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Review Article

A STUDY ON DIRECTIVES FOR HOSPITAL FORMULARY**K. Jyothi*¹, Dr. S. Rajesh Raja²**¹Student Dr. K.V. Subbareddy Institute of Pharmacy²Assistant Professor, Department of Pharmacy Practice, Dr. K.V. Subbareddy Institute of Pharmacy**Abstract:**

The hospital formulary is a list of pharmaceutical agents with its important information which reflects the current clinical views of the medical staff. The hospital formulary system is a method whereby the medical staff of a hospital with the help of pharmacy and therapeutic committee selects and evaluate medical agents and their dosage form which are considered to be most important in the patient care. The first hospital formulary in India was published in 1968 by the Department of Pharmacy, CMC, Vellore. Pharmacist in the PTC has a key role in developing policies and procedures governing the hospital formulary. The chief pharmacist has the primary responsibility for the preparation of hospital formulary. Pharmacist with the advice and guidance of PTC shall as certain the quantity and source of supply of all drugs, chemicals, biological and pharmaceutical preparations used for the diagnosis, and treatment of patients.

Keywords: Hospital Formulary, Pharmacy and Therapeutic Committee (PTC).

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INTRODUCTION:**HOSPITAL**

An institution that is built staffed and equipped for the diagnosis of diseases, providing medical & surgical treatment and nursing care for sick or injured people.

FORMULARY

A list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits.

Traditionally, a formulary contained a collection of formulas for the compounding and testing of medication (as a pharmacopoeia today). Today, the main function of a drug formulary is to specify particular medications that are approved to be prescribed at a particular hospital, in a particular health system.

Hospital formulary is a list of pharmaceutical agents with its important information's which reflects the current clinical views of the medical staff. The hospital formulary system is a method whereby the medical staff of a hospital with the help of pharmacy and therapeutic committee selects and evaluate medical agents and their dosage form which are considered to be most useful in the patient care.

The hospital formulary system provides the information for procuring, prescribing, dispensing and administration of drugs under brand/generic names.

OBJECTIVES OF HOSPITAL FORMULARY

- Differentiate between hospital formulary and drug list
- Know the preparation and revision of hospital formulary.
- Understand the concept to addition and deletion of drug from hospital formulary.

ORIGIN IN INDIA

The first hospital formulary in India was published in 1968 by the Department of Pharmacy, CMC, and Vellore. The first hospital formulary for the development of government hospital teachings was published in 1997 at Government Medical College, Trivandrum.

THE NEED FOR HOSPITAL FORMULARY

- The increasing number of new drugs manufactured and marketed by drug companies.
- Increasing complexity of untoward effects of modern potent drugs. Newer sales

promotion strategies of pharmaceutical industry.

- The public interest in getting possible health care at lowest possible cost

ADVANTAGES OF HOSPITAL FORMULARY

- It provides the practitioner with approved and efficacious medicines to treat disease.
- Hospital formulary reduces the inventory cost of the drugs. It regulates the number of medicines by improving the procurement and inventory management.
- It improves the quality assurance and easier dispensing.
- It gives stress on medicine information and focused on patient's education efforts.
- It removes the irrational combinations of drugs and also improves adverse drug reaction management.

DISADVANTAGES OF HOSPITAL FORMULARY

- The hospital formulary system deprives the physician of the right and prerogative to prescribing and obtained the brand of his choice.
- The system may sometimes permit the pharmacist to act as the sole judge to which the brands of the drugs to be purchased and dispensed.

GENERAL PRINCIPLE

- ❖ The hospital formulary system shall not contain any policies (or), procedure which before the time of prescribing provides the consent by the physician to the dispensing of non - porosity drug to the dispensing of a print brand different from the brand which he has prescribe.
- ❖ It shall with in this prescription at the dispensing time of a prescribing non to approve (or) disapprove the of the different brand. parity drug (or) the dispensing of the different brands
- ❖ The medical staff shall adopt the policy of including drugs by their non- priority names.
- ❖ In the formulation of policies and procedures the terms substitute (or) substitution should be avoided because these terms can be used for dispensing entirely different drugs.
- ❖ If there is any chance in hospital system (or) in the contents it must be informed to the "medical staff.
- ❖ The pharmacist with the advice & guidance of PTC. Shall make, arrangements for all the drugs, chemicals, biological and pharmaceutical preparations used for diagnosis and treatment of patients.
- ❖ The labeling of medicine with, non-priority names should always be done in a proper way

the format for non-priority drug is as follows:

- ❖ To develop an effective formulary system, PTC has to consult various references on a drug regarding its pharmacokinetic profile, drug food interactions, poisoning etc.
- ❖ While discussing a particular proprietary name physician interest must be so based upon its pharmacological activity, safety

TYPES OF HOSPITAL FORMULARY

There are three basic types of hospital formulary

1. Open formulary
2. Closed or restricted formulary
3. Incentive based formulary

An open formulary serves merely as a guide; a physician may prescribe any drug, but is encouraged to use the formulary list in prescribing decisions.

In contrast, a closed or restricted formulary lists the drugs that will be reimbursed by the health care provider; non-formulary drugs will be reimbursed only if they are authorized prior to prescribing.

An incentive-based formulary represents a hybrid between the open and closed formulates patients pay a higher price for non-formulary drugs.

FORMAT OF HOSPITAL FORMULARY

The format of the Hospital formulary is decided by the PTC Although the physical appearance and structure of the formulary play an important influence on its use elaborate and expensive artwork in the formulary is of no use, as it is meant for professional use, so it should be visually pleasing, easily readable with proper grammar, correct spelling and with neat designing. It is the main point for improving drug therapy in hospitals and is dependent on the abilities of a pharmacist.

The general format of the hospital formulary includes:

1. It should be in bound form
2. It should be light in weight, and easy to carry
3. It should contain all essential information
4. The format of printing includes white pages and black ink
5. The pages should not be colored

CONTENTS OF HOSPITAL FORMULARY

The typical composition of hospital formulary is

1. Title page
2. Names & titles of the members of the PTC
3. Table of contents
4. Information on hospital policies & procedures concerning drugs
 - The pharmacy and therapeutics committee of hospital

- Objective and operation of the formulary systems
 - Hospital regulations and procedures for prescribing and dispensing drugs.
 - Hospital pharmacy services and procedures.
 - How to use the formulary
5. Products accepted for use at hospital
- Items added and deleted from the previous edition.
 - Generic, Brand name cross-reference list.
 - Pharmacologic/therapeutic index with relative cost codes.
 - Descriptions of formulary drug products by pharmacological therapeutic class.

GUIDELINE FOR HOSPITAL FORMULARY

- The governing body of the hospital shall appoint a pharmacy and therapeutic committee composed of physician and pharmacist which will prepare the hospital formulary system.
- The medical staff in the governing body shall sponsor and outline the purpose, organization function and scope of the hospital formulary system. it should adopt the principle as per the need of particular hospital.
- The pharmacy and therapeutic committee shall develop policy and procedure governing the hospital formulary and the medical staff shall adopt these policies and procedures subject to administrative approval.
- The policy and procedures shall afford guidance in the appraisal selection, procurement, storage, distribution, use, safety procedure: and other matter relating to drug in the hospital and shall be published in the hospital's formulary or other media available to the member of medical staff.
- The medical staff shall adopt the policy formula, and procedure for including drugs in the formulary by their nonproprietary name: even though proprietary names continue to being use in the hospital physicians.
- In the absence of written policies approved by the medical staff: related to the operation, the hospital shall make it certain that the nursing personnel are informed in writing though its system of new: of communication that there exists the formulary system in the hospital and the procedure governing its operations
- In the formulation of policies and procedure the term substitute or substitution should be avoid since this term have been used to imply the unauthorized dispensing of entirely different drug, neither of which takes place

under a properly operated hospital formulary system.

- It shall be made known to the medical staff about the changes in the working in the hospital formulary system or in the content of the hospital system.
- Provision shall be made for the appraisal of the member of the medical staff for the use of the drug not included in the formulary or the investigation drugs.
- The pharmacist with the advice and guidance of the pharmacy and therapeutic committee shall ascertain the quantity and source of supply of all drugs, chemical, biological and pharmaceutical preparation used for diagnosis and treatment of patient.
- Labeling of drug and medicine container with non-proprietary name of the content always should be proper. The use of proprietary name other than that describing the actual content is not correct and proper if it is used in a manner that can be taken as description of the content.

INFORMATION ON DRUG PRODUCTS

This section is the heart of formulary & consists of each item to facilitate its use" like Entries in Formulary

- ◆ Generic name of basic drug.
- ◆ Common Names (The brand Names)
- ◆ Dosage forms, strength, packaging
- ◆ Formulation. (Name of active ingredient, formulation of errors)
- ◆ Route of administration
- ◆ Cost.

Entry of a drug into the formulary is a complex "matter because only the members alone are not competent enough to decide each drug, Clinical experts from various departments is invited for their valuable comments on specialized drugs.

Selected drugs may be official in IP, BP, USP etc. Any preparation whose formulary is not disclosed does not qualify for its entry into the formulary. The guidelines are framed by pharmacy & therapeutic committee for inclusion (or) non- inclusion of drugs in the formulary. The concerned medical staff is informed about the decision at every stage & they remain aware of reasons for not including any drug.

FORMULARY CONTENTS & ORGANIZATION:

The formulary should consist of three main parts:

1. Information on hospital policies & procedures concerning drugs.

2. Drug products listing
3. Special information

1. Information on hospital policies & procedures concerning drugs

1. Categories of drugs
E.g.: formulary drugs, non-formulary drugs, etc.
2. Brief description of the PTC including its membership, responsibilities and operation.
3. Hospital regulations about prescribing, dispensing & administration of drugs including writing of drug orders, verbal drug orders, automatic stop orders, self- administration of drugs by patients
4. Pharmacy operating procedures such as prescription labeling, handling of drug information request and outpatient prescription police
5. Information on using the formulary: It includes how formulary entries are arranged and the information contained in each entry

2. Drug products listing

1. Formulary item entries

- (a) Alphabetically by generic name
- (b) Alphabetically within therapeutic class

2. Type of information

- Generic name of the product
- Dosage form, strength, packing
- Active ingredients
- Adult/pediatric dose
- Route of administration, Cost etc.
- Indexes to the drug products listing
- Generic name/brand name
- Therapeutic /pharmacological index

3. Special information

- Hospital approved abbreviations
- Rules for calculating pediatric dosages
- List of sugar free drugs
- Metric conversion tables
- Poison control information

PREPARATION OF HOSPITAL FORMULARY

Preparation of a hospital formulary is a principal responsibility of the pharmacy and therapeutic committee However it is also resting primarily on the chief pharmacist service etc. The committee is free to make necessary decisions, regarding the material to be included in the formulary and pharmacist undertaken the production of formulary that is compiling and printing etc.

The physical appearance & structure of the formulary if important influence on its use. The formulary should visually pleasing, easily readable and should appeal professional.

1. Introductory information

- Acknowledgement
- List of abbreviations
- Intended usage of the formulary manual

2. Basic information of the drug

- Generic Name
- Dosage Form, Strength Indications
- Pharmacological Actions
- Precautions
- Side effects
- Dosage Form, Frequency, Drug Interactions

3. Supplementary information on each drug

- price
- Regulatory Category
- Storage Guidelines
- Patient counseling Information
- Brand names

4. Prescribing & dispensing guidelines

- Principles of prescription writing
- Strength of prescribed medication must be given in accepted metric system
- Correct dispensing guidelines
- Prevention and Reporting of ADRs

5. General drug use advice

- Use of IV drugs
- Special situations like pregnancy, breastfeeding liver/kidney diseases
- Poisoning information and Antidotes
- Treatment of snake bites and insect bites

6. Miscellaneous section

- Children's dose
- Renal adjustments
- Metric units
- Diagnostic aids

MANAGEMENT OF HOSPITAL FORMULARY

The formulary is a periodically revised list of medicines that reflects the current judgment of the medical staff.

The formulary system utilizes the medical and pharmacy staff: to evaluate, appraise, and select from among the numerous available medicines those products that are the most efficacious, safest, of adequate quality, and available at a reasonable price. When completed, the formulary should conform to the following principles

1. Medicines should be selected based on the

needs of the community; they should treat the locally identify diseases and conditions.

2. The formulary list should have a limited number of medicines, only those necessary to provide for the needs of the hospital or clinic; duplication of agents that have therapeutic equivalence should not occur.
3. International non-proprietary names (INN) (i.e., generic names) should be used.
4. Combination (fixed-dose) products should be used only in specific proven conditions (e.g., to treat tuberculosis).
5. The formulary must be consistent with any national or regional formulary or approved standard treatment guidelines.
6. Medicines should be restricted to appropriate practitioners.

DISTRIBUTION OF THE FORMULARY

- Copies of the formulary should be placed at each patient care unit including clinics & the emergency room.
- Each division of the pharmacy (IP pharmacy, OP pharmacy, drug information Centre etc.) should receive a copy.
- Head of the department as well as each member of the medical staff should receive a copy.
- Head of the department as well as each member of the medical staff should receive a copy.
- A formulary is the painstaking effort of any hospital to guide medical and paramedical staff.
- The formulary is very educative and useful to the members of the "Health CareTeam" and
- Hence copies of the formulary should be placed at each patient care unit, including clinics, out-patient care areas, and emergency room.

REVISION OF FORMULARY

1. The PTC holds meetings to discuss about the revision of the formulary.
2. The annual revision is necessary because of the changes in the drug products, removal of certain drugs from the market and changes in the hospital policies.
3. The addition of details of a drug is done by attaching the supplement sheets at the back of the formulary.
4. The addition of any drug to the formulary is a

complex decision.

5. All steps prior to the addition or deletion of a drug must be reported to the medical staff.

MAINTAINING A FORMULARY SYSTEM

The formulary maintenance process is dependent on two key components

1. additions and deletions of medicines, and
2. therapeutic medicine class reviews

Additions and deletions should be handled following specific policies and procedures developed for the PTC. A transparent methodology must be developed for these important decisions concerning addition or deletion of a medicine.

Routine medicine class reviews are important to maintain the formulary. The medicine class review involves the evaluation of a complete section of medicines.

To maintain the formulary, regularly scheduled meetings must be established and attended by committee members. Ideally, the committee would meet monthly or, at the very least, every four months. Selecting medicines for the formulary should follow carefully considered policies and procedures for determining the most useful medicines. These policies should be followed routinely and accurately each time an evaluation is needed.

A request for addition of a medicine to the formulary, which can be made only by a physician or pharmacist, is done by completing a "Request for Addition/Deletion" form.

Medicine information resources should be obtained, including primary literature, international newsletters, standard treatment guidelines, textbooks, and Internet sources.

The evaluation is performed using established criteria. The medication information monograph is written. The medication monograph should include details about the medicine obtained from several information sources. At a minimum, the monograph should include

- Pharmacology
- Pharmacokinetic
- Efficacy compared to placebo and other medicines Clinical trial analysis
- ADRS
- Medicine interaction
- Cost comparison

- Sources of supply (to ensure availability)

Expert opinions and recommendations should be obtained from knowledgeable and respected physicians and pharmacists.

The PTC makes a formulary decision (at the PTC meeting). Information should be presented to the PTC at a regularly scheduled meeting.

The results of the evaluation and PTC's recommendations and actions must be disseminated to the health care staff in the form of minutes or newsletters, or through department meetings.

SELECTION CRITERIA FOR NEW MEDICINES

Selecting medicines for the Formulary is the most important function of the formulary system. The process, which is multi factorial, ultimately brings the best medicines to the health care system. The following are the major criteria to be considered when evaluating all new requests for addition to the formulary Country disease patterns.

- Efficacy/effectiveness
- Safety
- Quality
- Patient's acceptability
- Cost

Disease patterns

The morbidity of the region needs to be assessed carefully before adding or deleting any medicines. Formulary medicines should be approved only after confirmation of actual need to treat the known diseases and medical conditions of the community.

Efficacy

Proven efficacy is one of the most important criteria in selecting new medicines for the formulary. Reviewing information from systematic reviews, e.g., the Cochrane Collaboration, international pharmaceutical information newsletters or bulletins, and current textbooks will provide the reviewer with additional supporting information concerning efficacy.

Safety

Determining the safety of a medicine requires close attention to established information on the medicine as well as current post marketing surveillance of the medicine's safety record. A careful risk-benefit assessment will be necessary for all medicines before they are added to the formulary.

Quality

The quality of a medicine that is requested for the formulary is important. Poor- quality medicines that are administered to patients may have adverse effects, including

-lack of therapeutic effect, toxic and adverse reactions waste of financial resources etc.

Patient's acceptability

Patient's acceptability is very important especially for orally administered drugs where repeatability and ease of swallowing will contribute to acceptability.

Cost

Cost considerations are also important since the aim of formulary is to encourage rational and cost-effective prescribing. Cost effective prescribing involves the use of a drug with lowest costs, minimal toxicity and is applicable to patients.

DIFFERENTIATION OF HOSPITAL FORMULARY AND DRUGLIST:

Hospital formulary

- Listing of drugs by their generic names followed by information on strength, form, and posology. Toxicology, use & recommended quantity to be dispensed.
- Prepared locally by its own clinical staff.
- Information provided is subject to local needs and desires
- Published in convenient size
- Addition or deletion of drug with greater frequency

Drug list

Generic names followed by data on strength & form. Prepared by country's outstanding clinicians, pharmacologists and pharmacists. According to their pharmacological properties.

ROLE OF PHARMACIST IN HOSPITAL FORMULARY

- Pharmacist in the PTC has a key role in developing policies and procedures governing the hospital formulary. The chief pharmacist has the primary responsibility for the preparation of hospital formulary.
- Pharmacist with the advice and guidance of PTC shall ascertain the quantity and source of supply of all drugs, chemicals, biological and pharmaceutical preparations used for the diagnosis, and treatment of patients.
- Pharmacist should ensure that quality of drugs is not compromised by economic considerations.
- He will evaluate various drugs as per the guidance of PTC.

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