The world health and drug situation *

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1. Overview

This paper reviews the major health and pharmaceutical developments in developing countries for the past 25 years and suggest what may occur over the next 25 years. Major health, social, economic and development changes have occurred during this period. The Alma Ata declaration was pronounced in 1978 suggesting an approach to health and health services. An integral part of this approach was the essential drugs concept which has had a global impact. The International Dispensary Association (IDA) has been a major influence in this development. Before considering pharmaceutical issues it is necessary to consider the underlying health and development situation of countries where essential drugs are of critical importance.

The health and economic situation of a country has a direct impact on the demand and use of pharmaceuticals. One of the ongoing major health developments has been the demographic transition [1]. In this phenomena death rates fall due to improved living and health conditions. As a result the population grows rapidly for a period. Once people realize that large families are no longer necessary for survival birth rates fall and the population stabilizes. When this happens the population ages. The speed at which this transition occurs varies greatly and is affected by rates of economic growth, availability of family planning technologies and government policies. In conjunction with the demographic transition the epidemiological transition is also occurring [2]. In this process, as life expectancy increases, the incidence of infectious diseases decline and the prevalence of chronic diseases increase. This leads to an increase in total health care costs as the treatment of infectious diseases is short term while chronic diseases are life long usually. There have been other health developments in the period 1972–1997 with the emergence of new and resistant diseases such as viral haemorrhagic diseases such as Ebola [3], and HIV/AIDS [4]. Malaria resistant to common antimalarials [5], and Multiple Drug Resistant Tuberculosis (MDRT) [6] have complicated therapeutic choices for these common severe diseases.

Major health system developments have occurred during the period 1972–1997.

The Alma Ata Conference in 1978 proposed a comprehensive approach to Primary Health Care (PHC) and advocated an integrated approach to Health for All through combining an egalitarian development approach with the use of appropriate health technologies which included essential drugs [7]. A rapid reaction to this radical approach occurred with the emergence of selective Primary Health Care approach which advocated placing emphasis on a few cost-effective technological interventions [8]. This approach held sway through the 1980s. However by the 1990s Health Sector reform including decentralization, privatization and cost recovery became the mantra of development agencies. There was also a major change

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** Correspondence: Richard Laing, Associate Professor, Department of International Health, Boston University School of Public Health, 715 Albany Street, T4W Boston, MA 02118, USA. E-mail: richardl@bu.edu.
in the roles of WHO and the World Bank. Until the 1990s, the World Bank had a minimal involvement in health policy and programming. However that has changed in the 1990 as signaled by the publication of the 1993 World development report “Investing in Health” [9]. During the 1980s and continuing today has been a shift in the role of Non Governmental Organizations NGO’s. While originally small organizations made up by well meaning enthusiastic volunteers some have grown into large professional efficient organizations able to provide services, or drugs under challenging circumstances. Examples of such organizations are the IDA in Holland, Medicins sans Frontieres in Europe, MEDS in Kenya, Baptist Convention in Cameroun and the United Mission to Nepal. Such organizations are likely to play an ever more important part in countries where the central government is withdrawing from providing services and private sector providers are unwilling to meet rural people’s needs.

Within the field of Essential Drugs many significant developments have occurred over the past 25 years. The major events include in 1972, IDA was formed offering an alternative source of supply of good quality drugs. In 1977, the first WHO Essential Drug List was published [10]. This signaled a global recognition that a limited list of drugs could meet the health needs of most of the population in developing countries. The manual Managing Drug Supply was published in 1981 by Management Sciences for Health [11]. This comprehensive manual described how a health system could select, pro-
cure, distribute and promote rational drug use at a cost nearly all countries could afford. In the same year, the WHO established the Essential Drugs Programme initially within the Director General’s office. This initiative moved WHO from a more usual normative role to that of an advocacy or activist position. By 1985, controversy had developed about this activist role and a conference of experts was convened in Nairobi [12]. From this conference emerged the Revised Essential Drugs Strategy which has guided the programme since that time. In 1988, WHO published the World Drug Situation which reviewed the global access to pharmaceuticals and showed that 75% of the world’s population living in developing countries consumed only 21% of the world’s drugs. By 1989 recognition that while access to essential drugs was improving the use of the drugs remained problematic. To address this problem the International Network for the Rational Use of Drugs (INRUD) was formed. By 1991 as the World Bank became active in the health field they also began to develop policies concerning pharmaceuticals. These are clearly enunciated in the World Development Report 1993 which generally follows the WHO revised drug strategy. The latest significant development has been the publication of a second edition of the manual Managing Drug Supply. This publication updates the information included in the first edition and synthesizes global experience as to how best to manage essential drugs [13].

2. World drug situation 1997

2.1. Selection

The WHO Essential Drug list is revised every two years with minor changes occurring usually. However when a therapeutic advance occurs action to include the drug occurs quickly. This recently occurred when the benefit of magnesium sulphate for treating and preventing eclampsia was demonstrated. More than 100 countries now have Essential Drug Lists (EDL). These are revised on fairly regular basis and are often used in other policy areas. For example, the allocation of foreign exchange may be applied preferentially to EDL drugs. Standard Treatment Guidelines (STG’s) are now widely available and are used in many developing countries. In some countries STG’s are used at all levels of the health system and have now been adapted into both pocket and desktop guides. The STG’s have now incorporated input from vertical programs, are used for training, examination and as the basis for clinical audit [14]. Within developed countries Standard treatment guidelines are now being at national, regional or local levels. The evolution of the treatment guidelines produced by the Victorian Medical and Postgraduate Foundation in Australia have shown the influence of such an approach [15].

2.2. Procurement and distribution

Despite being introduced in the 1980s as emergency measures to assure drug distribution essential drug kits still are being used in many countries. While kits ensure that some drugs do reach peripheral units the system is inherently inefficient as the choice of drugs and the quantity supplied are arbitrary and do not take account of differing prescribing and morbidity patterns or the different utilization rates which occur [16]. Also when cost recovery or revolving drug funds are started resupply must be on the basis of need and the use of a “push” system of drug supply dooms such popular approaches. In developing countries national procurement of drugs by governments continues to occur with varying efficiency. Some countries have pooled their procurement efforts. An outstanding example of this approach is that of the Eastern Caribbean Drug Supply system [17,18]. In Indonesia drugs are tendered for centrally but
distribution to district level workshops is undertaken by the manufacturers on an as needed basis. This system appears to work efficiently despite the geography of the country. The World Bank has reviewed its experience with Open Competitive Bidding (OCB) with pharmaceuticals [19]. This report showed that World Bank funded drug procurements for countries in Eastern Europe in the early 1990s took in excess of one year. The message of this report was that OCB was not an efficient method of procurement. Some countries have attempted to address this problem by establishing parastatal or privatized organizations to be responsible for procurement. Non Governmental Organizations (NGO’s) such as IDA in Amsterdam and MEDS in Kenya have become major procurement agencies and have started to undertake focused training for their clients. A further useful resource to assist countries has been the production of comparative price lists. Management Sciences for Health produces such a list based on the prices quoted by non-profit suppliers and national tender prices [20].

2.3. Rational use

Considerable progress has occurred during this decade in improving the use of drugs. This has been due to members of the International Network for the rational Use of Drugs (INRUD) with strong support from WHO. The publication of standard indicators to measure drug use in the WHO manual “How to investigate drug use in health facilities” [21]. A similar manual is available for use in the community [22]. To investigate the reasons for irrational prescribing or dispensing behaviors qualitative methods of investigation are needed. A manual to answer the question “Why?” is available from INRUD [23].

Many experiences in changing drug use in developing countries now exist. These were reported at a conference held in Chang Mai, Thailand in April 1997. These presentations are now available on the World Wide Web [24].

2.4. Quality assurance and regulation

Confusion continues to exist about counterfeit and substandard drugs. Counterfeit drugs are fraudulent products which contain no active ingredient. Substandard drugs are products which contain the active ingredients but do not meet pharmacopeial standards usually due to inadequate quality assurance during production, distribution or storage. The response to these two situations are very different. Counterfeit drugs producers need to be prosecuted to the full extent of the law. Substandard producers frequently need assistance to improve the quality assurance of their production process.

There are many worrying changes occurring in registration practices. In some Latin America as a result of economic pressure to deregulate economies drug registration has been weakened allowing many ineffective or unnecessary drugs to be registered [25].

The International Conference on Harmonization (ICH) convened by the regulatory authorities of the US, Japan and the European Union may define technical specifications for pharmaceuticals which may marginalize producers in developing countries [26]. The fact that this is a private conference, with a secretariat provided by IFPMA, with WHO in an observer role and with developing country regulators and generic manufacturers excluded has created concern in many developing countries.

Quality Control laboratories at regional or national level in developing countries often appear to struggle to provide timely drug analyses. Their costs are usually similar to those of developed countries. A better alternative may be for academic or private laboratories to provide services to regulatory authorities on a contract basis as occurs in South Africa. The use of thin layer chromatography may be a useful and practical technique for assessing quality and detecting counterfeit drugs [27].
2.5. Financing for pharmaceuticals

Revolving Drug Funds (RDF’s) have been established in many countries with very mixed results [28]. What is clear from the accumulated experience is that a high level of management expertise is required with economic and political stability in the environment where the fund operates. The Bamako Initiative is a unique form of a revolving drug fund promoted by UNICEF in Africa and Asia. The Initiative has been widely criticized but some reports of success have been published. The World Bank has become active in funding pharmaceuticals in many developing countries. However, I would like to question the probity of financing a recurrent expenditure with loan funds. I believe that in general such funds should be used for capital development rather than to meet a recurrent need. In many countries the donor role remains important, if not critical in ensuring that essential drugs are available in public sector health facilities to cater for the poor. While donors have struggled to move away from this role, in many of the poorest countries the resources needed are not allocated to drugs by central government.

2.6. Education of health professional in essential drugs

Pharmacists clearly play a crucial role in the management of Essential Drugs Programs. In many countries students are trained with an outdated curricula but change appears to be coming especially in Africa. Meetings were held during 1997 in Africa and in the Middle East with schools of Pharmacy and concrete proposals were made as to how to update curricula [29].

There has been improvement in the training of doctors particularly with the publication of the Groningen developed WHO publication “Guide to Good Prescribing” [30]. However very little is being taught to doctors about other aspects of drug management. Nurses are now being trained in diagnosis and basic drug management in many countries. This has been an important development as in many developing countries nurses provide most diagnoses, treatment and drug management in public sector facilities. Within Schools of Public Health in both developed and developing countries very little is being taught despite the fact that in many developing countries drug expenditures exceed 25% of total health expenditure.

2.7. Unresolved issues

There are many unresolved issues in the world of essential drugs and I will identify a few which concern me. Within WHO there are two pharmaceutical programs, the normative Drug Management Programme (DMP) and the operational Action Programme on Essential Drugs. While it is clear that both programmes have different responsibilities, I believe that merging of these two complementary programs into an integrated organization would be desirable. A code of conduct exists to regulate drug promotional activities of the drug industry but this is widely ignored in both developed and developing countries. The tools exist in countries to regulate and control drug representatives but there is a singular lack of commitment to enforce the code of conduct. Another concern to me is the lack of pharmaceutical research on developing country diseases. Related to this issue has been the setting of new drug prices particularly of the new AIDS drugs, new antibiotics and psychiatric drugs. Action needs to be taken to make these drugs available to people in developing countries who desperately need them.

3. Conclusions

In the next 25 years the health situations of countries will be closely related to their economic and AIDS situation. Most Asian, Latin American and Caribbean countries will improve rapidly. However,
within these countries the gap between rich and poor will continue to increase and subpopulations of the very poor will increase in number and need. Their ability to access health services and pharmaceuticals will be very limited. In most African countries the situation will deteriorate with increasing mortality, decreased life expectancy, increasing health costs and reduced economic capacity. This will be due to the combined impact of economic decline combined with the effect of the AIDS epidemic. Pharmaceutical consumption in Asia, Latin America and Caribbean will increase with a shift to chronic disease drugs such as antihypertensives, antidiabetic drugs, H2 blockers, NSAIDs and cytotoxics. Pharmaceutical consumption will also increase in Africa due to HIV, poverty and urbanization with the main drugs being the anti-TB, antifungals, antibiotics, analgesics as well as some chronic disease drugs. The role of the private and NGO sector will become more significant over the next 25 years. In urban areas, the private sector is or will become the dominant provider. However, in rural areas NGO’s may well become the major providers. Examples of organizations already playing this role are MEDS in Kenya, the Cameroon Baptist Convention, the United Mission to Nepal, and in many Islamic countries, the Red Crescent organization.

The role of government has changed and will change further in the future. The major responsibilities of government will be to regulate, support and provide a safety net for those who have no access to other services. It is to be hoped that as the government’s role changes that policies which obstruct essential drugs programs will be eliminated. Such policies as regulatory obstructions, high duties and protecting a local industry which may benefit a small elite in a developing nation but do not help the poor of the country.

International organizations will also need to change to find ways to promote the essential drugs concept to NGO’s and to support these organizations in their work to provide essential drugs to the rural poor. This may need changes in the way both international organizations and NGO’s function and cooperate.

There has been great progress in improving access to essential drugs and in improving the use of these drugs. However much remains to be done in the political, economic and development area to ensure that barriers to access for geographical, economic or social reasons are addressed. Improving the use of medicines will require better training, supervision, regulation and information provision to prescribers, dispensers and patients.

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References
