

## Editorial

# Essential medicines twenty-five years on: closing the access gap

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When the World Health Organization (WHO) produced the first Model List of Essential Drugs in 1977 and the Declaration of Alma-Ata in 1978 identified provision of essential drugs as one of the eight elements of primary health care, it was estimated that at most one-half of the world's population had regular access to essential medicines. The concept of essential medicines was that a limited range of medicines selected to meet priority health needs would lead to better health care, better drug management, better use of financial resources and thereby greater access to care. What has been achieved in the 25 years since the first WHO Model List, and what remains to be done to close the access gap?

In 1977, the concept of national drug policies was barely known. Perhaps a dozen countries had what would today be considered an essential medicines list. The approach to drug selection for health services was relatively informal. Independent, unbiased information on medicines was extremely limited with little attention to systematic teaching about rational prescribing and generic prescribing. There was virtually no publicly available price information and few countries encouraged generic substitution. Regulation of drug promotion was haphazard in many countries and there were no international criteria for ethical promotion. A network of national centres monitored drug safety, but it had limited membership and support structures. While standards for good manufacturing practices had been developed, these were largely unknown outside industrialized countries.

Today, 25 years later, over 100 countries have national drug policies in place or under development and 156 countries have national or provincial essential medicines lists, three-quarters of which have been recently updated. Over 130 countries have developed national treatment guidelines and/or formulary manuals to provide objective, unbiased guidance on rational use of medicines. At least 88 countries have introduced the essential medicines concept into curricula for medicine and pharmacy students, and the WHO Guide to Good Prescribing has been translated into 18 languages and adopted by teaching institutions throughout the world. Generic competition is encouraged in scores of countries. Over a dozen countries provide price information on public world-wide-web sites and WHO, with other partners, maintains pricing services for the full range of essential medicines, for active ingredients and for HIV-related medicines. The WHO Programme for International Drug Monitoring now includes 76 member and associate member countries

and a major global effort has been mounted to assure the quality of pharmaceutical production worldwide.

Most significant, however, is that the number of people estimated to have regular access to essential drugs has risen from 2.1 billion in 1977 to over 4 billion today. Despite this impressive gain, there remains a huge unfinished agenda: roughly 2 billion people – one-third of the world's population – still lack regular access to essential medicines.

What are the causes of this 'access gap' and what actions are needed to close the gap? Much of it is attributable to fundamental economic, social and educational factors that lie beyond the health sector. Economic development in the poorest countries, greater social justice in countries with the greatest disparities in income distribution and substantial reductions in illiteracy, especially among girls and women, will contribute greatly to closing the access gap.

Within the health sector, however, there are four critical obstacles to overcome: (1) irrational use of medicines, (2) unfair financing for health care, including medicines, (3) unreliable delivery systems and (4) high medicines prices. Addressing these obstacles requires skills and strategies that extend far beyond those envisioned when the essential medicines concept was introduced 25 years ago.

Overuse, underuse and misuse of medicines are wasteful and widespread hazards to health. Studies from both developed and developing countries indicate that 25 to 75% of antibiotic prescriptions in teaching hospitals are inappropriate and 30 to 60% of patients in primary health care centres receive antibiotics (perhaps twice what is clinically needed). Of 15 billion injections administered worldwide each year half are unsterile and a large share are unnecessary. Only one-in-two countries actively regulate drug promotion, and less than 50% of people with chronic illnesses such as diabetes and hypertension adhere to prescribed treatment.

Rational use depends first on selecting essential medicines that reflect the best combination of efficacy, safety and comparative cost-effectiveness. Selection should be evidence-based and free from commercial influence. In 2002, WHO introduced new procedures aimed at establishing a model selection process for updating its Model List of Essential Medicines. This process includes tying selection directly to treatment guidelines, preparing systematic reviews of the

clinical evidence for proposed choices, making this evidence publicly available in advance of decision-making meetings, providing an opportunity for all stakeholders (including industry and patient advocacy groups) to comment on proposed changes in the list, taking the final decisions in a closed meeting of independent experts and publicly documenting the reasons for each decision.

Effective use of medicines also depends on the actions of health care providers, formal and informal distribution channels, the pharmaceutical industry and the public. Over the last decade through the efforts of the International Network for Rationale Use of Medicines (INRUD) and a host of operational research initiatives, much has been learned about improving the use of medicines. For example, it has been shown that interventions such as unfocused drug information, treatment guidelines without active follow-up and non-interactive communication efforts have no measurable impact. It has also been shown, however, that focused and actively implemented interventions can have a substantial impact. For example, standard treatment guidelines supported by effective training programmes reduce mortality from acute respiratory infections in children; training of licensed drug sellers which targets specific practices can increase dispensing of effective treatments and reduce dispensing of unsafe ones for diarrhoea and acute respiratory infections; and interactive group discussions involving prescribers and mothers can dramatically reduce the overuse of injections. The challenge for health-policy-makers is to learn from these lessons, supporting inventions which work and avoiding those which do not.

Unfair health financing mechanisms is another critical barrier to access. When the notion of essential medicines was conceived in the 1970s, the assumption was that these medicines would be provided with public financing, through publicly managed supply systems, to patients treated at government health facilities. Today, however, the reality is quite different. In most low-income countries, 50 to 90% of medicines are paid for by patients themselves. This is in sharp contrast with high-income countries, in which most medicines are largely funded by publicly managed health services or publicly mandated reimbursement programmes. As a result, the burden of financing medicines in poor countries falls most heavily on those most in need, but least able to pay. Medicines are typically the largest out-of-pocket household health expenditure in such countries, consuming for example, 61% of household health expenditures in Azerbaijan, 73% in Bangladesh, 80% in Mali and 85% in Burkina Faso. Some of this spending on medicines is through public sector user-fee programmes, but most is through private sector pharmacies and other drug outlets.

Today, in most countries provision of health care, and especially provision of medicines, depends on multiple sources of financing. Funding through government budgets, risk-sharing prepayment (insurance) schemes and development assistance provide the fairest financing. Though public budgets in poorer countries are limited, there remain substantial variations in financial commitments to health among countries with similar, albeit low, per capita incomes.

There is growing support for approaching access to health care, including access to medicines, as a human right. Such a rights-based approach would send the signal to governments that they should make reasonable progress toward appropriate levels of equitable and non-discriminatory health financing, including financing for essential medicines.

Social and private health insurance which includes drugs benefits is expanding in countries as diverse as Argentina, the People's Republic of China, Egypt, India, the Islamic Republic of Iran, Georgia, South Africa, Thailand and Vietnam. Over 70 countries now provide coverage for medicines within public health insurance programmes. Some of these programmes have special arrangements for providing medicines for rural and low-income populations. Social health insurance, private health insurance and community prepayment schemes have all found that application of the essential medicines concept and effective drug management are critical to the financial viability and health impact of such programmes.

The establishment in 2002 of the Global Fund to Fight AIDS, Tuberculosis and Malaria and recent developments in the financing of treatment for HIV/AIDS by employers in Africa hold great promise that new, fairer, more direct and more streamlined sources of financing for health in general and essential medicines in particular may help to close the access gap. It is vital, however, that such funding mechanisms strengthen rather than undermine local capacity, contribute to greater integration of delivery systems rather than proliferation of parallel systems, and add to rather than substitute for current domestic and international funding for health.

Unreliable delivery systems represent the third critical factor in the access gap. Considerations of equity make public involvement in health financing essential. But problems with efficiency, reliability and security of government-operated supply systems have led to an increased role for the private sector and for non-governmental organizations in medicines supply. Among high-income countries in which the majority of medicine costs are publicly funded, delivery systems are largely in private hands. When the first WHO Model List was released in 1977, centralized public sector supply systems were the prototype delivery systems for essential medicines. Today, countries such as Benin, Colombia, Guatemala, South Africa and Thailand have developed different combinations of public and private, centralized and decentralized approaches to drug supply. Not-for-profit mission services in Kenya, Uganda and elsewhere have developed reputations for reliability in essential drugs supply and, in some countries, are now also supplying government health facilities. These experiences support the value of a pragmatic approach based on supply system performance (reliability, efficiency, security, ability to assure product quality), rather than an arbitrary insistence on either public or private, centralized or decentralized systems.

The fourth critical factor in the access gap is the price of medicines. Medicines represent the largest government health service cost after personnel and also the largest part of household health expenditure. Therefore, governments,

other health care providers and households in developing countries are each highly sensitive to medicine prices. Even in Europe and North America, recent annual increases of 10 to 18% in 2000 and 2001 are raising concerns among public reimbursement schemes and health insurers. Over the last 3 years, decreases of up to 95% in the price of treatment for HIV/AIDS (down from at least \$10 000 per person per year to under \$500) and for multi-drug resistance tuberculosis (down from \$8000 per person per year to under \$800) have attracted increased funding for these conditions and thereby increased access. Yet, variations in wholesale prices of six-fold or more among countries are not uncommon. In high-income countries, consumer prices are rarely more than twice the producer or importer price. But in low-income countries, the combined effects of multiple middlemen, taxes, duties, distribution costs and retail margins result in a final price that is commonly more than double – and sometimes three to five times – the producer or importer price. Reducing the final price of medicines to health systems and to consumers depends on transparent price information, generic and therapeutic competition to reduce producer and importer prices, greater distribution efficiency, reasonable dispensing fees, and elimination of duties and taxes on essential medicines.

Prices for newer medicines have been of particular concern in recent years. Drug development is a costly process. It is therefore necessary to strike the right balance between incentives for innovation and assurances of affordability. In 1977, Switzerland was just adopting pharmaceutical product patents, several other developed countries had not yet adopted such patents, few countries had pharmaceutical patent protection greater than 15 years, and most developing

countries had even less stringent patent systems. Today, the 144 members of the WTO are bound by the WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which establishes for WTO members a global minimum for patent protection. Many experts predict that, unless countries appropriately apply TRIPS safeguards, the price of new essential medicines will be unaffordable for many millions of people. The November 2001 Doha Declaration on the TRIPS Agreement and Public Health provided needed clarifications. In addition to these clarifications, it is vital that market-driven drug development is supplemented by even greater support for development of drugs for neglected diseases such as malaria and tuberculosis.

Over the last 25 years, the essential medicines concept has proven itself to be an effective global concept that is central to expanding access to medicines which improve health, reduce suffering and extend lives. The 2001 Report of the Commission on Macroeconomics and Health (CMH) estimated that by 2015 over 10 million deaths per year could be averted by scaling up interventions for communicable diseases, non-communicable diseases, and maternal and perinatal conditions. The majority of these interventions depend on essential medicines. Access to essential medicines is one of 17 health-related Millennium Development Goals. Realizing this goal and achieving the reductions in death and suffering projected by the CMH report depend critically on closing the access gap. Closing this gap requires that governments, international organizations, non-governmental organizations, consumers, the private sector, professional associations and other stakeholders work to mount a coordinated assault on irrational use of medicines, unfair financing mechanisms, unreliable delivery systems and high prices.