Twenty-five years of essential medicines

Jonathan D. Quick,[1] Hans V. Hogerzeil,[2] Germán Velásquez,[3] & Lembit Rägo[4]

The twentieth century opened with only one widely available modern medicine: acetylsalicylic acid (aspirin). In the 1940s the first antibiotic, the first mass produced antimalarial, and the first antitubercular were introduced. The 1950s and 1960s saw the rapid introduction of oral contraceptives, medicines for diabetes, and then medicines for mental illness, many infectious diseases, cardiovascular diseases, and cancer. By the 1970s effective medicines — though not always ideal — existed for nearly every major illness.Yet for half the world's population, it was as if they were still living in the nineteenth century. For them, modern medicines were unavailable, unaffordable, of poor quality, or ineffective because not properly used.

In 1975 the World Health Assembly introduced the concepts of "essential drugs" and "national drug policy", and they quickly became part of the global public health vocabulary. The Health Assembly was building on precedents set in Scandinavia, North America and some pioneering developing countries, such as Papua New Guinea, Peru, Sri Lanka, and the United Republic of Tanzania, in the hope that they would provide a way to begin closing the huge gap between those who were benefiing from the pharmaceutical harvest of the mid-1900s and those who were not.

In October 1977, WHO produced the first Model List of Essential Drugs and in 1978 the Declaration of Alma-Ata identified "provision of essential drugs" as one of the eight elements of primary health care. According to the current WHO Expert Committee on the Selection and Use of Essential Medicines, "Essential medicines are those that satisfy the priority health needs of the population. They are selected with due regard to disease prevalence, evidence of 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 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." Thanks partly to the recognition and application of these principles, the situation has changed enormously since 1977. The following examples give some idea of the contrast.

In 1977, perhaps a dozen countries had what would now be considered an essential medicines list or an essential drugs programme. Today, four out of five countries — at least 156 countries in total — have adopted national essential medicines lists. National lists are widely used for public procurement systems, reimbursement schemes, training, public education, and other national health activities. Most countries have recently updated their lists, and WHO has updated its own model list of essential medicines on average every two years for the 25 years.

In 1977, the concept of a national drug policy was unknown to almost everyone. Today, over 100 countries have national drug policies in place or under development. These policies are being introduced at increasing speed in every region. More importantly, a growing number of countries are moving directly from policy to action. The national drug policy is increasingly serving as a framework within which interested parties can work for pharmaceutical sector reform within countries.

In 1977, objective information on rational use of drugs was extremely limited, especially in developing countries. Today, at least 135 countries have their own therapeutic manuals and formularies, which provide health professionals with current, accurate and unbiased advice on the rational use of drugs. In addition, this year the WHO Model Formulary was launched.

In 1977, medical training was often based on brand names, and little attention was given to systematic teaching about rational drug use. Today, generic names are the norm in medical training, and the WHO Guide to Good Prescribing is being adopted by leading medical universities in rich and poor countries alike. Over 60% of the countries in the world report having some provision for generic substitution in private pharmacies.

In 1977, the WHO Programme for International Drug Monitoring was just being formally established. Today, a network of 68 countries provides global monitoring for adverse drug reactions and regularly picks up signals of medicines posing potential safety problems.

In 1977 there was virtually no publicly available price information, few countries actively encouraged generic substitution, and many countries forbade generic substitution. During the first half of the 1980s, world market prices for drugs on the WHO model list fell by 40% through increased demand and competition. At least 12 countries now provide pharmaceutical price information on public web sites.

Perhaps most importantly: in 1977, less than half the world's population had regular access to essential medicines, while today nearly two-thirds do, through a combination of

[1] Director, Essential Drugs and Medicines Policy, World Health Organization, 1211 Geneva 27, Switzerland (quickj@who.int). Correspondence should be addressed to this author.
[2] Coordinator, Policy, Access, and Rational Use, Essential Drugs and Medicines Policies, World Health Organization, Geneva, Switzerland (hogerzeilh@who.int).
[3] Coordinator, Drug Action Programme, Essential Drugs and Medicines Policies, World Health Organization, Geneva, Switzerland (velasquezg@who.int).
[4] Coordinator, Quality and Safety of Medicines, Essential Drugs and Medicines Policies, World Health Organization, Geneva, Switzerland (ragol@who.int).
Ref. No. **02-0457**

public and private health systems. In absolute terms, the number of people estimated to have access to essential medicines grew from roughly 2.1 billion in 1977 to 3.8 billion in the late 1990s.

These improvements and others related to them have been achieved over the last 25 years through the efforts of individual governments, nongovernmental organizations, universities, professional associations, the private sector, international organizations such as WHO and UNICEF, and other stakeholders.

In spite of so much achievement, however, it is estimated that a third of the world's population — roughly two billion people — lack regular access to essential medicines. In the poorer parts of Africa and South-East Asia 50% of the population lack such access. The Report of the Commission on Macroeconomics and Health (2001) estimates that by 2015 over 10 million deaths per year could be averted by scaling up interventions for communicable diseases, noncommunicable diseases, and maternal and perinatal conditions. The majority of these interventions depend on essential medicines.

In short, millions of children and adults are still needlessly suffering and dying because for them essential medicines are unavailable, unaffordable, unsafe, or wrongly used. Closing the gap between potential and reality entails action in five areas: drug financing, drug affordability, rational selection and use of medicines, effective drug regulation, and efficient supply systems.

While in many developed countries over 70% of pharmaceuticals are publicly funded through reimbursement plans and other mechanisms, in developing and transitional economies 50–90% of drugs are paid for by the patients themselves. Medicines are the major out-of-pocket health expense for poor households in most developing countries. Fairer drug financing can only come through a combination of efforts, including appropriate government funding (often this means increased), expansion of health insurance coverage and pharmaceutical benefits, extension of employer roles in health and drug financing, support from NGOs and community financing sources, and better use of out-of-pocket spending.

For governments, health insurers and households alike, the price of pharmaceuticals represents a substantial barrier to access. Pharmaceutical prices vary widely among countries and within countries, and differences in wholesale prices commonly vary from fivefold to tenfold. Price information for products of assured quality is indispensable for achieving optimum value for money. Generic and therapeutic competition are two of the most powerful tools for bringing down drug prices. For newer medicines, the World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") has established for WTO members a global minimum for patent protection. Many experts predict that, unless countries appropriately apply TRIPS safeguards and unless further progress is made to deal with some of the outstanding issues concerning the TRIPS agreement, the price of new drugs will be unaffordable for many millions of people.

Unsafe and wasteful drug use persists: 25–75% of antibiotic prescriptions in teaching hospitals are inappropriate, half of the world's 15 billion injections per year are unsafe, and 50% of patients worldwide fail to take medicines correctly. Over the last decade, evidence has accumulated demonstrating that rational use can be measurably improved by focused interventions such as treatment guidelines linked to essential medicines lists, training and supply; by active formulary management through hospital drugs and therapeutics committees; by feedback to providers based on their own prescribing and dispensing practices; and by training of licensed drug-sellers. Interventions shown to be efficient need to be implemented, and additional research is needed to develop even more effective methods.

Estimates of the share of substandard and counterfeit drugs on national markets vary from under 5% for many high-income countries to over 15%. In a recent WHO report 60% of the substandard and counterfeit drugs listed had no active ingredient and half were antibiotics and other anti-infective agents. It is estimated that fewer than one in three developing countries have fully functioning drug regulatory authorities. In addition, failure to comply with good manufacturing practices often results in toxic, sometimes lethal, products. Effective drug regulation requires political commitment at the highest level, a sound legislative and judicial base, drug regulatory authorities that are adequately staffed and financed, up-to-date information support, manufacturers that are responsible and responsive, a well-organized pharmacy profession, and an enlightened public, including the media.

Finally, many countries still have to contend with an inefficient combination of private supply systems serving mostly urban areas, and unreliable public supply systems attempting to serve the entire country. Inadequate staffing, corruption, lack of incentives, and inability to learn from past experience all contribute to unreliable supply systems. Yet examples of efficient drug supply systems combining public and private, centralized and decentralized approaches exist in some countries in Africa, Asia, Latin America and elsewhere. Reliable essential drug services are run by nongovernmental organizations in several countries in Africa. The potential to improve access through the private sector has been documented in several recent studies. And successful subregional bulk procurement schemes operate in the Eastern Caribbean, Latin America, the Middle East, among a number of Pacific Islands, and elsewhere. Critical to success in these examples has been a focus on results and a willingness to learn from the experience of other countries and other regions.

Essential medicines are perhaps the most cost-effective element of public health after immunizations and key health promotion habits such as regular exercise. Safe, effective medicines of good quality that are appropriately used already save millions of lives each year and prevent untold suffering. Much has been achieved in the 25 years since the first WHO model list of essential medicines was drawn up. But there is a large unfinished agenda. Fairer financing, affordable prices, rational selection and use, effective drug regulation, and efficient supply systems are all central to closing the gap between those who today benefit from essential medicines and those who do not. ■

Conflicts of interest: none declared.