

# Hospital Formulary Concept: Is India Ready and How it will Benefit from it?

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## ABSTRACT

Formulary system is evidence-based process employed by health organization to aid the physicians in decision making and ensuring rational prescribing. Under this system, a formulary manual is developed that contains the clinically relevant pharmacological information about the selected drugs. It helps in selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration, and monitoring of drugs work in concert to ensure optimal outcomes. In many developed countries, hospital formulary system has contributed massively to provide safe, effective and economically favorable medical care to its population. India is in process to make its health care system more efficient. The Indian drug regulatory system is not yet developed enough to ensure availability of safe and efficacious medications. Numerous irrational, unapproved and poor quality medications are floating in Indian market leading to health of millions at stake. By implementing hospital formulary system, the quality assured safe, efficacious and cost effective drugs would be available. The hindrances in implementing hospital formulary system in India is lack of resources such as adequate drug information, proper guidelines, transparency in functioning of regulatory bodies and pharmaceutical companies, lack of

interest among medical practitioners, understaffing in majority of hospitals. If all these criteria are looked after and hospital formulary system is made mandatory for all private and public hospitals, the health care system of India could achieve new heights.

**Key words:** Medical practitioners, hospital formulary, pharmaceutical companies

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## INTRODUCTION

Providing adequate health facilities is currently the prime focus in most of the countries including India. One important factor that can contribute to human health is availability of safe and effective drug therapies and their rational use. With advancement of technology, the pharmaceutical companies are flooding the market with new drugs. Two third of them are duplicate and non-essential and there is wide variation of cost among different brands available for same drug. It is not only difficult for any hospital to maintain inventory of all the drugs available in the market but also for physician to decide the safest and most appropriate therapy for patients. To aid the healthcare providers in decision-making and to ensure rational prescribing, the practice of developing formularies for health care centers was introduced. According to WHO, formulary can be defined 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."<sup>[1]</sup>

It helps to limit the drug budgets, increases number of therapeutic alternatives, checks improper prescribing and use of medications, ensures presence of safe and efficacious drugs, provides unbiased drug information, and cuts high costs of handling large numbers of drugs.

Many developed countries have well established hospital formulary system which has India is grappling from last few decades to ensure adequate health services to its citizens. Due to weak regulatory system, the India's public health outcomes are not improving as expected. One of the hurdles is availability of suitable drugs. The four-core drug related areas that need to be refined are access, delivery, quality and affordability. One successful option to achieve them is having effective hospital formulary system. Formulary systems have evolved over time. It began as rudimentary drug lists in 1940 by the military but gained widespread use during the 1950s. In the late 1950s, the American Society of Hospital Pharmacists (ASHP) laid down the minimum standard for the implementation of a formulary system in health care settings.<sup>[2]</sup>

## HOSPITAL FORMULARY SYSTEM

It is a system whereby medical staff of the hospital can select and

evaluate medicinal agents and their various dosage forms with the help of pharmacy and therapeutics committee (PTC). It provides them the required information on procuring, prescribing, dispensing and administration of drugs under brand/generic names.<sup>[1]</sup>

A comprehensive, well-maintained formulary is tailored to the organization's patient care needs, policy framework and medication-use systems. The selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration, and monitoring of drugs work in concert to ensure optimal outcomes. It identifies the medicines that are appropriate and cost-effective to the patient population. It includes the review and approval of all drug related policies. The PTC should complete the review of policy before giving the final approval. The review process should be done at regular interval according to availability of new information related to the drug.

## PREPARATION AND MANAGEMENT OF HOSPITAL FORMULARY

At the hospital level, PTC is responsible for establishing a limited list of drugs approved for procurement and use. Drug formulary list is formed after thorough examination of morbidity, consumption and treatment costs. Appropriate steps should be followed to formed hospital formulary.<sup>[3,4]</sup>

## Drug formulary has four stages of development

### Stage I

It is the administrative stage that requires forming the PTC. PTC

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develops the concept for policies and procedures for medication use in the hospital. Selection of the suitable manufacturers for all the medications in terms of quality, quantity and source of supply.<sup>[5]</sup>

### Stage II

It deals with development of drug formulary list. This includes selection of therapeutic classification scheme, collection of necessary data for analyzing existing drug use patterns, analyze morbidity and drug utilization patterns, to conduct drug class reviews, approve the formulary list for use in the health facility and educate hospital personnel about policies and procedures on non-formulary drug use, additions and deletions to the formulary, and generic and therapeutic substitution.

### Stage III

After development of drug formulary list, then it proceed to third stage to develop drug formulary manual which includes to decide on formulary manual versus formulary list, to develop policy and general information section, drug information monographs for the formulary manual, special information section, indexes to facilitate the use of the manual and to produce and distribute the manual.

### Stage IV

The last stage is to maintain formulary process that includes developing and implementing standard treatment guidelines, to design and conduct an ongoing drug use evaluation program, to design and to implement adverse drug reaction monitoring system and update the formulary list or manual. A formal process to review medication-use policies should be in place in the organization. It include the use of expert panels or subcommittees of the PCT. PCT may also have subcommittees that address specific therapeutic areas like antimicrobial, cancer chemotherapy, cardiovascular, adverse-drug reaction, or biotechnology subcommittees. The PCT should always have formal interactions with other committees whose functions may affect the medication-use process.

## FORMULARY MANUAL

Hospitals frequently develop formulary lists into a formulary manual, which is concise reference book containing basic drug information about each drug on the formulary list. PTC makes the manual in such a way that it contains enough information to aid physicians in making rapid prescribing decisions. Drug monograph of each drug is the heart of the manual in the formulary. The PTC decides on the sections to be contained in each monograph, and how much information will be included.

The physical appearance of a printed formulary manual has an important impact. The formulary manual should be visually pleasing, easy to read, and professional in appearance. It can be loose-leaf book, or a bound volume resembling a paper-back book. It should be readily available to physicians, pharmacists and nurses, at all times. It can be distributed to all the individuals in the healthcare setup or it can place in patient care areas and the pharmacy department.<sup>[6]</sup>

## Implementation of hospital formulary

Ensuring the implementation of formulary is as important as developing and maintaining it. If the health care professionals are not properly educated on how to utilize formulary then the efforts of developing it may go in vein. Healthcare professionals can be trained to use formulary by in service education, grand rounds, interactions between pharmacists and prescribers at the time of prescribing or dispensing, staff meetings, newsletters, mailings, prescriber detailing, and pharmacy or institutional websites.

## Strategies for managing medication use

Strategies followed by organization for managing medication use includes use of generic drugs, therapeutic interchange, guided-use policies, clinical practice guidelines, and policies for off-label prescribing and the use of research pharmaceuticals. Medication Use Evaluation (MUE) is also important in managing medication use.<sup>[7]</sup>

## Advantages of hospital formulary

The advantages of hospital formulary are:

1. It provides the practitioner with approved and efficacious medicines to treat disease of the region or country.
2. Hospital formulary reduces the inventory cost of the drugs. It regulates the number of medicines by improving the procurement and inventory management.
3. It improves the quality assurance and easier dispensing.
4. It gives stress on medicine information and focused on patient's education efforts.
5. It removes the irrational combinations of drugs and also improves adverse drug reaction management.<sup>[8]</sup>

## Disadvantages of hospital formulary

1. The hospital formulary system deprives the physician of the right and prerogative to prescribing and obtained the brand of his choice.
2. 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.
3. The system may allow buying inferior quality of drugs and it may also not reduce the cost of drug dispensed to the patient or the third party payer.

## What are the hurdles in implementing formulary system in India?

The lack of resources such as adequate drug information, proper guidelines, transparency in functioning of regulatory bodies and pharmaceutical companies, lack of interest among medical practitioners, understaffing in majority of hospitals are the some basic hindrances in implementing hospital formulary system in India.

For Indian hospitals to have effective formulary system, the government bodies like CDSCO have to be made more efficient like other international agencies like FDA and Health Canada. For now medical practitioners depend on medical representative's information about drugs, which is a commercial source of drug information and cannot be completely relied upon. The detailed monographs and other authentic information pertaining to the drugs available in India should be made available on website maintained by government. Such information should also be updated timely. Pharmaceutical companies should be made more accountable for the information submitted by them in the public domain. The drug licensing procedure should be made more transparent so that irrational drugs particularly the fixed dose combination are checked. Audits and inspections in market should be done to control availability of counterfeit and spurious drugs.

Understaffing and poor training of hospital and pharmacy personnel is another issue to be dealt with. Moreover the doctor to patient ratio is too low in India that contributes to lack of time and interest among practitioners to indulge in hospital formulary system.

It is difficult to have hospital formulary system in India until it is made mandatory by the government in all public and private hospitals. Guidelines need to be formulated for initiating and maintaining hospital formulary system. Government agencies should inspect the hospital formulary system from time to time.

Once these above mentioned measures are in place, there are better chances of having functional formulary system in India.

## HOW INDIA WILL BENEFIT FROM IT?

### Check on spurious, sub-standard drugs and irrational drugs

India is one of the major contributors to international market of spurious drugs. About 12-25% of drugs manufactured in India are reported to be substandard, contaminated or counterfeit. PSM. Recently in March 2013, CDSCO declared 1091 formulations of 344 fixed dose combinations irrational but due to legal aid taken by the pharmaceutical companies, CDSCO was not able to ban these irrational FDCs. Such drugs could be harmful to human health and there free access is not a positive move towards human health. Presence of hospital formulary can check the dispensing of such irrational, substandard and spurious drugs to the patients.

### Promotion of dispensing of generic drugs

As per recent directive of Medical Council of India under code of medical ethics 1.5 which states "Every physician should as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs".<sup>[9,10]</sup> In India, even the generic drugs are sold under Brand names given by the manufacturer, which leads to confusion among the generic and brand drugs not just among the consumers but also the prescribers. The establishment of hospital formulary system will promote the prescribing of proper generic drugs.

### Easy access to essential medicines

Indian pharmaceutical market faces a grave scarcity of essential medicines. Tamil Nadu has made efforts to ensure that essential medicines are available free at cost at government hospitals. This has helped to check the substandard, spurious and expensive drugs. This sets an example that if government adequately checks the procurement, storage and distribution of drugs then the health facilities can be improved.<sup>[11]</sup> This step of having access to essential medicine is one of the essential elements of hospital formulary system that will contribute to improved human health at lesser price.

### Availability of cost effective drugs

Numerous drugs are available under numerous brand names in India. Consumers are at the mercy of the pharmacist that which drug is dispensed to them. Since the medicines which are overpriced outnumber those that are cost-effective, thus the consumers often end of paying more. Hospital formulary will ensure availability of cost effective drugs.

## Reduction in disease burden

As per WHO Global Disease Burden Data 2012, India is a major contributor to global disease burden. One of the causes of it is poor availability of right medication at right cost. Although no clear data is available to show how many counterfeit medications are circulating in the India market but Indian pharmaceutical market is crippled with presence of counterfeit drugs.<sup>[12,13]</sup>

## CONCLUSION

A formulary system is the multidisciplinary, evidence-based process employed by health organization to select and use medications that offer the best therapeutic outcomes while minimizing potential risks and cost patients. If it is implemented with full force it is not only helpful to doctors in decision making but also cuts medication costs for the patients. In countries like India where use of generic drugs is being promoted to reduce the health care burden on patients, formulary system can serve the purpose. Additionally it also ensures that high quality medicines are available to patients. All these will eventually lead to effective health management and decreased disease burden. Thus strong appeal is made to the health authorities to make hospital formulary mandatory in all public and private hospitals of India and a highly effective system should be available to keep a check on their functioning.

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