Status of Essential Medicines in India

Vijay Thawani, Mahesh Kumar Jain*

Department of Pharmacology, People's Institute of Medical Sciences & Research Centre, Bhanpur, Bhopal

INTRODUCTION

The health care system consumes nearly 50% of the health budget on medicines in developing economies, increasing the poverty level in the societies, while developed economies are trying to reduce their health expenditure by embracing the concept of essential medicine (EM).[1] Limited range of carefully selected EMs aid better health care, better medicine management (because the medicine number is manageable), improved prescription monitoring and more rational prescribing, improved medicine supply, improved access to medicines, and cost effectiveness. The EM concept leads to decrease in the medicine price to the patients, and thus are important for resource limited countries.

Number of newly approved or in the process of approval medicines are increasing exponentially every year, out of which two thirds are replica or "me too" medicines and therefore not essential.[1,2] According to Alma Ata declaration a healthy nation is beyond the imagination if the availability of necessary medicines is not the part of health care systems. It is one of the eight essential components of Alma Ata declaration of 1978.[3,4] The WHO has defined EM as "those that satisfy the priority health care needs of the population. They should therefore be available at all times in adequate amount and in appropriate dosage forms, at a price the community can afford".[5]

HISTORY

Tanzania was the first country to introduce EM concept in 1970. Five years later in 1975, on the request of World Health Assembly, the WHO was asked to assist its member states in EM. In 1977, WHO published the first edition of model list of EM.[6] After revisions and amendments WHO published its 20th edition in March 2017 (amended in August 2017).[7] The WHO moved one step ahead and also published WHO model list of EM for children (EMLc), sixth edition of which was published in march 2017 (amended in August 2017).[8]

INDIAN CONTEXT

The Indian National List of EM (NLEM) was based on three important characteristics of

*Corresponding Author: Dr. Mahesh Kumar Jain, Assistant Professor, Department of Pharmacology, People's Institute of Medical Sciences & Research Centre, Bhanpur, Bhopal - 462037. Email: drmaheshkumarjain01@gmail.com

reducing cost, ensuring highest safety and efficacy to supplement the health need in the country for general population. Additionally, it promotes the rational use of medicines. The first NLEM was published in 1996, which was then revised in 2003, 20119 and 2015.[10] In 2017, new core committee was constituted to review and revise the NLEM, vide Ministry of Health & Family Welfare (MoH&FW) order F No. X.11035/923/2017-DRS, dated 03 July 2018. The Indian Academy of Paediatrics (IAP) introduced first List of EM (LEM) for children of India in 2011.[11] States were directed to prepare their own list of EM as per their need. Tamil Nadu and Delhi promoted the concept of EM since 1994.[12,13]

PROCEDURE TO INCLUDE A NEW MEDICINE ON THE WHO MODEL LIST OF EM

This is a multifactorial process in which identification of the health care needs for medicines is the first and foremost. Others being, the developmental phase of new medicines in clinical trials, regulatory approval in number of countries, presence of more effective and highly efficacious medicines in the market, report of the post marketing surveillance, and price indication for public sector use. All these are reviewed by WHO disease programme and finally WHO identifies comparative effectiveness and safety in real-life situations, comparative cost-effectiveness and public health relevance. After this the medicine is included in the treatment guidelines and following submission to WHO expert committee on EM and when it matches all the criteria, it is included in WHO model list.[14] A new committee has been constituted by WHO for 21st revision of WHO model list of EM.[15]

WHO criteria to guide selection of an EM

The WHO selects the medicine for inclusion in EML from the clinical data available globally on safety and efficacy of medicines, treatment facilities, pattern of the disease, genetic, demographic factors and financial resources. When more options of medicines exist, choice is made on the basis of relative efficacy, safety, quality, price and availability. Cost benefit ratio is a major consideration. Up gradation and reviewing of the EML is a regular, continuing process. Choice on EML is influenced by pharmacokinetics, manufacturing, shelf life and storage needed. EML contains single compound and rarely fixed dose combinations (FDCs), if necessary and when combination offers a proven advantage. Not only should the unit cost of the medicine but also the total cost of the treatment be considered.[14] Evidence based medicine is also one of the major contributors in the selection of drug for EM.

The Impact of EM

The EM saves lives and improves health by closing the gap between the potential that EM have to offer and the reality for millions of people, particularly the marginalized to whom the medicines are unavailable, unaffordable, unsafe or improperly used. Effective medicine treatment now exists for most leading infectious diseases, non-communicable diseases (NCDs) such as ischemic heart disease (IHD) and cardio vascular diseases (CVD). The EM save lives and reduce suffering. The EM increases the credibility of a health system. Effective and transparent drug procurement increases

the confidence of Governments. Medicines are the second largest Government public health expenditure and in low- and middle-income countries (LIC and MIC) represent the largest out of the pocket household health expenditure, hence have great economic impact.

NOTABLE CHANGES IN THE WHO EML

Branded pharmaceutical preparations have been replaced with generic medicines. Comparison of benefit and safety of specific medicines lead to evolution of more national selection process. It has changed the evolution, from being experience based to evidence-based inclusion in the list.[5]

THE CRITERIA FOR INCLUSION OF A MEDICINE IN NLEM

The medicine to be included in NLEM should be approved or licensed in India. It should be useful in a disease which is public health concern in the nation. Medicine should have proven efficacy and safety profile based on valid scientific evidence. Utmost important is its cost effectiveness. It should be aligned with the current standard treatment guidelines (STG) for the disease. It must be stable under the storage conditions. Price of total treatment needs to be considered and not the unit price of a medicine.[6]

CRITERIA FOR DELETION FROM NLEM

If the medicine is banned in India due to any reason, or its safety profile has changed it is deleted from NLEM. More efficacious medicine, with better safety profile and more cost effectiveness has now become available, then the previous one needs deletion. Deletion is warranted if the disease burden for which it was recommended is no longer a health concern in the country. In case of antimicrobial agents (AMAs) the deletion is justified if the resistance has rendered the AMA ineffective.[6]

POINTS OF CONSIDERATION FOR PREPARING NLEM

Essentiality: A medicine might be necessary for specific condition or disease but may not be essential because this has to be viewed in the context of the population as a whole to match the definition of EM. This does not exclude the medicine because the medicine is not essential.

Disease burden: The existing / emerging disease burden is an important point for consideration. Medicines to be used in highly prevalent and emerging diseases should be given preference to control / prevent these diseases.

Efficacy and Safety: Medicines which qualifies to be an EM should have an undisputable efficacy and highest safety margin.

Cost effectiveness: For the LIC and MIC this is a major determinant for selecting an EM. If there are two medicines with equal efficacy and safety, the one which costs less should be chosen without compromise in quality. Overall cost of treatment should be considered instead of price of individual medicine.

Formulation and feasibility of storage: The EM should be available in a form which has optimal quality and offers stable shelf life under recommended storage conditions.

FDCs and sales turnover: Single drug is preferred mostly, whereas FDCs are preferred where the resistance prevention and compliance are improved e.g. medicines meant for HIV-AIDS, Malaria, Tuberculosis. The FDCs should be rational. Sales turnover should never guide the inclusion of medicines in the EML.

Hierarchy of health care structure: In India health care facilities are divided on the basis of available resources into primary, secondary, tertiary and super specialty. Each center manages patients according to the availability of the equipment, medicines, specialist etc. Therefore, the need of EM differs for different healthcare setups.[6]

ADVANTAGES OF NLEM

It promotes safe and effective treatment, increases awareness and promotion of Rational Use of Medicines (RUM), and succeeds in optimization of resources. It helps us to prepare EML as per geographic distribution of diseases. It enables maintaining EM stock through manageable procurement and can be utilized in public sector also. It helps in reimbursement of the cost of medicines by insurance companies / organizations to its employees. It is useful for teaching and training of health care professionals.

IMPLEMENTATION OF EM IN INDIA

Initiatives were taken at Government of India (GOI) as well as at pharmaceutical industry level which introduced a policy aimed at increasing the availability of EM at affordable prices. In 2011 GOI proposed increase in number of medicines from initial 74 to 348 under the purview of Pharmaceutical Pricing Policy. In 2012, commonly used medicines increased to 642, in 27 therapeutic areas. It established a balance between production cost, profitability and affordability of the medicines for consumers intensifying the initiatives to ensure availability and affordability of medicines in less affluent markets. “Access to Medicine Index” 2012, clearly indicates medicine makers response to rising social pressure to provide affordable medicines.[1]

NEGATIVE REPERCUSSIONS

The GOI actions ironically have an adverse impact on their own policies and implementation. Pharmaceutical companies operating in India are against new GOI policies. Price capped medicines become unprofitable for manufacturers. Hence pharmaceutical companies discontinue the availability of such medicines in the country. “Such a scenario renders price-control-efforts counter-productive”. Small domestic generic medicine manufacturers raise the prices of their low-cost medicines closer to the price cap level and increase in the average price of medicines.

CONCLUSION

Implementing the concept of the NLEM is the dire need of the hour. It needs to be reviewed periodically and sincerely. Individual states can modify their NLEM as per the needs. It needs to be well understood that NLEM saves money for optimal utilization. No lip sympathy but critical implementation is required.

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