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40th anniversary of essential medicines: a loud call for improving its access

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The soaring costs of medicine are a global dilemma. It was hoped that the concept of essential medicines would help countries and policymakers contain the climbing costs of medicine over the last 40 years. This concept was conceived to help control the cost of essential medicines, making them more accessible to patients. The aim of this discussion paper is to provide a detailed analysis of the essential medicines concept and a brief overview of the origin, evolution and current status of access to essential medicines. It charts the positive aspects of the essential medicines concept from its inception to now. The concept has made great progress, however, the situation is still complex and there are challenges related to access, unequal distribution, high prices, low quality of medicines and additional hidden issues. This paper also looks at the barriers to access to medicines, implications of a 'lack of access to medicines', and the economic burden of medicine costs for patients and national health services. To better ensure that everyone has full access to medicines, policy suggestions have been made which need attention from state and non-state actors. Gaining full access to medicines means there are more treatment options and health shocks can be prevented. Lessons learned over the last 40 years are critical if we are to reach the goal of 'health for all'. Issues preventing access to medicines need to be explored, understood and addressed to ensure all on earth have access to this basic human right.

Keywords: Affordability, access barriers, essential medicines, medicine prices

Background

Our health is important and access to medicines is a basic human right that should be exercised without discrimination [1, 2]. Medicines are important tools for preventive, curative and rehabilitative health care [3]. To ensure that everyone receives the medicine they need, the concept of 'essential medicines' was introduced by the World Health Organization (WHO) in 1975. This was followed by the first model of the essential medicines list (EML) in 1977 and the inclusion of essential medicines as one of the eight components of primary health care in 1978 [4]. The overall aim of the EML is to ensure equal access to medicines [5]. Essential medicines, as defined by WHO, are those that 'satisfy the healthcare needs of the majority of the population' and should therefore 'be available at all times in adequate amounts' [6]. 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 [7]. In principal, 'access' may also mean that healthcare services are available whenever and wherever the patient needs them [8, 9].

The concept of essential medicines has been adopted by many international organizations, including the United Nations Children's Fund (UNICEF) and the Office of the United Nations High Commissioner for Refugees (UNHCR), as well as by non-governmental organizations and international non-profit supply agencies. Many of these organizations base their medicine supply system on the model list. List 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, and furthermore, are widely used as information and education tools by health professionals. In addition, health insurance schemes and companies are increasingly using the EMLs of respective countries for reference purposes [10].

Between 1975 and 2015, much has been done with respect to promoting and implementing the concept of essential medicines, approximately 100 countries have National Medicine Policies (NMPs) and more than 156 countries have national or provincial EMLs [11]. Today, more than 135 countries have their own therapeutic manuals and national formularies [11], more than 83 countries are involved in global monitoring of adverse drug reactions (ADR), and more than 33 countries have collected information on medicine prices and availability by conducting almost 70 rapid sample surveys [12]. In addition, India and China have emerged as generics manufacturers with highly specialized manufacturing capabilities which cover almost the entire range of modern medicines [13].

One year after the introduction of the first model of the EML in 1977, the Alma-Ata conference in 1978 reaffirmed that health is a fundamental human right and that the attainment of the highest possible level of health is an important worldwide social goal whose realization requires the action of social and economic sectors, in addition to the health sector [14]. The conference further supported the primary healthcare principles of equality, social justice, health for all, community participation, health promotion and appropriate use of resources [15]. The essential medicines policies outlined have since made an important contribution to primary health care [15]. As the essential medicine concept is now understood worldwide, brand substitution has been encouraged, which has ensured the penetration of quality assured generic medicines into healthcare

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systems across the globe. To increase the access to essential medicines in developing countries, large pharmaceutical companies have become engaged in reducing the price of selected medicines. National governments are also active, playing their part in ensuring equal access to medicines for all. For example, the Indian Government recently reduced the prices of 440 essential medicines by including them in their national EML [16]. Even for patented medicines, governments can decrease prices by parallel importing [17, 18], as is done in Sweden [19]. Similar steps could and should be taken in developing countries.

Discussion

Major health reforms and remarkable efforts were made in 1977 with adoption of the WHO model EML [20]. However, there are still gaps when it comes to regular access to medicines [21] and basic health services [22]. In the Alma-Ata Declaration, it was stated that all people would have access to health by 2000, denoted 'Health for all'. Nevertheless, after more than 15 years, children under five years of age still die every day from dehydration, undernourishment and preventable diseases due to a lack of adequate access to medicines [23]. According to WHO, almost two billion people – one-third of the global population – do not have regular access to essential medicines [24], with large gaps in the availability of medicines in both the public and private sectors [25]. According to WHO, access to treatment is heavily dependent on the availability of affordable medicines and a benchmark of 80% is now set for medicine availability [6]. Based on the World Medicine Situation 2011 Report the availability of generic medicines in the public sector is less than 60% across WHO regions [26]. According to the report, the BRICS countries (Brazil, Russian Federation, India, China and South Africa), which are major emerging national economies, are facing healthcare challenges, which include access to health services and medicines, and the growing cost of health [27]. Of these countries, India has shown the least improvement in public funding for health [28].

As per recent reports, 79% of people with tuberculosis (TB) do not have access to treatment [29]. These figures are supported by research, stating that 'only 23% of the world's population have access to the WHO tuberculosis control strategy' [30].

It appears that more effort is required to achieve global access to medicines as advocated by WHO. In a 2002 report, Hans Hogerzeil, Professor of Global Health at Groningen University, The Netherlands, reported that: 'irrational drug use remains a widespread hazard to health.' He further added that 'half of all countries have no regulation of drug promotion, 75% of antibiotic use is inappropriate, finance, delivery and other constraints still limit the access to essential drugs. These concerns, coupled with the fact that new essential medicines are expensive, reinforce the importance of ongoing and concerted actions being taken in relation to enhancing access to and use of pharmaceuticals' [29].

Even in its third version (2011), the list of essential medicines for children, remains incomplete and certainly unsatisfactory as there is still a lack of appropriate medicines for children worldwide [31], and this overall lack of medicine formulations suitable for children is a global concern [32].

The soaring cost of medicines and health expenditure affects both developing and developed countries. Pharmaceutical expenditure in the US rose by 18% in 1999, 16% in 2000, and 17% in 2001. In Canada, the average cost per prescription rose by 93% between 1987 and 1993 [33].

Reasons for the lack of access to medicines

There are multiple cost and non-cost related barriers to essential medication access for patients. These include: high cost, irregular availability at health clinics, lack of prescribing and dispensing skills of healthcare workers, inadequate funding, a lack of incentives for maintaining stocks, inability to forecast needs accurately, inefficient purchasing/distribution systems and the leak of medicines from the public to private sector for resale [34]. According to Bigdeli et al., 'barriers to access to medicines are complex and occur at multiple levels of the health system' [35]. Access to medicines can be hindered by policy that restricts technical and resource-related aspects which further hampers the adaptation of health systems to the changing epidemiological profile of their populations [36].

Implications of a 'lack of access to medicines'

Due to poor infrastructure in developing countries, medicines are not always available in the local drug stores. Low-income patients also cannot afford to spend a day travelling to receive or purchase the medicine they need. Even if a clinic or pharmacy is nearby, the medicine they need may not be available or could be out of stock [37]. Access to treatment has a close association with the availability of affordable medications; the cost of medicines is one of the major factors limiting access, as it forces the patients to pay out of their own pockets and limits their access to treatment [38]. This situation has wide implications for low-income countries where the majority are unwilling and/or unable to pay for their medication. Recently, a great deal of social, political and economic attention has been given to the high cost of prescription medications [39], as the high prices of medicines are key barriers to access to treatment in many low- and middle-income countries [34, 40-44]. When patients have no access to medicines, it leads to a change in the form of disease from acute to chronic, promotes non-adherence to treatment and causes increased costs to the healthcare system, in the form of unnecessary hospitalizations.

Ensuring access to medicines involves recording and understanding the reasons for the price of medicines [38]. In Afghanistan, one of the poorest countries in the world, pharmaceutical expenditure levels are high and the presence of a 'free market economy' means that costs are often double what they could be. Malaysia also practices a 'free market economy' together with a 'price deregulation system' in which manufacturers, distributors and retailers set medicine prices without government control. In Malaysia, medicine prices have been reported to rise even faster than prices in the developed world, and are higher than overall international prices causing high pharmaceutical expenditure [45].

Economic costs of medicines for households and government

The burden of pharmaceutical expenditure continues to increase globally, especially in the least developed countries. The amount of money spent on purchasing pharmaceuticals is high, with approximately 40–60% of the total public health budget of any country going towards buying medicine [17], which is catastrophic [46]. However, despite this high proportion of spending, one-third of the world's population lacks access to essential medicines [47]. The

economic burden of illness and limited access to pharmaceuticals has a significant negative impact on patient groups and their families [48]. To a great extent, pharmaceutical expenditure undermines national economic development, especially in countries with low gross domestic products (GDPs) and a dependent economy [49]. Even in countries where medicines are provided for free through the public sector, they can often be unavailable [34]. As such, patients are forced to pay out of their own pockets when they are ill, especially in developing countries [50]. Countries which rely heavily on out-of-pocket (OOP) payments are not likely to achieve universal health coverage [51]. It is reported that, in Afghanistan, more than 75% of patients pay OOP, of which 98.4% of the payments constitute purchasing medicines [52]. In Moldova, the OOP payments account for 45% of total health expenditures [51]. In Bangalore, India, it was reported that 69.6% of households made OOP payments for outpatient care for chronic conditions during a 30-day period [53]. According to Kumar et al., each year approximately 7% and 8% of the population in China and India, respectively, are in poverty due to out-of-pocket health expenditure (OOPHE) [54]. In Uganda, 38% of households experience catastrophic OOPHE due to limited access to affordable medicines [55].

Additionally, the high prices of medicines and OOP is paving the way for health shocks in poor countries via the emergence of unpredictable illnesses that may weaken the health status of households [56].

Recommendations: how to better ensure access to medicines

Access to affordable medicines is a basic human right and considered a fundamental goal of any welfare state [54]. Below are a series of recommendations necessary to achieve the goal of global access to medicines.

- Strengthen the concept of essential medicine by exploring new approaches and closely working to implement them in WHO Member States or donor agencies
- Appraise the performance of all WHO Member States. This is critical to ensure implementation of essential medicines policies and access to medicines programmes. The annual performance report should be disseminated to all WHO Member States
- Improve the quality of information and evidence on medicine prices, availability and affordability
- Establish and strengthen medicine pricing committees of WHO Member States in order to control medicine prices and their uncoordinated distribution in private and public sector, respectively
- Review and update medical and pharmacy curriculum, continued medical education (CME) and professional development programmes to improve rational use of medicines and usage of health technologies
- Ensure sustainable health financing at central and community level
- Reform and modernize the pharmaceutical supply chain/inventory system
- Waive taxes, markups and retail-ups or bring them to a minimum for essential medicines
- Develop political commitments for tackling the issues related to access to affordable medicines by controlling prices to ensure each individual has access to the right medicine at the right time and the right price
- Promote Corporate Social Responsibility (CSR) among developed countries, in order to reach patients in need who may be at risk of dying from preventable diseases [57]
- Undertake strategic purchasing in collaboration with the private sector and formulate more effective purchasing strategies
- Make the retail prices of medicine uniform and printed on medicine packs, ensuring that these prices are those available to the public
- Ensure community-based health insurance and its reform in developing countries, which will contribute significantly to the performance of health financing systems [58]
- Develop clear and transparent selection criteria and processes to select medicines on the basis of cost-effectiveness in addition to clinical and pharmacological criteria
- Establish national online databases to monitor costs compared with other countries, both developing and developed
- Lobby for generics substitution and the promotion of generics
- Improve access to medicines by paying attention to manufacture and distribution processes [13]
- Approve sufficient budgets for medicines by parliament, to meet public health needs (governments of low-income countries spend an average of US$3 per capita per year on medicines, which is clearly inadequate)

Conclusion

Gaining full access to medicines widens treatment options and brings many advantages to patients and healthcare systems. Now, the question is how to bridge the 'lack of access' gap and ensure that people have access to this basic human right. If we hope to halt the development of acute to chronic diseases, and prevent diseases progressing with fatal consequences, more needs to be done to ensure all people across the globe have access to essential medicines. We must not wait another 40 years for the situation to get worse and illness costs to go beyond the household's budget, especially for households in rural environments in the developing world. All WHO Member States should intensify efforts to ensure that everyone within the scope of their responsibility promotes access to affordable medicine without delay. Policies that are directed at low-income individuals must be considered to address issues surrounding soaring medicine prices and inadequate access. Each Member State should eliminate or minimize duties and taxes on medicines to ensure adequate access. All issues preventing access to medicines for all need to be explored and addressed if we are to ensure that there is universal access to this human right.

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References 49 to 58 can be found on page 184.

40th anniversary of essential medicines: a loud call for improving its access

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