non-formulary drug products when demonstrated to be clinically justified by the physician or other prescriber.
- Institute an efficient process for the timely procurement of non-formulary drug products and impose minimal administrative burdens.
- Provide access to a formal appeal process if a request for a non-formulary drug is denied.

Include policies that state that practitioners should not be penalized for prescribing non-formulary drug products that are medically necessary.[22]

The Pharmacy and Therapeutics (P&T) Committee

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

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

- Oversees quality improvement programs that employ drug use evaluation.
- Implements generic substitution and therapeutic interchange programs that authorize exchange of therapeutic alternatives based upon written guidelines or protocols within a formulary system. (Note: Therapeutic substitution, the dispensing of therapeutic alternates without the prescriber's approval, is illegal and should not be allowed.
- Develops protocols and procedures for the use of and access to non-formulary drug products.
- Physicians, pharmacists, and other healthcare professionals provide oversight of the formulary system.

- Healthcare organization policies should ensure appropriate oversight of the P&T
- Committee and its decisions by the medical staff or equivalent body.
- The formulary system must have its own policies, or adhere to other organizational policies, that address conflicts of interest and disclosure by P&T committee members.[23]

Malm H Martikainen J et al. have carried out a study, on prescription of hazardous drugs during pregnancy, risk assessment must always be made on an individual basis, and present women with illnesses requiring treatment must be treated adequately.[24]

In study of Anasuya Gehlat she had mentioned that, caution with some commonly used drugs during pregnancy; in pregnant women the decision to administer the drug should be correct.[26] J B Sharma in his review article, the role of Folic acid and Vitamin B12 supplementation in anemia during pregnancy, Folic acid and Vitamin B12 are necessary for the normal production of red blood cells. Vitamin B12 in order to prevent the morbidity and mortality associated with anemia in pregnancy and improve outcome.[25] Dr. Thomas Jack in his review article, when folic acid supplements are required, fetal development occurs rapidly in the first trimester (even in the first four weeks) of pregnancy, and it is during this period that basic structures and tissues in neural tube defects.[27]

Before marketing a new drug, the manufacturer almost never tests the product in pregnant women to determine its effects on the fetus. Consequently, most drugs are not labeled for use during pregnancy. Typically, descriptions of drugs that appear in the physicians desk reference and similar sources contain statements such as, 'Use in pregnancy is not recommended unless the potential benefits justify the potential risks to the fetus. Since the risk has been adequately established for only a few drugs, physicians caring for pregnant women have very little information to help them to decide whether the potential benefits to the mother outweigh the risks to the fetus.

Pregnancy induces significant changes in the functions of the body's systems and in its fluid and tissue composition. It is helpful to how these changes are likely to affect drug dosing and drug interactions in the pregnant women.[28]

French health insurance service surveyed the prescription of drugs used during pregnancy, concluded that 1000 women are too frequently exposed to drugs, the known risks of which outweigh their benefits or for which there are no available data about their use in pregnancy. Drug use in French pregnant women should be continuously monitored and physicians and women should be more aware of the potential risks to the fetus.[29]

Most of the drugs pass into breast milk in concentrations too low to have any unwanted effects on the baby, breast-feeding mothers still need to be careful. Always ask your doctor or pharmacist before taking any medicine while breast-feeding. A doctor or pharmacist can tell how to adjust the timing and dosing of most medicines so the baby is exposed to the lowest amount possible, or whether the drugs should be avoided altogether.[30]

Mc.Creadie SR, Stumpf JL, Benner TD stated that, the printed formulary evolved into a compilation of approved medications thought to best meet the needs of patients and a source of prescribing and procedural information that documented the actions of the pharmacy and therapeutics (P&T) committee. However, the best method to provide this institution-specific information in a timely, easily accessible manner has remained elusive.[31]

The WHO model list of essential medicines (WMLEM) identifies over 300 medicinal agents and devices for the prevention or treatment of priority diseases. In 2002, WHO released the first edition of the WHO model formulary. The second revised edition based on the 13th Model list of essential medicines was published in 2004. This formulary contains detailed information about the indications, dosage, adverse effects, contra-indications and warnings for medicines included in the WMLEM, together with summaries of recommendations on their appropriate use.[32]

Uretsky SD in his article suggested that, compiling hospital formulary is a professional responsibility of pharmacist. The formulary should represent the best possible collection of drugs, taking into account the probable need of the patient population of the institution.[33]

According to Odedina FT, Sullivan J, Nash R, Clemmons CD the formulary management is one of the major strategies employed in hospital settings to manage the quality and costs of pharmaceuticals. The Use of a formulary can ensure quality and control cost if its use is based on appropriate clinical and pharmacoeconomics considerations. Use of pharmacoeconomics data in making hospital formulary decisions has become more common both nationally and internationally.[34]

Spooner JJ, Gandhi PK, Connelly SB in there study stated that adoption of a systematic formulary review process may lead to an increase in pharmaceutical spending in health programs as per evidence.[35]

Cassano AT suggested that, a well-written and organized hospital formulary facilitates standard drug concentrations, intra-venous (IV) infusion administration guidelines (including recommended rates, IV access types, monitoring parameters, etc), and sample order sheets/protocols. These

data frequently dictated how certain drugs were listed and on which units they could be used.[36]

Lehmann DF, Guharoy R, Page N et al stated that, formulary management can be used as a way of providing quality and mechanisms that create efficiencies in the medication-use process (therapeutic) with the P&T committee confining its purview to adding new drugs to the hospital formulary.[37]

Formularies with tiered co-payment structures or preferred drug lists have become increasingly popular, as plans seek to provide financial inducements for enrollees to select the least expensive drugs while avoiding the restrictions of entirely closed formulary systems.[38]

Motheral evidence suggests that incentive-based formularies are associated with lower costs and smaller increases in drug utilization and expenditures compared with control groups.[39]

The Florida Medicaid program lists prescription products on a preferred drug list selected by the pharmaceutical and therapeutics committee as "efficacious, safe, and cost effective choices when prescribing for Medicaid patients.[40]

The 2004 ASHP national survey of pharmacy practice in hospital settings that pertain to prescribing and transcribing are presented were the response rate was 41.7%. Compared with the results of the 2001 survey, the number of times pharmacy and therapeutics committees met increased, suggesting an increase in efforts to monitor and manage medication use in hospitals. There was an increase in the use of quality-of-life information to make formulary decisions, indicating a shift away from cost-based formularies. There was a decrease in the rates of formulary compliance, but an increase in the use of evidence-based clinical practice guidelines, suggesting the emergence of more comprehensive approaches to improving prescribing.[41]

CONCLUSION

The development of formulary was promoted on evidence based standard practice. It will ensure the Clinical efficacy, Patient safety, and Cost effective prescription for the rational drug use, by identifying effective and safe medications. It provides impartial drug information to counteract biased promotional activities. It can be used as a tool to rationalize the range of medicines.

The implementation of the formulary will have significant impact on health care professionals' clinical practice to upgrade indirectly the quality of life in the patients, by promoting rational use of prescriptions and proper utilization of drugs. It also helps physicians for periodical evaluation or analysis of treatment protocols and procedures to ensure that they are consistent with optimum therapies in better inventory control. This is helpful to the entire health care professionals in the hospital.

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