pill overload, expenses, and drug toxicity, particularly among HIV-infected individuals who live in marginalised conditions. In the absence or failure of ART, prophylaxis should be recommended in severely immunosuppressed patients to prevent toxoplasmic encephalitis and early death. Health education should also be introduced as the prime source of awareness among HIV-infected patients who are seronegative for T gondii even though less than 5% of toxoplasmic encephalitis cases are caused by primary or recently acquired T gondii infection.

T gondii is a cosmopolitan zoonosis and should be regarded not only as a food-borne, water-borne, and blood-borne parasite but also transmittable through organ transplantation, laboratory accidents, or congenitally. Therefore, an educational approach is the basic method that is still relevant to promote wellbeing among HIV-infected patients. Toxoplasmosis is a preventable and treatable parasitic disease. However, without early diagnosis and proper treatment, this opportunistic infection can lead to a life-threatening disorder in immunocompromised individuals such as those with HIV infection.

Veeranoot Nissapatorn
Department of Parasitology, Faculty of Medicine, University of Malaya, Kuala Lumpur 50603, Malaysia
nissapat@gmail.com

I declare no competing interests.


Access to medicines: lessons from the HIV response

Just two decades ago, HIV/AIDS treatments were prohibitively expensive and accessible in only a few affluent countries. But remarkable reductions in costs have enabled treatment expansion that has reduced mortality and transmission. Today, first-line HIV drugs cost less than US$100 per person per year, a 99% reduction from more than $10,000 in 2000. The number of people receiving HIV treatment doubled in just 5 years, from 9 million in 2011 to more than 18 million today.

In a world facing growing inequalities, the HIV response has lessons for low and middle-income countries (LMIC)—but also for high-income countries—on access to care and treatment for communicable diseases and for non-communicable chronic diseases, a global pandemic that dwarfs the HIV epidemic in scale. The transformative power of the HIV response was underpinned by moral rather than technical arguments. A unique coalition of activists, scientists, celebrities, and religious and community leaders from all over the world argued that no one should be denied life-saving treatment because of area of residence or income. The moral imperative was operationalised by activism for more urgent drug discovery, regulatory approval, and voluntary and compulsory licensing, followed by shifts towards large-scale generic production. Economies of scale underpinned a drive towards more efficient, cheaper production, and drove prices down. Major donors such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria and the US President’s Emergency Plan for AIDS Relief bought generic drugs. The Clinton Health Access Initiative negotiated price-volume discounts
through high volume purchasing. New mechanisms, including the UNITAID-supported Medicines Patent Pool, facilitate access to patents to enable competitive generic production and the development of improved products. Finally, operational revolutions, such as task-shifting and treatment simplification further reduced costs and amplified scale-up.7

These changes were backed by innovations in international trade regulation. The fourth World Trade Organization conference in Doha in 2001 recognised “the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics”. The Doha Declaration also acknowledged the need for the Trade Related Aspects of Intellectual Property rights (TRIPS) Agreement “to be part of the wider national and international action to address these problems”. Although intellectual property rights are important for drug development, concerns were expressed about the effect of these rights on drug prices. The declaration concluded that TRIPS should be interpreted and implemented to support the public health and to promote access to medicines for all, including the sovereign determination of the grounds under which compulsory licences may be issued.4

The lesson from the HIV response that is most relevant to other health inequalities is the principle of universalism. Unfortunately, elements of HIV/AIDS activism are hard to reproduce for other diseases—such as hepatitis C, cancer, cardiovascular diseases, and diabetes—for which unacceptable inequalities in access to innovative interventions exist.5

To tackle other disease inequalities globally we need additional approaches based on the concept that life-saving medicines should be framed as global public goods. These are defined as being both non-excludable (ie, people cannot be excluded from using the good, thus it is available to everyone) and non-competitive (ie, there is no rivalry between potential users of the good, one person can use it without diminishing its availability to others). Just like clean air, parks, lighthouses, peace and security, law and order.6 Unfortunately, medicines are impure public goods, because huge investments are needed to develop them, and knowledge linked to drug discovery includes significant intellectual property rights challenges. Reasonable protection of intellectual property rights is important for the pharmaceutical industry to deliver innovation: the constructive role that pharmaceutical companies have had in innovative drug development indisputably contributed to curbing the HIV/AIDS epidemic. Many companies also pursued tiered pricing or voluntary licensing of drugs, thus helping expand HIV treatment. Hepatitis C illustrates the limits of such approaches when applied to other high burden diseases: voluntary licensing agreements allowing Indian manufacturers to produce generic sofosbuvir and ledipasvir for many LMICs are commendable, but cover just over half of those needing treatment.7

Without generalising to the entire pharmaceutical field, some common misconceptions that challenge the current drug-pricing framework should be noted. Private research costs are often backed by public investment in basic and clinical research contributing to drug discovery and development. Pharmaceutical investments are often directed to the development of medicines that offer few benefits over existing treatments, while research on medicines for neglected areas has been lagging behind because of the small projected return from sales in developing countries. Many pharmaceutical companies are reducing in-house drug discovery research and increasingly buying licences from small biotech companies. Manufacturing costs are a fraction of proprietary drug prices.8 Finally, more transparency is needed on how much is spent on communication rather than development.

Lack of access to essential and innovative medicines, for both prevention and treatment, is clearly not the only reason for the growing health inequalities, but it is an essential element of the quest for universal access to health, together with innovating health-care systems.9–11 Without innovative drug pricing frameworks, reflecting a fair balance between intellectual property and public health rights, the goal of universal access to quality care and medicines is at stake.12,13

Mechanisms put in place to foster access to medicines for HIV could be applied to chronic disease pandemics in LMICs, where huge global inequalities exist in premature mortality due to lack of access to new medicines for disease prevention and treatment, and access to advanced diagnostics and medical devices. An estimated 10 million premature deaths per year are attributed to lack of access to life-saving medicines, with at least part of this problem due to high monopoly prices.14 A significant proportion of patients with chronic diseases
can effectively be treated with cheaper medicines, provided that they are procured and made available by governments; however, an increasing number will only respond the new ones, to which universal access is far from becoming a reality.

Access to life saving medicines is not only a problem in poor countries. High income countries face escalating and progressively unsustainable health costs. They will be increasingly unable to provide quality health to all their citizens when faced with social and demographic pressures, increased demand for health care, and remarkably effective but costly technological advances. If innovative pricing mechanisms are not put in place, these countries may choose to apply approaches similar to those used for the HIV response, including TRIPS flexibilities. 15

A short term way forward is to negotiate fair and equitable prices with manufacturers according to the public health value of the medicine and to the real research investment; or to foster the production of low-cost, quality generic versions, using large procurement mechanisms or TRIPS flexibilities; or even through public licensing of patents.

In the longer term, radical innovation in drug-development models is needed. One option is the suggestion of delinking drug prices from research and development, which consist in finding alternative mechanisms for governments to finance pharmaceutical innovation, with drug pricing approaching marginal costs. 16 Additional options include new forms of public-private partnerships, with the public sector investing heavily in drug discovery with the pharmaceutical industry, sharing the risks of drug development, and, in return, recouping the investment through patent sharing or reduced final drug prices. 17 Examples of successful partnerships are numerous, although still limited to address AIDS vaccine, malaria, tuberculosis, neglected diseases, and innovative diagnostics for diseases of poverty. The ongoing development of an Ebola vaccine is inspiring 18 and offers a model that could be extended to medicines for chronic diseases in low, middle, and high income countries.

Universal access to HIV treatment is one of the greatest global health successes. The core principle of the HIV response—that no one should be denied treatment by accident of geography or income—must become an overarching principle for all diseases, everywhere.

“Stefano Vella, David Wilson
Director, Center for Global Health, Istituto Superiore di Sanità, Rome, Italy (SV); and Global HIV/AIDS Program Director, The World Bank, Washington, DC, USA (DW)

stefano.vella@iss.it

We declare no competing interests.


