

SECTION – I

CHAPTER 1

ESSENTIAL MEDICINES

Introduction

In general, essential medicines are in need of each developed and developing countries to fulfil health care needs of majority of the populations. Essential medicines are defined by the WHO as *"those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford"*. In other words, essential medicines are the medicines that address the priority health care requirements of a given population, are life-saving and affordable to the consumer as well as health care professionals (Fig. 1.1). Today 1/3rd of world population and 50% population of developing countries are lacking access to essential drugs. Hence, the concept underlying the use of essential medicines is that despite the availability of a humongous number of medicines only a limited number of medicines are very much essential, important, indispensable and necessary with respect to the requirements of a given population. Moreover the careful selection of a limited number of medicines lead to complete and detailed drug information, better management of medicines, better ADR monitoring, rational drug use, better supply of drugs with good quality at affordable costs and ease of storage, distribution and dispensing leading to better health care. The term 'essential drug' was coined by the WHO and currently the term 'essential medicines list' is being used.

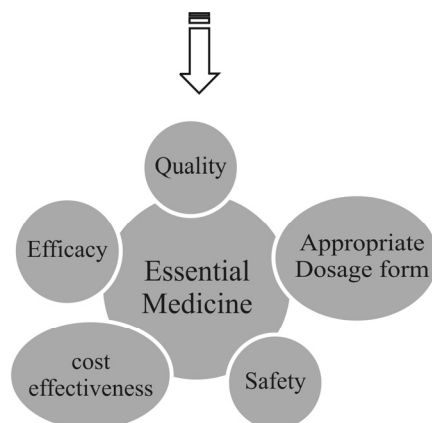
Disease Burden

Fig. 1.1 Pre-requisites for essential medicine.

Essential Medicines List (EML)

The first EML of WHO was created in 1977 which included 208 medicines; aimed to provide safe and effective treatment against the global burden of disease at that time. The list is revised by a committee of independent experts every two years to reflect new health challenges, pharmaceutical developments and changing resistance patterns. The current versions are the 18th WHO Essential Medicines List and the 4th WHO Essential Medicines List for Children updated in April 2013 which address most global priority conditions, including malaria, HIV/AIDS, tuberculosis, reproductive health and, increasingly, chronic diseases such as cancer and diabetes. This model list serves as a guide for the developing national and institutional essential medicines lists taking into consideration their local priorities.

The EML published by WHO contains a core list and a complementary list. According to the WHO, core list presents a list of minimum medicine needs for a basic health-care system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. While the complementary list presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed. In case of doubt, medicines may also be listed as complementary on the basis of consistent higher costs or less attractive cost effectiveness in a variety of settings. The symbol [c] placed next to the complementary list signifies that the medicine(s) require(s) specialist diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training for their use in children while the [c] symbol placed next to an individual medicine or strength of medicine signifies that there is a specific indication for restricting its use to children. Other symbol used in the list is

the square box symbol (□) which primarily intends to indicate similar clinical performance within a pharmacological class. And the symbol [a] indicates that there is an age or weight restriction on use of the medicine.

Aim of Essential Medicines List (EML)

Principally, medicines in EML should cover a range of medical conditions from symptomatic relief, public health care, management of infections as well as for “life threatening” - emergency situations and for critical care. Therefore, categorising EML serves as a valuable tool to determine the drugs which are the most needed for safe and effective treatment. Moreover, it aids in the selection of quality assured pharmaceuticals so as to provide the quality health care and safe use.

EML helps in managing the purchase and distribution of medicines thereby improving the cost-effectiveness of health care. It brings transparency in healthcare system.

Selection Criteria of Essential Medicines

An independent expert committee is held responsible for selection of essential medicines. The main focus of the committee is to make such a list which can cover the large part of the population in terms of economical, safety and efficacy, with due regard to disease prevalence. Selection of essential medicine is a stepwise process and the important steps are as follows:

1. Applications for inclusions, changes or deletions get submitted.
2. Secretary of the expert committee review the application.
3. Assessments are made of the data on comparative economical, safety and efficacy.
4. An expert invited to formulate a draft recommendation for the committee, also summarizes the outcome of the assessments.
5. The relevant departments and experts advisory panels review the draft recommendation and proposed text of the model formulary.
6. The comments get reviewed and expert committee finally get the text for consideration which forward the application as a recommendation to the head of Institution.
7. After the meeting and the final approval by the head of Institution, the recommended changes to the model list, Translations of the report are published as soon as possible for the benefit of the population.

Factors on which the selection of essential medicines depends:

- Disease prevalence
- Benefit/risk ratio in terms of efficacy and safety
- Relative cost-effectiveness of medicines and treatment
- For two or more therapeutically equivalent drugs, priority given to drug with most favourable pharmacokinetic properties or its availability

6 Advanced Pharmacology

- Single compounds preferred over fixed dose combinations
- Fixed dose combinations selected if it shows advantage over using different doses individually

However, it is noteworthy that no single factor can govern the selection of a medicine and all factors are equally important while selecting essential medicines. In addition, the choice of essential medicines is a continuous process and requires regular revision due to ever changing priorities of public health activities and continuous development in the field of pharmacology and pharmaceuticals. Information on cost and cost-effectiveness should preferably refer to average generic world market prices as listed in the *International Drug Price Indicator Guide*, provided by WHO and maintained by Management Sciences for Health. If this information is not available, other international sources, such as the WHO, UNICEF and *Médecins sans Frontières* price information service, can be used. Always cost analyses should specify the source of the price information selected.

Number of Drugs in EML

The number of drugs present in the EML is maintained in such a fashion that EML should not be bulky enough, so that, it will be impossible for the hospitals to keep all the drugs listed in EML. During the selection process, ideally the best one in each class is selected, so as to avoid confusion originating due to multiplicity. However, in order to achieve flexibility in procurement generally up to 2-3 alternatives are listed.

Advantages of EML

The WHO's model essential medicines list plays a crucial role in placing access to essential drugs as a national and international agenda. In addition, it offers several advantages which are as follows:

- Serve as a tool for countries to identify and choose their drug priorities
- Promote rational drug use
- Development of standard protocols and rational prescribing policies
- Provide latest unbiased clinical information on essential drugs like dosages, usage, contraindications and adverse effects
- Better management of medicines, complete and detailed drug information, better ADR monitoring and ease of storage, distribution and dispensing

Global Status of Essential Medicines

There exists great variation among different countries in terms of prevalence of disease, economy of the country, drug policies etc., so the EML is intended to be flexible and adaptable accordingly. Thus, it is the national responsibility to adapt the model list as per local requirements.

The concept of essential medicines is rising and advanced. EML made it important to frequently update medicine's selection in order to reflect new therapeutic options and changing therapeutic needs which further enhance drug quality. It also incorporates the need for continued development of better medicines with respect to emerging diseases and resistance. In last 30 years period, the EML has led to a world acceptance of the concept by governments and healthcare suppliers worldwide as a robust means that to push health equity even though it was not designed as global standard. Currently, over 150 countries have published their official essential medicines lists. Many major international agencies like UNICEF, UNHCR, UNFPA and IDA as well as non-governmental organizations and international non-profit supply agencies have based their catalogue on the WHO Model List.

It has been estimated that 60-80% of the population in developing nations, specifically in rural areas, still deprived of the essential drugs and WHO highlighted that, about 2,000 million of people do not have even access to essential medicines. Thus, lack of access to essential medicines is a major concern for many developing countries. The current international trade agreement leads to increased prices in these countries which ultimately deprived the population from getting essential medicines. Poor status of research and development (R&D) in the developing economies is another reason for inaccessibility of essential drugs. Other underlying factors for poor accessibility of essential medicines are poor medicine supply and distribution systems and insufficient health facilities and staff. To increase the availability of essential medicines in developing countries an international campaign-The Campaign for Access to Essential Medicines has been started by Medecins Sans Frontieres (MSF)- an international campaign has been started which aim to stimulate and enhance research and development in the field of new diseases that primarily affect the poor, aid in lowering the prices of existing drugs, vaccines and diagnostic tests, and overcome other barriers that prevent patients getting the treatment they need. It is paramount that policies which favour access to essential drugs should be enhanced by promoting research and innovation in areas relevant to developing countries, and those which provide safeguards to ensure affordable access to essential medicines. Effective utilization of all available flexibilities in the TRIPS Agreement, greater integration of traditional medicine systems, building capacity for local manufacture and price control policies are some of the pivotal steps that should be included while making policies. Rebate for generic drug prescribing, appropriate and cost effective prescribing practices and consumer awareness should be the important components of policies for essential medicines. In order to implement the concept of essential medicine, the co-ordination and co-operation at both global and local level is necessary. Local co-operation can widen affordable access to essential drugs. Development of technical expertise on utilizing available flexibilities in trade agreements such as TRIPS; enhancing research and manufacturing capacity of countries in the region; developing technical and infrastructural capability for regulating medicines; and establishing regional procurement systems for pharmaceuticals are the important aspects of local co-operation.

Essential Medicines Library

As the concept of EML is getting strengthen WHO has developed a web based essential medicines library which provide access to the information regarding the evidence for selection such as the reasons for inclusion of a drug, the most important systematic reviews, and important references, summaries of relevant WHO clinical guidelines and price information. WHO model formulary and information on nomenclature and quality assurance standards is also provided (Fig. 1.2). This WHO Essential Medicines Web Library is currently based on the 16th WHO Model List of Essential Medicines and the 2nd WHO Model List of Essential Medicines for Children. Its aim is to facilitate the work of national, hospital and institutional essential medicines selection committees. WHO Essential Medicines internet Library is presently supported the 16th World Health Organization Model List of Essential Medicines and also 2nd World Health Organization Model List of Essential Medicines for children. To facilitate the work of national, hospital and institutional essential medicines choice committees are some of its main objectives.

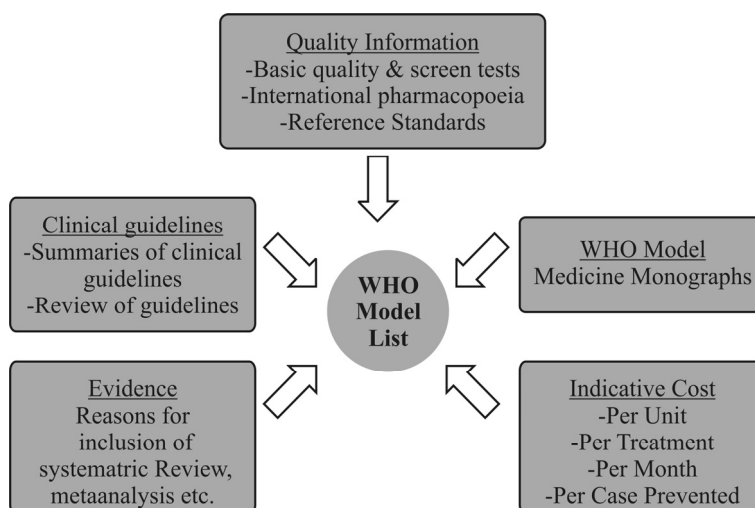


Fig. 1.2 Components of WHO essential medicines list.

Emergency Essential Medicines

To facilitate the emergency response arising from various situations like natural, political and economic disasters, the WHO has designed 'The Interagency Emergency Health Kit 2006' (IEHK 2006). Its aim is to encourage the standardization of medicines and medical supplies needed in emergencies to allow efficient and effective response with medicines and medical devices using standard, pre-packed kits to meet priority health needs in emergencies. IEHK 2006 is the third edition of the WHO Emergency Health Kit which was the first such kit when it was launched in 1990. The second kit, 'The New

Emergency Health Kit 98' was revised and further harmonized by the WHO in collaboration with a large number of international and non-governmental agencies. The next version of the "Interagency Emergency Health Kit" is due in 2010. The updated third edition provides background information on the composition and use of the emergency health kit. It takes into account the global HIV/AIDS epidemic, the increasing parasite resistance to commonly available anti-malarials and the field experience of agencies using the emergency health kit. IEHK 2006 consists of two different sets of medicines and medical devices, named a *basic unit* and a *supplementary unit*. The basic unit contains essential medicines and medical devices to be used by primary health care workers with limited training. It contains oral and topical medicines, none of which is injectable. The supplementary unit contains medicines and medical devices to be used only by professional health workers or physicians. It is noteworthy that no kit can completely meet the requirements because an ideal kit can only be designed with an exact knowledge of the population characteristics, disease prevalence, morbidity patterns and level of training of those using the kit. However, the concept of emergency health kit is being accepted and adopted by many countries so as to cope with the disastrous situations.

Challenges for Essential Medicines Concept

Despite many great developments and achievements in the field, still some pending major obstacles are unfair financing, high prices, unreliable systems for procurement, poor quality and the irrational use of medicines. Thus, to successfully implement the concept of essential medicines following actions should be taken on the priority basis: fair financing, affordable prices, reliable systems for procurement and distribution, effective regulation of quality and rational use of medicine.

Essential Medicine List of India

The National list of essential medicines (NLEM) is the EML of India and made in the objective of WHO i.e., by considering the 3 important aspects i.e., cost, safety and efficacy and also promote prescription by generic names. The list prepared under the Ministry of Health & Family Welfare (MOHFW), Government of India who is responsible to ensure the quality healthcare system by promoting rational use of medicines in India. The first EML was prepared and released in 1996. Further, list was revised in 2003 with 74 bulk drugs and next in 2010 and the list released in 2011. In 2013, MOHFW have direction from the Supreme Court and other alliance to revise 2011 NLEM in the ordnance of new pharmaceutical pricing policy (NPPP). The NLEM is one of the key instruments in Indian healthcare delivery system includes accessible, affordable quality medicine at all the primary, secondary and tertiary levels of healthcare.

Conclusion

Model List of Essential Medicines is a process, model product and public health tool as a limited range of carefully selected medicines which cater for most health care needs especially in developing countries. WHO EML acts as a guideline as well as an outline to select proper advantageous medicine for the targeted population. Sometime, the Essential Medicines Library of WHO serves as an informative database for all member states, international organisations, drugs and therapeutic committees and health insurance organisations. However, despite some promising developments, much work remains to be done to ensure the successful implementation of the concept in different countries, since developing countries still need a good EML for their population.

Suggested Readings

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