



The essential medicines concept: selecting a limited range of medicines to improve access to health care and quality of health care

What are essential medicines?

Essential medicines are medicines that meet priority health care needs. They are also medicines for which strong evidence of efficacy and safety exists, and which represent good value for money. They should be available at all times, in sufficient quantity, in appropriate dosage forms, and with adequate information for both prescribers and patients. They should also be of assured quality, and sold at a price that individuals and the community can afford.

The essential medicines concept was defined in 1975, and followed up, in 1977, with the *First WHO Model List of Essential Medicines*. The *Model List* has been updated regularly. It aims to guide countries in their efforts to draw up national essential medicines lists. Countries need their own lists because disease patterns, treatment facilities, levels of human and financial resources all vary. So too do genetic, demographic and environmental factors. In other words, not all medicines selected for one country, will be essential in another country.

A list of essential medicines is an immensely useful tool, for ...

...policy-making

Governments who develop an essential medicines list can define pharmaceutical sector policy more effectively and efficiently. Such a list helps to focus decision-making – for example, regarding procurement, medicines training for health professionals and public information on medicines – on those medicines that have the greatest public health impact. It can also be used as a basis for monitoring medicines availability and medicines pricing.

National essential medicines lists are also helpful for international donors when selecting medicines for donations and international aid.

...selection, procurement, distribution and quality assurance

A limited list of medicines helps to identify priorities for medicines supply in the public sector. This is true whether procurement is undertaken at national or regional level. By minimizing the number of different products that must be stocked, distributed and monitored, economies of

scale are created and greater efficiency can be attained. Moreover, more favourable prices can be negotiated from suppliers when the number of different medicines used to treat a particular clinical problem is limited and larger quantities therefore needed. (Essential medicines are usually available from multiple suppliers.) Last but not least, ensuring medicines quality becomes much easier, since fewer medicines need to be controlled and checked.

...for financing

The number of medicines available within a country can run into tens of thousands. But no public sector or health insurance system can afford to supply or reimburse every medicine. By consulting their country's national essential medicines list, however, health policy-makers can determine where resources can be spent most cost-effectively, including selection of medicine benefits for reimbursement under health insurance schemes. In countries with limited financial resources, attention to selection is especially important.

...for promoting rational use

When a limited list of essential medicines represents prescribers' consensus on the treatment of first choice, quality of care generally improves. Not only do patients receive the treatment of choice, but irrational treatments are avoided. At the same time, prescribers become more familiar with a smaller number of medicines. Such improved effectiveness and efficiency in patient treatment helps to lower health care costs.

...for training of health professionals

By using a selected list of essential medicines as the basis for training in medicines use, optimal training for health professionals can be provided. This may well include training in the principles of good prescribing.

...for providing medicines information and education

Patient education and efforts to promote proper use of medicines by patients are enhanced when centred on specific medicines. Consistent messages from multiple providers, on a limited number of medicines, ensures development of a common understanding of what medicines should be used.

How are essential medicines selected?

The WHO Expert Committee on the Selection and Use of Essential Medicines has developed criteria for updating the *WHO Model List of Essential Medicines*. It recommends that these methods should also be used when creating a national list of essential medicines. (They can be found at: <http://www.who.int/medicines/organization/par/edl/procedures.shtml>). Selection of medicines should follow a consultative and transparent process.

Additionally, medicines selected should be linked to evidence-based standard clinical guidelines for diagnosis and treatment. Those guidelines, together with the list, should be divided into levels of care. For example, treatments that should be prescribed by specialists only should be indicated. The guidelines and list should be reviewed and updated regularly.

How can use of essential medicines lists be encouraged?

Use of a national essential medicines list can be encouraged by:

- active support from medical opinion leaders, senior clinicians, training institutions, professional organizations, nongovernmental organizations and the public
- wide distribution of the national list of essential medicines, formulary manuals and clinical guidelines to all health care facilities, and to all health care teachers, providers and students, in both printed and electronic versions
- public launches of new or revised lists, with the involvement of government officials, such as the minister of health, and intensive press coverage
- regular updating of the list so that it reflects therapeutic advances and changes in cost, resistance patterns and public health relevance.

For further information go to:
<http://www.who.int/medicines/>



WORLD HEALTH ORGANIZATION

The essential medicines concept – from its beginnings until today



The essential medicines concept emerged in response to the need for a tool to optimize selection and use of pharmaceuticals. First defined in 1975, the concept is of increasing relevance in today's world of complex health issues and limited health budgets. The chart presents illustrative, key dates in the concept's evolution and application.

1970s – The need for systematic medicines evaluation and selection becomes urgent. Why? Because few countries have medicines lists, little independent information on medicines and prices is publicly available, and teaching on prescribing is unsystematic. Worst of all, up to 40% of developing country health budgets is being absorbed solely by medicines' expenditure. These factors stimulate development of the essential medicines concept.

1972 Sri Lanka adopts national pharmaceutical policy, illustrating benefits of planned approach to pharmaceutical sector

1975 WHO Director-General Dr Halfden Mahler defines essential medicines as "those considered to be of utmost importance and hence basic, indispensable and necessary for the health needs of the population"

1976 WHO collects medicines lists from Member States, prepares criteria for selecting essential medicines

1977 First WHO Model List of Essential Drugs issued, offering countries a clear model for producing their own lists

1978 In May, 31st World Health Assembly urges Member States to establish essential medicines lists and demands creation of Action Programme on Essential Drugs, while in September, WHO/UNICEF Conference in Alma Ata identifies essential medicines as key component of primary health care

1980s – The essential medicines concept begins to be applied, amidst intense technical debate about how best to do so. Meanwhile, developing countries suffer from producing less than 10% of the world's medicines, and accounting for less than 25% of global medicines expenditure.

1981 Creation of WHO's Action Programme on Essential Drugs formalizes WHO's involvement in essential medicines

1981 Management Sciences for Health publishes *Managing Drug Supply*, bringing together knowledge on selection, procurement, distribution and rational use of essential medicines

1983–1989 National essential medicines programmes established in Africa (Kenya, Malawi, Tanzania, Uganda, Yemen, Zimbabwe) and other regions (e.g. in Asia in Bhutan and Nepal), stimulating formulation of national pharmaceutical policies

1985 WHO Conference of Experts in Nairobi, Kenya, generates common understanding of the essential medicines concept among global public health community

1986 World Health Assembly endorses *Revised Drugs Strategy* arising from 1985 WHO Conference of Experts

1988 WHO publishes *Guidelines for Developing National Drug Policies*, providing countries with a framework for developing sound pharmaceutical policies

1989 International Network for Rational Use of Drugs (INRUD) established, with six interdisciplinary developing country teams, to develop and test interventions to promote rational drug use

1990s – TB, HIV/AIDS and malaria rates soar. Effective new treatments are expensive. Political change threatens many health systems and access to medicines. Efficient procurement, distribution and rational use are clearly vital – the essential medicines concept continues to prove its value.

1991 Break up of Soviet Union creates severe difficulties for medicines regulation and supply, but in following years, Newly Independent States start to resolve these by developing national essential medicines lists and national pharmaceutical policies

1993 World Bank's *World Development Report: Investing in Health* recognizes importance of essential medicines

1995 Australia develops national policy on quality use of medicines demonstrating relevance of essential medicines concept to high-income countries, while Delhi State implements an essential medicines policy that later replicated throughout most of India

1996 South Africa establishes national drug policy following broad-based, national, rather than purely expert dialogue

1997 First International Conference on Improving Use of Medicines (ICIUM) defines agenda for research into rational use of medicines

1998 WHO's mission in essential medicines defined as, "to help save lives and improve health by closing the huge gap between the potential that essential drugs have to offer and the reality that for millions of people – particularly the poor and disadvantaged – medicines are unavailable, unaffordable, unsafe or improperly used"

1999 World Health Assembly requests WHO to monitor and analyse impact of trade agreements on access to patented medicines

21st century – Recognition at the highest international levels of the importance of essential medicines to human well-being. Increasing disease burdens in many countries, and the availability of substantial new funds for medicines procurement, make the essential medicines concept more valid than ever before.

2000 UN Committee on Economic, Social and Cultural Rights states, "Functioning public health and health-care facilities, goods and services have to be available in sufficient quantity within the State party...[and] include essential drugs", and UN defines "access to affordable essential drugs" as one of 17 health-related Millennium Development Goals

2001 UN Commission on Human Rights recognizes access to medicines as, "one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of health", while Doha World Trade Organization Ministerial Declaration stresses importance of implementing and interpreting Agreement on Trade-Related Aspects of Intellectual Property Rights in a manner supportive of public health, by promoting access to existing therapies and research into new medicines.

2001 Global (TB) Drug Facility and Global Fund to Fight AIDS, Tuberculosis and Malaria launched to generate funds for increasing access to essential medicines

2002 25th anniversary of Essential Medicines Concept celebrated worldwide (156 countries have national essential medicines lists) and the first WHO Model Formulary issued, providing unbiased information on all 325 medicines on the WHO Model List of Essential Medicines, which now includes 12 antiretrovirals for treating HIV/AIDS

2003 Canada becomes first G8 country to introduce draft legislation aimed at allowing pharmaceutical manufacturers to manufacture and export lower-cost generic medicines to developing countries

Before and into the 1960s – New and powerful medicines offer the possibility of significant public health gains, while high-volume manufacturing and patent protection help generate large profits for the pharmaceutical industry. But pharmaceutical risks grow too.

1941 Penicillin isolated – first clinical use

1943 Chloroquine trial against malaria

1944 Streptomycin first effective anti-tuberculosis (TB) medicine

1948 Antibiotics tetracycline and chloramphenicol introduced

1951 Isoniazid introduced against TB

1952 Erythromycin introduced for patients with penicillin allergy

1954 Sulfonylureas introduced as first oral anti-diabetic and nystatin as first antifungal agent

1955 Oral contraceptive trials

1961 Thalidomide tragedy leads to global recognition of need for medicines safety monitoring and regulation