

The Selection of Essential Medicines



June 2002
World Health Organization
Geneva

The concept of essential medicines

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.

After immunization for common childhood illnesses, appropriate use of essential medicines is one of the

most cost-effective components of modern health care. The selection of essential medicines is one of the core principles of a national drug policy because it helps to set priorities for all aspects of the pharmaceutical system. This is a global concept which can be applied in any country, in private and public sectors and at different levels of the health care system.

Advantages

Careful selection of a limited range of essential medicines results in a higher quality of care, better management of medicines (including improved quality of prescribed medicines), and more cost-effective use of health resources. Numerous studies have documented the impact of clinical guidelines and lists of essential medicines on the availability and proper use of medicines within health care systems. All of this is even more important in resource-poor settings where the availability of drugs in the public sector is often erratic. Under such circumstances measures to ensure a regular supply of essential medicines will result in real health gains and in increased public confidence in the health services.

A global concept

By the end of 1999, 156 countries had official essential medicines lists, of which 127 had been updated in the previous five years (Figure 1). Most countries have national lists and some have provincial or state lists as well. National lists of essential medicines usually relate closely to national guidelines for clinical health care practice which are used for the training and supervision of health workers. No public sector or health insurance system can afford to supply or reimburse all medicines that are available on the market. Therefore, lists of essential medicines also guide the procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations, and local medicine production. Many international organizations, including UNICEF and UNHCR, as well as

Box 1 Key policy issues

- ❖ Access to essential medicines depends on four factors: rational selection, affordable prices, sustainable financing and reliable health systems.
- ❖ The selection of essential medicines, preferably linked to standard clinical guidelines, is a crucial step in ensuring access to health care and in promoting rational use by health professionals and consumers.
- ❖ Official adoption of the essential medicines concept identifies priorities for government involvement in the pharmaceutical sector in general, and for medicine supply in the public sector and medicine benefits as part of health insurance in particular.
- ❖ Establishment of systematic and transparent procedures for defining the national list(s) of essential medicines, on the basis of evidence-based treatment guidelines.



non-governmental organizations and international non-profit supply agencies, have adopted the essential medicines concept for their supply systems. Several developed countries also use the same approach (Box 3).

The essential medicines concept is relevant to the challenges of today

The emergence of new epidemics such as HIV/AIDS, widespread increase in infectious diseases such as malaria and tuberculosis, the emergence of anti-microbial resistance and an increase of chronic diseases in many parts of the world have made the essential medicines concept more relevant than ever. In many developed countries total medicine expenditure is rising by 10–18% per year, much faster than the consumer price index or the annual growth in GNP. This rise is mostly linked to the introduction of newer higher priced medicines and to an overall increase in consumption. In developing countries, newer combination anti-malarial medicines may be 30–200 times more expensive than chloroquine; medicines to treat multi-drug resistant tuberculosis may cost 20–30 times more than the usual DOTS treatment; and

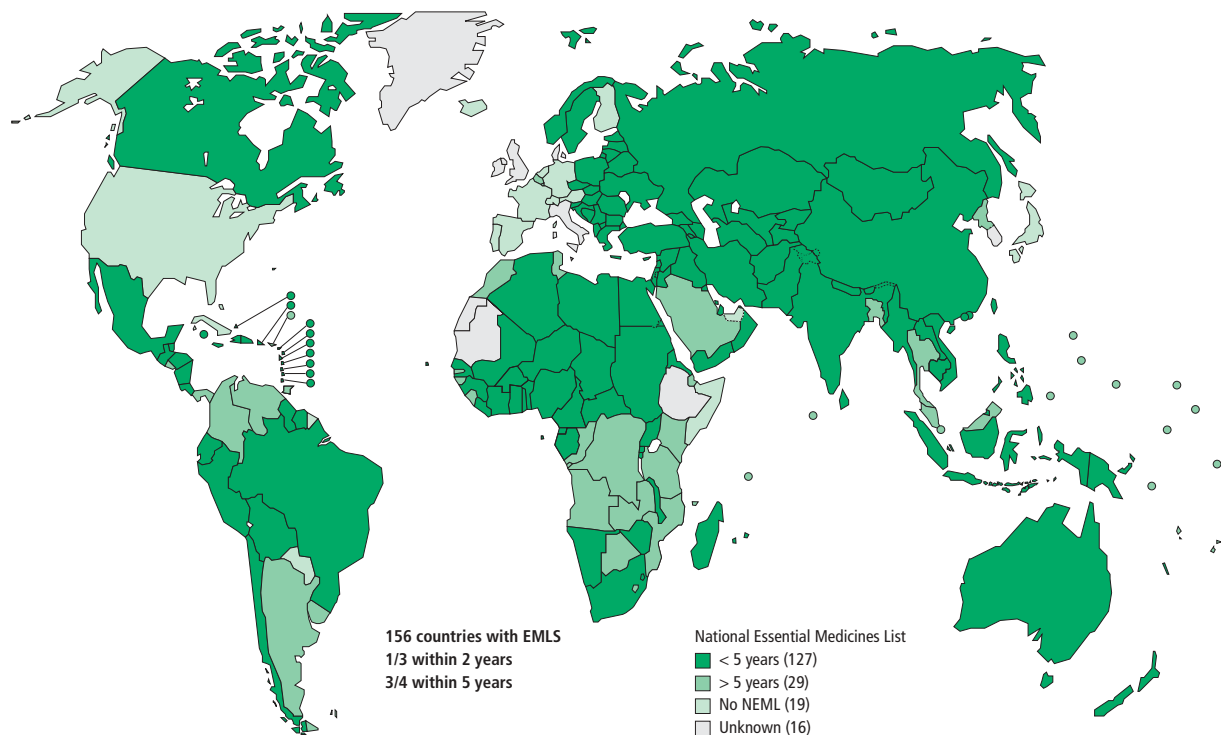
Box 2 Practical applications of the essential medicines concept

- ✦ Basic and in-service training of health care providers
- ✦ Public-sector procurement and distribution
- ✦ Medicine benefits as part of health insurance
- ✦ Drug donations and international aid
- ✦ Monitoring systems on availability and pricing
- ✦ Public education.

treatment of HIV/AIDS with anti-retroviral medicines may cost between \$400–2500 per year.

Most medicine budgets in developing countries are below \$30 per person per year, with 38 countries having less than \$2 per person per year. Hence, it is vital that countries work both to increase drug financing within overall health financing and that they apply the essential medicines concept to achieve the best possible health outcomes within available resources.

Figure 1 Countries with a national essential medicines list* (EML)



* Countries with an official selective list for training, supply, reimbursement. Some countries have state/provincial lists instead of or in addition to national lists. Source: WHO, World Drug Situation Survey, 1999

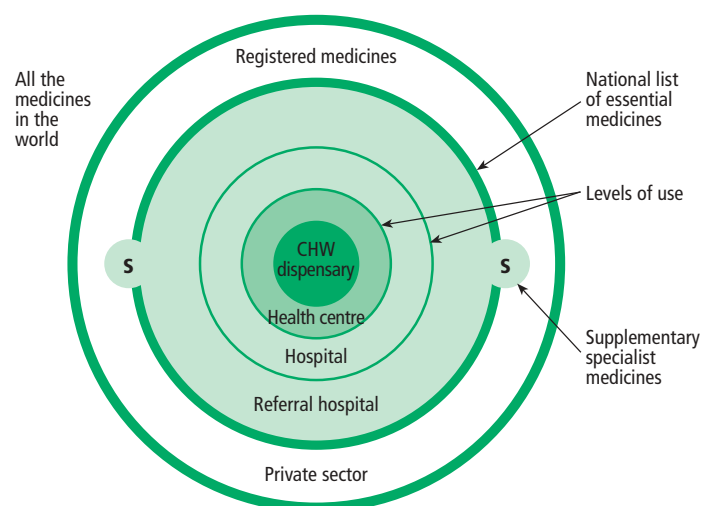
Box 3 Example of the essential medicines concept in a developed country

In Australia the Pharmaceutical Benefit Scheme ensures full or partial reimbursement of over 80% of all medicines prescribed in primary care settings. Over the years the scheme has developed a very systematic procedure to decide which medicines will be reimbursed, including systematic reviews of efficacy, safety and comparative cost-effectiveness. As a result, only around 650 active ingredients in around 1100 dosage forms (1600 products) are reimbursed under the scheme.

Selection of essential medicines

The selection of essential medicines is a two-step process. First, market approval of a pharmaceutical product is usually granted on the basis of efficacy, safety and quality, and rarely on the basis of a comparison with other products already on the market, or cost. This regulatory decision defines the availability of a medicine in the country. In addition, most public drug procurement and insurance schemes have mechanisms to limit procurement or reimbursements of drug costs. For these decisions an evaluation process is necessary, based on comparison between various drug products, and on considerations of value for money. This second step leads to a list of essential medicines. A list of essential medicines is best developed for different levels of care, and on the basis of

Figure 2 The essential medicines target: the national or institutional list of essential medicines is a subset of registered medicines, divided by level of care



standard clinical guidelines for common diseases and complaints that can and should be diagnosed and treated at that level.

Selection criteria

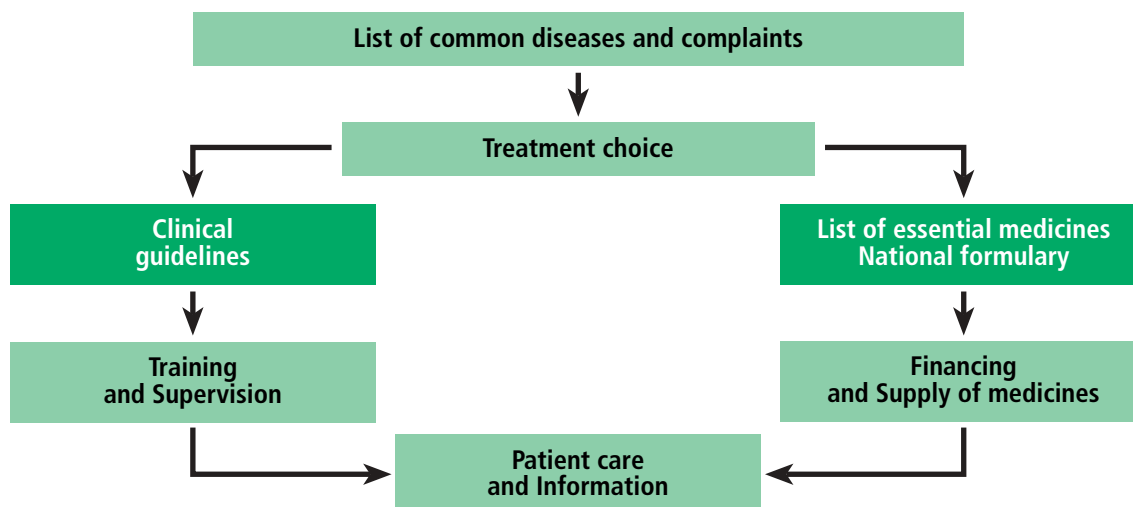
Which treatment is recommended and which medicines are selected depend on many factors, such as the pattern of prevalent diseases, treatment facilities, the training and experience of available personnel, financial resources, and genetic, demographic and environmental factors. The following criteria are used by the WHO Expert Committee on the Selection and Use of Essential Medicines:

- Only medicines for which sound and adequate evidence of efficacy and safety in a variety of settings is available should be selected
- Relative cost-effectiveness is a major consideration for choosing medicines within the same therapeutic category. In comparisons between medicines, the total cost of the treatment – not only the unit cost of the medicine – must be considered, and be compared with its efficacy
- In some cases, the choice may also be influenced by other factors such as pharmacokinetic properties or by local considerations such as the availability of facilities for manufacture or storage
- Each medicine selected must be available in a form in which adequate quality, including bioavailability, can be ensured; its stability under the anticipated conditions of storage and use must be determined
- Most essential medicines should be formulated as single compounds. Fixed dose combination products are selected only when the combination has a proven advantage in therapeutic effect, safety, adherence or in decreasing the emergence of drug resistance in malaria, tuberculosis and HIV/AIDS.

How to develop a national list of essential medicines

The process by which medicines are selected is critical. An essential medicines list which is imposed from above will not reflect the needs of the users or be accepted by them. It is therefore very important that the process be consultative and transparent, that the selection criteria be explicit, that the selection of the medicines be linked to evidence-based standard clinical guidelines, that the clinical guidelines and the list be divided into levels of care, and that both are regularly reviewed and updated. A review of the clinical guidelines and the list should be carried out

Figure 3 The list of common health problems guides the formulation of clinical guidelines, the list of essential medicines, training, financing, and supply – leading to improved patient care



at least every second year, and their use and the impact should be monitored.

A standing committee should be appointed to give technical advice. This committee may include people from different fields, such as medicine, nursing, pharmacology, pharmacy, public health, consumer affairs and health workers at grass-roots level. Formal and informal consultations may be organized with interested parties, including representatives of professional bodies, pharmaceutical manufacturers, consumer organizations and the government budget and finance group. However, the final medicines selection by the committee members should be carried out independently.

An important principle that needs to be accepted by the committee is that not all evidence is equally strong. For example, the result of a systematic review of clinical trials carries more weight than the result of an observational study without controls, and much more than personal experiences of individual experts. The strength of the evidence defines the strength of the recommendation.

How to implement a national list of essential medicines

When the clinical guidelines and the essential medicines list are finalized and printed, they should be launched and made widely available. In case of an update it may be useful to issue an information leaflet which summarizes the changes or to make the changes known through a newsletter or drug bulletin. The intended use, legitimacy and authority

Box 4 Key factors for successful implementation of an essential medicines list

- ❖ Establish a transparent process for creating and updating the list of essential medicines, provide a voice for key stakeholders, but ensure a scientific, evidence-based process
- ❖ Link the essential medicines list to clinical guidelines for diagnosis and treatment, involving both specialists and primary care providers
- ❖ Actively engage support from medical opinion leaders, senior clinicians, training institutions, professional organizations, non-governmental organizations and the public
- ❖ Make the list of essential medicines, formulary manuals and clinical guidelines widely available in all health care facilities and to all health care providers in both printed and electronic versions
- ❖ Consider launching new or revised lists with the involvement of government officials, such as the minister of health or the president, and intensive press coverage
- ❖ Make clear the specific legal or administrative authority of the essential medicines list for training, procurement, reimbursement and public information
- ❖ Consider establishing an administrative or budgetary “safety valve” for the limited supply and use of non-listed medicines, e.g. by certain specialist units
- ❖ Regularly update the list so that it reflects therapeutic advances and changes in cost, resistance patterns and public health relevance

of the list should be clear to all. Key factors for successful implementation are listed in Box 4.

Box 5 Access to essential medicines is fundamental to human rights

- ❖ The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition¹.
- ❖ Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services².
- ❖ Governments and the international community have an obligation to see the right to health progressively realized, which includes the responsibility for prevention, treatment and control of disease; and the creation of conditions to ensure access to health facilities, goods and services³.
- ❖ Access to goods and services include – of course – the provision of essential medicines necessary for the prevention and treatment of prevalent diseases⁴.

Sources:

¹ Constitution of the World Health Organization, including amendments adopted up to 31/12/2000. *Basic Documents, Forty-third edition, Geneva, 2001.*

² Universal Declaration of Human Rights. Adopted by the General Assembly of the United Nations on 10 December 1948.

³ United Nations Economic and Social Council. *International Covenant on Economic, Social and Cultural Rights. Adopted 16 December 1966.*

⁴ United Nations Economic and Social Council. *Committee on Economic, Social and Cultural Rights. 22nd session, Geneva 25 April – 12 May 2000. Substantive issues arising in the implementation of the International Covenant on Economic, Social and Cultural Rights. General Comment No. 14.*

Reference materials available from WHO

The WHO Model List of Essential Medicines

The WHO Model List has been updated every two years since 1977. The Model List of 2002 contains 325 active ingredients and is divided into a main list and a complementary list. Medicines are specified by international nonproprietary name (INN) or generic name without reference to brand names or specific manufacturers. The Model List represents both a model product and a model process.

As a model product, the WHO Model List aims to identify cost-effective medicines for priority conditions, together with the reasons for their inclusion, linked to evidence-based clinical guidelines and with special emphasis on public health aspects and considerations of value for money.

The procedures for updating the Model List follow the WHO recommended process for developing clinical practice guidelines. Key components are a systematic approach to collecting and reviewing evidence and a transparent development process with several rounds of external review. This process is intended as a model for developing or updating national and institutional clinical guidelines and lists of essential medicines.

WHO Essential Medicines Library

It is important for national or institutional selection committees to have access to information that supports the selection of essential medicines, such as summaries of relevant WHO clinical guidelines, the most important systematic reviews, important references, indicative cost information, information on nomenclature, and quality assurance standards. This information is provided in an expanding *WHO Essential Medicines Library*, available on the WHO web site, on CD-ROM, and in print.

The *WHO Essential Medicines Library* also includes the *WHO Model Formulary*, which presents model formulary information for all medicines on the WHO Model List of Essential Medicines. Besides being a useful reference to individual prescribers it is mainly intended as a reference and starting point for developing national or institutional formularies.

Key documents

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*World Health Organization. *WHO Global Strategy for Containment of Antimicrobial Resistance*. Geneva: World Health Organization, 2001 (document reference WHO/CDS/CSR/DRS/2001.2).

*World Health Organization. *The Selection and Use of Essential Medicines*, including the 12th WHO Model List of Essential Medicines. Geneva: World Health Organization, 2002 (in press)

*World Health Organization. *Procedure to update and disseminate the WHO Model List of Essential Medicines*. Document EB109/8 (Annex 1), Dec 2001.

*World Health Organization. *WHO Model Formulary*. Geneva: World Health Organization, 2002 (in press).

The documents marked with* are also available on <http://www.who.int/medicines/>



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